Appendix I: Evidence Tables

1.1 2014 Evidence tables

Update information
February 2017: Sections that have been updated (see addendum files) have been marked with dark grey shading'

1.1.1 Maternal and neonatal outcomes associated with different birth settings?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Blix,E., Huitfeldt,A.S., Oian,P., Straume,B., Kumle,M., Outcomes of planned home births and planned hospital births in low-risk women in Norway between 1990 and 2007: A retrospective cohort study, Sexual and Reproductive Healthcare, 3, 147-153, 2012 Ref Id 272469 Country/ies where the study was carried out Norway Study type Cohort study Aim of the study A descriptive and comparative study comparing outcomes of planned home births with	Sample size n = 17941 Characteristics >93% of women were cephalic presentations. 99.98% of women >37 weeks Planned home births = 1,631 Planned hospital births = 16,310 Nulliparas home birth (n = 369) / Nulliparas hospital birth (n = 6913) / Multiparas home birth (n = 1262) / Multiparas hospital birth (n = 9397) Age (SD): 28.2 (4.5) / 26.4 (4.7) / 32.2 (4.2) / 30.2 (4.5) Breech birth (per cent): 5 (1.3) / 168 (2.5) / 7 (0.6) / 156 (1.7) >42 weeks gestation: 7 (2%) / 0 / 30 (2.4) / 0 Women who planned home births were older than women	Interventions Home births attended by midwife in Norway vs. hospital births in Norway.	Details Home birth group: Data were collected from the patient files of midwives who had attended at least 30 home births in Norway. These filled in a register form for each birth, or gave the same information to the researchers by telephone. Hospital group: data were taken from the MBRN files. Data were descriptively analysed: proportions, means and 95% CIs. Analysis was stratified for nulliparas and multiparas. Analysis was done on an intention-to-treat basis. Multiple imputations were used for missing	Results Nulliparas home birth (n = 369) / Nulliparas hospital birth (n = 6913) / Multiparas home birth (n = 1262) / Multiparas hospital birth (n = 9397) Spontaneous vaginal delivery: 329 / 5443 / 1243 / 1243 / 9034 Assisted vaginal: 21 / 1024 / 7 194 Caesarean section: 19 / 446 / 12 / 169 Epidural: 345 / 5158 / 1250 / 8635 Postpartum hemorrhage >500ml: 26 / 742 / 24 / 619 Stillborn: 0 / 1 / 1 / 1 Number who did not transfer sites: 252	Limitations No p values or SDs given for results. No description given of home or hospital environments. Inconsistency in data collection: Both written and oral reporting to researchers. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
outcomes of planned hospital births. Study dates January 1990 - December 2007 Source of funding Finnmark Health Trust and University Hospital of North Norway	who planned hospital births. More single mothers planned hospital births. Level of education generally higher in home birth group. Inclusion criteria Spontaneous onset of labour Singleton fetus 37 - 42 weeks gestation No pre-pregnancy diseases No complications in pregnancy No previous caesarean section or fetal death Exclusion criteria Women who did not meet inclusion criteria.		data (a dataset of 12 imputations was judged to be sufficient).	/ na / 1182 / na	
Full citation Davis,D., Baddock,S., Pairman,S., Hunter,M., Benn,C., Anderson,J., Dixon,L., Herbison,P., Risk of severe postpartum hemorrhage in low-risk	Sample size n = 16,210 Characteristics Mean age range in years: 27.7 - 30.04	Interventions Planned birth at one of the following: home, primary unit, secondary	Details Data were collected retrospectively from the New Zealand College of Midwives research database. Analysis was planned with	Results Home group: n = 1,830 / Primary unit group: n = 2,877 / Secondary hospital: n = 7,380 / Tertiary	Limitations Little information given on place of birth. No crude results for effect of birth-place on PPH.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
childbearing women in new zealand: exploring the effect of place of birth and comparing third stage management of labor, Birth, 39, 98-105, 2012 Ref Id 272584 Country/ies where the study was carried out New Zeland Study type Observational study Aim of the study To investigate the effect of birth-place on the risk of postpartum haemorrhage (PPH), and the effect different modes of management have on severe PPH in the third stage of labour. Study dates 2006 and 2007 Source of funding	Home group: n = 1,830 / Primary unit group: n = 2,877 / Secondary hospital: n = 7,380 / Tertiary hospital: n = 4,123 Mean parity: 1.4 (1.4) / 1.1 (1.2) / 0.9 (1.2) / 0.7 (1.0) Inclusion criteria Low risk Exclusion criteria Previous caesarean section, stillbirth or PPH. Hypertension, diabetes, thyroid disease, Rh sensitisation, IBO incompatability, alcohol abuse, heart/lung/blood/neuro/renal/skeletal disorder, multiple birth, transfer during pregnancy, <36 or >42 weeks gestation, induced labour, breech, shoulder presentation, transverse lie, caesarean section.	hospital, tertiary hospital.	multinomial logistic regression controlling for maternal age, parity and mode of birth. Outcomes were attributed to birth-place at the onset of labour and analysed on an intention-to-treat basis.	hospital: n = 4,123 Percentage of unassisted vaginal births: 95.4 / 94.7 / 84.5 / 72.7 Percentage of emergency ceasarian sections: 2.6 / 3.2 / 8.5 / 14.9 Percentage active management: 25.9 / 47.1 / 73.2 / 77.8 Relative risk of birth-place on blood loss >1,000: 0.93 (0.53 to 1.65) / na / 1.20 (0.80 to 1.79) / 1.47 (0.96 to 2.24)	Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not stated					
Full citation de,Jonge A., Mesman,J.A., Mannien,J., Zwart,J.J., van,Dillen J., van,Roosmalen J., Severe adverse maternal outcomes among low risk women with planned home versus hospital births in the Netherlands: nationwide cohort study, BMJ, 346, f3263-, 2013 Ref Id 272589 Country/ies where the study was carried out Netherlands Study type Cohort study Aim of the study To test the hypothesis that low risk women (at the onset of labour) with planned home birth have a higher rate of severe acute maternal morbidity than	Sample size n = 146,752 (included) n = 20,182 (excluded) Characteristics Parity 0 = planned home birth: 38,728 (41.9);planned hospital birth: 26,499 (48.7) 1+ = planned home birth: 53, 602 (58.1); planned hospital birth: 27,919 (21.3) Maternal age <25 = planned home birth: 9,142 (9.9); planned hospital birth: 9407 (17.3) 25 - 34 = planned home birth: 66,554 (72.1); planned hospital birth: 35,137 (64.6) >35 = planned home birth: 16,630 (18); planned hospital birth: 9,868 (18.1) Inclusion criteria	Interventions Planned home birth vs planned hospital birth	Details Information from the LEMMoN study database and national perinatal register were merged. In short, all cases of severe acue maternal morbidity were collected from all 98 hospitals in the Netherlands. Each month a local co-ordinator reported all cases via a web-based form. Number and percentage of outcomes were calculated for each place of birth. Logistic regression analysis was used for severe acute maternal morbidity because of the low number of events in other outcomes. Analyses were done for nulliparas	Results Secure acute maternal morbidity = planned home birth: 141; planned hospital birth: 147. Blood transfusion >4 packed cells = planned home birth: 134; planned hospital birth: 122. Postpartum haemorrhage (>1000ml) = planned home birth: 2,699; planned hospital birth: 2,172	Limitations Author disclosed that (given the large n value) some registration data was missing or may have been misclassified. Data was collected over a two year period meaning that, theoretically, midwifery management and women's characteristics might have changed. Women who had had a relatively difficult previous birth may have been more likely to plan a hospital birth next time causing selection bias. Planned hospital births are associated with risks There were not many variables for women's characteristics. E.g. body mass index was not given. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
women with planned hospital birth, and and to compare the rate of postpartum haemorrhage (PPH) with manual removal of the placenta (MRP). Study dates August 2004 - August 2006 Source of funding A career grant from (VENI) from ZonMw. It was declared that the funder had no role in any aspect of the study.	Low risk with cephalic presentationInformation from the datesets of the LEMMoN study and the In primary care at start of labour Term singleton pregnancy Exclusion criteria Planned place of birth unknown at onset of labour (n = 18,070). Medium risk (n = 2,012) History of retained placenta or PPH (n = 1,248) Prolonged ruptured membranes (n = 6,039)		and multiparas women separately, and for planned home births versus planned hospital births. Multivariable logicistic regression was used to control for potential confounders. Missing data was excluded because they were less than 5% for all variables.		
Full citation Gaudineau,A., Sauleau,E.A., Nisand,I., Langer,B., Obstetric and neonatal outcomes in a home-like birth centre: a case-control study, Archives of Gynecology and Obstetrics, 287, 211-216,	Sample size n = 1206 Characteristics HLBC group: n = 316 TLU group: n = 890 HLBC / TLW Maternal age (years): 29 / 28.7	Interventions A home-like birth centre versus a traditional labour ward.	Details A retrospective study using data collected from women admitted to the HLBC and TLW. Women in the TLW were randomly selected.	Results HLBC / TLW Spontaneous vaginal delivery: 280 / 737 p = 0.034 Instrumental extraction: 28 / 106 p = 0.034 Caesarean section:	Limitations Other information None of the women in the TLW group desired to be admitted to the HLBC.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
2013 Ref Id 272673 Country/ies where the study was carried out France Study type Observational study Aim of the study To compare the intervention rates associated with labour in low risk women who began their labour in a "Home-like birth centre" (HLBC) and a traditional labour ward (TLW). Study dates January 2005 - June 2008 Source of funding Received a Gallia Fund.	Gestational age: 39.5 / 39.2 Nulliparas: 142 / 361 Primiparas: 120 / 319 Multiparas: 54 /210 Inclusion criteria Low risk women admitted to the HLBC or TLW with no complications. Exclusion criteria Women with high risk pregnancies. Women with diabetes, previous caesarean section or uterine surgery or fetopelvic disproportion. Multiple pregnancy, toxemia, intrauterine growth restriction, non-cephalic presentation, placenta praevia, obstetric risk.		The Baysian information criterion was used to select the best predictive model. Medical files of all admitted women were viewed daily by the obstetric team (midwives and doctors). The HLBC and TLW shared the same staffing. In the HLBC, midwives cared for the women without any physicians present, and epidural analgesia was not available. Instead, continuous midwifery care, acupuncture, relaxation techniques and birth pools were widely used as analgesia. Transfer time between HLBC and TLW was 5 minutes and the midwife would stay with her charge if transfer was required.	8 / 47 p = 0.034 Postpartum haemorrhage >500ml: 9 / 46 p = 0.089 Breast feeding initiation: 290 / 701 p = <0.0001 Epidural analgesia: 65 / 539 p = <0.0001 5 min AGPAR score: 10 / 10 p = 0.0117 Major neonatal morbidity: 23 / 64 p = 0.852	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Population characteristics were retrospectively and anonymously collected from computerised medical files. Intention-to-treat analysis was applied to minimise bias. The groups were compared using a X squared test, Fisher's exact test or analysis of variance, as needed. Quantitative variables were expressed by their mean values and SD, and were compared by Student's t test or a Wilcoxon test, as appropriate. Admission variables were introduced and forced into the multivariate models. Linear regression models were used for continuous variables, and binary logistic or polychotomous		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			regression for the others. Alpha risk was set at 0.05.		
Full citation Nove,A., Berrington,A., Matthews,Z., Comparing the odds of postpartum haemorrhage in planned home birth against planned hospital birth: results of an observational study of over 500,000 maternities in the UK, BMC Pregnancy and Childbirth, 12, 130-, 2012 Ref Id 272947 Country/ies where the study was carried out UK Study type Observational study Aim of the study To compare the odds of postpartum haemorrhage (PPH) among women co-opting for home birth against the odds of PPH	Sample size n = 273,872 Characteristics Heterogenous population as data taken from centres in mixed areas. Age range: <20 to 40+ Inclusion criteria Low risk. Planning place of birth. Stillbirth or live birth. Inclusions: n = 273,872 Exclusion criteria High risk, unplanned home births, gestation<37 weeks, elective caesarean section, unattended in labour,	Interventions Planned home birth vs. planned hospital birth	Details Secondary analysis of maternity records, in which information was recorded contemporaneously by health professionals as pregnancies progressed. Data were taken from St Mary's Maternity Information System. The 15 participating hospitals were in a wide range of locations. Statistical analyses were carried out using a logistic binary regression model. Co-variates were selected following a literature review of characteristics associated with place of birth.	Results Percentage of women suffering PPH Home: 5,998 Hospital: 267,874 13,881 women who had PPH <20 years 4,231 women who had PPH >40 years 73,862 women who had PPH were medium risk.	Limitations Little description of birth sites. Time period for births finished twelve years before date of paper. Recommendations were bold (recommended women should be advised they are at higher risk of PPH if they plan a hospital birth) and based on old data. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
planning a hospital birth. Study dates 1998 - 2000 Source of funding Not stated	indeterminate sex of baby. Exclusions: n = 5,998.				
Full citation Ackermann-Liebrich,U., Voegeli,T., Gunter-Witt,K., Kunz,I., Zullig,M., Schindler,C., Maurer,M., Home versus hospital deliveries: Follow up study of matched pairs for procedures and outcome, British Medical Journal,BMJ, 313, 1313-1318, 1996 Ref Id 174682 Country/ies where the study was carried out Switzerland Study type Prospective cohort with matched pairs	Sample size N = 874 Characteristics The following characteristics relate to the whole study population (i.e. not just matched pairs) unless otherwise stated Age at conception/years (mean ± SD) Home: 29.2 ± 4.3 Hospital: 29.2 ± 4.6 Parity (n (%)) 1st child Home: 201 (41.1) Hospital: 182 (47.3) 2nd child	Interventions Planned (booked) birth at home (n = 489) Planned (booked) birth in hospital (n = 385) (Note: there were 214 matched pairs, which constitute the main population of interest)	Details Selection of study groups There was no formalised policy for accepting women for home birth. Planned hospital births were initially only included if they were planned to take place at one of the reference hospitals (in order to access data more easily); however, there were not enough women wanting hospital births being recruited, therefore, other centres were asked to participate. Of 951 women initially recruited (493 for home and 458	Results The following data are reported for the matched pairs only, as there were no particular stated restrictions on risk for planned home births. Maternal mortality (n/total (%)) Home: 0/214 (0) Hospital: 0/214 (0) Mode of birth (n/total (%)) a. Caesarean section Home: 12/207 (5.8) Hospital: 24/207 (11.6)	Limitations Choice of treatment unrelated to confounders (selection bias): Matching was done to try to control for confounders Groups comparable at baseline: Hospital arm are significantly heavier than home arm, even in the matched pairs analysis. The home birth arm overall were taller but not in the matched pairs. Overall (total study population), women with planned home birth were more likely to be living with a partner and be employed, but this is not reported for the matched pairs Groups received

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess procedures and outcomes in births planned at home versus those planned in hospital among women choosing the place of birth Study dates March 1989 to March 1991 Source of funding Swiss National Science Foundation	Home: 175 (35.8) Hospital: 143 (37.1) 3rd child or more Home: 113 (23.1) Hospital: 60 (15.6) Maternal weight / kg (mean (95% CI)) Total Home: 56.9 (56.2 to 57.6) [n = 449] Hospital: 59.1 (58.2 to 60.0) [n = 352] p < 0.001 Matched pairs Home: 57.3 (56.2 to 58.4) [n = 183] Hospital: 60.4 (59.0 to 61.8) [n = 183] P < 0.001 Babies with birth weight < 2500 g (n (%))* Total Home: 12 (2.5) Hospital: 13 (3.6)		for hospital), 22 were excluded for being unmatchable due to nationality, 5 due to medical history, 44 because their birth was planned in a setting that did not conform with study criteria, and 6 moved away. 489 planned home births and 385 planned hospital births were included; however, only 214 matched pairs were formed, and these are the data that will be reported. Study populations were matched by: - Age: < 16, 16-19, 20-29, 30-34, > 34 - Parity: 1, 2-4, > 4 - Gynaecological and obstetric history (none or 24 categories which could be combined) - Medical history (none or 12 categories)	OR 0.45 (95% CI 0.19 to 1.00) p = 0.05 b. Forceps or vacuum extraction* Home: 8 (4.6) Hospital: 18 (10.4) OR 0.41 (95% CI 0.14 to 1.04) p = 0.06 Vaginal/perineal trauma (n (%))* a. Perineal lesion Home: 65 (37.6) Hospital: 29 (16.8) OR 3.25 (95% CI 1.83 to 6.10) p < 0.001 b. Perineal and vaginal lesion Home: 1 (0.6) Hospital: 4 (2.4) OR 0.25 (95% CI	same/similar care (apart from intervention): Unclear - very few details of care are reported Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: Unclear what the denominator is for forceps/vacuum extraction and measures of perineal trauma. It is reported as excluding women with CS, but subtracting that from denominator does not give reported %. 7 women had miscarriages, leaving 207 of the 214 matched pairs. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: - 1.5% of home birth arm and 4.5% of hospital arm

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	p = 0.42 Matched pairs Home: 4 (2.0) Hospital: 5 (2.5) p = 1.00 Gestational age at birth (n (%))* a. < 259 days Total Home: 7 (1.5) Hospital: 13 (3.5) p = 0.07 Matched pairs Home: 2 (1.0) Hospital: 5 (2.5) p = 0.45 b. > 293 days Total Home: 24 (5.0) Hospital: 15 (4.1)		- Partner situation (living with partner, living with other people, living alone) - Social class (5 categories described by Beer) - Nationality Setting/care protocol No specific details of care in labour are reported Transfer criteria Not reported Data collection, analysis and monitoring Sample size calculations suggested that it would not be possible to detect a difference in perinatal mortality. Therefore, the team aimed to collect about 500 in two years, to assess more frequent outcomes like caesarean section	0.005 to 2.53) p = 0.38 c. Intact perineum Home: 63 (36.4) Hospital: 16 (9.2) OR 6.22 (95% CI 3.05 to 14.31) p < 0.001 d. Episiotomy without perineal lesion Home: 45 (26.0) Hospital: 128 (74.0) OR 0.09 (95% CI 0.04 to 0.18) p < 0.001 * this is reported as excluding women with CS; however, it is unclear what the denominator is because subtracting the number of CS from the denominator does	were breech presentations - 1.4% of hospital arm were twins and 1.0% of women had vaginal bleeding - 1.4% of home birth arm and 2.4% of hospital arm had hypertension - 7.9% of home birth arm and 8.9% of hospital arm were pre- (< 259 days) or post-term (> 293 days) - 3.4% of home birth arm and 16.9% of hospital arm had induction of labour (p < 0.001) (Note: with the exception of induction, none of these differences were significant at the 5% level) Other information Comparison: HOME vs. OU [This study was included in the 2007 guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	p = 0.53 Matched pairs Home: 14 (6.9) Hospital: 13 (6.4) p = 1.00 * this excludes the twin births Inclusion criteria Intention to deliver at home or in hospital (recorded during first antenatal visit or when decision was taken) Exclusion criteria Unmatchable due to medical history or nationality Birth planned in setting that did not meet study criteria		(CS). The study team recorded antenatal information on specially designed forms, which were coded and and computerised. A delivery form was also completed by midwives. However, the hospitals did not use the same forms, and their data had to be coded in the same way. Records of both hospital and home births were coded by trained personnel not associated with the study. The babies were examined immediately after birth by the GP or obstetrician, and then on the third day by specially trained paediatricians. The mothers completed three questionnaires:	not give the reported %. For the GRADE table, it is assumed to be 207 per arm, as per the other outcomes. Other priority outcomes Perinatal death is referred to in the text, but it is not restricted to the matched pairs analysis; therefore, it will not be reported here. Transfer Very few details are given about transfer in the matched pair analysis - the majority of information is for the whole study population. The authors report that, out of the 874	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			two during pregnancy (one about attitudes to childbirth and one about medical and social history), and one three months after birth. Data were analysed for both unmatched data and matched pairs. A one sample t-test was used to compare means between cases and controls, and McNemars test was used to compare dichotomous outcomes. In matched analyses, odds ratios were estimated by the ratio of discordant pairs. Outcomes reported 1. Maternal mortality 2. Mode of birth: rate of CS and rate of forceps/vacuum extraction are reported	women in the study who planned birth at home or in hospital, 17 women had miscarriages, of which 7 were from the matched pairs. Therefore, out of an initial 214 matched pairs, only 207 remained for analysis. In the entire study population, there were 37 antenatal referrals (8%) in the home birth group and 15 (3.1%) women changed their mind. Therefore, 439 women began labour at home. Similarly, there were 8 (2.1%) women that changed their minds in the hospital group and. combined with transfers, 418	

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			3. Vaginal/perineal trauma: reported as excluding women who gave birth by CS	women began labour in hospital. After the onset of labour, 70 (15.9%) of women in the home birth arm had to be transferred, so that 369 births actually occurred at home. Of the transfers, 20 had signs of fetal distress, 16 underwent CS and 14 had an instrumental vagi nal delivery. Two women planning birth in hospital gave birth unattended, one at home and one in a taxi, and were transferred to hospital for postnatal care.	
Full citation Begley,C., Devane,D., Clarke,M., McCann,C., Hughes,P., Reilly,M.,	Sample size N = 1653	Interventions Planned (booked) birth in an	Details Setting Both hospitals were located in large towns,	Results Maternal mortality (n/total (%)) MLU: 0/1101 (0)	Limitations Appropriate randomisation: Yes Allocation concealment:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Maguire,R., Higgins,S., Finan,A., Gormally,S., Doyle,M., Comparison of midwife-led and consultant-led care of healthy women at low risk of childbirth complications in the Republic of Ireland: A randomised trial, BMC Pregnancy and Childbirth, 11 , 2011. Article Number, -, 2011 Ref Id 155852 Country/ies where the study was carried out Ireland Study type Randomised trial Aim of the study To compare midwife-led (MLU) versus consultant-led (CLU) care for healthy pregnant women without risk factors for labour and delivery	Characteristics Age/years (mean ± SD) MLU: 29 ± 4.9 CLU: 28.7 ± 5.0 Parity (n/total (%)) 0 MLU: 565/1101 (51.3) CLU: 276/552 (50) > 0 MLU: 536/1101 (48.7) CLU: 276/552 (50) Marital status (n/total (%)) Single MLU: 415/1101 (37.7) CLU: 229/552 (41.5) Married, not separated MLU: 664/1101 (60.3) CLU: 312/552 (56.5) Weight/kgs (mean ± SD) MLU: 65.9 ± 8.9 CLU: 66.1 ± 8.93 Height/metres (mean ± SD) MLU: 1.66 ± 0.07 CLU: 1.66 ± 0.08	alongside midwife led unit (MLU) (n = 1101) Planned (booked) birth in a consultant led unit (CLU) (n = 552)	and served semi-urban and rural populations of a mixed racial background but with the majority white Irish. The MLUs were housed within the hospitals in refurbished existing accommodation close to the labour ward. Of the two units, one employed 12 staff midwives and the other employed 7 staff midwives. Recruitment and randomisation There was a pilot study for the first seven months, which allowed refinement of the eligibility criteria and practice guidelines. No changes were made to the methods after the start of the trial. Recruitment for the main study was between February 2005	CLU: 0/552 (0) Mode of birth (n/total (%)) a. Caesarean section MLU: 163/1101 (14.8%) CLU: 84/552 (15.2%) RR 0.97 (95% CI 0.76 to 1.24) b. Instrumental birth MLU: 139/1101 (12.6%) CLU: 79/552 (14.3%) RR 0.88 (95% CI 0.64 to 1.14) c. Spontaneous vaginal birth MLU: 761/1101 (69.1%) CLU: 372/552 (69.0%)*	Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: The authors state that "assessors for certain outcome, such as laboratory tests, were blinded to study group" Missing data/loss to follow-up: Data for 5 MLU women and 3 CLU women were incomplete because they moved during pregnancy and could not be traced; however this is less than 1% of the study population Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes, apart from the method of assessing blood loss is not report

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates July 2004 to June 2007 Source of funding Funding to support the introduction of the computerised Maternity Information System in the study sites was received from the Health Research Board The former North-Eastern Health Board, now Health Service Executive - Dublin North East, provided funding for the study	Inclusion criteria See exclusion criteria Exclusion criteria ≥ 40 years or ≤ 16 years old at birth Grand multiparity (> 5) Height < 152 cm (5 feet) BMI < 18 or > 29 Medical history: respiratory, renal, infective, immune, neurological, cardiovascular, gastrointestinal, endocrine, haematological, mental ill-health, muscoskeletal Current history of drug misuse Smoking at least 20 cigarettes per day Latex allergy Previous obstetric history:		and November 2006. The data for the main study are reported here. Women were introduced to the MLU service by sending information and study invitations through the post or via GP to women receiving public care in the area. At the booking clinic, women who had not completed 24 weeks of pregnancy were assessed for eligibility by midwives, and gave written consent. 9804 women were informed about the study, of which 4190 were eligible and 2260 agreed to participate. This was 607 women for the pilot and 1653 in the main study. (note: this was 1206 from one unit and 447 from the other)	RR 1.03 (95% CI 0.96 to 1.10) * this % is as reported in the paper, although the technical team calculate that the figure should be 67.4% Epidurals (n/total (%)) MLU: 202/1101 (18.3%) CLU: 134/552 (24.3%) RR 0.76 (95% CI 0.62 to 0.92) Postpartum haemorrhage [over 500 ml] (n/total (%)) MLU: 144/1101 (13.1%) CLU: 75/552 (13.6%) RR 0.96 (95% CI	Intention-to-treat analysis performed: Yes Access to MLU was only through the trial. Indirectness: 22.5% of MLU arm and 19.9% of CLU arm experienced pregnancy complications; 22.5% of MLU arm and 25% of CLU arm received induction of labour Other information Comparison: ALONGSIDE MLU vs. OBSTETRIC UNIT [Study is new since 2007 guideline] This study evaluates a package of care, from antenatal care onwards, not just intrapartum care. Women required physical transfer in the event of a complication requiring an obstetrician.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	- history of preterm birth at < 34 weeks gestation - recurrent miscarriage - moderate to severe pre-eclampsia - intrauterine growth restriction - previous stillbirth - caesarean section - eclampsia - uterine rupture - placental abruption - PUPP - obstetric cholestasis - 3rd or 4th degree tear - postpartum haemorrhage (> 500 ml or symptomatic) - manual removal of placenta - shoulder dystocia - mid-trimester miscarriage - neonatal death - infant with HIE Previous gynaecological history - uterine surgery - myomectomy - hysterotomy - cone biopsy (unless subsequent term vaginal birth) - two previous Letz procedures		Women were randomised to MLU or CLU in a 2:1 ratio, on the grounds of making cost effective use of the new MLU. Randomisation was done using an independent randomisation service. Random sequences of blocks of 2, 3, 4 or 5 were used, stratified by study centre with a separated list for each centre and by random permutations of group allocations within each block. The midwife enrolling the woman collected demographic, eligibility, consent and contact details. This was given to the randomisation service and then the midwife was informed of allocation. Blinding was not	0.74 to 1.25) Vaginal/perineal trauma (n/total (%)) a. Intact perineum MLU: 421/1101 (38.2%) CLU: 225/552 (40.8%) RR 0.96 (95% CI 0.85 to 1.09) b. Episiotomy MLU: 126/1101 (11.4%) CLU: 68/552 (12.3%) RR 0.93 (95% CI 0.70 to 1.23) Admission to special care baby unit (n/total (%)) MLU: 128/1101 (11.6%) CLU: 60/552 (10.95) RR 1.07 (95% CI	Reasons for not receiving allocated intervention MLU arm (n = 1101) 48 (4.4%) did not receive their allocated intervention - ineligible: 19 - changed mind: 24 - requested private consultant care: 5 6 (0.05%) were lost to follow-up or had their intervention discontinued - moved house/country during pregnancy: 5 - opted for home birth: 1 CLU arm (n = 552) 2 (0.4%) did not receive their allocated intervention - ineligible: 2 5 (0.09%) were lost to follow-up or had their intervention discontinued - moved house/country during pregnancy: 3 - opted for home birth: 2

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	- uterine fibroids - cervical cerclage - infertility - uterine anomaly - perineal reconstruction (more than 24 hours post birth)		possible for this study. Access to MLU was only through the trial. Care protocol - CLU Women received standard antenatal care from obstetricians, and, if requested, from their GP. Midwives did not usually perform assessment. Intrapartum care was provided by midwives unless complications developed, with consultant overview. Postpartum care, consisting of 2-3 days in hospital, was also provided by midwives. - MLU Women received midwife-led care, and care was given by the same small group of midwives throughout pregnancy, birth and	0.80 to 1.43) Death of the baby (n/total (%)) a. Fetal loss prior to 24 weeks MLU: 17/1101 (1.5%) CLU: 5/552 (0.9%) RR 1.70 (95% CI 0.63 to 4.60) b. Fetal loss after 24 weeks MLU: 1/1101 (0.09%) CLU: 0/552 (0) RR: not reported c. Early neonatal death MLU: 2/1101 (0.18%) CLU: 2/552 (0.36%) The authors also report that perinatal mortality rates were	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			the postnatal period (12 in one unit, 7 in the other). Antenatal assessment and care was done by midwives in the unit or outpatient clinic, and if desired by the woman's GP. Where complications arose during pregnancy, labour or postpartum period, women and/or babies were transferred to the CLU according to the criteria below. After assessment by a clinician, they were transferred back to the MLU or remained in CLU, depending on the clinical situation. Continuous EFM and epidural were not available in the MLU Women remained in the MLU for up to 2 days postnatal. After	2.76 per 1000 live and still births in the MLU and 3.66 per 1000 in the CLU. Causes of death are not reported. Permanent transfer to CLU (n/total (%)) During antenatal period: 492/1101 (44.7%) - Most common reason was for induction of labour: 202/492 (41.1%) - Next most common was fetal assessment: 38 (8%) During labour: 144/1101 (13.1%) - Most common reason was slow progress: 61/144 (42.4%) - Next most common was meconium stained liquor:	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			discharge, midwives visited at home or provided telephone support up to the seventh postpartum day. Transfer criteria DURING PREGNANCY Maternal: - Rhesus disease - Atypical antibodies - Antepartum haemorrhage - Multiple pregnancy - Maternal request for prenatal screening - Placental abruption - Unstable lie - Malpresentation after 37 completed weeks - Placenta praevia - Preterm labour before 37 completed weeks - Prolonged pregnancy, over 40+10 - Preterm, spontaneous, rupture of membranes	26/144 (18.1%) During postnatal period: 5/1101 (0.5%) - No details given about reasons	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Gestational hypertension (≥ 140/90 mmHg) - Eclampsia - Pre-eclampsia - Proteinuria ≥ 1+ on repeat specimen at same visit - Suspected thromboembolism - Any itchy rash - Hb < 10 g/dl - Gestational diabetes - Pre-labour rupture of membranes at term for > 48 hours - Induction of labour - Symptomatic vaginal discharge - Unbooked pregnancy - Group B Strep - More than two admission in ≥ 48 hours at term and not in established labour Fetal: - Clinically suspected SGA baby - Known fetal anomaly		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Oligohydramnios - Polyhydramnios - Reduced fetal movements INTRAPARTUM Maternal: - Placental abruption - Pyrexia > 38°C on two occasions at least 1 hour apart - Lack of progress in the first stage of labour (absent or slower cervical dilatation than 0.5 cm/hour for primigravidae and 1 cm/hour for multigravidae) - Delay in second stage of labour (active pushing for more than 90 minutes in primigravidae and 40 minutes in multigravidae) - Shoulder dystocia - Request for epidural - Unbooked and presenting in early labour		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Retained placenta (> 1 hour) - PPH (> 1000 ml or symptomatic) - 3rd or 4th degree perineal tears Fetal: - Abnormal fetal heart rate on auscultation - if prolonged deceleration ≥ 2 minutes < 110 bpm was diagnosed, the woman was transferred - Meconium stained liquor - Malpresentation (with the exception of mento-anterior) - Intrapartum haemorrhage - Cord presentation/prolapsed - Fetal demise - Absence of liquor POSTNATAL Maternal: - Postpartum haemorrhage (> 500		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			ml) - Pyrexia > 38°C on two occasions at least 1 hour apart - Concerns for psychological well being - Signs of deep vein thromboembolism (DVT), leg pain or discomfort (especially in the left leg), swelling, tenderness, increased temperature and oedema, and lower abdominal pain - Signs of pulmonary thromboembolism, dyspnoea, collapse, chest pain, haemoptysis, faintness and signs and symptoms associated with DVT - Any other condition causing concern Data collection, analysis and monitoring A sample size		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			calculation found that 1539 women were needed, based on randomisation and two tailed tests. This used an alpha of 0.05 and 80% power to detect differences of at least 6% in the various primary outcomes: induction of labour (23% to 17%), episiotomy (31% to 24%), and augmentation of labour (24.4% to 17.9%). The authors also report that this sample size would also detect differences in: Apgar at 5 minutes of 8-10, CS, use of continuous electronic fetal monitoring, initiation of breastfeeding, instrumental vaginal birth, PPH and umbilical cord pH. Data were collected		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			manually from women's and babies' charts by research assistants, and data were double entered into a database where they was checked and cleaned. Statistical analysis was done using SPSS and was based on intention-to-treat. An independent Data and Safety Monitoring Board was established and conducted an interim analysis following recruitment of the first 495 women in to the main study. The stopping alpha was 0.001. The study was recommended to continue as there was insufficient evidence of benefit or harm.		
Full citation Bernitz,S., Rolland,R., Blix,E., Jacobsen,M.,	Sample size N = 1111	Interventions Planned (intended at	Details Setting The hospital	Results Note: the following data are as reported	Limitations Appropriate randomisation: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Sjoborg,K., Oian,P., Is the operative delivery rate in low-risk women dependent on the level of birth care? A randomised controlled trial, BJOG : an international journal of obstetrics and gynaecology, 118, 1357-1364, 2011 Ref Id 159535 Country/ies where the study was carried out Norway Study type Randomised controlled trial Aim of the study To investigate if there were differences in operative delivery rates in low risk women giving birth in an alongside, midwifery-led unit compared with an obstetric unit Study dates Recruitment stopped in	Characteristics Parity (n/total (%)) Nulliparous Midwife led unit (MLU): 278/412 (67.5%) Normal obstetric unit (NU): 285/417 (68.3%) Special obstetric unit (SU): 184/282 (65.2%) Multiparous MLU: 134/412 (32.5%) NU: 132/417 (31.7%) SU: 98/282 (34.8%)* * this is reported as 35.4% in table 1 of the study; however, that is not the % based on those numbers Education (n/total (%)) Primary school MLU: 20/412 (4.9%) NU: 25/417 (6.0%) SU: 23/282 (8.2%) High school MLU: 182/412 (44.2%) NU: 168/417 (40.3%)	the onset of labour) birth in an alongside midwife led unit (MLU) (n = 412) Planned (intended at the onset of labour) birth in a normal obstetric unit (NU) (n = 417) Planned (intended at the onset of labour) birth in a special obstetric unit (SU) (n = 282)	(approximately 3000 births per year) was divided into three separate units on separate floors: - Midwife-led unit: Organised for low risk women with expected normal births who want as little intervention as possible. No epidural is available, and there is no augmentation unless needed for second stage. If extended surveillance is needed or an obstetrician needs to take over, women need to be transferred. Obstetricians are not present in the unit unless called for a specific reason. - Normal unit: Organised for women with expected normal births. The unit has access to extended	in the paper; however, for the purposes of our analysis, NU and SU will be pooled to form the OU arm in the meta-analysis Mode of birth (n/total (%))* a. Spontaneous birth MLU: 345/412 (83.7%) NU: 342/417 (82.0%) SU: 229/282 (81.2%) p: not significant (NS) (value not reported) b. Operative vaginal birth with indication (all women) MLU: 43/412 (10.4%) - labour dystocia: 26 - fetal distress: 14	Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No, but the statistician was blinded Missing data/loss to follow-up: Unclear Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes, apart from the method of assessing blood loss is not reported Intention-to-treat analysis performed: Yes Indirectness: Obstetricians could be called to the unit Other information Comparison: ALONGSIDE

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
March 2010, but it is not clear when the study started Source of funding The Regional Health Trust The National Advisory Committee for Obstetrics in Norway Østfold Hospital Trust	SU: 112/282 (39.7%) College/university MLU: 202/412 (49.0%) NU: 218/417 (52.3%) SU: 139/282 (49.3%) Unknown MLU: 8/412 (1.9%) NU: 6/417 (1.4%) SU: 8/282 (2.8%) Age / years (n/total (%)) < 25 MLU: 103/412 (25.0%) NU: 100/417 (24.0%) SU: 64/282 (22.7%) 25 - 35 MLU: 263/412 (63.8%) NU: 270/417 (64.7%) SU: 181/282 (64.2%) > 35 MLU: 46/412 (11.2%) NU: 47/417 (11.3%) SU: 37/282 (13.1%) Social status (n/total (%)) Married		surveillance, epidurals and operative vaginal delivery. There are also facilities for elective caesareans and inductions after spontaneous rupture of membranes - Special unit: Organised for women who are in need of extended surveillance in the antenatal period, during labour and after birth Women expecting normal births can give birth at any of the units, but only low risk women are accepted at the MLU. Each unit has separate staff, and midwives are responsible for all normal deliveries. All units provide intrapartum and postpartum care.	NU: 51/417 (12.2%) - labour dystocia: 23 - fetal distress: 20 SU: 30/282 (10.6%) - labour dystocia: 21 - fetal distress: 9 p: NS c. Caesarean section with indication (all women) MLU: 24/412 (5.8%) - labour dystocia: 13 - fetal distress: 5 NU: 24/417 (5.8%) - labour dystocia: 8 - fetal distress: 6 SU: 23/282 (8.2%) - labour dystocia: 11 - fetal distress: 4 p: NS Mode of birth, split	MLU VS. OU [Study is new since 2007 guideline] This study evaluates intrapartum care only. Physical transfer is required in the event of complications, but obstetricians could be called to the unit Women not receiving allocated intervention MU: 5/412 (1.2%) NU: 9/417 (2.2%) SU: 6/282 (2.1%) No reasons are given; however, it is a very small proportion.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	MLU: 155/412 (37.6%) NU: 165/417 (39.6%) SU: 120/282 (42.6%) Cohabiting MLU: 236/412 (57.3%) NU: 229/417 (54.9%) SU: 152/282 (53.9%) Single MLU: 19/412 (4.6%) NU: 20/417 (4.8%) SU: 9/282 (3.2%) Unknown MLU: 2/412 (0.5%) NU: 3/417 (0.7%) SU: 1/282 (0.4%) Inclusion criteria Healthy low risk women without any disease known to influence the pregnancy One baby in cephalic presentation Pre-pregnancy BMI of ≤ 32 Not smoking more than 10		Recruitment and randomisation Information about the study was sent to all women planning to give in the Hospital when they were being called for ultrasound. At the ultrasound appointment (18-20 weeks), each woman who seemed to be suitable was given additional written and verbal information. If she was found to be eligible and consented, she was recruited. Then, if she met the inclusion criteria at the onset of spontaneous labour, she was randomised. 2884 women were assessed as eligible and willing to participate. Of these, 1773 did not meet the inclusion criteria or were not	by parity (n/total (%)) a. Operative vaginal birth MU: - Nulliparous: 42/278 (15.1%) - Multiparous: 1/134 (0.7%) NU: - Nulliparous: 49/285 (17.2%) - Multiparous: 2/132 (1.5%)† SU: - Nulliparous: 29/184 (15.8%) - Multiparous: 1/98 (1.0%) b. Caesarean section MU: - Nulliparous: 23/278 (8.3%) - Multiparous: 1/134 (0.7%) NU:	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	cigarettes per day No prior operation on the uterus No prior complicated deliveries Spontaneous onset of labour between 36+1 and 41+6 weeks of gestation Exclusion criteria See above		included at the time of onset of spontaneous labour: - no longer low risk due to pre-eclampsia, placenta praevia, intrauterine growth restriction, breech presentation, haemorrhage in the third trimester, pre or post dates (n = 607) - changed their minds about participating (n = 300) - study paused over Christmas vacation because the MLU was closed (n = 254) - other reasons (n = 552) Randomisation was performed using a digital randomisation database. Allocation was concealed and the randomisation was stratified by parity. The SU served women with	- Nulliparous: 24/285 (8.4%) - Multiparous: 0/132 (0%) SU: - Nulliparous: 22/184 (12.0%) - Multiparous: 1/98 (1.0%) † reported as 0.7% in paper, but this does not match the numbers Epidural (n/total (%)) MU: 65/412 (15.8%)* NU: 97/417 (23.3%)* SU: 70/282 (24.8%)* p < 0.01 Postpartum haemorrhage (n/total (%)) a. > 1000 ml	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			extended needs, therefore their capacity to receive low risk women was limited and they were allocated to receive a smaller proportion of the trial population. Transfer criteria Not reported. Data collection, analysis and monitoring Data were registered by the midwife in charge of the electronic journal system of the department, as is routine for all births. One midwife at each unit monitored entries and documentation. All the participants' data were then also checked by a midwife who did not work at any of the three units. The study was powered	MU: 7/412 (1.7%) NU: 9/417 (2.2%) SU: 9/282 (3.2%) p: NS b. 500 - 999 ml MU: 33/412 (8.0%) NU: 38/417 (9.1%)* SU: 36/282 (12.8%)* p: NS c. 1000 - 1500 ml MU: 4/412 (1.0%) NU: 6/417 (1.4%) SU: 3/282 (1.1%) p: NS d. > 1500 ml MU: 3/412 (0.7%)* NU: 3/417 (0.7%)* SU: 6/282 (2.1%)* p: NS Note: of the 25 women with PPH of at least 1000 ml, 17	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			on detection a reduction in operative delivery from 10% to 5%. With power of 80% and p < 0.05, 1642 women were needed. However, inclusion was slow and funding limited; therefore, the inclusion stopped at 1111 women. Analysis was done using chi-squared and Pearson's two-sided asymptomatic significance level p values were calculated. The MLU was set as the reference standard. The statistician was blinded to allocation. Analysis was by intention-to-treat.	were due to atonic PPH, 3 were due to retained placenta and 5 had no reason given Vaginal/perineal trauma (n/total (%)) a. Episiotomy (of all vaginal births) MU: 88/388 (22.7%) NU: 105/393 (26.7%) SU: 75/259 (29.0%) p: NS Third or fourth degree tear (of all vaginal births) MU: 5/388 (1.3%) NU: 9/393 (2.3%) SU: 5/259 (1.9%) p: NS (The authors provided the following details regarding the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				women who had sphincter injuries in each setting: - MLU: none of the women with tears had episiotomy - 1 had an operative vaginal births and 4 had spontaneous births. - NU: 4 had episiotomy and operative vaginal birth, 1 had spontaneous birth with episiotomy and 4 had spontaneous birth with no episiotomy - SU: 3 had episiotomy and operative vaginal birth, 1 had spontaneous birth with episiotomy and 1 had spontaneous birth with no episiotomy) Need for transfer to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				NICU [defined as within first two hours postpartum] (n/total (%)) MU: 32/412 (7.8%)* NU: 26/417 (6.2%)* SU: 19/282 (6.7%)* p: NS Metabolic acidosis [defined as umbilical cord artery pH < 7.05 and base excess < 12 mmol/l) (n/total (%)) MU: 5/412 (2.0)‡ NU: 7/417 (3.0)‡ SU: 4/282 (2.0)‡ p: NS ‡ these are as reported in the paper, but using the denominators reported, the technical team calculate that the % should be 1.2%,	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.7% and 1.4% respectively. Intrapartum transfer (n/total (%)) MU: 117/412 (28.4%) NU: not applicable (NA) SU: NA The reasons for transfer were (%): - Need for pain relief: 39.3 - Stained amniotic fluid: 18.8 - Fetal distress: 9.4 - Labour dystocia: 23.9 - Other reasons: 8.5 Mean dilatation of the cervix was 6.4 cm at time of transfer; 51% were transferred with dilatation < 7. Of those transferred intrapartum, 61	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(52.0%) had an operative delivery, of which 39.3% were CS and 60.7% were operative vaginal deliveries. * reported as whole % in paper	
Full citation Birthplace in England Collaborative Group., Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study, BMJ, 343, d7400-, 2011 Ref Id 164646 Country/ies where the study was carried out England Study type Prospective cohort study	Sample size N = 64,538 Characteristics OU: obstetric unit Fr-MLU: freestanding midwifery unit Al-MLU: alongside midwifery unit Maternal age/years (n (%)) Mean ± SD OU: 28.2 ± 6.0 Home: 31.1 ± 5.2 Fr-MLU: 28.8 ± 5.8 Al-MLU: 28.3 ± 5.7 < 20 OU: 1506 (7.7) Home: 218 (1.3)	Interventions Planned birth in an obstetric unit (n = 19,706) Planned birth at home (n = 16,840) Planned birth in a freestanding midwifery unit (n = 11,282) Planned birth in an alongside midwifery unit (n = 16,710)	Details Selection of study groups Women meeting the inclusion criteria were classified according to their planned place of birth at the start of care in labour. They were included in this group even if they were transferred during labour or postpartum. Setting/care protocol Details of care in labour are not reported, as this was a study of multiple units. Transfer criteria	Results Note: All incidences and ORs are weighted to reflect unit's duration of participation and probability of being sampled. The calculations of ORs are also restricted to women not missing any confounder data. Adjusted odds ratios are adjusted for: maternal age, ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of	Limitations Choice of treatment unrelated to confounders (selection bias): No; however, the adjusted odds ratios aim to control for these confounders Groups comparable at baseline: No, women planning a home birth were more likely to be white, older, fluent in English and live in a more socio-economically advantaged area. Women planning birth in midwifery units fell between the home and hospital groups. There were also significantly more women with complicating conditions

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare maternal outcomes, perinatal outcomes and interventions during labour by planned place of birth at the start of care in labour for women with low risk pregnancies Study dates Birth between April 2008 and April 2010 Source of funding The study combines the Evaluation of Maternity Units in England Study (funded by the National Institute of Health Research Service and Delivery and Organisation) and the Birth at Home in England study (funded by the Department of Health Policy Research Programme)	Fr-MLU: 677 (6.0) Al-MLU: 1069 (6.4) 20-24 OU: 4251 (21.6) Home: 1706 (10.2) Fr-MLU: 2132 (18.9) Al-MLU: 3489 (20.9) 25-29 OU: 5701 (29.0) Home: 4346 (25.9) Fr-MLU: 3267 (29.0) Al-MLU: 5001 (30.0) 30-34 OU: 5063 (25.7) Home: 5848 (34.8) Fr-MLU: 3248 (28.8) Al-MLU: 4582 (27.5) 35-39 OU: 2640 (13.4) Home: 4017 (23.9) Fr-MLU: 1690 (15.0) Al-MLU: 2232 (13.4) > 40 OU: 520 (2.6) Home: 671 (4.0)		No detail given Data collection, analysis and monitoring The authors aimed to collect data in every NHS trust in England that provided home birth services, every freestanding and alongside midwifery unit, and a random sample of obstetric units, which were stratified by size and region. The target sample size was 57,000 women in total: 17,000 planned home births, 5000 each planned in alongside and freestanding midwifery units, and 30,000 planned in obstetric units. Coordinating midwives were designated in each unit or trust. Data collection forms were	multiple deprivation score, parity and gestational age at birth. Maternal mortality (reported in the Hollowell et al. report only) (n/total (%)) OU: 0/19706 (0) Home: 0/16840 (0) Fr-MLU: 0/11282 (0) Al-MLU: 0/16710 (0) [Note: the authors report that there were no maternal deaths, but no other details are given; therefore, denominator must be assumed] Mode of birth (n/total (incidence per 1000 [99% CI]) [Note: for mode of birth outcomes the	identified at the start of labour in the OU group. Groups received same/similar care (apart from intervention): Unclear - because the study is based in multiple units, no specific details are given Blinding of those assessing outcomes: No Missing data/loss to follow-up: There are missing data for confounders; however, this is under 5%. For outcome data, less than 1% have missing data Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Some forms were completed retrospectively for eligible women that were missed Intention-to-treat analysis performed: Yes Indirectness: Out of the main study population, 10% had complicating

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Fr-MLU: 254 (2.3) Al-MLU: 299 (1.8) Missing data OU: 25 Home: 34 Fr-MLU: 14 Al-MLU: 38 Body mass index in pregnancy (n (%)) Mean ± SD OU: 24.4 ± 4.0 Home: 24.0 ± 3.7 Fr-MLU: 24.1 ± 3.7 Al-MLU: 24.0 ± 3.8 Not recorded in maternity notes OU: 3566 (18.1) Home: 3268 (19.5) Fr-MLU: 1861 (16.5) Al-MLU: 2927 (17.6) < 18.5 OU: 570 (2.9) Home: 321 (1.9) Fr-MLU: 234 (2.1) Al-MLU: 438 (2.6)		provided to be started by the midwife providing intrapartum care, move with the woman if she was transferred, and be completed on at least the fifth postpartum day. Where the initial form indicated that the mother or baby had been admitted for higher level care or there was another adverse outcome, there were additional neonatal and maternal morbidity forms to be completed. These were designed to validate outcome events and capture additional events diagnosed after the end of labour. The forms were completed by midwives (assisted by neonatal unit staff where relevant) from medical notes or records.	data available for OR calculations was 62,592/64,483 (97.1%) of the data available for raw calculations, due to missing confounder data] a. Spontaneous vertex birth OU: 14645/19688 (73.8 [71.1 to 76.4]) Home: 15590/16825 (92.8 [91.7 to 93.7]) Fr-MLU: 10150/11280 (90.7 [89.1 to 92.0]) Al-MLU: 14413/16690 (85.9 [83.7 to 87.9]) TOTAL: 54798/64483 (76.4 [73.8 to 78.7]) - Unadjusted OR OU: 1.00 Home: 4.49 (99% CI 3.67 to 5.49) Fr-MLU: 3.45 (99%	conditions identified at the start of labour (OU: 19.5%; Home: 5.4%; Fr-MLU: 5.5%; Al-MLU: 6.9%) Other information Comparison: ALL [This study is new since 2007 guideline] Note: some information has been accessed from the full report: Hollowell J, Puddicombe D, Rowe R, Linsell L, Hardy P, Stewart, M, et al. The Birthplace national prospective cohort study: perinatal and maternal outcomes by planned place of birth. Birthplace in England research programme. Final report part 4. NIHR Service Delivery and Organisation programme; 2011. Information on interactions between parity and planned place of birth for

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	18.5 - 24.9 OU: 8856 (45.1) Home: 8155 (48.7) Fr-MLU: 5605 (49.8) Al-MLU: 8218 (49.4) 25.0 - 29.9 OU: 4731 (24.1) Home: 3776 (22.5) Fr-MLU: 2653 (23.6) Al-MLU: 3789 (22.8) 30.0 - 35.0 OU: 1928 (9.8) Home: 1226 (7.3) Fr-MLU: 912 (8.1) Al-MLU: 1272 (7.6) Missing data OU: 55 Home: 94 Fr-MLU: 17 Al-MLU: 66 Previous pregnancies ≥ 24 weeks (n (%)) 0 OU: 10 626 (54.0) Home: 4568 (27.2)		Units and trusts provided monthly counts. Any eligible women that were missed were completed retrospectively. The analysis included all eligible healthy women with low risk pregnancies. Robust variance estimation was used to account for the clustered nature of the data. Probability weights were used in order to account for the varying probability of a woman being selected for inclusion, linked to period of participation and probabilities of selection of obstetric units in strata. Odds ratios were calculated using logistic regression, accounting for clustering and sample weights.	CI 2.76 to 4.31) Al-MLU: 2.16 (99% CI 1.74 to 2.70) - Adjusted OR OU: 1.00 Home: 3.61 (99% CI 2.97 to 4.38) Fr-MLU: 3.38 (99% CI 2.70 to 4.25) Al-MLU: 2.22 (99% CI 1.76 to 2.81) b. Vaginal breech birth OU: 43/19688 (0.2 [0.1 to 0.3]) Home: 63/16825 (0.4 [0.3 to 0.5]) Fr-MLU: 39/11280 (0.4 [0.2 to 0.6]) Al-MLU: 26/16690 (0.2 [0.1 to 0.3]) TOTAL: 171/64483 (0.2 [0.2 to 0.3]) - Unadjusted OR OU: 1.00 Home: 1.83 (99% CI 0.97 to 3.45)	primary outcome In all women: the test for interaction between planned place of birth and parity generated the following p-values for parity adjusted regression tests of heterogeneity: overall 0.06; and then pairwise against OU: home 0.01; freestanding midwifery unit 0.99; alongside midwifery unit 0.69 In women without complicating conditions at start of labour: the test for interaction between planned place of birth and parity generated the following p-values for parity adjusted regression tests of heterogeneity: overall 0.03; and then pairwise against OU: home 0.006; freestanding midwifery unit 0.47; alongside midwifery unit 0.66

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Fr-MLU: 5187 (46.0) Al-MLU:8350 (50.1) 1 OU: 5757 (29.3) Home: 6528 (38.8) Fr-MLU: 3913 (34.7) Al-MLU: 5621 (33.7) 2 OU: 2028 (10.3) Home: 3663 (21.8) Fr-MLU: 1513 (13.4) Al-MLU: 1933 (11.6) ≥ 3 OU: 1264 (6.4) Home: 2065 (12.3) Fr-MLU: 652 (5.8) Al-MLU: 769 (4.6) Missing data OU: 31 Home: 16 Fr-MLU: 17 Al-MLU: 37 Gestation/completed weeks (n (%)) Mean ± SD		Adjusted odds ratios adjusted for: maternal age, ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score, parity and gestational age at birth. Stata 11.1 was used for all analyses. Subgroup analyses A pre-specified subgroup analysis was done based on parity. A test for statistical interaction between place of birth and parity was also done. In order to assess robustness, a subgroup analysis was also done restricting the analysis to units or trusts with at least 85% of eligible women included. Then, propensity score	Fr-MLU: 1.79 (99% CI 0.86 to 3.72) Al-MLU: 0.94 (99% CI 0.43 to 2.07) - Adjusted OR OU: 1.00 Home: 2.13 (99% CI 1.15 to 3.96) Fr-MLU: 2.00 (99% CI 1.00 to 3.99) Al-MLU: 0.94 (99% CI 0.44 to 2.04) c. Ventouse delivery OU: 1535/19688 (8.1 [6.4 to 10.1]) Home: 342/16825 (2.0 [1.6 to 2.5]) Fr-MLU: 321/11280 (2.7 [2.0 to 3.5]) Al-MLU: 755/16690 (4.8 [3.6 to 6.2]) TOTAL: 2953/64483 (7.3 [5.9 to 9.0]) - Unadjusted OR OU: 1.00 Home: 0.24 (99% CI	INFORMATION ON VARIOUS COMPONENTS OF PRIMARY OUTCOME FROM APPENDICES The following details the individual components of the primary outcome that were designated by the GDG as priority outcomes. However, it should be noted that the study was not powered for these individual components. a. Stillbirth (n/total [incidence per 1000]) - All low risk women OU: 3/19706 (0.2) Home: 6/16839 (0.3) Fr-MLU: 4/11282 (0.4) Al-MLU: 1/16708 (0.1) - Nulliparous women OU: 1/10626 (0.1) Home: 4/4568 (0.9) Fr-MLU: 1/5187 (0.3) Al-MLU: 1/8349 (0.1)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	OU: 39.8 ± 1.1 Home: 39.8 ± 1.0 Fr-MLU: 39.8 ± 1.0 Al-MLU: 39.7 ± 1.0 37 OU: 717 (3.6) Home: 378 (2.3) Fr-MLU: 315 (2.8) Al-MLU: 474 (2.8) 38 OU: 1969 (10.0) Home: 1568 (9.3) Fr-MLU:978 (8.7) Al-MLU: 1565 (9.4) 39 OU: 4557 (23.2) Home: 4089 (24.3) Fr-MLU: 2669 (23.7) Al-MLU: 4132 (24.8) 40 OU: 6976 (35.5) Home: 6596 (39.3) Fr-MLU: 4364 (38.8) Al-MLU: 6492 (39.0) 41		methods were used to explore the effect of differences in baseline characteristics on the primary outcome. Due to differences in the risk status of the women at the onset of labour (19.5% in OU group had complicating condition(s) at the onset of labour, compared to under 7% in all other settings), further analysis was done restricting the analysis to women without complications at the start of labour. This was agreed before the start of the analysis. Outcomes reported 1. Composite perinatal/neonatal outcome: stillbirth after start of care in labour, early neonatal death, neonatal	0.17 to 0.33) Fr-MLU: 0.31 (99% CI 0.21 to 0.46) Al-MLU: 0.57 (99% CI 0.39 to 0.83) - Adjusted OR OU: 1.00 Home: 0.29 (99% CI 0.21 to 0.40) Fr-MLU: 0.32 (99% CI 0.22 to 0.47) Al-MLU: 0.56 (99% CI 0.39 to 0.82) d. Forceps delivery OU: 1307/19688 (6.8 [5.4 to 8.4]) Home: 372/16825 (2.1 [1.8 to 2.5]) Fr-MLU: 365/11280 (2.9 [2.3 to 3.7]) Al-MLU: 769/16690 (4.7 [3.5 to 6.4]) TOTAL: 2813/64483 (6.2 [5.1 to 7.6]) - Unadjusted OR OU: 1.00	- Multiparous women OU: 2/9049 (0.2) Home: 2/12255 (0.1) Fr-MLU: 3/6078 (0.5) Al-MLU: 0/8322 (0) b. Early neonatal death (within 7 days) (n/total [incidence per 1000]) - All low risk women OU: 5/19637 (0.3) Home: 5/16759 (0.3) Fr-MLU: 5/11263 (0.4) Al-MLU: 3/16633 (0.1) - Nulliparous women OU: 4/10593 (0.4) Home: 2/4544 (0.4) Fr-MLU: 3/5180 (0.5) Al-MLU: 2/8304 (0.1) - Multiparous women OU: 1/9013 (0.1) Home: 3/12199 (0.3) Fr-MLU: 2/6066 (0.3) Al-MLU: 1/8293 (0.1) c. Neonatal encephalopathy (clinical diagnosis) (n/total

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	OU: 4908 (25.0) Home: 3866 (23.0) Fr-MLU: 2821 (25.1) Al-MLU: 3797 (22.8) ≥ 42 OU: 523 (2.7) Home: 302 (1.8) Fr-MLU: 108 (1.0) Al-MLU: 195 (1.2) Missing data* OU: 56 Home: 41 Fr-MLU: 27 Al-MLU: 55 * when the recorded "estimated date of delivery" was ≤ 31 weeks, the birth weight was compared with growth reference centiles, and if the weight was > 95th centile for the gestational age and > 5th centile for a gestation of 37 weeks, the birth was assumed to be term but the gestation was recoded as 'missing'. A gestation of > 44 weeks was considered implausible and		encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus, fractured clavicle 2. Mode of birth: spontaneous vertex, vaginal breech, ventouse, forceps, intrapartum CS 3. Use of epidural 4. Vaginal/perineal trauma: incidence of third or fourth degree perineal trauma is reported; rates of episiotomy are reported 5. Measures of blood loss: incidence of blood transfusion is reported 6. Admission to NICU 7. Maternal mortality: reported in Hollowell et	Home: 0.30 (99% CI 0.22 to 0.40) Fr-MLU: 0.41 (99% CI 0.29 to 0.58) Al-MLU: 0.68 (99% CI 0.45 to 1.01) - Adjusted OR OU: 1.00 Home: 0.43 (99% CI 0.32 to 0.57) Fr-MLU: 0.45 (99% CI 0.32 to 0.63) Al-MLU: 0.70 (99% CI 0.46 to 1.05) e. Intrapartum caesarean section OU: 2158/19688 (11.1 [9.5 to 13.0]) Home: 458/16825 (2.8 [2.3 to 3.4]) Fr-MLU: 405/11280 (3.5 [2.8 to 4.2]) Al-MLU: 727/16690 (4.4 [3.5 to 5.5]) TOTAL: 3748/64483 (9.9 [8.4 to 11.5])	[incidence per 1000]) - All low risk women OU: 34/19587 (1.9) Home: 34/16589 (1.8) Fr-MLU: 17/11210 (1.5) Al-MLU: 17/16569 (1.4) - Nulliparous women OU: 20/10560 (2.2) Home: 19/4500 (3.8) Fr-MLU: 12/5163 (2.3) Al-MLU: 14/8282 (2.5) - Multiparous women OU: 14/8997 (1.7) Home: 15/12074 (1.1) Fr-MLU: 5/6031 (0.9) Al-MLU: 3/8252 (0.3) d. Neonatal encephalopathy (signs: defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress) (n/total [incidence per 1000]) - All low risk women

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	also recorded as missing. Complicating conditions identified at the start of care in labour (n (%)) a. Type of complication Prolonged rupture of membranes (> 18 hours) OU: 1462 (7.4) Home: 395 (2.4) Fr-MLU: 231 (2.1) Al-MLU: 383 (2.3) Meconium stained liquor OU: 1254 (6.4) Home: 242 (1.5) Fr-MLU: 140 (1.2) Al-MLU: 233 (1.4) Proteinuria (≥ 1) OU: 347 (1.8) Home: 80 (0.5) Fr-MLU: 110 (1.0) Al-MLU: 370 (2.2) Hypertension OU: 502 (2.6) Home: 92 (0.6) Fr-MLU: 78 (0.7) Al-MLU: 113 (0.7)		al., 2011	- Unadjusted OR OU: 1.00 Home: 0.23 (99% CI 0.17 to 0.30) Fr-MLU: 0.28 (99% CI 0.21 to 0.37) Al-MLU: 0.37 (99% CI 0.28 to 0.49) - Adjusted OR OU: 1.00 Home: 0.31 (99% CI 0.23 to 0.41) Fr-MLU: 0.32 (99% CI 0.24 to 0.42) Al-MLU: 0.39 (99% CI 0.29 to 0.53) Use of epidural or spinal analgesia (n/total (incidence [99% CI]) OU: 5817/19576 (30.7 [27.5 to 34.2]) Home: 1418/16799 (8.3 [7.3 to 9.4]) Fr-MLU: 1251/11251 (10.6 [9.1 to 12.3]) Al-MLU: 2464/16661	OU: 8/19706 (0.4) Home: 4/16840 (0.3) Fr-MLU: 2/11282 (0.2) Al-MLU: 4/16710 (0.2) - Nulliparous women OU: 7/10626 (0.6) Home: 3/4568 (1.0) Fr-MLU: 1/5187 (0.2) Al-MLU: 3/8350 (0.3) - Multiparous women OU: 1/9049 (0.1) Home: 1/12256 (0.0) Fr-MLU: 1/6078 (0.2) Al-MLU: 1/8323 (0.1) LOW RISK WOMEN WITHOUT COMPLICATING CONDITIONS AT ONSET OF LABOUR (n/total (%)) Note: the denominators presented here are those presented for the composite subgroup a. Stillbirth OU: 3/15676 (0.019%)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Abnormal vaginal bleeding OU: 274 (1.4) Home: 41 (0.2) Fr-MLU: 22 (0.2) Al-MLU: 37 (0.2) Non-cephalic presentation OU: 108 (0.6) Home: 37 (0.2) Fr-MLU: 25 (0.2) Al-MLU: 29 (0.2) Abnormal fetal heart rate OU: 393 (2.0) Home: 68 (0.4) Fr-MLU: 52 (0.5) Al-MLU: 65 (0.4) Other complications OU: 54 (0.3) Home: 14 (0.1) Fr-MLU: 17 (0.2) Al-MLU: 17 (0.1) b. Number of complications per woman 0 OU: 15794 (80.5) Home: 15757 (94.6)			(15.3 [13.2 to 17.7]) TOTAL: 10950/64287 (27.6 [24.6 to 30.8]) - Unadjusted OR OU: 1.00 Home: 0.20 (99% CI 0.17 to 0.25) Fr-MLU: 0.27 (99% CI 0.21 to 0.33) Al-MLU: 0.41 (99% CI 0.32 to 0.51) - Adjusted OR OU: 1.00 Home: 0.25 (99% CI 0.20 to 0.31) Fr-MLU: 0.27 (99% CI 0.22 to 0.34) Al-MLU: 0.40 (99% CI 0.32 to 0.50) [Note: data available for OR calculations was 62434/64287 (97.1%) of data available for raw data calculations, due to missing	Home: 6/15538 (0.039%) Fr-MLU: 3/10571 (0.028%) Al-MLU: 0/15342 (0) b. Early neonatal death (within 7 days) OU: 2/15676 (0.013%) Home: 4/15538 (0.026%) Fr-MLU: 3/10571 (0.028%) Al-MLU: 3/15342 (0.020%) c. Neonatal encephalopathy (clinical diagnosis) OU: 20/15676 (0.128%) Home: 28/15538 (0.180%) Fr-MLU: 15/10571 (0.142%) Al-MLU: 15/15342 (0.098%) d. Neonatal encephalopathy (signs: defined as admission to a neonatal unit within 48 hours of birth for at least 48 hours with evidence of feeding difficulties or respiratory distress) OU: 7/15676 (0.045%)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Fr-MLU: 10643 (94.5) Al-MLU: 15512 (93.1) 1 OU: 3345 (17.0) Home: 847 (5.1) Fr-MLU: 572 (5.1) Al-MLU: 1078 (6.5) ≥ 2 OU: 490 (2.5) Home: 51 (0.3) Fr-MLU: 50 (0.4) Al-MLU: 78 (0.5) Missing data OU: 77 Home: 185 Fr-MLU: 17 Al-MLU: 42 Ethnic group (n (%)) White OU: 16068 (81.7) Home: 15937 (94.8) Fr-MLU:10329 (91.6) Al-MLU: 13485 (80.9) Indian OU: 477 (2.4)			confounder data] Third or fourth degree perineal trauma (n/total (incidence per 1000 [99% CI]) OU: 625/19638 (3.2 [2.7 to 3.7]) Home: 318/16800 (1.9 [1.6 to 2.3]) Fr-MLU: 259/11262 (2.3 [1.9 to 2.9]) Al-MLU: 535/16654 (3.2 [2.6 to 4.0]) TOTAL: 1737/64354 (3.1 [2.7 to 3.6]) - Unadjusted OR OU: 1.00 Home: 0.58 (99% CI 0.45 to 0.76) Fr-MLU: 0.72 (99% CI 0.56 to 0.94) Al-MLU: 1.02 (99% CI 0.77 to 1.34) - Adjusted OR OU: 1.00	Home: 3/15538 (0.019%) Fr-MLU: 2/10571 (0.019%) Al-MLU: 4/15342 (0.026%) SUBGROUP ANALYSIS of secondary outcomes for women without complicating conditions at onset of labour (REPORTED IN APPENDIX 5 OF HOLLOWELL ET AL. REPORT) Spontaneous vertex birth Nulliparous women OU: 5171/7791 Home: 3216/4033 Fr-MLU: 3858/4714 Al-MLU: 5694/7378 - Adjusted OR OU: 1 Home: 2.54 (99% CI 2.04 to 3.16) Fr-MLU: 2.61 (99% CI 2.01 to 3.39) Al-MLU: 1.77 (99% CI 1.39 to 2.24) Multiparous women OU: 6737/7429

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Home: 67 (0.4) Fr-MLU: 87 (0.8) Al-MLU: 509 (3.1) Pakistani OU: 636 (3.2) Home: 41 (0.2) Fr-MLU: 164 (1.5) Al-MLU: 545 (3.3) Bangladeshi OU: 297 (1.5) Home: 14 (0.1) Fr-MLU: 147 (1.3) Al-MLU: 130 (0.8) Black Caribbean OU: 265 (1.3) Home: 127 (0.8) Fr-MLU: 48 (0.4) Al-MLU: 198 (1.2) Black African OU: 670 (3.4) Home: 112 (0.7) Fr-MLU: 94 (0.8) Al-MLU: 520 (3.1) Mixed OU: 328 (1.7)			Home: 0.77 (99% CI 0.57 to 1.05) Fr-MLU: 0.78 (99% CI 0.58 to 1.05) Al-MLU: 1.04 (99% CI 0.79 to 1.38) [Note: the data available for the OR calculations was 62482/64354 (97.1%) of the data available for raw data calculations, due to missing confounder data] Episiotomy (n/total (incidence per 1000 [99% CI]) OU: 3780/19678 (19.3 [17.4 to 21.4]) Home: 933/16670 (5.4 [4.8 to 6.1]) Fr-MLU: 995/11275 (8.6 [7.3 to 10.1]) Al-MLU: 2098/16689 (13.1 [11.4 to 14.9]) TOTAL: 7806/64312 (17.8 [16.0 to 19.6])	Home:11141/11338 Fr-MLU: 5595/5714 Al-MLU: 7381/7629 - Adjusted OR OU: 1 Home: 6.44 (99% CI 4.75 to 8.74) Fr-MLU: 5.10 (99% CI 3.43 to 7.60) Al-MLU: 2.90 (99% CI 2.04 to 4.12) All women (calculated by technical team) OU: 11908/15220 Home: 14357/15371 Fr-MLU: 9453/10428 Al-MLU: 13075/15007 Ventouse birth Nulliparous women OU: 866/7791 Home: 241/4033 Fr-MLU: 270/4714 Al-MLU: 570/7378 - Adjusted OR OU: 1 Home: 0.39 (99% CI 0.28-0.56) Fr-MLU: 0.42 (99% CI

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Home: 280 (1.7) Fr-MLU: 124 (1.1) Al-MLU: 293 (1.8) Other OU: 938 (4.8) Home: 241 (1.4) Fr-MLU: 284 (2.5) Al-MLU: 993 (6.0) Missing data OU: 27 Home: 21 Fr-MLU: 5 Al-MLU: 37 Understanding of English (n (%)) Fluent OU: 18044 (92.3) Home: 16724 (99.5) Fr-MLU: 10927 (97.1) Al-MLU: 15196 (91.3) Some OU: 1130 (5.8) Home: 75 (0.4) Fr-MLU: 273 (2.4) Al-MLU: 1176 (7.1)			- Unadjusted OR OU: 1.00 Home: 0.24 (99% CI 0.20 to 0.29) Fr-MLU: 0.39 (99% CI 0.31 to 0.49) Al-MLU: 0.63 (99% CI 0.51 to 0.77) - Adjusted OR OU: 1.00 Home: 0.33 (99% CI 0.28 to 0.39) Fr-MLU: 0.40 (99% CI 0.32 to 0.51) Al-MLU: 0.62 (99% CI 0.50 to 0.77) [Note: the data available for the OR calculations was 62422/64312 (97.1%) of the data available for raw data calculations, due to missing confounder data]	0.28-0.62) Al-MLU: 0.64 (99% CI 0.43-0.94) Multiparous women OU: 250/ 7429 Home: 52/11338 Fr-MLU: 24/5714 Al-MLU: 91/7629 - Adjusted OR OU: 1 Home: 0.12 (99% CI 0.07 to 0.21) Fr-MLU: 0.11 (99% CI 0.05 to 0.22) Al-MLU: 0.37 (99% CI 0.22 to 0.62) All women (calculated by technical team) OU: 1116/15220 Home: 293/15371 Fr-MLU: 294/10428 Al-MLU: 661/15007 Forceps birth Nulliparous women OU: 754/ 7791 Home: 268/ 4033

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	None OU: 380 (1.9) Home: 15 (0.1) Fr-MLU: 55 (0.5) Al-MLU: 274 (1.6) Missing data OU: 152 Home: 26 Fr-MLU: 27 Al-MLU: 64 Marital status (n (%)) Married or living with partner OU: 17097 (88.2) Home: 16056 (96.0) Fr-MLU: 10444 (93.6) Al-MLU: 15014 (91.2) Single or unsupported by partner OU: 2289 (11.8) Home: 673 (4.0) Fr-MLU: 718 (6.4) Al-MLU: 1453 (8.8) Missing data OU: 320 Home: 111 Fr-MLU: 120			Blood transfusion (n/total (incidence per 1000 [99% CI])) OU: 241/19579 (1.2 [1.0 to 1.6]) Home: 101/16687 (0.6 [0.5 to 0.9]) Fr-MLU: 67/11230 (0.5 [0.4 to 0.7]) Al-MLU: 136/16548 (0.9 [0.7 to 1.2]) TOTAL: 545/64044 (1.2 [0.9 to 1.4]) - Unadjusted OR OU: 1.00 Home: 0.54 (99% CI 0.36 to 0.80) Fr-MLU: 0.42 (99% CI 0.28 to 0.64) Al-MLU: 0.72 (99% CI 0.52 to 1.00) - Adjusted OR OU: 1.00 Home: 0.72 (99% CI 0.47 to 1.12) Fr-MLU: 0.48 (99% CI 0.32 to 0.73)	Fr-MLU: 276/ 4714 Al-MLU: 582/ 7378 - Adjusted OR OU: 1 Home: 0.54 (99% CI 0.38 to 0.76) Fr-MLU: 0.50 (99% CI 0.34 to 0.74) Al-MLU:0.78 (99% CI 0.52 to 1.17) Multiparous women OU: 135/7429 Home: 46/11338 Fr-MLU: 42/5714 Al-MLU: 80/7629 - Adjusted OR OU 1 Home 0.20 (99% CI 0.11 to 0.35) Fr-MLU 0.34 (99% CI 0.19 to 0.61) Al-MLU 0.58 (99% CI 0.31 to 1.11) All women (calculated by technical team) OU: 889/15220

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Al-MLU: 243 Deprivation score (quintile [measured with index of multiple deprivation]) (n (%)) 1st (least deprived) OU: 3157 (16.1) Home: 3688 (22.1) Fr-MLU: 2496 (22.2) Al-MLU: 2535 (15.2) 2nd OU: 3618 (18.5) Home: 3483 (20.8) Fr-MLU: 2582 (22.9) Al-MLU: 2648 (15.9) 3rd OU: 3698 (18.9) Home: 3650 (21.8) Fr-MLU: 2304 (20.5) Al-MLU: 3245 (19.5) 4th OU: 4084 (20.9) Home: 3336 (19.9) Fr-MLU: 2080 (18.5) Al-MLU: 3852 (23.1) 5th (most deprived)			Al-MLU: 0.75 (99% CI 0.55 to 1.02) [Note: data available for OR calculations was 62219/64044 (97.2%) of data available for raw calculations due to missing confounder data] Composite perinatal/neonatal outcome (n/total (incidence per 1000 [95% CI])) a. All women OU: 81/19551 (4.4 [3.2 to 5.9]) Home: 70/16553 (4.2 [3.2 to 5.4]) Fr-MLU: 41/11199 (3.5 [2.5 to 4.9]) Al-MLU: 58/16524 (3.6 [2.6 to 4.9]) TOTAL: 250/63827 (4.3 [3.3 to 5.5]) - Unadjusted OR:	Home: 314/15371 Fr-MLU: 318/10428 Al-MLU: 662/15007 Intrapartum caesarean section Nulliparous women OU: 994/7791 Home: 300/4033 Fr-MLU: 299/4714 Al-MLU: 520/7378 - Adjusted OR OU:1 Home: 0.51 (99% CI 0.37 to 0.71) Fr-MLU: 0.46 (99% CI 0.34 to 0.62) Al-MLU: 0.54 (99% CI 0.39 to 0.73) Multiparous women OU: 294/7429 Home: 65/11338 Fr-MLU: 38/5714 Al-MLU: 70/7629 - Adjusted OR OU: 1 Home: 0.13 (99% CI 0.08

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	OU: 5023 (25.7) Home: 2565 (15.3) Fr-MLU: 1789 (15.9) Al-MLU: 4382 (26.3) Missing data OU: 126 Home: 118 Fr-MLU: 31 Al-MLU: 48 Inclusion criteria Attended by an NHS midwife during labour in their planned place of birth (for any amount of time) Healthy women with low risk pregnancies (i.e. before the onset of labour, they were not known to have any of the medical or obstetric risk factors listed in the NICE 2007 guideline Intrapartum Care) Exclusion criteria Elective caesarean section Caesarean section before the			OU: 1.00 Home: 0.96 (95% CI 0.65 to 1.42) Fr-MLU: 0.82 (95% CI 0.52 to 1.28) Al-MLU: 0.84 (95% CI 0.54 to 1.30) - Adjusted OR: OU: 1.00 Home: 1.16 (95% CI 0.76 to 1.77) Fr-MLU: 0.92 (95% CI 0.58 to 1.46) Al-MLU: 0.92 (95% CI 0.60 to 1.39) [Note: data available for OR calculations is 62036/63827 (97.2%) of data available for raw calculations, due to missing confounder data] b. Women without complicating conditions at the start of labour	to 0.22) Fr-MLU: 0.16 (99% CI 0.09 to 0.31) Al-MLU: 0.22 (99% CI 0.12 to 0.41) All women (calculated by technical team) OU: 1288/15220 Home: 365/15371 Fr-MLU: 337/10428 Al-MLU: 590/15007 Epidural or spinal analgesia Nulliparous women OU: 2838/7753 Home: 868/4022 Fr-MLU: 893/4698 Al-MLU: 1699/7367 - Adjusted OR OU: 1 Home: 0.38 (99% CI 0.29 to 0.49) Fr-MLU: 0.36 (99% CI 0.27 to 0.46) Al-MLU: 0.51 (99% CI 0.39 to 0.66)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	onset of labour Presenting in preterm labour (< 37 weeks gestation) Multiple pregnancy 'Unbooked' (receiving no antenatal care) Stillbirth before the start of care in labour			OU: 48/15676 (3.1 [2.2 to 4.2]) Home: 62/15538 (4.0 [3.0 to 5.3]) Fr-MLU: 35/10571 (3.2 [2.3 to 4.6]) Al-MLU: 54/15342 (3.4 [2.4 to 4.9]) TOTAL: 199/57127 (3.1 [2.4 to 4.0]) - Unadjusted OR: OU: 1.00 Home: 1.34 (95% CI 0.88 to 2.05) Fr-MLU: 1.11 (95% CI 0.69 to 1.77) Al-MLU: 1.19 (95% CI 0.74 to 1.91) - Adjusted OR: OU: 1.00 Home: 1.59 (95% CI 1.01 to 2.52) Fr-MLU: 1.22 (95% CI 0.76 to 1.96) Al-MLU:1.26 (95% CI 0.80 to 1.99) [Note: data available	Multiparous women OU: 1061/7403 Home: 320/11333 Fr-MLU: 201/5705 Al-MLU: 416/7622 - Adjusted OR OU: 1 Home: 0.16 (99% CI 0.12 to 0.20) Fr-MLU: 0.20 (99% CI 0.14 to 0.27) Al-MLU: 0.35 (99% CI 0.26 to 0.47) All women (calculated by technical team) OU: 3899/15156 Home: 1188/15355 Fr-MLU: 1094/10403 Al-MLU: 2115/14989 Episiotomy Nulliparous women OU:2180/7783 Home:645/4026 Fr-MLU: 762/4712 Al-MLU:1573/7377 - Adjusted OR

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				for OR calculations is 55572/57127 (97.3%) of data available for raw calculations, due to missing confounder data] c. Nulliparous women only OU: 52/10541 (5.3 [3.9 to 7.3]) Home: 39/4488 (9.3 [6.5 to 13.1]) Fr-MLU: 24/5158 (4.5 [2.8 to 7.1]) Al-MLU: 38/8256 (4.7 [3.1 to 7.2]) TOTAL: 153/28443 (5.3 [4.0 to 7.0]) - Unadjusted OR: OU: 1.00 Home: 1.76 (95% CI 1.10 to 2.82) Fr-MLU: 0.85 (95% CI 0.49 to 1.48) Al-MLU: 0.90 (95% CI 0.53 to 1.54)	OU:1 Home:0.41 (99% CI 0.33 to 0.50) Fr-MLU: 0.45 (99% CI 0.34 to 0.60) Al-MLU:0.69 (99% CI 0.54 to 0.87) Multiparous women OU: 553/7432 Home: 161/11322 Fr-MLU: 118/5712 Al-MLU: 249/7628 - Adjusted OR OU: 1 Home: 0.18 (99% CI 0.13 to 0.24) Fr-MLU: 0.27 (99% CI 0.18 to 0.39) Al-MLU: 0.46 (99% CI 0.34 to 0.62) All women (calculated by technical team) OU: 2733/15215 Home: 806/15348 Fr-MLU: 880/10424 Al-MLU: 1822/15005 Third or fourth degree

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Adjusted OR: OU: 1.00 Home: 1.75 (95% CI 1.07 to 2.86) Fr-MLU: 0.91 (95% CI 0.52 to 1.60) Al-MLU: 0.96 (95% CI 0.58 to 1.61) [Note: data available for OR calculations is 27669/28443 (97.3%) of data available for raw calculations, due to missing confounder data] d. Multiparous women only OU: 29/8980 (3.3 [2.2 to 5.0]) Home: 31/12050 (2.3 [1.6 to 3.2]) Fr-MLU: 17/6025 (2.7 [1.6 to 4.6]) Al-MLU: 20/8234 (2.4 [1.4 to 4.3]) TOTAL: 97/35289 (3.1 [2.2 to 4.5])	perineal trauma Nulliparous women OU: 363/7773 Home: 176/4023 Fr-MLU: 190/4706 Al-MLU: 362/7369 - Adjusted OR OU:1 Home: 0.86 (99% CI 0.61 to 1.21) Fr-MLU: 0.87 (99% CI 0.61 to 1.24) Al-MLU:1.07 (99% CI 0.78 to 1.46) Multiparous women OU:123/7424 Home:112/11325 Fr-MLU: 50/5704 Al-MLU:111/7611 - Adjusted OR OU:1 Home:0.59 (99% CI 0.37 to 0.93) Fr-MLU: 0.55 (99% CI 0.32 to 0.95) Al-MLU:0.89 (99% CI 0.57 to 1.37)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Unadjusted OR: OU: 1.00 Home: 0.70 (95% CI 0.40 to 1.21) Fr-MLU: 0.86 (95% CI 0.44 to 1.69) Al-MLU: 0.77 (95% CI 0.38 to 1.57) - Adjusted OR: OU: 1.00 Home: 0.72 (95% CI 0.41 to 1.27) Fr-MLU: 0.91 (95% CI 0.46 to 1.80) Al-MLU: 0.81 (95% CI 0.40 to 1.62) [Note: the data available for OR calculations is 34367/35289 (97.4%) of data available for raw calculations, due to missing confounder data] e. Nulliparous	All women (calculated by technical team) OU: 486/15197 Home: 288/15348 Fr-MLU: 240/10410 Al-MLU: 473/14980 Blood transfusion Nulliparous women OU: 121/7755 Home: 44/4014 Fr-MLU: 36/4704 Al-MLU: 78/7321 - Adjusted OR OU: 1 Home: 0.76 (99% CI 0.46 to 1.26) Fr-MLU: 0.50 (99% CI 0.31 to 0.82) Al-MLU: 0.78 (99% CI 0.52 to 1.18) Multiparous women OU: 48/7386 Home: 44/11256 Fr-MLU: 24/5678 Al-MLU: 42/7575

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				women without complicating conditions at the onset of labour OU: 28/8018 (3.5 [2.4 to 5.1]) Home: 36/4063 (9.5 [6.6 to 13.7]) Fr-MLU: 22/4785 (4.5 [2.8 to 7.4]) Al-MLU: 35/7518 (4.4 [2.7 to 7.0]) TOTAL: 121/24384 (3.8 [2.8 to 5.1]) - Unadjusted OR: OU: 1.00 Home: 2.81 (95% CI 1.66 to 4.76) Fr-MLU: 1.33 (95% CI 0.72 to 2.46) Al-MLU: 1.31 (95% CI 0.71 to 2.39) - Adjusted OR: OU: 1.00 Home: 2.80 (95% CI 1.59 to 4.92) Fr-MLU: 1.40 (95%	- Adjusted OR OU: 1 Home: 0.62 (99% CI 0.33 to 1.19) Fr-MLU: 0.48 (99% CI 0.21 to 1.12) Al-MLU: 0.99 (99% CI 0.55 to 1.77) All women (calculated by technical team) OU: 169/15141 Home: 88/15270 Fr-MLU: 60/10382 Al-MLU: 120/14896 Neonatal unit admission Nulliparous women OU: 228/7781 Home: 101/4007 Fr-MLU: 106/4712 Al-MLU: 163/7340 - Adjusted OR OU: 1 Home: 0.86 (99% CI 0.57 to 1.28) Fr-MLU: 0.68 (99% CI 0.43 to1.09) Al-MLU: 0.87 (99% CI 0.55 to 1.36)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				CI 0.74 to 2.65) Al-MLU: 1.38 (95% CI 0.75 to 2.52) [Note: the data available for OR calculations is 23742/24384 (97.4%) of data available for raw calculations due to missing confounder data] f. Multiparous women without complicating conditions at the start of labour OU: 20/7637 (2.6 [1.5 to 4.4]) Home: 26/11461 (2.0 [1.4 to 2.9]) Fr-MLU: 13/5772 (2.2 [1.3 to 3.8]) Al-MLU: 19/7792 (2.5 [1.4 to 4.5]) TOTAL: 78/32662 (2.5 [1.6 to 3.9])	Multiparous women OU: 122/7417 Home: 134/11258 Fr-MLU: 64/5700 Al-MLU: 96/7582 - Adjusted OR OU: 1 Home: 0.73 (99% CI 0.47 to 1.11) Fr-MLU: 0.68 (99% CI 0.41 to 1.14) Al-MLU: 0.84 (99% CI 0.52 to 1.36) All women (calculated by technical team) OU: 350/15198 Home: 235/15265 Fr-MLU: 170/10412 Al-MLU: 259/14922

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Unadjusted OR: OU: 1.00 Home: 0.80 (95% CI 0.41 to 1.54) Fr-MLU: 0.90 (95% CI 0.42 to 1.94) Al-MLU: 1.04 (95% CI 0.47 to 2.30) - Adjusted OR: OU: 1.00 Home: 0.83 (95% CI 0.44 to 1.58) Fr-MLU: 0.97 (95% CI 0.46 to 2.04) Al-MLU: 1.09 (95% CI 0.50 to 2.39) [Note: the data available for OR calculations is 31830/32662 (97.5%) of data available for raw calculations, due to missing confounder data] NOTE: SEE 'OTHER INFORMATION'	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				FOR DETAILS OF THE INDIVIDUAL COMPONENTS OF THE COMPOSITE OUTCOME THAT WERE LISTED BY GDG AS PRIORITY OUTCOMES Neonatal unit admission (n/total (incidence per 1000 [99% CI]))* OU: 543/19642 (28.3 [21.7 to 36.9]) Home: 284/16696 (17.3 [14.3 to 20.8]) Fr-MLU: 194/11257 (16.7 [12.3 to 22.6]) Al-MLU: 307/16580 (19.8 [14.8 to 26.4]) - Unadjusted OR OU: 1 Home: 0.61 (99% CI 0.43 to 0.85) Fr-MLU: 0.58 (99% CI 0.38 to 0.87) Al-MLU: 0.70 (99% CI 0.46 to 1.05)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Adjusted OR OU: 1 Home: 0.73 (99% CI 0.53 to 1.01) Fr-MLU: 0.61 (99% CI 0.40 to 0.91) Al-MLU: 0.75 (99% CI 0.50 to 1.11) * reported in BMJ appendix but not in main article SUB-GROUP ANALYSIS BY PARITY (REPORTED IN APPENDIX 8 TO BMJ ARTICLE) Spontaneous vaginal birth (n/total (% [99% CI])) Nulliparous women OU: 6589/10617 (61.3 [57.8 to 64.7]) Home: 3577/4565 (78.6 [76.3 to 80.8]) Fr-MLU: 4201/5186 (82.3 [79.1 to 85.0])	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Al-MLU: 6357/8336 (75.8 [72.5 to 78.9]) - Unadjusted OR (99% CI) OU: 1 Home: 2.28 (1.87 to 2.77) Fr-MLU: 2.92 (2.27 to 3.75) Al-MLU: 1.97 (1.57 to 2.47) - Adjusted OR (99% CI) OU: 1 Home: 2.77 (2.25 to 3.41) Fr-MLU: 2.97 (2.32 to 3.79) Al-MLU: 1.99 (1.57 to 2.52) Multiparous women OU: 8030/9041 (88.7 [86.6 to 90.4]) Home: 11998/12244 (98.0 [97.7 to 98.4]) Fr-MLU: 5937/6078 (97.8 [97.1 to 98.3])	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Al-MLU: 8025/8317 (96.3 [95.2 to 97.2]) - Unadjusted OR (99% CI) OU: 1 Home: 6.36 (4.87 to 8.30) Fr-MLU: 5.46 (3.88 to 7.69) Al-MLU: 3.33 (2.36 to 4.70) - Adjusted OR (99% CI) OU: 1 Home: 6.85 (5.23 to 8.96) Fr-MLU: 5.65 (3.98 to 8.01) Al-MLU: 3.33 (2.35 to 4.71) Vaginal breech birth (n/total (% [99% CI])) Nulliparous women OU: 18/10617 (0.2 [0.1 to 0.3])	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 13/4565 (0.3 [0.1 to 0.5]) Fr-MLU: 15/5186 (0.3 [0.1 to 0.6]) Al-MLU: 15/8336 (0.2 [0.1 to 0.4]) - Unadjusted OR (99% CI) OU: 1 Home: 1.64 (0.58 to 4.66) Fr-MLU: 1.72 (0.59 to 4.96) Al-MLU: 1.10 (0.39 to 3.11) - Adjusted OR (99% CI) OU: 1 Home: 2.15 (0.77 to 6.02) Fr-MLU: 1.91 (0.67 to 5.40) Al-MLU: 1.10 (0.41 to 2.98) Multiparous women OU: 25/9041 (0.3 [0.2 to 0.5])	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 50/12244 (0.4 [0.3 to 0.6]) Fr-MLU: 24/6078 (0.4 [0.2 to 0.8]) Al-MLU: 11/8317 (0.2 [0.1 to 0.4]) - Unadjusted OR (99% CI) OU: 1 Home: 1.61 (0.78 to 3.31) Fr-MLU: 1.74 (0.75 to 4.03) Al-MLU: 0.72 (0.26 to 2.01) - Adjusted OR (99% CI) OU: 1 Home: 2.02 (0.98 to 4.16) Fr-MLU: 2.03 (0.90 to 4.59) Al-MLU: 0.74 (0.27 to 2.05) Ventouse birth (n/total (% [99% CI]))	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Nulliparous women OU: 1204/10617 (11.8 [9.4 to 14.7]) Home: 282/4565 (5.9 [4.9 to 72]) Fr-MLU: 295/5186 (5.3 [3.9 to 7.2]) Al-MLU: 654/8336 (8.1 [6.2 to 10.6]) - Unadjusted OR (99% CI) OU: 1 Home: 0.49 (0.35 to 0.67) Fr-MLU: 0.43 (0.29 to 0.65) Al-MLU: 0.66 (0.45 to 0.97) - Adjusted OR (99% CI) OU: 1 Home: 0.40 (0.29 to 0.56) Fr-MLU: 0.41 (0.28 to 0.60) Al-MLU: 0.63 (0.44 to 0.92)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Multiparous women OU: 330/9041 (3.7 [2.8 to 4.9]) Home: 60/12244 (0.5 [0.3 to 0.7]) Fr-MLU: 25/6078 (0.4 [0.2 to 0.7]) Al-MLU: 101/8317 (1.3 [0.9 to 2.0]) - Unadjusted OR (99% CI) OU: 1 Home: 0.14 (0.08 to 0.22) Fr-MLU: 0.10 (0.05 to 0.21) Al-MLU: 0.36 (0.22 to 0.60]) - Adjusted OR (99% CI) OU: 1 Home: 0.12 (0.07 to 0.20) Fr-MLU: 0.09 (0.04 to 0.20) Al-MLU: 0.35 (0.21 to 0.58)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Forceps (n/total (% [99% CI]) Nulliparous women OU: 1125/10617 (10.7 [8.6 to 13.2]) Home: 318/4565 (6.6 [5.6 to 7.8]) Fr-MLU: 318/5186 (5.4 [4.2 to 7.1]) Al-MLU: 673/8336 (8.2 [6.1 to 10.9]) - Unadjusted OR (99% CI) OU: 1 Home: 0.60 (0.45 to 0.81) Fr-MLU: 0.49 (0.34 to 0.70) Al-MLU: 0.74 (0.50 to 1.10) - Adjusted OR (99% CI) OU: 1 Home: 0.53 (0.39 to 0.72) Fr-MLU: 0.48 (0.33 to 0.69) Al-MLU: 0.74 (0.49	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 1.10) Multiparous women OU: 182/9041 (2.1 [1.5 to 2.9]) Home: 53/12244 (0.4 [0.3 to 0.6]) Fr-MLU: 46/6078 (0.7 [0.5 to 1.1]) Al-MLU: 92/8317 (1.1 [0.70 to 2.0]) - Unadjusted OR (99% CI) OU: 1 Home: 0.20 (0.12 to 0.33) Fr-MLU: 0.34 (0.20 to 0.59) Al-MLU: 0.55 (0.29 to 1.05) - Adjusted OR (99% CI) OU: 1 Home: 0.18 (0.11 to 0.31) Fr-MLU: 0.33 (0.19 to 0.56) Al-MLU: 0.55 (0.29	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 1.04) Intrapartum CS (n/total (% [99% CI]) Nulliparous women OU: 1681/10617 (16.0 [13.9 to 18.4]) Home: 375/4565 (8.5 [7.0 to 10.4]) Fr-MLU: 357/5186 (6.7 [5.5 to 8.1]) Al-MLU: 637/8336 (7.7 [6.3 to 9.3]) - Unadjusted OR (99% CI) OU: 1 Home: 0.49 (0.37 to 0.65) Fr-MLU: 0.37 (0.28 to 0.48) Al-MLU: 0.45 (0.34 to 0.58) - Adjusted OR (99% CI) OU: 1 Home: 0.45 (0.34 to 0.59) Fr-MLU: 0.39 (0.30	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 0.50) Al-MLU: 0.47 (0.35 to 0.62) Multiparous women OU: 474/9041 (5.3 [4.1 to 6.9]) Home: 83/12244 (0.6 [0.5 to 0.9]) Fr-MLU: 46/6078 (0.7 [0.5 to 1.1]) Al-MLU: 88/8317 (1.0 [0.7 to 1.5]) - Unadjusted OR (99% CI) OU: 1 Home: 0.11 (0.07 to 0.17) Fr-MLU: 0.13 (0.08 to 0.23) Al-MLU: 0.18 (0.11 to 0.30) - Adjusted OR (99% CI) OU: 1 Home: 0.11 (0.07 to 0.17) Fr-MLU: 0.14 (0.08	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 0.23) Al-MLU: 0.19 (0.11 to 0.32) Third or fourth degree perineal trauma (n/total (%)) Nulliparous women OU: 480/10585 (4.5) Home: 195/4555 (4.3) Fr-MLU: 206/5177 (4.0) Al-MLU: 405/8322 (4.9) - Unadjusted OR (99% CI) OU: 1 Home: 0.93 (0.69 to 1.25) Fr-MLU: 0.89 (0.66 to 1.21) Al-MLU: 1.08 (0.82 to 1.44) - Adjusted OR (99% CI) OU: 1 Home: 0.86 (0.62 to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.19) Fr-MLU: 0.89 (0.64 to 1.24) Al-MLU: 1.08 (0.81 to 1.45) Multiparous women OU: 145/9025 (1.6) Home: 123/12229 (1.0) Fr-MLU: 52/6068 (0.9) Al-MLU: 129/8295 (1.6) - Unadjusted OR (99% CI) OU: 1 Home: 0.64 (0.42 to 0.96) Fr-MLU: 0.57 (0.34 to 0.95) Al-MLU: 0.94 (0.61 to 1.44) - Adjusted OR (99% CI) OU: 1 Home: 0.63 (0.40 to 0.99)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Fr-MLU: 0.56 (0.33 to 0.95) Al-MLU: 0.93 (0.61 to 1.41) Blood transfusion (n/total (%)) Nulliparous women OU: 174/10564 (1.6) Home: 55/4540 (1.3) Fr-MLU: 42/5173 (0.8) Al-MLU: 93/8262 (1.3) - Unadjusted OR (99% CI) OU: 1 Home: 0.87 (0.52 to 1.45) Fr-MLU: 0.48 (0.31 to 0.76) Al-MLU: 0.74 (0.49 to 1.11) - Adjusted OR (99% CI) OU: 1 Home: 0.93 (0.54 to 1.58)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Fr-MLU: 0.52 (0.33 to 0.82) Al-MLU: 0.75 (0.51 to 1.10) Multiparous women OU: 67/8984 (0.7) Home: 46/12131 (0.4) Fr-MLU: 25/6040 (0.3) Al-MLU: 43/8250 (0.6) - Unadjusted OR (99% CI) OU: 1 Home: 0.48 (0.28 to 0.81) Fr-MLU: 0.39 (0.19 to 0.81) Al-MLU: 0.74 (0.44 to 1.27) - Adjusted OR (99% CI) OU: 1 Home: 0.51 (0.29 to 0.89) Fr-MLU: 0.42 (0.20	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 0.87) Al-MLU: 0.74 (0.44 to 1.26) Epidural or spinal analgesia (n/total (%) Nulliparous women OU: 4345/10550 (42.5) Home: 1049/4545 (22.7) Fr-MLU: 1021/5168 (18.9) Al-MLU: 1987/8320 (24.4) - Unadjusted OR (99% CI) OU: 1 Home: 0.40 (0.32 to 0.50) Fr-MLU: 0.32 (0.25 to 0.41) Al-MLU: 0.44 (0.35 to 0.56) - Adjusted OR (99% CI) OU: 1	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 0.35 (0.28 to 0.44) Fr-MLU: 0.31 (0.25 to 0.40) Al-MLU: 0.44 (0.35 to 0.57) Multiparous women OU: 1465/8998 (16.8) Home: 369/12238 (2.9) Fr-MLU: 224/6068 (3.5) Al-MLU: 472/8305 (5.9) - Unadjusted OR (99% CI) OU: 1 Home: 0.15 (0.12 to 0.20) Fr-MLU: 0.18 (0.13 to 0.25) Al-MLU: 0.31 (0.23 t0 0.41) - Adjusted OR (99% CI) OU: 1	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 0.14 (0.11 to 0.18) Fr-MLU: 0.17 (0.13 to 0.24) Al-MLU: 0.31 (0.24 to 0.41) Episiotomy (n/total (%)) Nulliparous women OU: 3087/10606 (29.3) Home: 756/4518 (16.0) Fr-MLU: 855/5183 (16.0) Al-MLU: 1804/8337 (22.1) - Unadjusted OR (99% CI) OU: 1 Home: 0.47 (0.39 to 0.56) Fr-MLU: 0.46 (0.36 to 0.60) Al-MLU: 0.68 (0.55 to 0.85) - Adjusted OR (99%	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				CI) OU: 1 Home: 0.41 (0.34 to 0.50) Fr-MLU: 0.45 (0.35 to 0.57) Al-MLU: 0.67 (0.53 to 0.84) Multiparous women OU: 689/9042 (7.5) Home: 176/12137 (1.5) Fr-MLU: 137/6076 (2.3) Al-MLU: 287/8315 (3.7) - Unadjusted OR (99% CI) OU: 1 Home: 0.19 (0.14 to 0.26) Fr-MLU: 0.29 (0.21 to 0.41) Al-MLU: 0.48 (0.36 to 0.65) - Adjusted OR (99% CI)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				OU: 1 Home: 0.18 (0.14 to 0.24) Fr-MLU: 0.28 (0.20 to 0.39) Al-MLU: 0.47 (0.35 to 0.64) Admission to NICU Nulliparous women (n/total (incidence per 1000)) OU: 372/10597 (36.1) Home: 127/4535 (28.5) Fr-MLU: 120/5181 (21.6) Al-MLU: 198/8281 (26.0) - Unadjusted OR (99% CI) OU: 1 Home: 0.81 (0.54 to 1.20) Fr-MLU: 0.59 (0.37 to 0.95) Al-MLU: 0.72 (0.46 to 1.12)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Adjusted OR (99% CI) OU: 1 Home: 0.79 (0.54 to 1.17) Fr-MLU: 0.59 (0.37 to 0.94) Al-MLU: 0.76 (0.49 to 1.17) Multiparous women (n/total (incidence per 1000)) OU: 171/9015 (19.2) Home: 157/12145 (13.1) Fr-MLU: 73/6060 (12.2) Al-MLU: 109/8262 (13.6) - Unadjusted OR (99% CI) OU: 1 Home: 0.68 (0.47 to 0.99) Fr-MLU: 0.64 (0.38 to 1.06)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Al-MLU: 0.70 (0.45 to 1.10) - Adjusted OR (99% CI) OU: 1 Home: 0.67 (0.46 to 0.98) Fr-MLU: 0.64 (0.38 to 1.06) Al-MLU: 0.74 (0.48 to 1.15) TRANSFER The following details of transfer are split by planned place of birth and timing of transfer, as well as whether women were nulliparous or multiparous. a. All women (n/total (%)) - Transferred before birth Home: 2387/16840 (14.2) Fr-MLU: 1863/11282	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(16.5) Al-MLU: 3539/16710 (21.2) - Transferred after birth Home: 1046/16840 (6.2) Fr-MLU: 545/11282 (4.8) Al-MLU: 719/16710 (4.3) - Timing of transfer missing Home: 97/16840 (0.6) Fr-MLU: 60/11282 (0.5) Al-MLU: 152/16710 (0.9) - Total transfers Home: 3530/16840 (21.0) Fr-MLU: 2468/11282 (21.9) Al-MLU: 4410/16710 (26.4)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				b. Nulliparous women only (n/total (%)) - Transferred before birth Home: 1605/4568 (35.1) Fr-MLU: 1535/5187 (29.6) Al-MLU: 2825/8350 (33.8) - Transferred after birth Home: 407/4568 (8.9) Fr-MLU: 306/5187 (5.9) Al-MLU: 427/8350 (5.1) - Timing of transfer missing Home: 45/4568 (1.0) Fr-MLU: 43/5187 (0.8) Al-MLU: 108/8350 (1.3) - Total transfers	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 2057/4568 (45.0) Fr-MLU: 1884/5187 (36.3) Al-MLU: 3360/8350 (40.2) c. Multiparous women only (n/total (%)) - Transferred before birth Home: 782/12256 (6.4) Fr-MLU: 321/6078 (5.3) Al-MLU: 707/8323 (8.5) - Transferred after birth Home: 639/12256 (5.2) Fr-MLU: 238/6078 (3.9) Al-MLU: 291/8323 (3.5) - Timing of transfer missing	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 51/12256 (0.4) Fr-MLU: 14/6078 (0.2) Al-MLU: 43/8323 (0.5) - Total transfers Home: 1472/12256 (12.0) Fr-MLU: 573/6078 (9.4) Al-MLU: 1041/8323 (12.5) The following details about reason for transfer have been extracted from the full Birthplace report (Hollowell et al., 2011). The denominators are as follows: Home: 16840 - Nulliparous: 4568 - Multiparous: 12256 Fr-MLU: 11282	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Nulliparous: 5187 - Multiparous: 6078 Al-MLU: 16710 - Nulliparous: 8350 - Multiparous: 8323 Most common reasons for transfer (at least 1% in any setting, as a proportion of all low risk women (n (%)) a. ALL WOMEN Failure to progress (any stage) Home: 1144 (6.8) Fr-MLU: 912 (8.1) Al-MLU: 1548 (9.3) Fetal distress Home: 246 (1.5) Fr-MLU: 259 (2.3) Al-MLU: 477 (2.9) Epidural request Home: 180 (1.1) Fr-MLU: 163 (1.4) Al-MLU: 585 (3.5)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Meconium staining Home: 432 (2.6) Fr-MLU: 301 (2.7) Al-MLU: 538 (3.2) Retained placenta Home: 250 (1.5) Fr-MLU: 179 (1.6) Al-MLU: 203 (1.2) Repair of perineal trauma Home: 386 (2.3) Fr-MLU: 184 (1.6) Al-MLU: 369 (2.2) Neonatal concerns (postpartum transfer) Home: 180 (1.1) Fr-MLU: 63 (0.6) Al-MLU: 5 (0.0) b. NULLIPAROUS WOMEN ONLY Failure to progress Home: 846 (18.5) Fr-MLU: 781 (15.1) Al-MLU: 1328 (15.9)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Fetal distress Home: 141 (13.1) Fr-MLU: 210 (4.0) Al-MLU: 356 (4.3) Meconium staining Home: 252 (5.5) Fr-MLU: 248 (4.8) Al-MLU: 404 (4.8) Epidural request Home: 135 (3.0) Fr-MLU: 139 (2.7) Al-MLU: 447 (5.4) Pain relief (epidural not specified or other) Home: 51 (1.1) Fr-MLU: 4 (0.1) Al-MLU: 4 (0.0) PPH Home: 54 (1.2) Fr-MLU: 37 (0.7) Al-MLU: 56 (0.7) Repair of perineal trauma	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 204 (4.5) Fr-MLU: 145 (2.8) Al-MLU: 263 (3.1) Retained placenta Home: 87 (1.9) Fr-MLU: 82 (1.6) Al-MLU: 96 (1.1) c. MULTIPAROUS WOMEN ONLY Failure to progress Home: 297 (2.4) Fr-MLU: 126 (2.1) Al-MLU: 215 (2.6) Fetal distress Home: 105 (0.9) Fr-MLU: 48 (0.8) Al-MLU: 121 (1.5) Meconium staining Home: 180 (1.5) Fr-MLU: 53 (0.9) Al-MLU: 133 (1.6) Epidural request Home: 182 (1.5) Fr-MLU: 38 (0.6) Al-MLU: 105 (1.3)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Repair of perineal trauma Home: 45 (0.4) Fr-MLU: 24 (0.4) Al-MLU: 137 (1.6) Retained placenta Home: 163 (1.3) Fr-MLU: 96 (1.6) Al-MLU: 106 (1.3) Neonatal concerns (postpartum transfer) Home: 138 (1.1) Fr-MLU: 31 (0.5) Al-MLU: 3 (0.0) Primary reason for transfer (as a proportion of all low risk women)(n (%)) a. Failure to progress in first stage: Home: 755 (4.5) Fr-MLU: 542 (4.8) Al-MLU: 849 (5.1)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				b. Fetal distress in first stage Home: 184 (1.1) Fr-MLU: 206 (1.8) Al-MLU: 305 (1.8) c. Meconium staining Home: 432 (2.6) Fr-MLU: 301 (2.7) Al-MLU: 538 (3.2) d. Epidural request Home: 180 (1.1) Fr-MLU: 163 (1.4) Al-MLU: 585 (3.5) e. Hypertension Home: 75 (0.4) Fr-MLU: 64 (0.6) Al-MLU: 98 (0.6) f. Malposition Home: 26 (0.2) Fr-MLU: 11 (0.1) Al-MLU: 32 (0.2) g. Malpresentation Home: 70 (0.4)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Fr-MLU: 42 (0.4) Al-MLU: 66 (0.4) h. APH Home: 60 (0.4) Fr-MLU: 46 (0.4) Al-MLU: 83 (0.5) h. Failure to progress in second stage Home: 385 (2.3) Fr-MLU: 368 (3.3) Al-MLU: 692 (4.1) i. Fetal distress in second stage Home: 41 (0.2) Fr-MLU: 35 (0.3) Al-MLU: 147 (0.9) j. Postpartum haemorrhage Home: 142 (0.8) Fr-MLU: 90 (0.8) Al-MLU: 123 (0.7) k. Retained placenta Home: 250 (1.5) Fr-MLU: 179 (1.6)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Al-MLU: 203 (1.2) l. Repair of perineal trauma Home: 386 (2.3) Fr-MLU: 184 (1.6) Al-MLU: 369 (2.2) m. Other reason with detail not recorded Home: 26 (0.2) Fr-MLU: 5 (0.0) Al-MLU: 9 (0.1) n. Missing (reason not stated) Home: 38 (0.2) Fr-MLU: 36 (0.3) Al-MLU: 112 (0.7)	
Full citation Byrne,J.P., Crowther,C.A., Moss,J.R., A randomised controlled trial comparing birthing centre care with delivery suite care in Adelaide, Australia, Australian and New Zealand Journal of Obstetrics and Gynaecology, 40, 268-274, 2000	Sample size N = 201 (However, data from 1 woman lost to follow-up because she moved are not reported) Characteristics Age / years (mean ± SD) Birth centre: 27.5 ± 5.6	Interventions Planned (booked) birth in the birth centre (alongside midwifery led unit [MLU]) (n = 100) Planning (boo	Details Setting The birthing centre consisted of two rooms set up close to the conventional delivery suite. The rooms were spacious, carpeted, and contained a double bed, lounge suite, and table/chairs. The rooms	Results Mode of birth (n/total (%)) a. Normal vaginal birth Birth centre: 74/100 (74)* Delivery suite: 69/100 (69) RR 1.07 (95% CI	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 174927 Country/ies where the study was carried out Australia Study type Randomised controlled trial Aim of the study To address the hypotheses that care of healthy pregnant women by midwives who have a philosophical commitment to the normality of the birthing process would increase satisfaction, lower rates of intervention without adversely affecting outcome, and be more cost effective than conventional care. Study dates June 1993 to January 1995 Source of funding Queen Victoria Foundation	Delivery suite: 26.8 ± 4.9 Parity (n/total (%)) Primiparas Birth centre: 47/100 (47%) Delivery suite: 46/100 (46%) Multiparas Birth centre: 53/100 (53%) Delivery suite: 54/100 (54%) Married/de-facto (n/total (%)) Birth centre: 97/100 (97%) Delivery suite: 99/100 (99%) Inclusion criteria Normal, uncomplicated pregnancy Exclusion criteria Any pregnancy risk factors Presenting to antenatal clinic later than 30 weeks gestation	ked) birth in the delivery suite (n = 101)	had en-suite bathrooms that had a deep bath and shower. All medical equipment was stored behind curtains or in cupboards. Epidural was not available. Recruitment and randomisation Women who attended the antenatal clinic in the hospital were given an information sheet about the trial early in their pregnancy, and were eligible for randomisation from 20 to 36 weeks gestation. All eligible women were given three choices: trial participation, birth in delivery suite, and birth in birthing centre. Randomisation was done using balanced variable blocks with stratification by parity; this was done by a clerical officer not	0.90 to 1.26) p = 0.43 b. Instrumental vaginal birth Birth centre: 17/100 (17) Delivery suite: 18/100 (18) RR 0.94 (95% CI 0.52 to 1.72) p = 0.85 c. Caesarean section Birth centre: 9/100 (9) Delivery suite: 14/100 (14) RR 0.64 (95% CI 0.29 to 1.42) p = 0.26 * not consistently reported in the study; however, data have been taken from table 8 as it is	Unclear Blinding of staff providing care: Unclear Blinding of outcome assessors: Unclear Missing data/loss to follow-up: 1 woman (0.5%) was lost to follow-up from the delivery suite arm, because she moved house and delivered at another hospital. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes, except for the method of assessing blood loss is not reported Intention-to-treat analysis performed: Yes Indirectness: - 20% of birth centre arm and 25% of delivery suite arm had induction of labour. 1 woman (1%) in birth centre arm had a breech presentation. - They report that medical

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Commonwealth Department of Human Services and Health Australian Nursing Foundation			involved in the study. Allocation was made by the clerical officer by opening the next in a sequence of sealed opaque envelopes. During the study period, 863 women were invited to participate, of which 201 accepted. Care protocol - Birthing centre (BC) Women allocated to the BC were cared for by a midwife committed to the normality of the birth process, who recognised women as "active, conscious participants with rights to exercise informed choice." The midwives encouraged women to retain control of their birth and postpartum care. Women were also encouraged to attend two designated classes about birthing and the	the most comprehensive Use of epidural block (n/total (%)) Birth centre: 37/100 (37) Delivery suite: 48/100 (48) RR 0.77 (95% CI 0.56 to 1.07) p = 0.11 Perineum (n/total (%)) a. Intact Birth centre: 20/100 (20) Delivery suite: 27/100 (27) RR 0.74 (95% CI 0.45 to 1.23) p = 0.24 b. Episiotomy Birth centre: 35/100 (35) Delivery suite:	equipment in the birth centre was stored behind cupboards or curtains but within easy reach, therefore, it is unclear whether electronic fetal monitoring (EFM) may have been available. It is reported that 56% of women in birth centre arm had external monitor and 26% had a fetal scalp electrode, but this may have been after transfer. Other information Comparison: ALONGSIDE MLU vs. OU [This study was included in the 2007 guideline] The study evaluates a package of care, from antenatal care onwards, not just intrapartum care. Women required transfer if epidural or other medical

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			birthing centre. During labour, partners and support people were encouraged to take an active role in emotional and physical support. Bathing, hot towels, movement and massage were available for pain management, as was pethidine. Midwives cared for women and families during antenatal care, intrapartum care and postpartum for up to 12 hours. - Delivery suite care Women were under the care of a midwife and a doctor, the former being the main care-giver who liaised with the latter. The midwife attempted to care for the individual needs of each woman, including offering alternative forms of pain	27/100 (27) RR 1.30 (95% CI 0.85 to 1.97) p = 0.22 c. 1st / 2nd degree tear Birth centre: 37/100 (37) Delivery suite: 32/100 (32) RR 1.16 (95% CI 0.79 to 1.70) p = 0.45 Blood loss > 300 ml (n/total (%)) Birth centre: 33/100 (33) Delivery suite: 37/100 (37) RR 0.89 (95% CI 0.61 to 1.30) p = 0.55 Neonatal:	interventions were needed.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			relief such as massage, showers, movement and hot towels. Fetal monitoring, IV fluids and pharmacological pain relief were used at the discretion of the doctor, midwife and woman. In both settings, progress in labour was monitored according to the hospital's protocol. Transfer criteria Not reported. Data collection, analysis and monitoring It was calculated that 1916 women would be needed to detect an 8% difference in episiotomy and tears rate from 40.7% in the delivery suite and 34.4% in birthing centre, at p < 0.05 or 80% power. The sample size was not	observation nursery Birth centre: 58/100 (58) Delivery suite: 71/100 (71) RR 0.82 (95% CI 0.66 to 1.01) p = 0.05 Transfer Birth centre Of the 100 women randomised to the birth centre, 1 delivered in the emergency room, 9 required a caesarean section (CS) and 67 delivered in the delivery suite for various reasons. Reasons from transfer from birth centre to delivery suite† (n): - induction of labour: 20	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			reached as the funds were used up. Data were collected from case notes and forms completed antenatally and in the puerperium. The chief researcher collected baseline demographic data on entry in to the trial, and outcome data from case notes and two questionnaires completed within 12 hours of birth and then at six weeks postpartum. Non-parametric statistical tests were used for non normally distributed variables and parametric tests for normally distributed variables. Analyses were by intention to treat.	- need for augmentation: 40 - CS: 9 - instrumental delivery: 16 - epidural: 37 - breech: 1 - staffing problems: 13 † More than one can apply Delivery suite 1 woman from the delivery suite transferred to the birth centre by her own request. 14 required a CS and the remaining 85 gave birth in the delivery suite.	
Full citation Campbell,R., Macfarlane,A.,	Sample size N = 1499	Interventions Planned	Details Setting	Results Mode of birth (n/total	Limitations Choice of treatment

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Hempsall,V., Hatchard,K., Evaluation of midwife-led care provided at the Royal Bournemouth Hospital, Midwifery, 15, 183-193, 1999 Ref Id 125391 Country/ies where the study was carried out England Study type Prospective cohort study Aim of the study To compare the outcome of care given to women 'booking' for delivery in a midwife-led maternity unit with that for comparable women 'booking' for care in a consultant obstetric unit Study dates 1st November 1992 to 30th June 1993 Source of funding	Characteristics MLU - midwifery led unit, OU - obstetric unit Parity (n (%)) 0 MLU: 388 (48.9) OU: 369 (52.3) 1 MLU: 272 (34.3) OU: 228 (32.3) 2 MLU: 96 (12.1) OU: 86 (12.1) 3+ MLU: 38 (4.8) OU: 22 (3.1) (p = 0.27) Age/years (n (%)) 15-19 MLU: 51 (6.4) OU: 58 (8.2)	(booked) place of birth in midwife-led unit (Bournemouth) (n = 794) Planned (booked) place of birth in obstetric unit (Poole) (n = 705)	The study compared women who 'booked' at the Royal Bournemouth Hospital (midwife-led unit) with women who satisfied the criteria for booking at Bournemouth, but instead booked at Poole General Hospital (consultant-led unit). The midwife-led unit was designed for women who do not have obstetric complications or are unlikely to develop them. It was based in a hospital, there was no adjacent consultant obstetric unit. However, the hospital operating theatres were located near the unit and there was an obstetric registrar always available on site, because the hospital	(%)) a. Spontaneous MLU: 657/782 (84.0) OU: 586/702 (83.5) Difference: 0.5 (95% CI -3.2 to 4.3) b. Assisted MLU: 61/782 (7.8) OU: 71/702 (10.1) Difference: -2.3 (95% CI -5.2 to 0.6) c. Caesarean section MLU: 63/782 (8.1) OU: 45/702 (6.4) Difference: 1.6 (95% CI -1 to 4.3) Use of epidural (n/total (%)) MLU: 107/782 (13.7) OU: 139/703 (19.8) Difference: -6.1 (95% CI -9.9 to -2.3)	unrelated to confounders (selection bias): Unclear: the same criteria were used, however there may be confounders that are not accounted for because there is no attempt to control for baseline risk Groups comparable at baseline: Yes Groups received same/similar care (apart from intervention): In general, although those booking at the MLU tended to book earlier compared with those booking at the OU Blinding of those assessing outcomes: No Missing data/loss to follow-up: Data for the 10 miscarriage/abortion/intrauterine deaths and the 4 women who had multiple pregnancies have been excluded, leaving 782 women in the MLU arm and 703 in the OU arm. For the outcome of blood

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Project was initially funded by East Dorset Health Authority	20-24 MLU: 187 (23.6) OU: 163 (23.1) 25-29 MLU: 344 (43.3) OU: 298 (42.3) 30-34 MLU: 176 (22.2) OU: 162 (23.0) 35-39 MLU: 36 (4.5) OU: 34 (3.4) (p = 0.54) Weight at 'booking'/kg (mean ± SD) MLU: 65.05 ±10.86 OU: 65.61 ± 11.94 Difference: -0.56 (95% CI -1.72 to 0.59) Height/metres (mean ± SD) MLU: 1.64 ± 0.058 OU: 1.64 ± 0.060		had a full gynaecology service. The unit was modern and attractive, but there was no attempt to achieve a 'home in the hospital' look (i.e. no individual bedrooms or use of domestic furnishings). However, the unit strives "to provide a non-medicalised model of care" and aims to put clients at the centre of decision making, promoting a feeling of self-confidence and awareness in preparation for pregnancy, labour and motherhood. The philosophy of the centre was to view labour as a 'normal physiological process rather than an illness.' Recruitment Neither unit had a computer system apart	State of perineum (n/total (%)) a. Episiotomy MLU: 131/780 (16.8) OU: 173/702 (24.6) Difference: - 7.8 (95% CI -12.0 to -3.7) b. Tear MLU: 338/780 (43.3) OU: 307/702 (43.7) Difference: -0.4 (95% CI -5.1 to -4.7) Blood loss over 500 ml (n/total (%)) MLU: 51/770 (6.6) OU: 38/695 (5.5) Difference: 1.2 (95% CI -1.3 to 3.6) Significant problems after delivery (n/total (%))	loss, there are missing data for 12/782 (1.5%) of women in MLU arm and 8/703 (1.1%) in OU arm. Precise definition of outcomes: Yes, except 'significant problems after delivery' are not defined Valid and reliable method of outcome assessment: Unclear how blood loss was assessed Intention-to-treat analysis performed: Yes Indirectness: - 66/1480 (4.5%) of women went in to labour prior to 37 weeks; 56/1480 (3.8%) of babies were non cephalic presentation; 257/1483 (17%) of women had their labour induced. The women met the low risk inclusion criteria at booking; however, it is not reported what their risk status was on admission in labour. - The MLU is not exactly

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Difference: -0.002 (95% CI -0.008 to 0.005) Gestational age (split by place) at booking/weeks (mean [n]) MLU: 14.2 [n = 781] - Midwife-led: 14.4 [n = 665] - GP & Domino: 12.6 [n = 116] OU: 15.3 [n = 688] - Consultant led: 15.5 [n = 642] - GP & Domino: 13.5 [n = 46] (Note: it was not stated for 13 women in the MLU arm and 17 women in the OU arm) Inclusion criteria Meeting inclusion criteria for MLU (see exclusion criteria) and booking at either the MLU or the general hospital during the study period Exclusion criteria Parity: Women expecting fifth or subsequent baby		from the patient administration system; therefore, data were collected from records by midwives using questionnaires. As the women were recruited to the study, the front page of the questionnaire with identifying information, was removed. These were used to compile a master list of everyone who fulfilled criteria for booking at the MLU. The rest of the questionnaire remained with the records until the woman gave birth, transferred out of the county, or miscarried. Of 903 women initially booked at the MLU, 74 did not meet the criteria and in 35 cases it was not known whether they met the criteria. Therefore, 794 women	MLU: 83/776 (10.7) OU: 84/695 (12.1) Difference -1.4 (95% CI -4.9 to 1.9) Babies transferred to special care from delivery suite (n/total (%)) MLU: 36/782 (4.6) OU: 43/702 (6.1) Difference: -1.5 (95% CI -3.8 to 0.8) [Note: Of those booked in the MLU, 17 babies requiring transfer to special care had mothers who had transferred to the OU prior to the onset of labour] TRANSFER 1.) Place of admission for labour, split by initial place	like an alongside midwifery unit, as it is in a different hospital to the main labour ward; however, there are doctors and theatre facilities available. Also, it is reported that 'medical staff are not present in the delivery suite unless a midwife has requested their assistance' Other information Comparison: ALONGSIDE MLU vs. OU [This study has been added for the update, because this comparison is now incorporating prospective cohort studies] This study evaluates a package of care at the MLU, commencing at antenatal care. Unclear whether women would always be transferred to the other hospital in the case of complications, or

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Age: - Multiparous women aged 38 and over - Primiparous women aged 35 and over Height of less than 5 feet Previous medical history: - Diabetes - Cardiac disease - Renal disease - Deep vein thrombosis - Pulmonary embolus Previous obstetric history: - Recent infertility - Caesarean section or hysterectomy - Proven or suspected pelvic disproportion - Rhesus antibodies - Habitual postpartm haemorrhage - More than 2 previous abortions - Previous stillbirth or neonatal death		remained in that arm of the study. Of the 839 women booked at the OU, 83 did not meet the criteria and in 51 cases it was not known whether they met the criteria. Therefore, 705 women remained in that arm. This gave a total sample size of 1499; however, 10 women had a miscarriage, abortion or intrauterine death and 4 women were found to have multiple pregnancies. Care protocol - Midwife led unit Antenatal clinics were provided by midwives. They were held at the same time as the consultant led sessions in case complications arose, in which case the consultant could be consulted immediately.	of booking (n (%)) a. Women booked for birth at MLU (n = 782) Admitted to MLU: 561 (71.7) - midwife led: 457 (58.4) - GP and domino: 104 (13.3) Admitted to OU: 212 (27.1) - consultant: 210 (26.9) - GP and domino: 2 (0.3) Admitted to home: 8 (10) Admitted to other hospitals: 1 (0.1) Place of admission not recorded: 0 [Note: For the women initially booking at an MLU,	whether a doctor would be called to the midwife unit

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Previous gynaecological history: - Pelvic floor repair or myomectomy		Medical staff were not present in the delivery suite during labour unless the midwife requested assistance. - Consultant led unit Antenatal care was from a consultant obstetrician or obstetric registrar, with resulting birth in a consultant led unit. Most women who booked at the MLU were booked under midwives (nominally under the care of a consultant obstetrician) but some were booked under the care of their GP. A domino delivery system (women stay at home with midwife during early labour and are then transferred for birth and return home a few hours later) was available in both units.	19.5% of parous women and 35% of nulliparous women ended up being admitted in labour to the OU (27.1% overall). The main reasons for transfer of nulliparous women were high head at term, hypertension and related conditions. Induction of labour was a main reason for both parous and nulliparous women] 72 women transferred in labour, of which the most frequent reasons were insufficient progress in first stage, request for epidural, or a high head. b. Women booked for birth at OU (n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Transfer criteria Not reported Data collection, analysis and monitoring The questionnaire for data collection was tested and revised in pilot studies. It contained sections for recording details about the woman, her care, and pregnancy outcome. They were completed by midwives working at the two units. Complication, checking and editing of data was done by the Clinical Audit Department of the Bournemouth Hospital. An anonymised data set was then made available to the authors for data analysis. Data on stillbirths and early neonatal deaths were available from records;	703) Admitted to MLU: 4 (0.6) - midwife led: 3 (0.4) - GP and domino: 1 (0.1) Admitted to OU: 697 (99.2) - consultant: 666 (94.7) - GP and domino: 33 (4.7) Admitted to home: 0 (0) Admitted to other hospitals: 0 (0) Place of admission not recorded: 2 (0.3) 2.) Actual place of birth by place of admission in labour a. Admitted in labour to MLU (n = 565) Gave birth in MLU:	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			however, the authors felt that information on later deaths might not be captured. Therefore, they made an application to the Wessex Regional Survey of Abortion, Stillbirth and Neonatal Death; however, the information was not released to them. Checks were made on the data at an earlier stage of the evaluation, which revealed that questionnaires had not been completed for some women who should have been in the study; therefore, an additional set of reviews were done at the hospital. The authors report that this led to virtually all eligible women at the MLU being enrolled, but not in the OU. A	490 (86.7) - midwife led: 369 (65.3) - GP and domino: 103 (18.2) - consultant: 18 (3.2) Gave birth in OU: 72 (12.7) - consultant: 72 (12.7) - GP and domino: 0 Gave birth at home: 0 Other place of birth: 0 Place of birth not recorded: 3 (0.5) b. Admitted in labour to OU (n = 909) Gave birth in MLU: 0 Gave birth in OU: 834 (91.7) - consultant: 808 (88.9)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			comparison of women for whom there were questionnaires and those identified in later checks did not identify systematic differences, except for the fact that those who booked the the OU tended to be older. The authors report that there may have been selective under-ascertainment and that the study group might not be completely representative. Data were analysed by intention to treat; therefore data are compared by place of initial booking.	- GP and domino: 26 (2.9) Gave birth at home: 0 Other place of birth: 0 Place of birth not recorded: 75 (8.2) c. In labour at home (n = 11) Gave birth at home: 8 Other place of birth: 1 Place of birth not recorded: 2	
Full citation Chapman,M.G., Jones,M., Spring,J.E., De,Swiet M., Chamberlain,G.V., The use of a birthroom: a randomized controlled trial comparing delivery with that	Sample size N = 148 Characteristics Age / years (mean) Birthroom: 28.5	Interventions Planned (intended at the onset of labour) birth in a birth room (n = 76)	Details Setting A birth room was set up close to the labour ward. Wallpaper, carpet, curtains, and a modern timber bedroom	Results Caesarean section (CS) (n/total (%)) a. Among women still in the trial when in labour Birthroom: 0/65 (0)	Limitations Appropriate randomisation: Unclear - method of randomisation is not reported Allocation concealment: Unclear if envelopes were

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
in the labour ward, British Journal of Obstetrics and Gynaecology, 93, 182-187, 1986 Ref Id 170886 Country/ies where the study was carried out England Study type Randomised controlled trial Aim of the study Not stated Study dates Not reported Source of funding Board of Governors at the Hospital	Labour ward: 29.7 Parity (n/total (%)) 1 Birthroom: 46/76 (60.5%) Labour ward: 46/72 (63.9%) 2 Birthroom: 21/76 (27.6%) Labour ward: 16/72 (22.2%) 3 Birthroom: 9/76 (11.8%) Labour ward: 10/72 (13.9%) Birth weight / kg split by weeks gestation (mean [n]) 37 weeks Birthroom: 3.00 (n = 3) Labour ward: 2.74 (n = 6) 38 weeks Birthroom: 2.95 (n = 8) Labour ward: 3.27 (n = 6) 39 weeks Birthroom: 3.39 (n = 23) Labour ward: 3.36 (n = 23)	Planned (intended at the onset of labour) birth in the labour ward (n = 72)	suite were used to furnish the room. The bed was a single divan, and there was also a bean bag, a lounge chair and a wash basin in the room. Any relevant medical equipment was available but stored out of site Recruitment and randomisation All women meeting the inclusion criteria were informed that epidural and continuous electronic fetal monitoring (EFM) would not be available in the birth room. Suitable women were offered the opportunity to participate by 30 weeks gestation. When they consented, a random envelope selection was made. Of the 253 asked to participate, 148	Labour ward: 3/62 (4.8%) b. Among all randomised women (intention-to-treat analysis) Birthroom: 3/76 (3.9%) Labour ward: 4/72 (5.6%) None of the other outcomes are reported for the entire study population (i.e. including the transferred women). Due to the high proportion of post-randomisation exclusions (23.6% of women) the data for other outcomes will not be reported here.	opaque Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: Unclear Blinding of staff providing care: Unclear Blinding of outcome assessors: Unclear Missing data/loss to follow-up: Data for women who were withdrawn from the trial are not available Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: No. They excluded a high proportion of women (24%) following randomisation, including those who required transfer or a CS. Only incidence of CS is reported intention to treat. (See

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	40 weeks Birthroom: 3.49 (n = 31) Labour ward: 3.55 (n = 23) 41 weeks Birthroom: 3.51 (n = 10) Labour ward: 3.70 (n = 9) 42 weeks Birthroom: 4.01 (n = 1) Labour ward: 3.78 (n = 4) Inclusion criteria Multiparous Previous normal pregnancies and births Under care of Queen Charlotte's Maternity Hospital community midwives Asked for early discharge Lived within 5 miles of hospital Exclusion criteria Not reported (however, reasons why women were		(59%) accepted. Care protocol Antenatal care for all the women in the study was the same. Withdrawal from the trial occurred if the woman was deemed to be unsuitable for birthroom delivery (either medical or social reasons). On admission in labour, women were directed to their allocated delivery site. Women were cared for by the same group of midwives in either place. Transfer criteria Not reported. Data collection, analysis and monitoring Records of events in labour and delivery were made on a		'other information' for details of the post-randomisation exclusions) Indirectness: In the birthroom, equipment was available but kept out of site; therefore, it it unclear whether this truly represents a midwifery led unit (MLU) Other information Comparison: ALONGSIDE MLU vs. OU [Study was included in 2007 guideline] This study evaluates intrapartum care only. Women required physical transfer in the event of a complication (however, these women were then excluded) Post randomisation exclusions: There were significantly

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	withdrawn from the trial are reported below)		specially designed form. Postnatal events, method of feeding, and complications were noted. Mann-Whitney U-tests and chi-squared tests were used to compare outcomes.		more women withdrawn from the birthroom group than the labour ward group. 22 women in the birthroom group were withdrawn (28.9%). 11 of these were before labour and before reaching birthroom, due to: - request for epidural (n = 2, at 27 and 36 weeks) - intrauterine growth restriction (IUGR) (n = 3, at 37, 37 and 38 weeks) - post-maturity (n = 3, at 41, 41, and 42 weeks) - pre-eclampsia (n = 1, at 35 weeks) - transverse lie (n = 1, at 37 weeks) - antepartum haemorrhage (APH) (n = 1, at 32 weeks) 7 were during labour but before reaching the birth room, due to: - incorrectly directed to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					labour ward (n = 2, at 39 and 40 weeks) - fever (n = 1, at 40 weeks) - meconium stained fluid (n = 1, at 39 weeks) - preterm labour (n = 3, at 34 and 36 weeks) 4 were transferred from the birthroom in labour: - forceps (n = 1, at 41 weeks) - meconium stained fluid (n = 1, at 39 weeks) - epidural requested (n = 1, at 40 weeks) - prolonged first stage of labour (n = 1, at 40 weeks) 13 women in the labour ward were withdrawn (18.1%). 10 before labour: - breech (n = 3, at 36, 36 and 37 weeks) - twins (n = 1, at 30 weeks) - APH (n = 1, at 38 weeks) - moved outside area (n =

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					2, at 32 and 34 weeks) - unsuitable for early discharge (n = 1, at 32 weeks) - pre-eclampsia (n = 2, at 38 and 41 weeks) 3 during labour (all required CS): - cord prolapse (n = 1, at 42 weeks) - failure to progress (n = 2, at 39 and 40 weeks)
Full citation David,M., von Schwarzenfeld,H.K., Dimer,J.A., Kentenich,H., Perinatal outcome in hospital and birth center obstetric care, International Journal of Gynaecology and Obstetrics,Int.J.Gynaecol.Obstet., 65, 149-156, 1999 Ref Id 174685 Country/ies where the study was carried out Germany Study type	Sample size N = 4072 Characteristics No comparative characteristics given apart from the following: - significantly more nulliparous women in the birth centre group - 70% of birth centre group and 76% of hospital group worked during pregnancy - 5% of birth centre group and 10% of hospital group were single mothers	Interventions Planned (intended at onset of labour) birth at a birth centre (n = 801) Planned (intended at onset of labour) birth in hospital (n = 3271)	Details Selection of study groups The criteria for exclusion from the birth centre are listed in exclusion criteria above. If birth was planned at a birth centre but was referred to the hospital either before or at the onset of labour, they were excluded (e.g. due to early rupture of membranes, vaginal bleeding or	Results Note: Where the authors have only reported %, it is not possible to accurately back-calculate raw event rate data due to the rounding. Maternal mortality (n/total) Birth centre: 0/801 Hospital: 1/3271 Mode of birth (%)	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear; there were differences at baseline and these were not controlled for and generally not well reported Groups comparable at baseline: No. There were significantly more nulliparous women in the birth centre group; 70% of birth centre mothers were working during pregnancy compared to 76% in the hospital group; 5% of the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Retrospective cohort study Aim of the study To compare birth complications and outcomes for the baby in hospitals and birth centres Study dates August 1992 to July 1994 Source of funding Not stated	Inclusion criteria See below Exclusion criteria Birth centre exclusion criteria: - Antenatal risks such as multiple gestation, gestational hypertension, gestational diabetes, fetal growth restriction, non-cephalic presentation, placenta praevia, vaginal bleeding, polyhydramnios or oligohydramnios, genital herpes and smoking during pregnancy - Significant past medical history of risks such as severe debilitating illness, diabetes, previous caesarean section (CS) or other uterine surgery, morbid obesity, and cephalopelvic disproportion - Intrapartum risks such as premature prolonged rupture of membranes over 24 hours, prematurity (prior to 37		hypertension). Those transferred intrapartum were included in the birth centre group. The comparison group of hospital births was extracted from the Berlin perinatal statistics, where obstetric units record every birth. It is recorded anonymously and monitored for completeness and plausibility by the authorities. The birth centre selection criteria were applied to the hospital data in order to get comparable low risk groups. Primary CS and inductions of labour were also excluded from the hospital group as neither of these would be possible in the birth centres. Then, any women with incomplete details were excluded,	a. Spontaneous Birth centre: 91.4 Hospital: 84.3 ($p < 0.001$) b. Caesarean section Birth centre: 3.0 Hospital: 4.6 ($p = 0.057$) c. Forceps or vacuum deliveries Birth centre: 5 Hospital: 11 ($p < 0.001$) [Note: The authors report that in the birth centre group, 25 of 30 vacuum extractions, all forceps, and 22 of 24 CS were in nulliparous women. They also report that the hospital group show a similar distribution. For the indications for CS or	birth centre group were single mothers compared to 10% of the hospital birth group. These are examples and no further details are given, but the authors report that the medical histories of the two groups were different. Groups received same/similar care (apart from intervention): No details given Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Generally, although women transferred at the onset of labour were excluded (any women transferred later were included)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	weeks), more than 14 days postdates, meconium stained amniotic fluid, non-reassuring cardiotocograph (CTG) and vaginal bleeding Women born in countries other than Germany, USA, and northern or central Europe		and finally the composition of the two groups was matched by profession in order to minimise the effect of differences in sociodemographic factors. This resulted in a comparable group of low risk women to the birth centre group. (Note: country restrictions were placed on the hospital group because the profile in the birth centre group was not comparable to the profile of births in Berlin in general and therefore, it needed to be matched) Setting/care protocol No details given apart from the fact that the birth centres were operated and staffed by midwives only.	instrumental birth, see 'other information' below.] Episiotomy (%) a. All women Birth centre: 15.7 Hospital: 54.8 (p < 0.001) b. Nulliparous women Birth centre: 21.1 Hospital: 69.9 c. Multiparous women Birth centre: 3.6 Hospital: 37.2 Third or fourth degree lacerations (%) Birth centre: 0.9 Hospital: 1.1 (p = 0.24) Intact birth canal (%) Birth centre: 30 Hospital: 22	Indirectness: None identified; however, this is likely to be a result of the lack of demographic information reported in the study Other information Comparison: FREESTANDING MLU vs. OU [This study was included in the 2007 guideline] Primary indications for operative delivery (n (%)) - Prolonged second stage of labour Birth centre: 32 (51.6) Hospital: 181 (36.4) - EFM indicative of fetal distress Birth centre: 23 (37.1) Hospital: 290 (58.1) - Failure to progress in the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Transfer criteria Data collection, analysis and monitoring Perinatal data for birth centre births were transferred from the charts to the birth documentation software. This recorded data on demographic characteristics, process of labour, interventions and other outcomes. Women in the hospital group were selected from the perinatal records as described above, which is also where the outcome data were recorded and therefore extracted from. Differences were tested for using chi-squared or Fisher's exact test. Outcomes with ordinal properties were assessed using the	(p < 0.001) Perinatal death (n/total) a. Intrapartum death Birth centre: 0/801 Hospital: 1/3271 b. Neonatal death Birth centre: 0/801 Hospital: 2/3271 Admission to neonatal intensive care unit within 12 hours (%) Birth centre: 2.6 Hospital: 2.0 (p = 0.39) Transfer 655 out of 801 (81.8%) of women planning birth in the birth centre delivered there. 146 (18.2%) women were transferred to hospital intrapartum,	first stage Birth centre: 6 (9.7) Hospital: 48 (9.6) - Meconium stained amniotic fluid Birth centre: 4 (6.5) Hospital: 38 (7.5) - Cephalopelvic malproportion Birth centre: 3 (4.8) Hospital: 32 (6.4) - Premature rupture of membranes Birth centre: 5 (8.1) Hospital: 16 (3.1) - Possible infant sepsis Birth centre: 4 (6.5) Hospital: 9 (1.8)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Mann-Whitney or Wilcoxon tests. The significance level was taken as p ≤ 0.01. Outcomes reported 1. Maternal mortality 2. Mode of birth 3. Vaginal/perineal trauma: rate of episiotomy, third or fourth degree laceration, and intact birth canal are reported 4. Perinatal mortality: rate of intrapartum and neonatal death are reported 5. Admission to NICU	with the primary indications being: - fetal distress: 32.9% - failure to progress: 28% - inadequate labour: 19.2% - prolonged labour: 15.7% Out of the women who were transferred, 56% delivered spontaneously in hospital. 16% had a CS, 6% had forceps and 21% had vacuum deliveries. 3.6% of women were transferred postpartum (this was calculated by the technical team as 29/801 women)	
Full citation de,Jonge A., van der Goes,B.Y., Ravelli,A.C., melink-Verburg,M.P.,	Sample size N = 529,688	Interventions Planned (intended at the onset of	Details Selection of study groups Only low risk women	Results Note: all RR are relative to a control of 1.0 for the	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear;

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Mol,B.W., Nijhuis,J.G., Bennebroek,Gravenhorst J., Buitendijk,S.E., Perinatal mortality and morbidity in a nationwide cohort of 529,688 low-risk planned home and hospital births, BJOG: An International Journal of Obstetrics and Gynaecology, 116, 1177-1184, 2009 Ref Id 116435 Country/ies where the study was carried out The Netherlands Study type Retrospective cohort study Aim of the study To compare perinatal mortality and severe perinatal morbidity between planned home and planned hospital births among low risk women who started their labour in primary care	Characteristics Parity (n (%)) - Multiparous Home: 189936 (59.1) Hospital: 86967 (53.3) - Primiparous (Nulliparous) Home: 131371 (40.9) Hospital: 76294 (46.7) (p < 0.0001) Gestational age / completed weeks (n (%)) - 37 Home: 12036 (3.8) Hospital: 7208 (4.4) - 38-40 Home: 238041 (74.1) Hospital: 122253 (74.9) - 41 Home: 71230 (22.2) Hospital: 33800 (20.7) (p < 0.0001) Maternal age / years (n (%)) - < 25	labour) home birth (n = 321,207) Planned (intended at the onset of labour) hospital birth (n = 163,261) [Note: it is reported that midwives recorded planned place of birth during pregnancy; however, they also report excluding women with risks at the onset of labour and the table classifies them by intended place of birth at onset of	were eligible for independent primary care by midwives. If risk factors arose during pregnancy, labour or the postpartum period, women were referred to secondary care, in which an obstetrician was responsible. Interventions such as pharmacological pain relief, fetal monitoring and augmentation of labour were only available in secondary care. The study identified all low risk women giving birth during the study period, who were in primary, midwife led care at the onset of labour and therefore were planning to give birth either at home or in a hospital. Intended place of birth during pregnancy was	hospital group. Adjusted RR are adjusted for parity, gestational age, maternal age, ethnic background and socioeconomic status Intrapartum death (n/total (%)) Home: 99/321307 (0.03) Hospital: 61/163261 (0.04) Crude RR 0.83 (95% CI 0.60 to 1.13) Adjusted RR 0.97 (95% CI 0.69 to 1.37) Intrapartum and neonatal death during the first 24 hours (n/total (%)) Home: 148/321307 (0.05) Hospital: 84/163261 (0.05)	however, they have performed adjusted analyses Groups comparable at baseline: There were significant differences in demographic characteristics at baseline (women planning a home birth were more likely to be 25 years or older, of Dutch origin, have a medium/high socioeconomic status, be multiparous, and give birth at 41 weeks) Groups received same/similar care (apart from intervention): Unclear, very few details are given Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: There are missing data on confounders - parity (n = 61), maternal age (n = 149), ethnic background (n = 5316), socioeconomic status (n = 3987) Precise definition of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates 1st January 2000 to 31st December 2006 Source of funding Dutch Ministry of Health	Home: 29416 (9.2) Hospital: 30304 (18.6) - 25-34 Home: 237603 (74.0) Hospital: 106564 (65.3) - ≥ 35 Home: 54288 (16.9) Hospital: 26393 (16.2) (P < 0.0001) There were also significant differences in ethnic background (women with planned home birth more likely to be Dutch) and socioeconomic status (women with planned home birth more likely to have medium or high socio-economic status) Inclusion criteria Low risk women in primary midwife-led care at the onset of labour Gave birth at 37-42 weeks gestation to a single baby	labour]	recorded, which for some women was 'unknown' because they either waited until labour to decide where to give birth or the midwife forgot to record planned place of birth. This study compared planned place of birth groups: 'home', 'hospital' and unknown; however, the unknown group will not be reported here as it does not form part of the comparison of interest. Setting/care protocol No particular details given apart from the fact that women were in midwife-led care at the onset of labour. Transfer criteria It is reported that women planning to give birth at home during pregnancy could	Crude RR 0.90 (95% CI 0.69 to 1.17) Adjusted RR 1.02 (95% CI 0.77 to 1.36) Intrapartum and neonatal death at 0-7 days (n/total (%)) Home: 207/321307 (0.06) Hospital: 116/163261 (0.07) Crude RR 0.91 (95% CI 0.72 to 1.14) Adjusted RR 1.00 (95% CI 0.78 to 1.27) Admission to NICU Home: 540/321307 (0.17) Hospital: 323/163261 (0.20) Crude RR 0.85 (95% CI 0.74 to 0.98) Adjusted RR 1.00 (95% CI 0.86 to 1.16)	outcomes: Yes Valid and reliable method of outcome assessment: Unclear whether all neonatal data would be captured, based on the fact that they report that data from academic hospitals would be captured, plus 50% of other data Intention-to-treat analysis: Yes Indirectness: Exact criteria of low risk are not reported; however, they do report excluding women with medium risk as well and all women were giving birth at term and did not have complications at the onset of labour 8.5% of the initial population of low risk women had planned place of birth coded as 'unknown' and therefore their data could not be used for the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Medical or obstetric risk factors known before labour, such as non-cephalic presentation or previous caesarean section Medium risk women (e.g. previous postpartum haemorrhage [PPH]) Prolonged rupture of membranes (more than 24 hours) without contractions Intrauterine death before the start of labour Child with congenital abnormality Gestational age at birth unknown		have ended up giving birth in hospital as a result of risk factors developing during labour such as failure to progress, abnormal fetal heart rate (FHR) or meconium stained liquor. The indications for referral are documented in the Obstetric Indication List. No further details are given. Data collection, analysis and monitoring Data were available from perinatal registration databases. The authors report that there are three databases, one for primary care, one for secondary care and one for paediatric care. These cover 99% of primary care data, 100% of secondary care data, and all		comparison of interest. Other information Comparison: HOME vs. OU (hospital setting under the care of a midwife at the onset of labour) [This study is new since the 2007 guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			neonatal care data from academic hospitals plus 50% of other paediatric data. The databases are combined into one national database via validated linkages. Perinatal outcomes were compared by planned place of birth. Crude relative risks were calculated for both outcomes and potential confounders known to be associated with the outcomes (parity, gestational age, maternal age, ethnic background and socioeconomic status). The relative risks were then adjusted in a logistic regression (enter method). Interaction methods were examined for each characteristic. There were missing		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			data on confounders: parity (n = 61), maternal age (n = 149), ethnic background (n = 5316), socioeconomic status (n = 3987). The effects of the missing data were analysed separately and added to the most comparable group. Outcomes reported 1. Mortality: intrapartum death, intrapartum and neonatal death up to 24 hours, intrapartum and neonatal death up to 7 days 2. Admission to NICU		
Full citation Dowswell,T., Thornton,J.G., Hewison,J., Lilford,R.J., Raisler,J., Macfarlane,A., Young,G., Newburn,M., Dodds,R., Settatree,R.S., Should there be a trial of home versus hospital delivery in the United	Sample size N = 11 Characteristics Not reported Inclusion criteria Low obstetric risk (as judged	Interventions Planned (booked) birth at home (n = 5) Planned (booked) birth in hospital	Details Setting No details given Recruitment and randomisation Out of 500 women booking with an obstetrician during the	Results Mode of birth (n/total (%)) a. Normal vaginal birth Home: 5/5 (100) Hospital: 6/6 (100) b. CS	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Unclear - no details are given Groups received same

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Kingdom?, British Medical Journal,BMJ, 312, 753-757, 1996 Ref Id 174681 Country/ies where the study was carried out United Kingdom Study type Randomised controlled trial (feasibility study) Aim of the study Not stated Study dates One year from January 1994 Source of funding None reported	by a consultant obstetrician - no further details given) Multiparous Likely to have suitable home support and home circumstances Exclusion criteria None reported	(n = 6)	study period, 71 of them, that were judged to be low risk, were given information about the trial during their first hospital visit. At a subsequent visit, 11 women agreed to participate in the trial and were allocated to delivery at home or in hospital. Randomisation was in balanced blocks of eight and was performed by opening the next in a series of numbered, opaque envelopes. Care protocol No details reported. Transfer criteria No details given, but it is reported that 1 woman was withdrawn from the study 24 hours after randomisation because she was found to have had a PPH in a	Home: 0/5 (0) Hospital: 0/6 (0) c. Instrumental vaginal birth Home: 0/5 (0) Hospital: 0/6 (0) Perineal sutures (n/total (%)) Home: 2/5 (40) Hospital: 3/6 (50)	care (apart from intervention): Unclear - no details are given Blinding of participants: Unclear - no details are given Blinding of staff providing care: Unclear - no details are given Blinding of outcome assessors: Unclear - no details are given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Unclear - no details are given Intention-to-treat analysis performed: Yes Indirectness: Women were reported as being low risk during pregnancy but criteria are not reported and no characteristics of the study population are reported to determine what

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			previous pregnancy. Her data is still reported though. Data collection, analysis and monitoring The 10 women who remained in the study were interviewed at 34 weeks about health, attitudes to birth and experience of pregnancy. Mode of birth, complications and interventions were then recorded for all 11 women. Outcomes reported 1. Mode of birth: vaginal birth, caesarean section (CS), and instrumental vaginal birth are reported 2. Vaginal/perineal trauma: need for perineal sutures is reported		their status was at the onset of labour. 1/11 (9.1%) was considered to be higher risk due to a previous PPH. Small sample size: N = 11 Other information Comparison: HOME vs. OU [This study was included in the 2007 guideline]
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Eide,B.I., Nilsen,A.B., Rasmussen,S., Births in two different delivery units in the same clinic--a prospective study of healthy primiparous women, BMC Pregnancy and Childbirth, 9, 25-, 2009 Ref Id 116850 Country/ies where the study was carried out Norway Study type Prospective cohort study Aim of the study To compare intervention rates associated with labour in low risk women who begin their labour in a midwife led unit and a conventional care unit Study dates November 3rd 2001 to October 1st 2002 (Note: data collection for the	N = 453 Characteristics [Note: CDW = conventional delivery ward, MLW = midwife led ward] Maternal age/years (n (%)) < 20* CDW: 12 (6.0) MLW: 10 (4.0) 20 - 24 CDW: 56 (27.9) MLW: 62 (24.6) 25 - 29 CDW: 77 (38.3) MLW: 109 (43.3) 30 - 34 CDW: 44 (21.9) MLW: 57 (22.6) > 34 CDW: 12 (6.0) MLW: 14 (5.6) (p = 0.7)	Planned (intended at the onset of labour) birth in a conventional delivery ward (CDW) (n = 201) Planned (intended at the onset of labour) birth in a midwife led ward (MLW) (n = 252)	Setting The following are listed as the characteristics of care in the two settings Conventional delivery ward - accepted low risk and high risk patients - 3500 births per year - antenatal care was by GPs or midwives at the standard antenatal clinic - environment was conventional hospital - provided intrapartum care only - no explicit written philosophy of care - staffed by midwives and obstetricians - induction and augmentation available - pain relief: opiates, pudendal analgesia, nitrous oxide, epidural, shower/bath, movement/massage, acupuncture	Adjusted odds ratios (OR) are adjusted for maternal age, smoking, education and marital status Mode of birth (n/total (%)) a. Spontaneous vaginal CDW: 161/201 (80.1) MLW: 205/252 (81.3) OR 0.9 (95% CI 0.6 to 1.5) Adjusted OR 0.9 (95% CI 0.6 to 1.5) b. Forceps CDW: 8/201 (4.0) MLW: 12/252 (4.8) OR 0.8 (95% CI 0.3 to 2.1) Adjusted OR 0.8 (95% CI 0.3 to 2.0) c. Vacuum	Choice of treatment unrelated to confounders (selection bias): Unclear - there may be unknown confounders relating to their risk status on admission in labour Groups comparable at baseline: No; there were significant differences in marital status, level of education, proportion of women working during pregnancy and proportion of women who were smokers at first prenatal visit (see 'characteristics' above). However, the authors did adjust for this in their calculations. Groups received same/similar care (apart from intervention): Yes Blinding of those assessing outcomes: Unclear, no details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
midwife led ward stopped in May 2002, but the data collection for the conventional delivery ward had to be extended because of the number of women expressing desire for epidural and therefore not being included) Source of funding None reported	Marital status (n (%)) Cohabiting CDW: 168 (83.6) MLW: 232 (92.1) Single motherhood CDW: 29 (14.4) MLW: 19 (7.5) Other or unknown CDW: 4 (2.0) MLW: 1 (0.4) (p = 0.014) Education (n (%)) Elementary CDW: 24 (11.9) MLW: 15 (6.0) Upper secondary CDW: 91 (45.3) MLW: 82 (32.5) University CDW: 85 (42.3) MLW: 134 (53.2) (p < 0.0001)		Midwife led ward - accepted low risk patients only - 1500 births per year - antenatal care was by GPs or midwives at the standard antenatal clinic - environment was home-like - provided intrapartum and postpartum care - written philosophy of care on supporting natural childbirth - staffed by midwives; obstetricians consulted in event of complications - women attended by same personnel from admittance to discharge - no induction or augmentation available - pain relief: opiates, pudendal analgesia, shower/bath, movement/massage, acupuncture (no	extraction CDW: 16/201 (8.0) MLW: 17/252 (6.7) OR 1.2 (95% CI 0.6 to 2.4) Adjusted OR 1.6 (95% CI 0.7 to 3.5) d. Emergency caesarean section CDW: 14/201 (7.0) MLW: 16/252 (6.3) OR 1.1 (95% CI 0.5 to 2.3) Adjusted OR 1.0 (95% CI 0.5 -2.2) Use of epidural (n/total (%)) CDW: 126/201 (62.7) MLW: 61/252 (24.2) OR 5.3 (95% CI 3.5 to 7.9) Adjusted OR 4.9 (95% CI 3.2 to 7.4)	Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: - Study includes primiparous women only - The authors report that women were transferred in the first stage of labour in the event of complications or request for epidural. However, in the second stage of labour women were only transferred if an emergency caesarean was needed and obstetricians could be consulted in the case of complications. Therefore, it is unclear how comparable unit is to the typical alongside midwifery unit because some instrumental vaginal births are reported to have occurred in women remaining in the midwifery unit.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Worked during pregnancy (n (%)) Yes CDW: 154 (76.6) MLW: 232 (92.1) No CDW: 45 (22.4) MLW: 19 (7.5) (p < 0.0001) Smoker at first prenatal visit (n (%)) Non-smoker CDW: 143 (71.1) MLW: 208 (82.5) 1 - 10 cigarettes/day CDW: 56 (27.9) MLW: 39 (15.5) > 10 cigarettes/day CDW: 0 (0) MLW: 4 (1.6) Unknown CDW: 2 (1.0) MLW: 1 (0.4)		epidural available) - require transfer if there were medical complications or a request for epidural in the first stage of labour The two units are located on the same floor. They share the same legally responsible obstetricians but the midwives are different (during the study period there was no rotation of midwives between the two units) Recruitment Allocating the participants was done with strict alternation as far as possible. After admission of a woman to the MLW, the next women who met the inclusion criteria but preferred birth at the CDW was allocated to	Episiotomy (n/total (%)) CDW: 73/201 (36.3) MLW: 72/252 (28.6) OR 1.4 (95% CI 0.97 to 2.1) Adjusted OR 1.6 (95% CI 1.05 to 2.4) Perineal tears of grade 3 or 4 (n/total (%)) CDW: 22/201 (11) MLW: 34/252 (14)* * % is as reported in the study, but with the reported numerator and denominator, the % is 13.49, implying a rounding error (Note: the authors report that, after adjustment, the rates of tears were not significantly different; however,	Other information Comparison: ALONGSIDE MLU vs. OU (This study is new and was not incorporated in the 2007 guideline) This study evaluates intrapartum care only. Women required physical transfer in the event of complications; however, obstetricians could be consulted in an emergency.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(p = 0.003) * reported as < 29 in the paper; however, the technical team have assumed this is a typo otherwise the categories are not mutually exclusive and the % do not total 100% Inclusion criteria Low risk primiparous women meeting the criteria for birth in the MLW: - healthy with uncomplicated pregnancies - no significant malformations or fetal/placental disease - regularly attended antenatal care Admitted in labour between 36 and 42 weeks gestation Exclusion criteria Expressed desire for fepidural analgesia at admission to hospital before admission to labour ward		the CDW. Place of birth was planned before admittance in 162 (81%) of the CDW group and 203 (81%) of the MLW. Reasons for choosing CDW: availability of more types of pain relief (n = 103, 51%) and belief that the ward was safer for mother and infant (n = 42, 21%) Reasons for choosing MLW: facilities like bathroom near delivery room, general positive impression of the ward after visit, recommendation from women with experience, possibility of natural birth, preferring pain relief without analgesia Care protocol - MLW	they do not report the adjusted ORs. Similarly, they report that the adjusted ORs for intact perineum were not significantly different) Other priority outcomes The authors report that there were no statistically significant differences in excessive postpartum bleeding (over 1000 ml) or transfer to NICU. However, the data are not reported; therefore, it cannot be incorporated in the GRADE table. Transfer 74 (29%) of women in the MLW cohort	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria of MLW: - rupture of membranes more than 24 hours - thrombophilia - haemophilia - drug or alcohol abuse		Pregnant women are selected for birth at the MLW at various times during pregnancy, according to their preference. Final selection occurs on admission to the labour ward. The remainder of care is as described above under setting. - CDW Midwives attended low risk births and obstetricians were not normally present, although they could be called in case of complications. Women in both cohorts received the same standardised antenatal care by general medical practitioners and midwives who were not involved in delivery. Transfer criteria	were transferred to the CDW during labour. There were three main reasons for transfer: - need for epidural (according to woman's preference or medical indication): 31 (42%) - need for CTG: 22 (30%) - protracted labour: 10 (14%) The authors report that the use of operative delivery was higher among those transfered intrapartum: - CS: 16/74 (22%) - Forceps: 10/74 (14%) - Vacuum: 5/74 (7%) The following sub-group analysis were	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Women were transferred if there were medical complications or request for epidural in the first stage of labour. In the second stage of labour, women were not transferred from the MLW to the CDW unless an emergency CS was needed. Data collection, analysis and monitoring Pre-study assessment of sample size (given an event rate of 10% in the CDW cohort) calculated that 200 women in each cohort would be needed. (Note: it is not reported what outcome this is based on) Data were collected from the pregnancy and hospital records and entered into a modified	calculated by the technical team based on the above data: Caesarean section: - transferred women: 16/74 (22%) - women who remained in MLW: 0/178 (0) Forceps: - transferred women: 10/74 (14%) - women who remained in MLW: 2 /178 (1.1%) Vacuum: - transferred women: 5/74 (7%) - women who remained in MLW: 12/178 (6.7%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			form. The same form was used for both cohorts, with the exception of the reason for transfer to CDW from MLW. Between admission and discharge, the forms were completed by two midwives. Forms were checked for systematic errors. Chi square, Fisher's exact test and logistic regression were used where appropriate. Unadjusted and adjusted odd ratios for maternal age, smoking habits, education level, and marital status were calculated.		
Full citation Feldman,E., Hurst,M., Outcomes and procedures in low risk birth: a comparison of hospital and birth center settings, Birth, 14, 18-24, 1987	Sample size N = 149 Characteristics Maternal age/years a. Mean ± SD	Interventions Planned (intended at the onset of labour) birth at a childbearing centre	Details Selection of study groups All women in the study had a low risk pregnancy at 37 weeks gestation. Charts were	Results In most cases, outcome data is reported in the form of % in the paper. For the purposes of the analysis, where	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear; however matching was done Groups comparable at

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 174680 Country/ies where the study was carried out USA Study type Retrospective matched cohort study Aim of the study To compare one hospital's labour and delivery procedures and outcome with those of an out-of-hospital birth centre Study dates Childbearing Centre group: May - July 1981 Hospital group: June 1981 Source of funding None stated	Hospital: 29.3 ± 4.4 Childbearing Centre: 28.7 ± 4.0 b. < 20 or ≥ 35 (%) Hospital: 11.0% Childbearing Centre: 6.5% Nulliparous (%) Hospital: 54.0 Childbearing Centre: 65.0 Married (%) Hospital: 97.0 Childbearing Centre: 93.5 Race/ethnicity (%) White* Hospital: 73.6 Childbearing Centre: 90.9 Black Hospital: 4.2 Childbearing Centre: 5.2 Hispanic Hospital: 15.3* Childbearing Centre: 2.6 Other	(n = 77) Planned (intended at the onset of labour) birth in a hospital (n = 72)	retrospectively analysed to match the two study groups for low risk status, using the Hobel risk factors modified for Childbearing Centre use. Therefore, all women in the hospital population met the criteria for giving birth in an out-of-hospital setting. The Childbearing Centre arm of the study consisted of 77 women enrolled at the centre and giving birth during the study period. Any women who were transferred out of the centre before 37 weeks were excluded; however, those transferred after 37 weeks were included. The hospital group consisted of 72 women	possible the technical team have back-calculated raw event rates based on the % and denominator data provided, and this is designated with † below. In some cases, it was not possible to back-calculate definitively (i.e. to get the % reported), in which case, it has not been done Maternal mortality (n/total (%)) Hospital: 0/72 (0) Childbearing Centre: 0/77 (0) Mode of birth (n/total (%)) a. Vaginal Hospital: 63/71 (88.7%) Childbearing Centre:	baseline: Significantly more women in the childbearing centre group had some college education; they were also more likely to be white and less likely to be Hispanic. Apart from that, the demographic characteristics were similar with regards to age, parity and marital status. Groups received same/similar care (apart from intervention): Women in the CbC received prenatal care there; therefore, it was evaluating a package of care Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: PPH and episiotomy/lacerations are only reported for women with a vaginal birth Precise definition of outcomes: Definition of PPH is not reported

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Hospital: 6.9 Childbearing Centre: 7.8 * p < 0.01 Note: almost all women in both groups had finished high school; however, significantly more women in the childbearing centre group had gone to some college when compared to the hospital group (95% compared with 76%) Inclusion criteria Low risk at 37 weeks gestation Exclusion criteria Not meeting Childbearing Centre criteria at 37 weeks Incomplete chart Medicaid patient (so that groups would be socioeconomically similar)		who gave birth under the care of private obstetricians during the study period. If they did not meet the low risk criteria at 37 weeks they were excluded, as were any women with incomplete charts. Setting/care protocol - Childbearing Centre It is a Maternity Centre Association health care facility, licensed to provide prenatal, intrapartum, postpartum and well-child care to low risk women and their families. During 1981, 701 women were enrolled and there were 265 births. Care was provided by nurse-midwives, backed up by obstetricians. Families participated in prenatal care, and childbirth preparation classes were mandatory. The	72/77 (93.5%) (NS) - All forceps Hospital: 31/71** (43.7%) Childbearing Centre: NC (5.6%) (p < 0.0001) - Midforceps Hospital: 9.5% Childbearing Centre: 2.7% (NS) [Note: raw event rate data cannot be back-calculated for the outcome of forceps in the CbC group because it is impossible to achieve a % that rounds to 5.6 with a denominator of 77 and no further details are given] b. Caesarean	Valid and reliable method of outcome assessment: Method of assessing blood loss is not reported Intention-to-treat analysis performed: Yes Indirectness: - Setting: women in the obstetric unit arm were all delivered by obstetricians, which is not necessarily comparable to obstetric unit care in the UK - Population: 4.2% of the hospital arm and 1.3% of the Childbearing Centre arm had induction of labour with oxytocin Other information Comparison: FREESTANDING MLU vs. OU [This study was included in the 2007 guideline] This study evaluates a package of care, because

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			intrapartum unit consisted of two birthing rooms, family room, examination room and kitchen. During labour, women could eat/drink and have visitors. They were also encouraged to ambulate and could give birth in a position of their choice. Families could leave within 12 hours of birth, during which time a paediatrician examined the baby. The baby remains with the parents at all times. Emergency equipment was available in the unit. Enemas and IV were rarely used, and oxytocin augmentation, electronic fetal monitoring (EFM), epidural and forceps were not used at the centre. However,	section Hospital: 8/71† (11.3%) Childbearing Centre: 5/77† (6.5%) (NS) Use of epidural (n/total (%)) Hospital: 40/71† (56.3%) Childbearing Centre: 4/77† (5.2%) (p < 0.0001) Episiotomy or lacerations [reported for vaginal births only] (n (%)) a. Episiotomy Hospital: NC (78.1%) Childbearing Centre: 34† (47.2%) (p < 0.0001) b. Laceration involving anal sphincter Hospital: 6† (9.5%)	women had prenatal care at the birth centre

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			analgesics could be given during the first stage of labour and local/pudendal infiltration at time of birth. Castor oil, nipple stimulation and ambulation could be used to stimulate labour. - Mount Sinai Hospital It is a large voluntary teaching hospital, conducting over 3300 deliveries during 1980. The authors report that the obstetric practices at the unit were comparable to those elsewhere in the eastern USA. This group received prenatal care from private or HMO-affiliated obstetricians. Childbirth preparation classes were optional but encouraged. The obstetric ward was	Childbearing Centre: 7† (9.7%) (NS) c. Laceration not involving anal sphincter Hospital: 4† (6.3%) Childbearing Centre: 19† (26.4%) ($p < 0.01$) d. Intact perineum Hospital: 4† (6.3%) Childbearing Centre: 18† (25.0%) ($p < 0.01$) [NOTE: for the purposes of the analysis, the technical team will use the full denominator. Excluding women with CS from the risk calculations does not give an accurate representation of the risk of a specific	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			staffed by nurses, obstetric residents and fellows, and private physicians. Women were cared for in small, two-bed labour rooms. The procedures varied between attending physicians, but generally included shave, enema, and placement of an IV catheter. EFM was routine, and epidural and other analgesics were available. One support person (i.e. husband) was allowed to stay with the woman throughout labour and birth, which took place in one of three delivery rooms. Neonates were cared for by the labour nurse or paediatric house staff. Private patients generally spent several hours in recovering and then	outcome for women planning birth in different settings] Postpartum haemorrhage [reported for vaginal births only] (n/total (%)) Hospital: 1/63† (1.6%) Childbearing Centre: 2/72† (2.7%) Perinatal mortality (n/total (%)) a. Fetal death at term Hospital: 1/72 (1.4%) Childbearing Centre: 0/77 (0%) b. Neonatal death Hospital: 0/72 (0) Childbearing Centre: 0/77 (0) Admission to neonatal intensive	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			were transferred to the postpartum floor. The babies stayed on the postpartum floor or were transferred to NICU. Women were discharged on the third or fourth day following vaginal birth and the seventh day following CS. Transfer criteria If women developed complications they were transferred at any time during the antepartum or intrapartum periods, generally to a nearby hospital where Childbearing Centre obstetricians were on staff. Mothers and babies were also transferred postpartum. Data collection, analysis and monitoring Data was collected from charts. Chi-squared or	care unit (n/total (%)) Hospital: 4/72† (5.6%) Childbearing Centre: 1/77† (1.3%) [Note: in the hospital group, 3 babies were transferred for respiratory distress and in the CbC group, 1 was transferred for a foul odour resulting in a sepsis work-up. No further details are given] Transfer Antepartum (i.e. between 37 weeks and birth): 8% Intrapartum: 14% Total transfer rate: 22% Note: The reasons	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Fisher's exact test were used to compare percentage distribution of outcomes. A one-tailed t-test was used for continuous outcomes. $p < 0.05$ was considered significant. Outcomes reported 1. Maternal mortality 2. Mode of birth 3. Use of epidural 4. Episiotomy or laceration: reported as episiotomy, laceration involving anal sphincter, laceration not involving anal sphincter, and intact perineum 5. Postpartum haemorrhage (PPH) 6. Perinatal mortality: fetal death at term and neonatal mortality are	for transfers are not given	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			reported 7. Transfer to neonatal intensive care		
Full citation Hundley,V.A., Cruickshank,F.M., Lang,G.D., Glazener,C.M., Milne,J.M., Turner,M., Blyth,D., Mollison,J., Donaldson,C., Midwife managed delivery unit: a randomised controlled comparison with consultant led care, BMJ, 309, 1400-1404, 1994 Ref Id 174929 Country/ies where the study was carried out Scotland Study type Randomised controlled trial Aim of the study To examine whether intrapartum care and delivery of low risk women	Sample size N = 2844 Characteristics Age at delivery/years (mean ± SD) MLU: 28 ± 4.4 [n = 1675] Labour ward: 28 ± 4.5 [n = 789] Height/cm (mean ± SD) MLU: 163 ± 5.8 [n = 1674] Labour ward: 163 ± 5.9 [n = 793] Gestation/weeks (mean ± SD MLU: 39.7 ± 1.8 [n = 1819] Labour ward: 39.8 ± 1.6 [n = 915] (p = 0.9) Parity (n (%)) Primiparous MLU: 929 (56) Labour ward: 451 (57)	Interventions Planned (booked) birth in midwifery led unit (MLU) (n = 1900) Planned (booked) birth in labour ward (n = 944)	Details Setting The midwives unit was a separate unit of 5 single rooms, located 20 yards from the consultant-led labour ward. The philosophy of care was to provide a safe, homely environment where women could retain choice and control in the management of their labour. Midwives took total responsibility for delivery of care. Labour was managed traditionally, i.e. monitoring was with a Pinard or hand held Doppler, active labour was encouraged, and there was minimal intervention. The unit was staffed and run by	Results Mode of birth (n/total (%)) a. Spontaneous vaginal birth MLU: 1422/1819 (78.2%) Labour ward: 689/915 (75.3%) b. Vaginal breech MLU: 23/1819 (1.3%) Labour ward: 12/915 (1.3%) c. Forceps or ventouse MLU: 221/1819 (12.2%) Labour ward: 122/915 (12.3%) d. Emergency CS MLU: 126/1819 (6.9%)	Limitations Appropriate randomisation: Method of sequence generation is not reported; although authors report that randomisation was done in a simple unstratified manner Allocation concealment: Yes Groups comparable at baseline: Groups received same care (apart from intervention): Yes Blinding of participants: Unclear, no details reported Blinding of staff providing care: Unclear, no details reported Blinding of outcome assessors: Unclear, no details reported Missing data/loss to follow-up: 43 women (1.5%) of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
in a midwife managed delivery unit differs from that in a consultant led unit Study dates October 1991 to December 1992 (all women had delivered by August 1993) Source of funding None reported	Multiparous MLU: 745 (44) Labour ward: 338 (43) Inclusion criteria Low risk women Exclusion criteria Pre-existing maternal disease Infertility Complicated obstetric history (e.g. previous caesarean section [CS], difficult vaginal delivery, poor obstetric outcome) Height < 150 cm Maternal age > 35 years old Multiple pregnancy		hospital midwives, who worked throughout the delivery suite as needed. The unit only admitted low risk women, and there were strict protocols for booking, admission and transfer. Recruitment and randomisation Low risk women were identified from GP's referral letters. Eligible women were invited to participate through an explanatory letter, and then further information was given by a midwife at the booking visits. Of 3451 women identified as eligible, 2844 agreed to participate. Women were randomised to deliver in the two units by opening the next consecutive sealed	Labour ward: 73/915 (8.0%) e. Elective CS MLU: 27/1819 (1.5%) Labour ward: 19/915 (2.1%) Use of epidural or spinal anaesthesia (n (%))* MLU: 246 (14.7%) Labour ward: 140 (17.7%) p = 0.05 * unclear what the denominator is, because use of those quoted in table would not give % reported. For the purposes of the meta-analysis, it is assumed to be as reported in the table (1819 and 915	women were lost to follow-up in addition to the 63 (2.2%) that miscarried or had an abortion; unclear what denominator is for epidural outcome, because % quoted does not match the table; data for intact perineum, episiotomy and tear excludes women with CS from denominator Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: 566 women (20.7%) had induction of labour; a further 143 (5.2%) had pre-eclampsia or preterm delivery; 46 (1.7%) had elective CS Other information Comparison: ALONGSIDE MLU vs. OU

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			opaque envelope. This was done in 2:1 ratio in favour of the MLU due to the expected rate of transfer, in order to ensure that the space in the MLU was fully utilised. Care protocol Antenatal care of participants was identical to that received by other women booking at the hospital. Transfer criteria Not reported Data collection, analysis and monitoring The sample size calculation established that 2700 women were needed for 80% power in detecting a difference of 5% in perinatal morbidity.	respectively) State of perineum (excluding those with CS) (n (%)) a. Intact MLU: 394 (23.7%) Labour ward: 171 (20.9%) b. Episiotomy MLU: 420 (25.2%) Labour ward: 238 (29.1%) p = 0.04 c. Tear MLU: 850 (51.15%) Labour ward: 410 (50.1%) Third degree tear (n/total (%)) MLU: 15/1819 (0.8%) Labour ward: 3/915 (0.3%) Mortality of baby	[Included in 2007 guideline] This study evaluates a package of care, from antenatal care onwards, not just intrapartum care. Women required transfer in the event of complications, because there was no input to the midwife unit by medical staff

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Data were collected from six sources: - staff questionnaire, completed by midwife in charge of birth as soon as possible after birth - client questionnaire, completed by the women after discharge home - interviews of a random sample of 400 women - case note review - Scottish Morbidity Register - Aberdeen maternity and neonatal data bank Data validation was carried out by cross checking key variables across different records held for each woman in the database manually with case records and by estimation of keying errors for a sub-sample of questionnaires. Data were analysed	(n/total (%)) a. Live born MLU: 1805/1820 (99.2%) Labour ward: 912/918 (99.3%) b. Stillbirth MLU: 6/1820 (0.3%) Labour ward: 4/918 (0.4%) [Note: in all cases of stillbirth, the fetal heartbeat was absent on admission. There was 1 in each group due to fetal abnormality. In the MLU arm, one was a direct result of a maternal death due to aortic aneurysm] c. Neonatal death MLU: 9/1820 (0.5%) Labour ward: 2/918 (0.2%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			intention to treat. Categorical variables were analysed using chi-squares, and continuous variables with a normal distribution using the Student's t test. Some variables required log transformations, and hence geometric means are reported. Data with non-normal distributions are analysed using Mann-Whitney.	[5 of the neonatal deaths resulted from fetal abnormalities, such as Potter's syndrome. Of the other 6 who died, four were less than 37 weeks gestation. The other 2 were in women randomised to MLU: One was suspected to be due to asphyxia after induction - the woman was transferred antenatally and never entered the MLU. The other woman started care in MLU, but thick meconium was diagnosed and she was immediately transferred and had an emergency CS 18 hours later] [Note: these denominators	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				exclude the 80 women from the MLU and the 26 from the OU arm that were lost to follow-up (1.5%) or had a miscarriage or an abortion] Admission to NICU (n/total (%)) a. Total MLU: 143/1820 (7.9%) Labour ward: 67/918 (7.3%) b. For up to 48 hours MLU: 24/1820 (1.3%) Labour ward: 13/918 (1.4) c. For more than 48 hours MLU: 119/1820 (6.6%) Labour ward: 54/918 (6.0%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				[Note: although the denominators for this outcome are reported as 1900 and 944 in the column heading, the quoted % match the denominators if those lost to follow-up and those women with a miscarriage/abortion are excluded] Transfer Of the 1900 women randomised to the midwives unit, 727 (38.3%) were transferred antepartum and 303 (15.9%) were transferred intrapartum. In total 870 women gave birth in the midwives unit. - ANTEPARTUM TRANSFER n (%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Induction of labour for post-maturity: 155 (21.3%) Pregnancy induced hypertension: 93 (12.850 Prolonged rupture of membranes: 69 (9.5%) Antepartum haemorrhage: 55 (7.6%) Malpresentation: 55 (7.6%) Preterm labour: 49 (6.7%) Reduced fetal movement or poor cardiotocograph (CTG): 37 (5.1%) Intrauterine growth restriction (IUGR): 20 (2.8%) Gestational diabetes or polyhydramnios: 17 (2.3%) Delivered in peripheral hospital: 14 (1.9%) Home delivery: 2	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(0.3%) Intrauterine death: 5 (0.7%) Fetal abnormality: 3 (0.4%) Born before arrival: 11 (1.5%) Maternal request: 9 (1.2%) Other: - Clinical (eg. staff error [n = 7], induction of labour for social reasons [n = 5], twins [n = 4]): 52 (7.2%) - Follow-up not possible (35 miscarried, 11 had abortion, 34 moved): 80 (11.1%) Total: 727 (100%) - INTRAPARTUM TRANSFER n (%) Meconium: 74 (24%) - Primigravida: 58 (23%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Multigravida: 16 (33%) Fetal heart rate: 47 (16%) - Primigravida: 41 (16%) - Multigravida: 6 (13%) Delay in first stage: 75 (25%) - Primigravida: 64 (25%) - Multigravida: 11 (23%) Delay in second stage: 33 (11%) - Primigravida: 32 (13%) - Multigravida: 1 (2%) Pregnancy induced hypertension: 28 (9%) - Primigravida: 25 (10%) - Multigravida: 3	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(6%) Epidural: 28 (9%) - Primigravida: 24 (9%) - Multigravida: 4 (8%) Other: 18 (6%) - Primigravida: 11 (4%) - Multigravida: 7 (15%) Total: 303 - Primigravida: 255/596 (43% of all primigravidae) - Multigravida: 48/577 (8% of all multigravidae)	
Full citation Hutton,E.K., Reitsma,A.H., Kaufman,K., Outcomes associated with planned home and planned hospital births in low-risk women attended by midwives in	Sample size N = 13384 (primary analysis) N = 13639 (sensitivity analysis) Characteristics	Interventions Planned (intended at the onset of labour) home birth (n = 6692)	Details Selection of study groups The two study groups were matched according to parity and previous lower segment	Results Note: relative risks are reported here where they are reported in the study - it is unclear why they are only	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear - there may be some confounders not reported Groups comparable at

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ontario, Canada, 2003-2006: A retrospective cohort study, Birth, 36, 180-189, 2009 Ref Id 60254 Country/ies where the study was carried out Canada Study type Retrospective cohort study Aim of the study To compare maternal and perinatal/neonatal mortality and morbidity and intrapartum intervention rates for women attended by Ontario midwives who planned a home birth compared with similar low-risk women who planned a hospital birth between 2003 and 2006 Study dates April 1st 2003 to March 31st 2006	Age/years (n (%)) < 25 Home: 729 (10.9) Hospital: 844 (12.6) 25-34 Home: 4428 (66.1) Hospital: 4630 (69.2) ≥ 35 Home: 1503 (22.5) Hospital: 1199 (17.9) Missing data Home: 32 (0.5) Hospital: 19 (0.3) Parity (n (%)) 0 Home: 2293 (34.3) Hospital: 2298 (34.3) 1-4 Home: 4172 (62.3) Hospital: 4289 (64.1) > 4 Home: 221 (3.3) Hospital: 105 (1.6)	Planned (intended at the onset of labour) hospital birth (n = 6692)	caesarean section. The medical record documented discussions between the midwife and woman about place of birth throughout pregnancy, and provided information about planned location of birth when labour began, as circumstances could change the original plan. Planned home birth group For the study, planned home birth included all client records where "planned place of birth at the outset of labour" was: "home", "other out of hospital" (there are no formal out-of-hospital alternative settings in Ontario, i.e. no birth centres) or "undecided". This was because a home birth	reported for some outcomes Maternal mortality (n/total (%)) Home: 0/6692 (0) Hospital: 0/6692 (0) Mode of birth (n/total (%)) a. Spontaneous vaginal Home: 6146/6692 (91.8) Hospital: 5852/6692 (87.4) b. Assisted vaginal Home: 195/6692 (2.9) Hospital: 293/6692 (4.4) RR 0.67 (0.56 to 0.80) c. Forceps Home: 81/6692 (1.2) Hospital: 141/6692 (2.1)	baseline: Unclear, because slightly different criteria were used to select the hospital arm when compared to the planned home birth arm. Groups received same/similar care (apart from intervention): Yes Blinding of those assessing outcomes: Unclear - no details given Missing data/loss to follow-up: For PPH outcomes there is 0.3% missing data in each arm Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Unclear how blood loss was measured Intention-to-treat analysis performed: Yes Indirectness: - Admission for NICU is reported as 'admission to NICU for more than 4 days'

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding None reported	Missing data Home: 6 (0.1) Hospital: 0 (0) Geographical location (n (%))* Rural Home: 1113 (16.7) Hospital: 1093 (16.3) Urban Home: 5576 (83.3) Hospital: 5598 (83.7) Missing data Home: 3 (0.0) Hospital: 1 (0.0) * Data for north and south rural and urban areas have been combined by the technical team, as the distinction between north and south is not relevant Repeat Ontario midwifery client (n (%)) Yes Home: 3044 (45.5) Hospital: 2331 (34.8)		was a possibility in all of these situations. In order to check for coding errors for planned place of birth, logic checks were carried out to identify those with contraindications to planned home birth or records inconsistent with planned home birth (oxytocin induction), or in which an antenatal transfer of care to a physician was documented. Two experienced midwives used an a priori algorithm to decide whether to include the birth. The authors report that they identified 7037 records indicating that at the outset of labour, birth was intended to take place at home. There were 419 records	d. Vacuum Home: 124/6692 (1.9) Hospital: 168/6692 (2.5) e. Caesarean section Home: 348/6692 (5.2) Hospital: 544/6692 (8.1) RR 0.64 (0.56 to 0.73) Use of epidural (n/total (%)) Home: 655/6692 (9.8) Hospital: 1405/6692 (21.0) Vaginal/perineal trauma or laceration (n/total (%)) a. Any laceration Home: 3612/6692 (54.0)	- 3.1% of the home birth arm and 3.1% of the hospital birth arm had at least one previous CS - 33/6692 (0.5%) of the planned home birth arm had breech or were born at 35-37 weeks - 1.7% of the home birth and 0.8% of the hospital birth were post-term - 2.6% of the home birth arm and 2.7% of the hospital birth arm had significant congenital anomalies - 1.5% of the home birth arm and 2.0% of the hospital arm had ARM before labour or prostaglandin induction An unknown proportion of women had their planned place of birth coded as 'unknown' and therefore might not have been planned home births. A logic check was used to identify those not

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	No Home: 3642 (54.4) Hospital: 4357 (65.1) Missing data Home: 6 (0.1) Hospital: 4 (0.1) Previous caesarean section (CS) (n (%)) 0 Home: 6479 (96.8) Hospital: 6485 (96.9) 1 Home: 200 (3.0) Hospital: 207 (3.1) > 1 Home: 6 (0.1) Hospital: 0 (0) Missing data Home: 7 (0.1) Hospital: 0 (0) Gestation at booking/weeks (median) At booking Home: 11.0		initially inconsistent with home birth criteria: - 74 were retained in the primary analysis: 13 were breech delivering at home or transferred in labour, 20 were preterm ≥ 35 weeks and 41 had antenatal transfer of care with possible return to midwifery care - 90 were removed from any analysis: 36 were breech with antenatal transfer of care and elective CS, 25 were very preterm ≤ 28 weeks, and 29 had antenatal transfer of care with conditions judged to be permanent - 255 were retained for a sensitivity analysis: 30 were breech with hospital delivery with no known transfer in labour, 41 were preterm at 28-35 weeks, 20 had antenatal transfer of	Hospital: 4081/6692 (61.0) b. 1st degree perineal Home: 1109/6692 (16.6) Hospital: 1186/6692 (17.7) c. 2nd degree perineal Home: 1695/6692 (25.3) Hospital: 1939/6692 (29.0) d. 3rd degree perineal Home: 78/6692 (1.2) Hospital: 123/6692 (1.8) e. 4th degree perineal Home: 21/6692 (0.3) Hospital: 22/6692 (0.3) f. Labial	compatible with planned home birth; however, as the study is retrospective, it is possible that there may have been some mis-classified. The authors report that those originally identified as a planned home birth but with later discrepancies in the record, it is likely that the midwife erroneously entered it as a planned home birth, when in fact it had just been planned or desired at an earlier point in pregnancy. Other information Comparison: HOME vs. OU [This study is new since the 2007 guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Hospital: 11.0 Gestation at birth/weeks Median Home: 40.0 Hospital: 40.0 < 37 weeks Home: 17/6692 (0.3) Hospital: 0/6692 (0) > 41+6 weeks Home: 117/6692 (1.7) Hospital: 54/6692 (0.8) Nb. There were no multiple pregnancies in either arm of the study. There were 12 breeches (0.2%) in the planned home birth arm and none in the planned hospital birth arm Inclusion criteria Midwife birth during study period Women planning a home birth, or comparable low-risk women planning a hospital birth at the		care with unclear possible return to midwifery, and 164 had induction. Note: only data from the primary analysis will be reported in the GRADE tables. The authors report that the sensitivity analysis did not make a difference to the findings, and for most outcomes, it is not reported. Planned hospital birth group The comparison group was identified from the remaining hospital records, all of which indicated that a hospital birth was planned at the onset of labour. To select a low-risk cohort, any records in which a home birth would have been contraindicated were removed or in	Home: 413/6692 (6.2) Hospital: 381/6692 (5.7) g. Vaginal Home: 474/6692 (7.1) Hospital: 542/6692 (8.1) h. Episiotomy Home: 286/6692 (4.3) Hospital: 393/6692 (5.9) RR 0.73 (0.63 to 0.84) i. Any 2nd - 4th degree perineal, labour, or vaginal tear, or episiotomy Home: 2589/6692 (38.7) Hospital: 2979/6682 (44.5) RR 0.87 (0.83 to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	outset of labour Exclusion criteria Excluded from planned hospital group: - > 1 previous CS - Breech - Multiple pregnancy - Preterm birth - Medical induction - Any antenatal transfer of care Excluded from planned home group: records where evidence from other data fields suggested that care was organised for a hospital birth or there were interventions inconsistent with home birth (e.g. induction) [See 'Methods' section for more details of analyses]		which a 'pre-labour intervention had occurred that was inconsistent with, or unlikely at, a home birth.' Therefore, breech, multiple pregnancy, more than 1 previous CS, preterm (prior to 37 weeks), induction with oxytocin, prostaglandin cervical ripening, or any antenatal transfer to a physician. They then stratified the low-risk hospital records by parity (0 or more than 1) and previous CS (none or 1) and randomly selected women to match the home birth group. Setting/care protocol Midwives registered with and regulated by the College of Midwives in Ontario attended all births in the study. No	0.90) Estimated intrapartum blood loss (n/total (%)) a. 500 - 1000 ml Home: 568/6692 (8.5) Hospital: 678/6692 (10.1) b. > 1000 ml Home: 56/6692 (0.8) Hospital: 82/6692 (1.2) RR 0.68 (0.49 to 0.96) [Note: missing data for 20 women in home birth arm and 23 women in hospital arm] c. Consultation or transfer of care for bleeding Home: 79/6692 (1.2) Hospital: 106/6692	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			further details are given. Transfer criteria Not reported Data collection, analysis and monitoring All outcomes were analysed by planned place of birth, regardless of where the birth occurred. All analyses were done in SPSS, and chi-square and relative risks were used. Possible misclassified home births were removed from the primary analysis and retained for a sensitivity analysis. Therefore, there were 6692 home births for the primary analysis and 6947 for the sensitivity analysis. 1. Maternal mortality: any death from an	(1.6) RR 0.75 (0.56 to 1.00) Mortality of the baby (n/total (%)) a. Any mortality Home: 9/6692 (0.1) Hospital: 9/6692 (0.1) b. Stillbirth Home: 3/6692 (0.0) Hospital: 4/6692 (0.1) (Note: no congenital anomalies noted in either group) c. Neonatal mortality Home: 6/6692 (0.1) Hospital: 4/6692 (0.1) (Note: this includes 2 infants with a major congenital anomaly in the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			obstetric cause (as determined by a provincial coroner's review) occurring between the onset of labour and 6 weeks postpartum. 2. Mode of birth: spontaneous vaginal, assisted vaginal, forceps, vacuum and CS are reported 3. Epidural 4. Vaginal/perineal trauma or laceration: any lacerations, degrees of perineal, labial, vaginal, and episiotomy are reported 5. Intrapartum blood loss: method of assessing blood loss is not reported; bleeding requiring consultation with a physician is reported as the authors	planned hospital group [1 brain tumour, 1 liver cirrhosis]) d. Infant death at 28-42 days Home: 0/6692 (0) Hospital: 1/6692 (0.0) Admission to NICU for more than 4 days (n/total (%)) Home: 102/6692 (1.5) Hospital: 115/6690 (1.7)* Composite neonatal outcome (n/total (%)) Home: 159/6692 (2.4) Hospital: 190/6690 (2.8)* RR 0.84 (0.68 to 1.03)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			felt that this would capture any symptomatic blood losses which the volume might be underestimated 6. Mortality of baby: reported overall, and split by stillbirth, neonatal and death at 28-42 days 7. Admission to NICU: for more than 4 days 8. Composite perinatal and neonatal mortality or serious morbidity: defined as the presence of one or more of the following: - death (stillbirth or neonatal death 0-27 days, excluding fetal anomalies and fetal demise before the onset of labour) - Apgar score < 4 at 5 minutes	* this excludes 2 babies with a major congenital anomaly SUBGROUP ANALYSIS BY PARITY Subgroup data are reported for the following outcomes Mode of birth (n/total (%)) a. Caesarean section - Nulliparous Home: 276/2293 (12.0) Hospital: 365/2298 (15.9) - Multiparous Home: 71/4393 (1.6) Hospital: 179/4394 (4.1) b. Assisted vaginal delivery - Nulliparous Home: 166/2293	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- neonatal resuscitation requiring both positive pressure ventilations and cardiac compressions - admission to a neonatal or paediatric intensive care unit with a length of stay of more than 4 days - birth weight < 2500 g	(7.2) Hospital: 221/2298 (9.6) - Multiparous Home: 28/4393 (0.6) Hospital: 72/4394 (1.6) Laceration: any 2nd-4th degree perineal, labial, or vaginal tear, or episiotomy (n/total (%)) - Nulliparous Home: 1406/2293 (61.3) Hospital: 1382/2298 (60.1) - Multiparous Home: 1182/4393 (26.9) Hospital: 1597/4394 (36.3) Episiotomy (n/total (%)) - Nulliparous Home: 229/2293	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(10.0) Hospital: 277/2298 (12.1) - Multiparous Home: 57/4393 (1.3) Hospital: 116/4394 (2.6) Estimated intrapartum blood loss > 1000 ml (n/total (%)) - Nulliparous Home: 29/2287 (1.3) Hospital: 31/2292 (1.3) - Multiparous Home: 27/4379 (0.6) Hospital: 51/4379 (1.2) Baby outcomes (n/total (%)) a. Composite perinatal/neonatal morbidity/mortality† - Nulliparous Home: 80/2293 (3.5)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Hospital: 85/2298 (3.7) - Multiparous Home: 79/4393 (1.8) Hospital: 105/4394 (2.4) b. Perinatal/neonatal mortality† - Nulliparous Home: 5/2293 (0.2) Hospital: 4/2298 (0.2) - Multiparous Home: 4/4393 (0.1) Hospital: 2/4394 (0.1) † 2 babies with congenital anomalies are excluded from hospital arm; however, the authors do not report their parity, therefore, it is not possible to adjust	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				denominators c. Neonatal morbidity - Nulliparous Home: 78/2293 (3.4) Hospital: 84/2298 (3.7) - Multiparous Home: 77/4393 (1.8) Hospital: 105/4394 (2.4) Details of transfers Actual place of birth (n (%)) - Home Home: 5259 (78.6) Hospital: 208 (3.1) - Hospital Home: 1371 (20.5) Hospital: 6467 (96.6) - Other location Home: 62 (0.9) Hospital: 17 (0.3) [Note: among the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				planned home births, 1364/2293 (59.5%) of nulliparous women and 3891/4393 (88.6%) of multiparous women gave birth at home] Ambulance transport from home during or immediately after birth (n (%)) - Yes Home: 361 (5.4) Hospital: 44 (0.7) - No Home: 6307 (94.2) Hospital: 6544 (97.8) - Missing data Home: 24 (0.4) Hospital: 104 (1.5) [Note: - among the planned home births, 188/2285 (8.2%) of nulliparas and	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				173/4377 (3.9%) of the multiparas used ambulance transport - among the planned hospital births, 14/2263 (0.6%) of nulliparas and 30/4326 (0.7%) of multiparas used ambulance transport] Transfer of care to a physician (n/total (%)) Intrapartum transfer of care Home: 837/6692 (12.5%) Hospital: 1270/6692 (19.0) RR 0.66 (95% CI 0.61 - 0.71) [Note: - among the planned home births, 638 (27.8%) of nulliparas	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				and 197 (4.5%) of multiparas required intrapartum transfer of care to a physician (it is unclear why this does not sum 837) - among the planned hospital births, 798 (34.7%) of nulliparas and 472 (10.7%) of multiparas required intrapartum transfer of care to a physician] Postpartum transfer of care Home: 119/6692 (1.8) Hospital: 104/6692 (1.6) RR 1.14 (95% CI 0.88 to1.49) [Note: - among the planned home births, 66	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(2.9%) of nulliparas and 53 (1.2%) of multiparas required postpartum transfer of care to a physician - among the planned hospital births, 49 (2.1%) of nulliparas and 55 (1.3%) of multiparas required postpartum transfer to a physician]	
Full citation Jackson,D.J., Lang,J.M., Swartz,W.H., Ganiats,T.G., Fullerton,J., Ecker,J., Nguyen,U., Outcomes, safety, and resource utilization in a collaborative care birth center program compared with traditional physician-based perinatal care, American Journal of Public Health, 93, 999-1006, 2003 Ref Id 168115 Country/ies where the study	Sample size N = 2957 Characteristics Maternal age/years (n (%)) < 20 Collaborative: 391 (21.6) Traditional: 250 (21.8) Difference -0.1 (95% CI -3.2 to 2.9) > 35 Collaborative: 54 (3.0) Traditional: 53 (4.6)	Interventions Planned (booked) birth in a collaborative care setting (birth centre) (n = 1808) Planned (booked) birth in a traditional care setting (hospital) (n = 1149)	Details Selection of study groups Women were enrolled in the study at the start of prenatal care, and they remained in their initial group regardless of eventual site of birth. Birth centre eligibility criteria (see exclusion criteria above) were used to select both study groups. For collaborative care women, this determination was	Results * adjusted for race/ethnicity, parity and CS history, education, age, marital status, country of origin, height and smoking during pregnancy ‡ adjusted for race/ethnicity. parity and CS history, education, age, marital status, country of origin, height and smoking	Limitations Choice of treatment unrelated to confounders (selection bias): Unlikely; however, adjustment was done to try and control for confounders Groups comparable at baseline: No; there were differences in proportion of women >35, parity and CS history, race/ethnicity, country of origin, language spoken, height, and smoking during pregnancy. However, adjusted analysis was done to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
was carried out USA Study type Prospective cohort study Aim of the study To compare outcomes between a collaborative management birth centre and traditional, physician-based care Study dates February 1st 1994 to November 1st 1996 Source of funding US Agency for Healthcare Research and Quality Sharp HealthCare of San Diego athenahealth of Boston	Difference -1.6 (95% CI -3.1 to 0.2) Parity (n (%)) Nulliparous Collaborative: 808 (44.7) Traditional: 460 (40.3) Difference 4.7 (95% CI 1.0 to 8.3) Multiparous without history of caesarean section (CS) Collaborative: 927 (51.3) Traditional: 571 (49.7) Difference 1.6 (95% CI -2.1 to 5.3) Multiparous with previous CS Collaborative: 73 (4.2) Traditional: 115 (10.0) Difference -6.0 (95% CI -7.9 to -4.0) Race/ethnicity (n (%)) Hispanic Collaborative: 1561 (86.3)		made at the initial prenatal visit. Medically eligible women were given the option to enrol in the birth centre program, and 65-75% tended to choose birth centre delivery. 2156 collaborative care women initially met study criteria; however, after birth centre eligibility process was completed 142 were not eligible at entry into prenatal care. For the traditional care group, women were recruited from those receiving perinatal care at 2 hospital-based prenatal care clinics and 7 private physician practices. The study group was selected based on those who would have been eligible, and this was	during pregnancy Mode of birth (n/total (%)) a. Normal spontaneous vaginal Collaborative: 1462/1808 (80.9) Traditional: 720/1149 (62.8) Crude difference 18.0 (95% CI 14.8 to 21.5) Adjusted difference 14.9 (95% CI 11.5 to 18.3)* b. Assisted vaginal Collaborative: 151/1808 (8.4) Traditional: 208/1149 (18.1) Crude difference -9.8 (95% CI -12.3 to -7.2) Adjusted difference -9.7 (95% CI -12.5 to	control for these differences. Groups received same/similar care (apart from intervention): Yes Blinding of those assessing outcomes: No, but those classifying eligibility for birth centre among traditional care group were blinded Missing data/loss to follow-up: No outcome data was available for 7.3% of the 2014 eligible women in collaborative care and 9.7% of the 1345 eligible women in traditional care, therefore they were excluded from the denominators of the study. Precise definition of outcomes: Yes, although many of the composite outcomes include components that the GDG were not interested in Valid and reliable method of outcome assessment: 361 women had to be

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Traditional: 703 (61.2) Difference 25.2 (95% CI 21.9 to 28.4) White, non-Hispanic Collaborative: 152 (8.4) Traditional: 233 (20.3) Difference -11.9 (95% CI -14.5 to -9.2) African American Collaborative: 59 (3.3) Traditional: 141 (12.3) Difference -9.0 (95% CI -11.1 to -7.0) Other/unknown Collaborative: 36 (2.0) Traditional: 72 (6.3) Difference -4.3 (95% CI -5.8 to -2.7) [Note: 74.3% of collaborative care group and 42.7% of traditional care group originated from Mexico]		done by providing certified nurse midwives (CNMs) with abstracted data from the medical record (collected up to and including the first prenatal visit) and asking them to classify women as eligible or not for birth centre care. 2 CNMs reviewed each record independently and any disagreements were referred to a third for decision. A perinatologist familiar with birth centre protocols also reviewed the eligibility data. Discrepancies (< 10%) were resolved through a conference. All reviews were blinded. 1577 traditional care women initially met study criteria; however, after birth centre eligibility process was completed 232 were not	-6.9)* c. Caesarean section Collaborative: 194/1808 (10.7) Traditional: 219/1149 (19.1) Crude difference -8.4 (95% CI -11.0 to -5.7) Adjusted difference -4.7 (95% CI -7.3 to -2.2)* Use of epidural (n/total (%))† Collaborative: 522/1779 (29.8) [technical team: 29.3%] Traditional: 742/1089 (68.6) [technical team: 68.1%] Crude difference -38.8 (95% CI -42.3	added via retrospective chart review in order to maintain sample size. Intention-to-treat analysis performed: Yes Indirectness: - Comparison group received care by physicians, which is less comparable to care in obstetric units in the UK - Population: 16.9% of birth centre group and 16.2% of traditional care group had prior medical or pregnancy risk factors; 8.4% of birth centre group and 14.7% of traditional care group were induced with oxytocin or prostaglandin; 6.4% of birth centre group and 6.5% of traditional care group were born before 37 weeks; 5.9% of birth centre group and 4.5% of traditional care group were small for gestational age; 4.2% of birth centre group and 10% of traditional care

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Body mass index (n (%)) Underweight (< 19.8) Collaborative: 180 (11.8) Traditional: 137 (14.6) Difference -2.8 (95% CI-5.5 to 0) Normal weight (19.8 - 26.1) Collaborative: 908 (59.7) Traditional: 532 (56.7) Difference 3.0 (95% CI -1.0 to 7.1) Overweight (> 26.1) Collaborative: 433 (28.5) Traditional: 270 (28.8) Difference -0.3 (95% CI - 4.0 to 3.4) Substance use (n (%)) Smoked during pregnancy Collaborative: 94 (5.3) Traditional: 111 (10.3) Difference -5.0 (95% CI -7.1 to -2.9)		eligible at entry into prenatal care. [Note: there were administrative problems at one site which led to women not being recruited at prenatal care. 361 women from this site and 1 other were added to the group via retrospective chart review to reach the sample size] No outcome data were available for 7.3% of the 2014 eligible women in collaborative care and 9.7% of the 1345 eligible women in traditional care. Then a further 87 women had an abortion or miscarriage and 38 women were found to have multiple pregnancy. This resulted in a final sample size of 2957.	to -35.3) Adjusted difference -35.7 (95% CI -39.5 to -31.8)* Episiotomy (n/total (%))† Collaborative: 209/1779 (13.1) [technical team: 11.7%] Traditional: 348/1089 (37.8) [technical team: 32.0%] Crude difference -24.8 (95% CI -28.3 to -21.2) Adjusted difference -22.5 (95% CI -26.4 to -18.5)* † excludes women admitted for CS without labour Composite maternal morbidity outcomes	group had a previous CS; 77% of the study population were Hispanic, which is not comparable to most UK settings Other information Comparison: FREESTANDING MIDWIFERY UNIT vs. OU [This study is new to the updated guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	History of substance abuse Collaborative: 68 (3.8) Traditional: 50 (4.7) Difference -0.9 (95% CI -2.4 to 0.7) Used alcohol during pregnancy Collaborative: 55 (3.1) Traditional: 35 (3.3) Difference -0.2 (95% CI -1.5 to 1.1) Prior pregnancy of medical risk factor (n (%))* Collaborative: 304 (16.9) Traditional: 186 (16.2) Difference 0.6 (95% CI -2.1 to 3.4) * defined as chronic hypertension, chronic renal disease, diabetes mellitus, heart disease class II-IV, HIV positive, prior pregnancy complications except CS and		Setting/care protocol Collaborative care/birth centre group This model of care had 3 components: 1. collaborative practice of certified nurse-midwives (CNMs) and obstetricians 2. comprehensive perinatal services including case management, health education, nutrition counselling and social services 3. option to deliver in freestanding birth centre for women remaining at low risk Obstetricians and CNMs worked together in the same practice; however CNMs provided 95% of prenatal care. During antepartum care, 30% saw only CNMs, 65% saw both, and 5% only	(n/total (%)) a. Major antepartum complications Collaborative: 104/1808 (5.8) Traditional: 73/1149 (6.4) Crude difference -0.6 (95% CI -2.4 to 1.2) Adjusted difference -0.5 (95% CI -2.5 to 1.5)* b. Major intrapartum complications Collaborative: 329/1808 (19.6) [technical team: 18.2%] Traditional: 201/1149 (20.2) [technical team: 17.5%] Crude difference -0.5 (95% CI -3.7 to 2.6) Adjusted difference	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	prior vaginal birth after CS Birth weight (n (%)) < 2500 grams Collaborative: 69 (3.8) Traditional: 46 (4.0) Difference -0.2 (95% CI -1.6 to 1.3) < 1500 grams Collaborative: 9 (0.5) Traditional: 7 (0.6) Difference -0.1 (95% CI -0.7 to 0.4) Small for gestational age Collaborative: 104 (5.9) Traditional: 50 (4.5) Difference 1.4 (95% CI -0.2 to 3.0) Inclusion criteria Low income pregnant women Exclusion criteria Birth centre eligibility criteria were used. They are not listed		obstetricians. When women remained low risk intrapartum, women were managed (or co-managed) by the CNMs. The birth centre had over 500 births per year and was within 15 minutes of 3 hospitals. It had a home like environment, where intermittent auscultation was done, and ambulation, continuous emotional support, warm baths and narcotic analgesia were used to assist women. No epidural was available. Family support was encouraged. Women and babies were discharged 4-24 hours after birth and then a home visit by a nurse was done after 24-48 hours, and then a	0.8 (95% CI -2.4 to 4.0)* c. Major postpartum complications Collaborative: 14/1808 (0.8) Traditional: 4/1149 (0.4) Crude difference 0.4 (95% CI -0.1 to 1.0) Adjusted difference 0.6 (95% CI -4.2 to 5.3)* Postpartum maternal readmission (n/total (%)) Collaborative: 8/1808 (0.4) Traditional: 11/1149 (1.0) Crude difference -0.5 (95% CI -1.2 to 0.1) Adjusted difference -0.9 (95% CI -4.8 to 3.0)*	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	in full, but examples are provided: - 2 or more prior CS - Undocumented uterine scar - Chronic hypertension - Substance abuse during pregnancy Women with private or military insurance (because focus was on low income women) Enrolment in prenatal care at 33 weeks or later		paediatric provider after 5 days. Women were later seen 6 weeks postpartum. Traditional care group Women were managed by obstetricians or obstetric residents throughout pregnancy, labour and birth, and gave birth in a hospital setting. The hospitals had 24 hour anaesthesia services, regular use of electronic fetal monitoring (EFM) and IV fluids, and NICUs. Women were discharged 12-48 hours following a vaginal birth with specialist followup (e.g. home visits) and the physician's discretion. Transfer criteria No details given apart from % of women transferred, as reported	Perinatal mortality (%) a. Intrauterine death (> 20 weeks) Collaborative: 0.4% Traditional: 0.4% Crude difference 0.0 (95% CI -0.5 to 0.4) Adjusted difference not reported (NR) b. Early neonatal death (0-28 days) Collaborative: 0.2% Traditional: 0.3% Crude difference -0.1 (95% CI -0.5 to 0.3) Adjusted difference NR Composite of neonatal complications [out of live births] (n/total (%))	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			below. Data collection, analysis and monitoring Most of the data were collected from medical records. Women also completed a self-administered questionnaire at entry, containing details about acculturation and choice of care. Aggregate variables were often used to analyse data due to the low incidence of some outcomes. Risk differences were used to compare groups. Adjusted analyses were done for confounders, retaining any variables that substantially changed the estimate of effect (e.g. by more than 10%). Race/ethnicity was maintained a priori in all	Collaborative: 80/1794 (4.5) Traditional: 73/1141 (6.4) Crude difference -1.9 (95% CI -3.6 to -0.2) Adjusted difference -1.8 (95% CI -3.8 to 0.1)‡ Neonatal intensive care unit admissions (n/total (%)) a. Any Collaborative: 171/1794 (9.7) [technical team: 9.5%] Traditional: 134/1141 (11.8) [technical team: 11.7%] Crude difference -2.2 (95% CI -4.5 to 0.1) Adjusted difference -1.3 (95% CI -3.8 to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			models due to the differences in the groups. Outcomes reported 1. Mode of birth 2. Use of epidural: reported excluding women admitted for CS without labour 3. Episiotomy: reported excluding women admitted for CS without labour 4. Major maternal complications: - antepartum complications: defined as placenta praevia, placental abruption, gestational diabetes, severe pregnancy induced hypertension, pregnancy induced hypertension with eclampsia, pyelonephritis,	1.1)‡ b. 1-3 days Collaborative: 60/1794 (3.3) Traditional: 64/1141 (5.6) Crude difference -2.3 (95% CI -3.9 to -0.7) Adjusted difference -1.8 (95% CI -3.9 to 0.2)‡ c. 4-10 days Collaborative: 81/1794 (4.6) [technical team: 4.5%] Traditional: 52/1141 (4.6) Crude difference 0.0 (95% CI -1.6 to 1.5) Adjusted difference 0.0 (95% CI -1.8 to 1.9)‡	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			intrauterine fetal death, Rh sensitisation, or other (not defined) - intrapartum complications: defined as cord prolapse, placenta praevia, placental abruption, severe pregnancy induced hypertension, pregnancy induced hypertension with eclampsia, heavy/thick meconium, premature (< 34 weeks), rupture of uterine scar, haemorrhage ≥ 1000 cc, shoulder dystocia, fourth degree perineal laceration, cervical laceration requiring repair, sulcus laceration requiring repair, intrauterine fetal death or other - postpartum complications: defined as anaesthesia complications, disseminated	d. > 10 days Collaborative: 30/1794 (1.7) Traditional: 18/1141 (1.6) Crude difference 0.1 (95% CI -0.8 to 1.0) Adjusted difference 0.1 (95% CI -2.6 to 2.4)‡ Neonatal readmission under 28 days of age (n/total (%)) Collaborative: 25/1794 (1.4) Traditional: 25/1141 (2.2) Crude difference -0.8 (95% CI -1.8 to 0.2) Adjusted difference -1.3 (95% CI -4.1 to 1.5)‡	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			intravascular coagulation, pulmonary embolus, haematoma, severe pregnancy induced hypertension, pregnancy induced hypertension with eclampsia, maternal death or other 5. Perinatal death: intrapartum death after 20 weeks and early neonatal death are reported 6. Major neonatal complications: defined as seizures, asphyxia, bacterial infection other than sepsis, bronchopulmonary dysplasia, cardiac failure, hypovolemia, hypotension, shock, intraventriuclar haemorrhage, necrotizing enterocolitis, persistent pulmonary	Transfer The authors report that of the women who chose birth centre delivery and were eligible, 45.3% remained at low perinatal risk and gave birth there. - 27.2% developed antepartum complications needing a transfer - 18.5% developed intrapartum complications needing a transfer - 8.5% transferred for reasons linked to patient choice, i.e. they changed their mind or wanted epidural [Note: it is not definitively clear that these transfer rates are for the precise study population of 1808 (as opposed to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			hypertension, pneumonia, renal failure, respiratory distress syndrome, retinopathy of prematurity, Rh disease, sepsis, gestational age < 34 weeks at birth, other including palsy or fracture 7. NICU admission (readmission to hospital is also reported)	the initial sample recruited); however, these are the only details on transfer reported and therefore have been reported here]	
Full citation Janssen,P.A., Lee,S.K., Ryan,E.M., Etches,D.J., Farquharson,D.F., Peacock,D., Klein,M.C., Outcomes of planned home births versus planned hospital births after regulation of midwifery in British Columbia, Canadian Medical Association Journal,Can.Med.Assoc.J., 166, 315-323, 2002 Ref Id	Sample size N = 2176 Characteristics Midwife attended hospital birth: MA hospital Physician attended hospital birth: PA hospital Age/years (n/total (%)) 15-19 Home: 16/858 (1.9) PA hospital: 11/740 (1.5) MA hospital: 15/571 (2.6)	Interventions Planned (intended at the onset of labour) home birth (n = 862) Planned (intended at the onset of labour) hospital birth (n = 1284)	Details Selection of study groups - Planned home births This group consisted of all women enrolled in the Home Birth Demonstration Project (HBDP). Women were registered with the HBDP at 36 weeks if they intended to give birth at home and met the eligibility requirements for a	Results Note: adjusted ORs are adjusted for maternal age, lone parent status, income quintile, use of any vs. no substances and parity. Mode of birth (n/total (%)) a. Spontaneous vaginal Home: 779/862	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear, although the authors have restricted the study population to low risk women Groups comparable at baseline: Significantly more women in hospital arm had previous CS; home birth women had significantly higher parity and more antenatal visits;

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
174684 Country/ies where the study was carried out Canada Study type Prospective cohort study Aim of the study To evaluate the safety of home birth by comparing perinatal outcomes for planned home births attended by regulated midwives with those for planned hospital births Study dates January 1st 1998 to December 31st 1999 Source of funding Supported by a financial contribution from the Health Transition Fund, Health Canada	20-24 Home: 138/858 (16.1) PA hospital: 112/740 (15.1) MA hospital: 70/571 (12.3) 25-29 Home: 276/858 (32.2) PA hospital: 251/740 (33.9) MA hospital: 142/571 (24.9) 30-34 Home: 255/858 (29.7) PA hospital: 218/740 (29.5) MA hospital: 209/571 (36.6) ≥ 35 Home: 173/858 (20.2) PA hospital: 148/740 (20.0) MA hospital: 135/571 (23.6) Home vs. PA hospital: p = 0.92 Home vs. MA hospital: p = 0.002 Pre-pregnancy weight/kilograms (mean ± SD) Home: 61.7 ± 11.1 PA hospital: 63.0 ± 14.1		home birth. They were included in the study if they still intended to give birth at home and met eligibility requirements at the onset of labour. - Planned hospital births This group consisted of two separate groups of women: those giving birth with a physician and those giving birth with a midwife. Exclusion criteria (see above) were applied to exclude any women who would not have been eligible for a home birth. The attendant was indicated on the form - if a midwife was indicated as any type of care giver, it recorded as midwife attended. For hospital births with a physician, subjects	(90.4) PA hospital: 508/743 (68.4) MA hospital: 433/571 (75.8) b. Assisted vaginal Home: 28/862 (3.2) PA hospital: 100/743 (13.5) MA hospital: 70/571 (12.3) c. Caesarean section Home: 55/862 (6.4) PA hospital: 135/743 (18.2) MA hospital: 68/571 (11.9) Home vs. PA hospital: - Crude OR 0.31 (95% CI 0.22 to 0.43) - Adjusted OR 0.30 (95% CI 0.22 to 0.43)	significantly more women in the home birth arm used illicit drugs Groups received same/similar care (apart from intervention): Unclear - very few details of care given Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Unclear how blood loss was assessed Intention-to-treat analysis performed: Yes Indirectness: - Population: 2.7% of planned home birth arm and 8.1% of hospital birth arm (midwife and physician combined) had a previous CS; 4.3% of home birth arm and 18.7%

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	MA hospital: 63.9 ± 11.6 Home vs. PA hospital: p = 0.05 Home vs. MA hospital: p = 0.001 Parity a. Nulliparous (n/total (%)) Home: 402/862 (46.6) PA hospital: 358/743 (48.2) MA hospital: 332/571 (58.1) Home vs. PA hospital: p = 0.54 Home vs. MA hospital: p < 0.001 b. Past pregnancies (mean ± SD) Home: 2.5 ± 1.6 PA hospital: 2.3 ± 1.4 MA hospital: 2.2 ± 1.3 Home vs. PA hospital: p = 0.01 Home vs. MA hospital: p < 0.001 Previous caesarean section		were matched to the planned home births, according to: - Age (< 15, 15-19, 20-24, 25-29, 30-34, ≥ 35) - Lone parent status (yes, no) - Parity (nulliparous, multiparous) - Hospital in which the midwife had admitting privileges For hospital births with a midwife, matching was not done because there were insufficient numbers. All eligible planned hospital births of midwives clients during the study period were included. Setting/care protocol No specific details about settings Transfer criteria Not reported Data collection,	Home vs. MA hospital: - Crude OR 0.50 (95% CI 0.35 to 0.73) - Adjusted OR 0.66 (95% CI 0.44 to 0.99) [Note: odds ratios are not reported for the other modes of birth] Overall mode of birth Home vs. PA hospital: p < 0.001 Home vs. MA hospital: p < 0.001 [Note: see 'other information' for the indications for CS] Caesarean section sub-group analysis a. Nulliparous women Home: 45/402 (11.2)	of hospital birth arm had induction of labour with oxytocin or prostaglandins; 1.2% of home birth arm and 2.5% of hospital birth arm had pregnancy induced hypertension; 0.6% babies in home birth arm and 1.4% of babies in hospital arms had major congenital anomalies - Intervention: 12.8% of home births were conducted by physicians Other information Comparison: HOME vs. OU [This study was included in the 2007 guideline] Primary indication for CS (n (%)) - Breech Home: 7 (0.8) PA hospital: 0 MA hospital: 0

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(CS) (n (%)) Home: 23/862 (2.7) PA hospital: 71/743 (9.6) MA hospital: 35/571 (6.1) Home vs. PA hospital: p < 0.001 Home vs. MA hospital: p = 0.002 Number of antenatal visits (mean ± SD) Home: 11.1 ± 3.2 PA hospital: 9.7 ± 3.0 MA hospital: 10.5 ± 3.5 Home vs. PA hospital: p < 0.001 Home vs. MA hospital: p = 0.001 There were no significant differences in the proportion of women who were lone parents, or in the quintile of the household income. Women planning a home birth were more likely		analysis and monitoring Data for the home births were obtained from the British Columbia Reproductive Care Programme (BCRCP). Midwives complete standard forms which include an antenatal record, birth summary and newborn record. The data contained in these forms were abstracted by BCRCP staff into a database. In the hospital, the same data were extracted and submitted to BCRCP. Personal Health Numbers could be used to matched those who ended up giving birth in hospital after planning a home birth. Data from hospitals not submitting to the BCRCP could be accessed by reviewing the HBDP forms which were designed	PA hospital: 77/358 (21.5) MA hospital: 51/332 (15.4) Home vs. PA hospital: p < 0.001 Home vs. MA hospital: p = 0.100 b. Multiparous women Home: 10/460 (2.2) PA hospital: 58/385 (15.1) MA hospital: 17/239 (7.1) Home vs. PA hospital: p < 0.001 Home vs. MA hospital: p = 0.001 c. Multiparous women without previous CS Home: 4/437 (0.9) PA hospital: 13/312 (4.2) MA hospital: 8/204	Home vs. PA hospital: p = 0.017 Home vs. MA hospital: p = 0.05 - Dystocia or CPD Home: 17 (2.0) PA hospital: 40 (5.4) MA hospital: 40 (7.0) Home vs. PA hospital: p < 0.001 Home vs. MA hospital: p < 0.001 - Fetal distress Home: 11 (1.3) PA hospital: 27 (3.6) MA hospital: 12 (2.1) Home vs. PA hospital: p = 0.002 Home vs. MA hospital: p = 0.28 - Repeat CS Home: 0 PA hospital: 31 (4.2) MA hospital: 1 (0.2)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	to use illicit drugs than either of the other groups. Inclusion criteria Intending to give birth at home or hospital Exclusion criteria Exclusion criteria were applied to the hospital arm to remove any women not eligible for a home birth. These criteria included: - multiple birth - heart disease (class I-IV or class unknown) - hypertensive chronic renal disease - pregnancy induced hypertension with proteinuria (> 30 mg/dl) - insulin-dependent diabetes, either pre-existing or gestational - antepartum haemorrhage after 20 weeks - active genital herpes - breech or other abnormal		specifically for the project. Data were analysed according to intended place of birth at onset of labour. Categorical variables were analysed using chi-squared test and Fisher's exact test. Continuous variables were analysed using Student's t-test. A Bonferroni correction was applied to account for multiple comparisons and yield a more conservative p-value. Multivariate analyses were done based on maternal demographic and obstetric variables, using unconditional logistic regression. Outcomes reported 1. Mode of birth: spontaneous vaginal,	(3.9) Home vs. PA hospital: p = 0.003 Home vs. MA hospital: p = 0.02 Epidural analgesia or anaesthesia (n/total (%)) Home: 66/862 (7.7) PA hospital: 205/743 (27.6) MA hospital: 150/571 (26.3) Home vs. PA hospital: - p < 0.001 - Crude OR 0.20 (95% CI 0.16 to 0.29) - Adjusted OR 0.20 (95% CI 0.14 to 0.27) Home vs. MA hospital: - p < 0.001 - Crude OR	Home vs. PA hospital: p < 0.001 Home vs. MA hospital: p = 0.40 - Abruptio placentae Home: 0 PA hospital: 0 MA hospital: 2 (0.4) Home vs. PA hospital: NA Home vs. MA hospital: p = 0.16 - Placenta previa Home: 0 PA hospital: 4 (0.5) MA hospital: 1 (0.2) Home vs. PA hospital: 0.04 Home vs. MA hospital: 0.40 - Malposition/malpresentation Home: 7 (0.8) PA hospital: 20 (2.7) MA hospital: 7 (1.2)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	presentation - gestational age of less than 37 weeks or more than 41 weeks at the onset of labour - more than one previous CS - mother transferred to hospital from another facility		assisted vaginal and CS are reported 2. Use of epidural 3. Episiotomy 4. Vaginal/perineal trauma: first or second degree lacerations, third or fourth degree lacerations, intact perineum and cervical tear are reported 5. Measures of blood loss: postpartum haemorrhage (> 1000 ml) and need for blood transfusion are reported. It is unclear how blood loss was assessed 6. Perinatal death: defined as still birth (intrauterine death after 20 weeks' gestation) or death during period of hospitalisation	0.23 (95% CI 0.17 to 0.32) - Adjusted OR 0.25 (95% CI 0.17 to 0.35) Episiotomy (n/total (%)) Home: 33/862 (3.8) - Median: 18 - Mediolateral: 15 PA hospital: 114/743 (15.3) - Median: 29 - Mediolateral: 80 MA hospital: 62/571 (10.9) - Median: 13 - Mediolateral: 46 Home vs. PA hospital: - p < 0.001 - Crude OR 0.22 (95% CI 0.14 to 0.33) - Adjusted OR 0.22 (95% CI 0.13 to	Home vs. PA hospital: 0.004 Home vs. MA hospital: 0.42 - Genital herpes Home: 1 (0.1) PA hospital: 0 MA hospital: 0 Home vs. PA hospital: p = 1.00 Home vs. MA hospital: p = 1.00 - Other Home: 12 (1.4) PA hospital: 13 (1.7) MA hospital: 5 (0.9) Home vs. PA hospital: 0.56 Home vs. MA hospital: 0.46

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			associated with birth. It does not included readmissions to hospital after the baby was discharged home. 7. Neonatal morbidity: rates of seizures, meconium aspiration, and birth asphyxia (coded as mild, moderate or severe) are reported	0.33) Home vs. MA hospital: - p < 0.001 - Crude OR 0.32 (95% CI 0.21 to 0.50) - Adjusted OR 0.43 (95% CI 0.27 to 0.69) Vaginal/perineal trauma (n/total (%)) a. First or second degree lacerations Home: 369/862 (42.8) PA hospital: 364/743 (49.0) MA hospital: 293/571 (51.3) Home vs. PA hospital: p = 0.01 Home vs. MA hospital: p = 0.002 b. Third or fourth degree lacerations	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home: 19/862 (2.2) PA hospital: 19/743 (2.6) MA hospital: 26/571 (4.6) Home vs. PA hospital: - p = 0.64 - Crude OR 0.86 (95% CI 0.45 to 1.63) - Adjusted OR 0.85 (95% CI 0.43 to 1.66) Home vs. MA hospital: - p = 0.02 - Crude OR 0.47 (95% CI 0.21 to 0.86) - Adjusted OR 0.53 (95% CI 0.28 to 1.00) c. Intact perineum Home: 474/862 (55.0) PA hospital: 360/743	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(48.5) MA hospital: 252/571 (44.1) Home vs. PA hospital: p = 0.009 Home vs. MA hospital: p < 0.001 d. Cervical tear Home: 1/862 (0.1) PA hospital: 1/743 (0.1) MA hospital: 0/571 (0) Home vs. PA hospital: p = 1.0 Home vs. MA hospital: p = 1.0 Measures of blood loss (n/total (%) a. Postpartum haemorrhage Home: 38/862 (4.4) PA hospital: 36/743 (4.8) MA hospital: 30/571 (5.3)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home vs. PA hospital: - p = 0.67 - Crude OR 0.91 (95% CI 0.57 to 1.44) - Adjusted OR 0.90 (95% CI 0.58 to 1.45) Home vs. MA hospital: - p = 0.52 - Crude OR 0.83 (95% CI 0.51 to 1.36) - Adjusted OR 0.83 (95% CI 0.50 to 1.38) b. Blood transfusion (n/total (%)) Home: 3/862 (0.3) PA hospital: 0/743 (0) MA hospital: 1/571 (0.2) Home vs. PA	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				hospital: p = 0.25 Home vs. MA hospital: p = 1.0 Perinatal death (n/total (%))* Home: 3/860 (0.3) PA hospital: 1/733 (0.1) MA hospital: 0/563 (0) Home vs. PA hospital: p = 0.63 Home vs. MA hospital: p = 0.28 [Note: 2/3 from the home birth arm and 1/1 from PA hospital arm were stillbirths - Among the home birth group: The first stillbirth had no obvious explanation and autopsy was refused by parents. Death appeared to have occurred before onset of	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				labour. In the second stillbirth, the autopsy could not identify a specific cause of death - the midwife had stopped hearing the heartbeat in early labour and emergency transport started. The baby was born at home "tangled in the cord" and could not be resuscitated. The neonatal death was at 2 days age and there was no final cause of death. There was no evidence of ischaemia during labour, and FHR was normal; however, the baby was asphyxiated at birth and there was evidence of severe hypoxic ischemic encephalopathy	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(HIE) with haemorrhage and infarction in other organs.] Neonatal morbidity (n/total (%))* a. Birth asphyxia Home: 5/860 (0.6) PA hospital: 6/733 (0.8) MA hospital: 1/563 (0.2) Home vs. PA hospital: p = 0.57 Home vs. MA hospital: p = 0.41 b. Seizures Home: 2/860 (0.2) PA hospital: 2/733 (0.3) MA hospital: 0/563 (0) Home vs. PA hospital: p = 1.0 Home vs. MA hospital: p = 0.52	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				c. Meconium aspiration Home: 2/860 (0.2) PA hospital: 1/733 (0.1) MA hospital: 2/563 (0.4) Home vs. PA hospital: p = 1.0 Home vs. MA hospital: p = 0.65 * excludes 5 babies in the home birth arm, 10 in the PA hospital arm and 8 in the MA hospital arm who had major congenital anomalies Transfer The overall rate of transfer from home was 21.7%. 142 (16.5%) occurred during labour.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				31 women had an emergency transfer: - avoidance of unattended home birth: 1 - no supervisor available for midwife who had not yet completed registration: 1 - fetal heart rate (FHR) decelerations: 7 - breech diagnosed in labour: 2 - active herpes in labour: 1 - thick meconium in labour: 2 - second stage arrest of labour: 1 - haemorrhage: 3 - retained placenta: 3 - repair of episiotomy: 2 - newborn with respiratory distress: 5 - newborn with birth	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				asphyxia: 2 - newborn with distended abdomen: 1 The median time from the call to emergency services to arrival at hospital was 37 minutes (range 15-93) For babies, it is reported how many needed transfer to other hospital: Home: 6/860 (0.7) PA hospital: 4/733 (0.5) MA hospital: 6/563 (1.1) Home vs. PA hospital: p = 1.00 Home vs. MA hospital: p = 0.52	
Full citation Janssen,P.A., Saxell,L., Page,L.A., Klein,M.C.,	Sample size N = 12,982	Interventions Planned (intended at	Details Selection of study groups	Results Maternal mortality (n/total (%))	Limitations Choice of treatment unrelated to confounders

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Liston,R.M., Lee,S.K., Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician.[Erratum appears in CMAJ. 2009 Oct 27;181(9):617], CMAJ Canadian Medical Association Journal, 181, 377-383, 2009 Ref Id 116452 Country/ies where the study was carried out Canada Study type Retrospective cohort (with matching) Aim of the study To compare outcomes of planned home births attended by midwives with those of planned hospital births attended by midwives or physicians	Characteristics Age/years (n (%)) 15-19 Home: 48 (1.7) MA hospital: 116 (2.4) PA hospital: 92 (1.7) 20-24 Home: 336 (11.6) MA hospital: 584 (12.3) PA hospital: 629 (11.8) 25-29 Home: 892 (30.8) MA hospital: 1371 (28.9) PA hospital: 1644 (30.8) 30-34 Home: 1025 (35.4) MA hospital: 1682 (35.4) PA hospital: 1883 (35.3) ≥ 35 Home: 598 (20.6) MA hospital: 999 (21.0) PA hospital: 1083 (20.3) Height/cm (mean ± SD) Home: 166.5 ± 6.6	onset of labour) home birth (n = 2899) Planned (intended at onset of labour) hospital birth with a midwife (n = 4752) Planned (intended at onset of labour) hospital birth with a physician (n = 5331)	Planned home birth The study included all births during the study period that were planned to take place at the woman's home at the onset of labour. The planned place of birth was documented for every birth on rosters submitted at 8 weeks postpartum, which could then be matched to registry data using unique personal health numbers. Women for whom the presentation was determined to be breech after the onset of labour were not excluded, and neither were women with 1 previous CS, as they were eligible under current standards. Planned hospital birth This comprised two groups. Firstly, women were selected if a	Home: 0/2899 (0) MA hospital: 0/4752 (0) PA hospital: 0/5331 (0) Mode of birth (n/total (%)) a. Spontaneous vaginal Home: 2605/2899 (89.9) MA hospital: 3910/4752 (82.3) PA hospital: 4007/5331 (75.2) b. Assisted vaginal Home: 86/2899 (3.0) MA hospital: 344/4752 (7.2) PA hospital: 736/5331 (13.8) Home vs. MA hospital: RR 0.41 (95% CI 0.33 to 0.52) Home vs. PA hospital: RR 0.22	(selection bias): Unclear; only some outcomes are adjusted and only for parity, Groups comparable at baseline: Women with one previous CS (88/2899 [3%]) were included in planned home birth group but not planned hospital group. The authors report that after removing them, the risk ratios did not change 'substantively'; however, these figures are not reported. Also, women in the home birth group were less likely to be single parents or to be nulliparous Groups received same/similar care (apart from intervention): unclear, as study is population based Blinding of those assessing outcomes: no details given Missing data/loss to follow-up: Episiotomy is reported

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates January 1st 2000 to December 31st 2004 Source of funding Canadian Institutes of Health Research	MA hospital: 166.4 ± 7.0 PA hospital: 164.3 ±7.0 Weight before pregnancy/kg (mean ± SD) Home: 63.1 ± 11.7 MA hospital: 64.4 ± 12.7 PA hospital: 62.6 ± 13.0 BMI (mean ± SD) Home: 22.8 ± 4.0 MA hospital: 23.3 ± 4.3 PA hospital: 23.2 ± 4.3 Use of illicit drugs during pregnancy (n (%)) Home: 39 (1.3) MA hospital: 57 (1.2) PA hospital: 71 (1.3) Use of alcohol during pregnancy (n (%)) Home: 10 (0.3) MA hospital: 25 (0.5) PA hospital: 35 (0.7) Nulliparous (n (%)) Home: 1215 (41.9) MA hospital: 2428 (51.1) PA hospital: 2204 (41.3)		midwife was in attendance during labour and the roster indicated that the birth was planned to be in hospital. They then restricted the population to those women meeting the criteria for a home birth (see inclusion/exclusion criteria). The midwives conducting these hospital births were the same cohort as those doing the home births. The second comparison group was women planning to give birth in hospital with a physician in attendance. This is the majority of Canadian hospital births (~6% are midwife attended). The physician-attended births were matched to the home births on a 2:1 basis by:	(95% CI 0.18 to 0.27) c. Caesarean section Home: 208/2899 (7.2) - Nulliparous: 158/1215 (13.0) - Multiparous: 50/1684 (3.0) MA hospital: 498/4752 (10.5) - Nulliparous: 453/2428 (18.7) - Multiparous: 45/2324 (1.9) PA hospital: 588/5331 (11.0) - Nulliparous: 481/2204 (21.8) - Multiparous: 107/3127 (3.4) Home vs. MA hospital: RR 0.76 (95% CI 0.64 to 0.91)*	for vaginal births only Precise definition of outcomes: PPH is not defined Valid and reliable method of outcome assessment: Yes; however the authors report that there is some risk of bias as a result of misclassification of planned place of birth as the data were reported postpartum and were analysed retrospectively. Intention-to-treat analysis performed: Yes Indirectness: 3% of home birth arm had previous CS; 0.6% of home birth group, 0.6% of MA hospital group and 0.7% of PA hospital group had major anomalies Other information Comparison: HOME vs. OU [This study is new since

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Gestational age at first prenatal contact/weeks (mean ± SD) Home: 12.2 ± 7.0 MA hospital: 12.2 ± 6.9 PA hospital: 11.8 ± 5.9 Inclusion criteria Singleton fetus Cephalic presentation Gestational age greater than 36 and less than 41 completed weeks of pregnancy No more than 1 previous caesarean section (CS) Labour is spontaneous or induced on an outpatient basis Mother has not been transferred to the delivery hospital from a referring hospital Exclusion criteria		- year of birth - parity (nulliparous vs. multiparous) - single parent (yes, no) - maternal age (< 15, 15-19, 20-24, 25-29, 30-34, > 35) - hospital where midwife attending home birth had privileges To control for setting, the physician births were restricted to those hospitals where midwives held privileges, and then comparison cases were randomly selected from the eligible matches Setting/care protocol Few details are given, as it is a population-based study Transfer criteria No details are given, as it is a population-based study	Home vs. PA hospital: RR 0.65 (95% CI 0.56 to 0.76) [See 'other information' for primary indication for CS] Use of epidural (n/total (%)) Home: 224/2899 (7.7) MA hospital: 901/4752 (19.0) PA hospital: 1487/5331 (27.9) Home vs. MA hospital: RR 0.39 (95% CI 0.33 to 0.46)* Home vs. PA hospital: RR 0.28 (95% CI 0.24 to 0.32) *adjusted for parity	the 2007 guideline] Primary indication for caesarean section (n (%)) - Breech Home: 34 (1.2) MA hospital: 0 PA hospital: 0 - Dystocia Home: 79 (2.7) MA hospital: 253 (5.3) PA hospital: 288 (5.4) - Non-reassuring fetal heart rate (FHR) Home: 32 (1.1) MA hospital: 112 (2.4) PA hospital: 143 (2.7) - Repeat CS Home: 2 (0.1) MA hospital: 0 PA hospital: 0 - Malposition or malpresentation Home: 39 (1.3) MA hospital: 89 (1.9)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Significant pre-existing disease, including heart disease, hypertensive chronic renal disease or type 1 diabetes Significant disease arising during pregnancy, including pregnancy induced hypertension with proteinuria (> 0.3 g/dl by urine dipstick), antepartum haemorrhage after 20 weeks' gestation, gestational diabetes requiring insulin, active genital herpes, placenta praevia, or placental abruption		Data collection, analysis and monitoring The primary outcome was perinatal death, and the authors projected 2750 home births would have 92% power to estimate perinatal death rates within 3 births per 1000 with 95% confidence. The Perinatal Database Registry was used as a source of women, and this is cross-referenced with the Department of Vital Statistics. Maternity care details were collected from standard forms issues by the Perinatal Health Programme. Neonatal outcomes were collected using data from the Perinatal Database Registry. The authors report that validation studies have reported 97% accuracy	Measures of blood loss (n/total (%)) a. Postpartum haemorrhage Home: 110/2899 (3.8) MA hospital: 285/4752 (6.0) PA hospital: 357/5331 (6.7) Home vs. MA hospital: RR 0.62 (95% CI 0.49 to 0.77) Home vs. PA hospital: RR 0.57 (95% CI 0.45 to 0.70) b. Blood transfusion Home: 2/2899 (0.1) MA hospital: 10/4752 (0.2) PA hospital: 15/5331 (0.3) Maternal morbidity during labour (n/total (%))	PA hospital: 78 (1.5) - Other Home: 22 (0.8) MA hospital: 44 (0.9) PA hospital: 79 (1.5)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			over all fields for the database, with < 0.01% missing data. It links outcomes for infants transferred from a birth hospital to referring hospitals up to final discharge or 1 years, whichever is shorter. Linked outcomes for newborns readmitted to any hospital up to 28 days of age are also included. Relative risks are calculated by planned place of birth, regardless of where it actually occurred. Weighting was done when adjustment altered summary relative risks by at least 10%. Outcomes reported 1. Maternal mortality 2. Mode of birth	a. Obstetric shock Home: 1/2899 (0.03) MA hospital: 1/4752 (0.02) PA hospital: 1/5331 (0.02) b. Uterine rupture Home: 0/2899 (0) MA hospital: 0/4752 (0) PA hospital: 2/5331 (0.04) c. Uterine prolapse Home: 1/2899 (0.03) MA hospital: 1/4752 (0.02) PA hospital: 2/5331 (0.04) Episiotomy (vaginal births only) (n/total (%)) Home: 84/2691 (3.1) MA hospital: 289/4254 (6.8) PA hospital: 800/4743 (16.9)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			3. Use of epidural 4. Measures of vaginal/perineal trauma: - Episiotomy: only reported for vaginal births - Perineal tear: 1st or 2nd degree, 3rd or 4th degree, and those with degree unknown - Cervical tear 5. Measures of blood loss: postpartum haemorrhage (not defined) and blood transfusion 6. Perinatal death: defined as stillbirth after 20 weeks' gestation or death in first 7 days of life 7. Neonatal morbidity is reported for babies without major anomalies: seizures,	Home vs. MA hospital: RR 0.49 (95% CI 0.38 to 0.63)* Home vs. PA hospital: RR 0.19 (95% CI 0.15 to 0.23) * adjusted for parity Perineal tear (n/total (%)) a. None Home: 1578/2899 (54.4) MA hospital: 2189/4752 (46.1) PA hospital: 2291/5331 (43.0) b. First or second degree Home: 1262/2899 (43.5) MA hospital: 2387/4752 (50.2) PA hospital: 2836/5331 (53.2)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			birth trauma (defined as subdural or cerebral haemorrhage; fracture of clavicle, long bones or skill; facial nerve injury; Erb palsy; or unspecified birth trauma), asphyxia	c. Third or fourth degree Home: 34/2899 (1.2) MA hospital: 137/4752 (2.9) PA hospital: 183/5331 (3.4) Home vs. MA hospital: RR 0.43 (95% CI 0.29 to 0.63)* Home vs. PA hospital: RR 0.34 (95% CI 0.24 to 0.49) [Note: RR are for women with vaginal birth only] d. Degree of tear unknown Home: 25/2899 (0.9) MA hospital: 39/4752 (0.8) PA hospital: 21/5331 (0.4) * adjusted for parity	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Cervical tear (n/total (%)) Home: 2/2899 (0.1) MA hospital: 5/4752 (0.1) PA hospital: 4/5331 (0.1) Perinatal death a. Incidence among newborns without major anomalies (n/total (%))† Home: 1/2882 (0.03%) MA hospital: 3/4723 (0.06%) PA hospital: 3/5294 (0.06%) Home vs. MA hospital: RR 0.61 (95% CI 0.06 to 5.88) Home vs. PA hospital: RR 0.55 (95% CI 0.06 to 5.25) b. Rate per 1000	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				births (95% CI) Home: 0.35 (95% CI 0 to 1.03) MA hospital: 0.57 (95% CI 0 to 1.43) PA hospital: 0.64 (95% CI 0 to 1.56) [Note: There were no deaths between 8 and 28 days] Neonatal morbidity (n/total (%))† a. Birth trauma Home: 7/2882 (0.2%) MA hospital: 35/4723 (0.7%) PA hospital: 49/5294 (0.9%) Home vs. MA hospital: RR 0.26 (95% CI 0.11 to 0.58) Home vs. PA hospital: RR 0.33 (95% CI 0.15 to 0.74)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				b. Asphyxia at birth Home: 6/2882 (0.2%) MA hospital: 14/4723 (0.3%) PA hospital: 14/5294 (0.3%) Home vs. MA hospital: RR 0.79 (95% CI 0.30 to 2.05) Home vs. PA hospital: RR 0.70 (95% CI 0.27 to 1.83) c. Seizures Home: 2/2882 (0.1%) MA hospital: 5/4723 (0.1%) PA hospital: 6/5294 (0.1%) Home vs. MA hospital: RR 0.61 (95% CI 0.12 to 3.03)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home vs. PA hospital: RR 0.66 (95% CI 0.13 to 3.38) d. Admission to hospital after home birth or readmission to hospital Home: 84/2882 (2.9%) MA hospital: 59/4723 (2.1%) PA hospital: 142/5294 (2.7%) Home vs. MA hospital: RR 1.09 (95% CI 0.83 to 1.42) Home vs. PA hospital: RR 1.39 (95% CI 1.09 to 1.85) ** excludes babies born with major anomalies: neural tube defects, other malformations of the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				nervous system, anomalies of the cardiac and cardiovascular system, and chromosomal abnormalities (home: n = 17; MA hospital: n = 29; PA hospital: n = 37) Transfer Of those who planned to give birth at home 2285 (78.8%) did so Of those who planned to give birth in hospital with a midwife 4604 (96.9%) did so.	
Full citation Klein,M., Papageorgiou,A., Westreich,R., Spector-Dunsky,L., Elkins,V., Kramer,M.S., Gelfand,M.M., Care in a birth room versus a conventional setting: a controlled trial, Canadian Medical Association	Sample size N = 114 Characteristics Parity (n/total (%)) Primiparas Birth room: 30/56 (53.6)	Interventions Planned (intended at the onset of labour) birth in birth room (n = 56) Planning	Details Setting The birth room: - attractive room with double bed and adjacent labour lounge - facilitated increased flexibility in position in labour and allowed her	Results Mode of birth (n/total (%)) a. Caesarean section - Total* Birth room: 2/56 (3.6) Conventional: 2/58	Limitations Appropriate randomisation: No; allocation was alternate Allocation concealment: Unclear; the authors state that only the research coordinator was aware of which setting was to be

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Journal, 131, 1461-1466, 1984 Ref Id 174934 Country/ies where the study was carried out Canada Study type Quasi-randomised controlled trial (alternate allocation) Aim of the study Not reported Study dates Not reported Source of funding Partly funded by le Conseil québecois de la recherche sociale, the Allan and Lucy Bronfman Family Foundation and the departments of family medicine and obstetrics-gynecology, and the Planning and Priorities	Conventional: 32/58 (55.2) Multiparas Birth room: 26/56 (46.4) Conventional: 26/58 (44.8) Age/years (mean) Primiparous Birth room: 27 Conventional: 27 Multiparous Birth room: 29 Conventional: 30 Inclusion criteria Low risk for obstetric complications Exclusion criteria Induction of labour Malposition Any increase in risk (e.g. bleeding on arrival, meconium stained amniotic fluid, post-term)	(intended at the onset of labour) birth in conventional setting (n = 58)	to have a guest beside her partner - "routine" perineal shaving and enema use, IV infusion and electronic fetal monitoring (EFM) were prohibited - need/request of IV infusion, oxytocin stimulation or epidural necessitated a transfer - surgical masks and caps were optional and almost never used - only a sterile underpad and gloves were used at birth - routines not specifically indicated were avoided Conventional setting: - nursing and obstetric staff behaved as they normally would using standard routines There were no specific instructions about	(3.4) - Primiparas Birth room: 2/30 (7) Conventional: 2/32 (6) (p: NS) - Multiparas Birth room: 0/26 (0) Conventional: 0/28 (0) (p: NS) b. Forceps - Total* Birth room: 18/56 (32.1) Conventional: 22/58 (37.9) - Primiparas† Birth room: 16/28 (57) Conventional: 16/30 (53) (p: NS) - Multiparas Birth room: 2/26 (8)	used next, however this is unlikely to be guaranteed Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No details given Blinding of staff providing care: No details given Blinding of outcome assessors: No - data collector was present at birth Missing data/loss to follow-up: Data on some outcomes are not reported for women who had a CS Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: It is unclear how closely this birth room resembles an alongside

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Committee of the Sir Mortimer B Davis-Jewish General Hospital			handling of the baby but in the birth room, the mother and partner stayed with the baby for an hour after birth. The authors report that a single obstetric and nursing staff serve the two settings. Recruitment and randomisation Couples were informed of the study using notices in the offices of participating obstetricians. Low risk women were enrolled at 36 to 38 weeks gestation by referral to the research coordinator. There was only one birth room available; therefore, the women could not be randomised as it would not be guaranteed that women randomised to	Conventional: 6/26 (23) (p: NS) * Calculated by the technical team, totalling data for primiparas and multiparas (and including those with CS in denominator) † This is as reported in the study, excluding those with CS from the denominator Epidural administration of anaesthetic (n/total (%)) a. Total* Birth room: 14/56 (25) Conventional: 15/58 (25.9) b. Primiparas Birth room: 11/30	MLU, because the staff are not well described. The only details given are that a "single obstetric and nursing staff serve the two settings" and that epidural/EFM etc. necessitated transfer. Similarly, standard care may not be exactly comparable to the standard care by midwives in obstetric units in the UK. Other information Comparison: ALONGSIDE MLU vs. OU [This study was included in the 2007 guideline as part of a Cochrane review by Hodnett et al.] This study is evaluating intrapartum care only. Epidural/EFM necessitated transfer, but it is not clear whether a doctor may have

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			the birth room could actually use it. Therefore, women were allocated using strict alternation. Only the research coordinator knew which setting would be used next. Nurses changed shifts regularly and were unaware of the site for the next allocation, and they and the obstetricians could not influence it. Subjects could be excluded between initial enrolment and arrival in labour, but before allocation to setting, if the obstetrician decided to induce labour or detected any increase in risk. Of 163 women initially eligible and enrolled, 30% were excluded before allocation (post term pregnancy and resulting	(37) Conventional: 14/32 (44) (p: NS) c. Multiparas Birth room: 3/26 (12) Conventional: 1/26 (4) (p: NS) Vaginal/perineal trauma (n/total (%)) a. Episiotomy - Total* Birth room: 29/56 (51.8) Conventional: 43/58 (74.1) - Primiparas† Birth room: 21/28 (75) Conventional: 26/30 (87) (p: NS) - Multiparas Birth room: 8/26 (31) Conventional: 17/26	been present in the unit.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			induction accounted for 35% of these; "obstetric decision" was 16%). Transfer criteria Stimulation of labour with oxytocin, epidural administration, forceps delivery and caesarean section were indications for transfer. Outlet forceps delivery was permitted, but obstetricians could elect to transfer. Data collection, analysis and monitoring The active phase of labour and birth was attended by the research coordinator or assistant, who collected information in a structured format. Medical records were also reviewed for additional information and verification. Data were analysed based	(65) (p < 0.01) b. Intact perineum (defined as no episiotomy and no tear) - Total* Birth room: 9/56 (16.1) Conventional: 0/58 (0) - Primiparas† Birth room: 5/28 (18) Conventional: 0/30 (0) (p < 0.05) - Multiparas† Birth room: 4/26 (15) Conventional: 0/26 (0) (p < 0.05) * Calculated by the technical team, totalling data for primiparas and multiparas (and	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			on original allocation, i.e. intention to treat. Chi-square was used to test for significant differences. Potential confounding residual differences between the two arms were controlled for by analysis of covariance. The study was originally designed to include 200 women; however, this was "thwarted" by the rates of exclusion and transfer, as well as low demand to participate.	including women with CS in denominator) † This is as reported in the study, excluding those with CS from the denominator Admission to Special Care Baby Unit (%) Birth room: 13 [Note: this equates to 7/56, as calculated by technical team] Conventional: 28 [Note: this equates to 16/58, as calculated by technical team] The authors report that when reasons for admission were analysed, more babies were being admitted from the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				conventional setting for observation or transitional/temporary states such as tachypnea or grunting respiration. All babies did well and none had sepsis, hypothermia, hypoglycaemia, or other conditions that could be attributed to mode or place of birth. Details of other priority outcomes The authors also report that there were no significant differences between the two arms in the frequency of postpartum haemorrhage. However, no figures are reported; therefore, this will not be reported in the GRADE table.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Transfer Transfer from the birth room for labour or delivery in another setting occurred in 63% (19/30) of primiparas and 19% (5/26) of multiparas. The most common reason for transfer was lack of progress in the first stage among primiparas. 4 (primiparas) were transferred due to a request for epidural, 4 were transferred due to second stage delay, 2 due to meconium stained fluid, 1 due to fetal distress, and 6 due to miscellaneous minor reasons. The authors report that oxytocin,	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				epidural anaesthesia and forceps delivery tended to be used for transferred women, regardless of indication	
Full citation Lindgren,H.E., Radestad,I.J., Christensson,K., Hildingsson,I.M., Outcome of planned home births compared to hospital births in Sweden between 1992 and 2004. A population-based register study, Acta Obstetricia et Gynecologica Scandinavica, 87, 751-759, 2008 Ref Id 116454 Country/ies where the study was carried out Sweden Study type Retrospective cohort study Aim of the study	Sample size N = 12,238 Characteristics Maternal age/years (n (%)) <25 Home: 88 (10) Hospital: 2173 (19) 25-34 Home: 579 (64) Hospital: 7578 (67) ≥35 Home: 230 (26) Hospital: 1590 (14) Parity (n (%)) First child Home: 229 (26) Hospital: 7039 (62) 2nd-3rd child	Interventions Planned (intended at the onset of labour) birth at home (n = 897) Planned (intended at the onset of labour) birth in hospital (n = 11341)	Details Selection of study groups Planned home births A birth was considered a planned home birth if the woman had decided to give birth at home, and the birth started at home with contractions or rupture of membranes. This was considered a planned home birth regardless of whether the woman was transferred to hospital during labour or immediately after birth. Twins (n = 16), pre-term (n = 11) and post-term (n = 9) births are included in the home birth group but not the planned hospital	Results * adjusted for parity, BMI, smoking and nationality † adjusted for parity, BMI, smoking, nationality, use of epidural and use of oxytocin The authors report that all analyses were done with and without complicated cases, and that their exclusion did not make a difference to results. The data are not reported though. Maternal death (n/total (%)) Home: 0/897 (0) Hospital: 0/11341 (0)	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear, because there are differences between the arms; however, adjustment was done to try to control for this Groups comparable at baseline: Twins (n = 16), pre-term (n = 11) and post-term (n = 79) births are included in the home birth group but not the planned hospital group. Women in the planned home birth group were more often: older than 35 years old, born in another country, employed in areas where educational qualifications were required, multiparous, non-smokers,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To evaluate the risk of an adverse outcome for mother and child following planned home births, regardless of where the birth actually occurred Study dates 1st January 1992 to 31st December 2004 Source of funding None reported	Home: 513 (57) Hospital: 3895 (34) 4th child or more Home: 155 (17) Hospital: 407 (4) Pre-pregnancy disease (n (%))* Home: 134 (15) Hospital: 1979 (17) * Diagnoses in the register included repeated urinary tract infections (UTIs), renal disease, epilepsy, asthma, ulcerative colitis, systemic lupus erythematosus (SLE) and hypertension BMI (n (%)) < 20 Home: 80 (14) Hospital: 1076 (12) 21-25 Home: 382 (65) Hospital: 5567 (60) > 25		group. Breeches are included in both groups. Planned hospital births The control group was a randomly selected group of hospital births, selected from the Swedish Medical Birth Register. Criteria for inclusion were spontaneous, full term (37-42 weeks) and singleton births during the study period. The control group was geographically matched. Setting/care protocol No details given Transfer criteria No details given Data collection, analysis and monitoring The study used register data to try to document outcomes of births	Mode of birth (n/total (%)) a. Caesarean section Home: 22/897 (2) Hospital: 776/11341 (7) RR 0.4 (95% CI 0.3 to 0.5) Adjusted RR 0.4 (95% CI 0.2 to 0.7)* p = 0.002 (for adjusted RR) b. Vacuum extraction Home: 20/897 (2) Hospital: 1089/11341 (10) RR 0.2 (95% CI 0.1 to 0.4) Adjusted RR 0.3 (0.2 to 0.5)* p < 0.001 (for adjusted RR) Vaginal/perineal	have a higher BMI. However, there was no difference in the prevalence of pre-pregnancy diseases. Groups received same/similar care (apart from intervention): No details given Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: 20% of women had BMI data missing; in addition, they report that 141 births that were reported as planned home births are missing from the study because there was no information about them in the register Precise definition of outcomes: Definition of haemorrhage is not reported Valid and reliable method of outcome assessment: The authors report that complicating conditions

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Home: 125 (21) Hospital: 2607 (28) Missing data Home: 313 (35) Hospital: 2081 (18) Inclusion criteria Planned home or hospital birth during the study period Full-term birth registered with Medical Birth Register [For further details of how groups were selected, see methods section below] Exclusion criteria Complicated pregnancies (2.1%) were excluded for a further analysis		during the study period. To classify women as having had a planned home birth, the Swedish Medical Birth Register (data on 97-99% of all births) plus other sources were used. Indirect recruitment was done by contacting all home birth midwives in Sweden. Direct recruitment was done by newspaper ads and the internet (n = 315). The home birth midwives (n = 43) aimed to contact all women they had assisted in a home birth during the study period (n = 448) recruited this way. All midwives and women were asked if they knew of other home births to try and identify all of them. This 'snowball' method did	trauma a. Vaginal tears Home: 161/897 (18) Hospital: 3577/11341 (31) RR 0.5 (95% CI 0.4 to 0.6) Adjusted RR 0.7 (95% CI 0.6 to 0.9)† p = 0.001 (for adjusted RR) b. Perineal tears Home: 178/897 (20) Hospital: 2587/11341 (23) RR 0.8 (95% CI 0.7 to 1.0) Adjusted RR 1.0 (95% CI 0.8 to 1.3)† p = 0.65 (for adjusted RR) c. Sphincter/rectal rupture	may be underreported in the register. There is also the possibility that some planned home births were missed in their method of identifying them Intention-to-treat analysis performed: Yes Indirectness: - 107/897 (11.9%) of planned home births were complicated: mother with diabetes (3), twins (8), preterm (11), post-term (79), or breech (7 - all born vaginally) and 146/11341 (1.3%) of planned hospital births were breech - 134/897 (15%) of women planning home birth and 1979/11341 (17%) of planned hospital birth arm had pre-pregnancy disease (however, not all of these would be considered high risk) Other information Comparison: HOME vs.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			not find many new births; therefore, the authors report that they consider their data collection nearly complete. A total of 757 women replied and had 1038 planned home births. Of these, 100 women (141 births) were not found in the register and it was reported that 100 of these were intentionally not assisted by a professional birth assistant, and therefore these births were not included in the study. After excluding births outside the study period, 1051 births (n = 551) births remained. Data from the returned forms were compared with register data and if there was any uncertainty about	Home: 3/897 (0.3) Hospital: 311/11341 (2.7) RR 0.1 (95% CI 0 to 0.4) Adjusted RR 0.2 (95% CI 0 to 0.7)† p = 0.01 (for adjusted RR) d. Episiotomy Home: 8/897 (1) Hospital: 820/11341 (7) RR 0.1 (95% CI 0 to 0.2) Adjusted RR 0.1 (95% CI 0 to 0.2)* p < 0.001 (for adjusted RR) Haemorrhage Incidence is not reported; however the authors report relative risks for planned home birth compared to	OU [This study is new since the 2007 guideline] Note: the authors report that the Swedish authorities do not recommend or fund home births; therefore women planning a home birth must find a licensed midwife willing to assist her and pay for it herself.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			intended place of birth, women were contact by phone. Any births that were not planned home births according to the interview were excluded, and this left 897 planned home births. Analysis was performed both with and without the complicated pregnancies (i.e. breech, twins, preterm, post-term). Risk ratios (with 95% CI) were calculated using Mantel-Haenszel method, and in the logistic regression model they were adjusted for potential confounders. Outcomes reported 1. Maternal death 2. Mode of birth	planned hospital birth: - Crude RR 0.4 (95% CI 0.2 to 0.8) - Adjusted RR 0.5 (95% CI 0.2 to 1.0)* Uterine rupture Home: 0/897 Hospital: 11/11341 (0.1) Perinatal death (n/total (%)) Home: 2/897 (0.2) Hospital: 7/11341 (0.06) RR 3.6 (95% CI 0.8 to 17.2) [Further details of deaths in home birth group: 1.) para 1; died on day 1 following a vaginal water birth; bath used as pain relief; 40 weeks	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			3. Haemorrhage: definition is not reported 3. Perinatal mortality: defines death intrapartum or during the first 28 days of age	gestation; born with asphyxia and transferred to ICU immediately after birth 2.) para 2; died on day 19 following a vaginal birth with no pain relief; 37 weeks gestation; born with neuroblastoma and transferred to ICU immediately after birth for 19 days Further details of deaths in hospital birth group: 1.) para 1; died on day 0 following vacuum extraction; enthonox, acupuncture and epidural used for pain relief; 37 weeks gestation; cause of death was asphyxia and shoulder dystocia	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				2.) para 1; died on day 0 following vacuum extraction; epidural used; 41 weeks gestation; epicranial haemorrhage caused by birth injury 3.) para 1; died on day 0 following vacuum extraction; enthonox and epidural used; 40 weeks; cause of death was dystocia, posterior presentation, asphyxia 4.) para 1; died on day 2 following vacuum extraction; pethidine, entonox, pudendus blockade and epidural used; 40 weeks; neonatal distress with cramps after birth 5.) para 5; died on day 2 following	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				vaginal birth; no pain relief; 40 weeks; neonatal heart defects with malformations of aorta 6.) para 1; died on day 2 following CS; birthing pool and general anaesthetic used; 39 weeks; asphyxia due to placenta abruption 7.) para 2; died on day 9 following vaginal birth; pethidine used; 41 weeks; microencephaly]	
Full citation MacVicar,J., Dobbie,G., Owen-Johnstone,L., Jagger,C., Hopkins,M., Kennedy,J., Simulated home delivery in hospital: a randomised controlled trial, British Journal of Obstetrics and Gynaecology, 100, 316-323, 1993	Sample size N = 3510 Characteristics Age/years (mean ± SD) Home from home: 25.3 ± 4.5 Control: 25.4 ± 4.6 Maternal height/cm (mean ± SD)	Interventions Planned (booked) birth in a home from home delivery suite (n = 2304) Planned (booked) birth in routine care	Details Setting The Home from Home delivery scheme (midwife-led) was set up to try and improve the experience of childbirth for women and try and give midwives more independence and	Results Note: none of these outcomes have reported denominators in the tables; therefore, the denominators will be assumed to be the number randomised Mode of birth (n	Limitations Appropriate randomisation: Method of sequence generation not reported Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Unclear,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 114786 Country/ies where the study was carried out England Study type Randomised controlled trial Aim of the study To compare the outcomes of two methods of maternity care during the antenatal period and at delivery. Study dates 1st March 1989 to 6 July 1990 [This was the recruitment period - all births occurred by February 1991] Source of funding Leicestershire District Research Committee awarded a Locally Organised Research Grant (funded by the	Home from home: 162.1 ± 6.3 Control: 162.1 ± 6.0 Smokers (n (%)) Home from home: 554 (26%) Control: 326 (29.8%) (p = 0.015) Gravidity (n (%)) Primigravida Home from home: 832 (36%) Control: 457 (38%) 2 - 3 Home from home: 1193 (52%) Control: 600 (48%) ≥ 4 Home from home: 276 (12%) Control: 149 (12%) Missing data Home from home: 3 Control: 0 Parity (n (%)) Primiparous Home from home: 1040 (45%) Control: 560 (46%)	(control group) (n = 1206)	professional responsibility. Women were looked after entirely by designated midwives, unless consultant advice was sought. Electronic fetal monitoring (EFM) and epidural were not available. Three rooms adjacent to the delivery suite were converted and furnished to resemble a normal bedroom (e.g. patterned wall paper, matching curtains, carpeted floors, pine beds, unobtrusive lighting). No equipment was in view. The equipment necessary for a normal delivery and maternal/neonatal resuscitation was available but hidden by a curtain. Two midwifery sisters (active in midwifery practice for several years) were in	(%))* a. Spontaneous vaginal Home from Home: 1847 (84%) Control: 931 (82%) b. Forceps or ventouse Home from Home: 187 (8%) Control: 114 (10%) c. Vaginal breech Home from Home: 32 (1%) Control: 11 (1%) d. Caesarean section Home from Home: 144 (7%) Control: 78 (7%) Chi-squared test: p = 0.286 * There appear to be missing data - totals are only 2210 in the	because only one arm were aware that they were participating in a trial. Consent was obtained post-randomisation for Home from Home arm, and not obtained for control arm. Blinding of participants: Not possible for this intervention Blinding of staff providing care: Staff were unaware if a woman was a control; however, no details about the Home from Home women are reported. Blinding of outcome assessors: No details given Missing data/loss to follow-up: Unclear. Reported % do not match the calculation if the denominator was number randomised; however, there is no report of missing data. 189/2304 (8.2%) of women randomised refused

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Leicestershire Health Authority and the Leicestershire Medical Research Foundation)	1 - 2 Home from home: 1131 (49%) Control: 570 (47%) ≥ 3 Home from home: 130 (6%) Control: 76 (6%) Missing data Home from home: 3 Control: 0 Inclusion criteria See exclusion criteria Exclusion criteria Previous caesarean section or difficult vaginal delivery Complicating general medical condition (e.g. diabetes, epilepsy, renal disease) Previous stillbirth or neonatal death Previous small for gestational age baby		charge, assisted by 8 staff midwives (volunteers with varying lengths of time experience). All worked a three shift per day system, and were not generally involved with women not in the scheme. Antenatal clinics were run 2-3 times per week. Recruitment and randomisation In order to select and randomise women, appointment clerks attached sealed envelopes to the case sheet for when women arrived at a consultant clinic. In the envelope was the allocation, which could not be read from the outside. Twice as many women were allocated to the Home from Home Scheme. When a	Home from Home arm and 1134 in the control arm and the % do not match if you use the number randomised as the denominator [neither do they total the number randomised subtracting those who refused to be allocated Home from Home] State of perineum (excluding those with CS) (n (%)) a. Intact perineum Home from Home: 669 (33%) Control: 308 (30%) b. Episiotomy Home from Home: 475 (23%) Control: 326 (31%) c. Vaginal and perineal tears Home from Home:	allocation to birth centre. There is missing information for over 200 women in the Home from Home arm for transfer outcomes. Out of 2304 randomised, they report that 539 were transferred antepartum; however, they only report 1553 women being admitted in labour. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes, except method of estimating blood loss is not reported Intention-to-treat analysis performed: Yes Indirectness: 9.9% of women were induced; 7.4% of babies were born before 37 weeks. A further 6% are reported as having hypertension, post dates, breech or a suspected fetal abnormality.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Multiple pregnancy Rhesus antibodies Raised level of serum alpha-feto protein on two occasions		woman was seen by a consultant, it was decided whether she was suitable for the scheme or not (based on exclusion criteria). If the woman was suitable, the envelope was opened. Any unused envelopes were returned to the statistician. During the study period, 7906 pregnant women were seen, of whom 3510 (44%) were considered appropriate for randomisation. It was felt that an explanation of the Home from Home scheme might result in high levels of dissatisfaction in women that ended up being allocated to the control arm. Therefore, a randomised consent design was used,	914 (45%) Control: 417 (40%) (Note: This included 15 third degree tears in the Home from Home group and 6 in the control group) Chi-squared test: p < 0.0001 Use of epidural, either alone or in combination (n (%)) Home from Home: 326 (16%) Control: 208 (20%) Measures of blood loss (n (%)) a. Primary PPH (≥ 500 ml blood loss at delivery) Home from Home: 118 (6%) Control: 63 (6%) Chi-squared: p = 0.77	Other information Comparison: ALONGSIDE MLU vs. OU [INCLUDED IN 2007 GUIDELINE] This study is evaluating a package of care, from antenatal care onwards, not just intrapartum care. Women required physical transfer in the event of a complication requiring an obstetrician.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			where consent and explanation were given post randomisation to those allocated to Home from Home. Consent was not sought from the control arm, as they received normal care available outside of the trial. If a woman refused to take part, following an explanation of the home from home scheme, she was booked for care similar to those in the control group. However, she was analysed in the group to which she was allocated. Care protocol Women allocated to the control arm were booked for hospital antenatal care, which was shared between the GP and community midwife. Birth was	b. Secondary PPH Home from Home: 29 (1%) Control: 9 (1%) Chi-squared test: p = 0.18 c. Blood transfusion Home from Home: 26 (1%) Control: 17 (2%) Chi-squared test: p = 0.43 Baby outcome (n (%)) a. Discharged alive and well Home from Home: 2157 (98%) Control: 1108 (98%) b. Retained in neonatal unit Home from Home: 31 (1%) Control: 20 (2%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			within the specialist unit by hospital staff. Women who were allocated to Home from Home, and consented, were booked and had an explanatory leaflet given to them. Information on pain relief and lack of epidural was reinforced throughout pregnancy, and women were free to transfer at any point. The rest of their antenatal care was performed by the midwives in the scheme and they were seen at 26, 36 and 41 weeks. Intervening care was by GPs or community midwives. Scheme midwives could take blood samples, use scanners, and organise antenatal cardiotocography (CTG) if necessary.	c. Stillbirth Home from Home: 13 (1%) Control: 5 (0%) [The majority of women with stillbirth in the Home from Home group had been transferred before the death occurred. No avoidable factors were found in all 5 of the control group and 11 of the Home from Home group. Possible avoidable factors were identified in the other 2: - In one, the mother had reported decreased fetal movement to the community midwife the week before being admitted in labour, and nothing	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			During labour in the Home from Home rooms, the mother was encouraged to ambulate and adopt any position. Membranes were only ruptured following discussion with the woman. Analgesia was pethidine hydrochloride or meptazinol by injection or nitrous oxide and oxygen by inhalation. If the woman required epidural, she was transferred. Episiotomies, if needed, were performed by midwives and the repair of these and perineal tears were done on the delivery bed. Discharge after birth was at the woman's request, provided there were no contraindications. After	was done except for checking the fetal heartbeat. There was no heartbeat on admission in labour. The authors report that referral for CTG would have been advisable when reduced movement was reported. - The other woman was admitted in early labour and the fetal heart rate (FHR) was 160 bpm. When labour became well established, the membranes were ruptured at 6cm and thick meconium was presented. The fetal heart was not heard following this. The woman was transferred and gave birth to a stillborn baby without obvious cause. The	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			discharge, routine care was from community midwives, health visitors and GPs. Transfer criteria Referral back to the consultant could be initiated by the GP, community midwife, or scheme midwife. After a 41 week visit, referral back was mandatory. If the midwife was concerned during labour, she contacted the registrar on call who made the decision about whether women should stay in the Home from Home room or be transferred. Data collection, analysis and monitoring It was felt that 1000 women in each arm would be feasible in terms of recruitment	authors report that a CTG recording at onset of labour or earlier rupture of membranes may have altered the course of events.] d. Early neonatal death Home from Home: 5 (0%) Control: 0 (0%) [Of the neonatal deaths: 2 women never attended the midwives clinic because they were both admitted with bleeding at 21 and 23 weeks, and then delivered a baby that only survived a few minutes. The other 3 women were referred to specialist care at various times prior to delivery, and the fetal outcome	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			during the study period; this sample would size would have adequate power to detect significant changes of outcome measures that had an incidence of about 15-20% (e.g. induction rates, perineal tears). However, 5000 controls would have been required to detect a doubling of perinatal mortality from 5 per 1000. Data sheets recording personal details and antenatal, perinatal and postnatal events were completed after birth for both cases and controls. Controls were not identifiable from case notes, so staff were unaware if a woman was a control.	was due to hydrocephaly, non-immune hydrops and beta-haemolytic streptococcal septicaemia. No avoidable factors were identified, and transfer to specialist care was at an appropriate time] (Nb: 24 women in the Home from Home arm and 15 women in the control arm had an abortion or miscarriage) Transfers 1044 women were transferred from the Home from Home unit to specialist care: Antepartum transfers [n (% of	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				transfers)] Hypertension: 94 (17%) Post 41 weeks: 64 (12%) Vaginal bleeding: 62 (12%) Breech: 45 (8%) Suspected small for dates: 34 (6%) Moved to another area: 23 (4%) Abortion: 18 (3%) No reason given: 17 (3%) Suspected fetal abnormality: 17 (3%) Preterm labour or premature rupture of membranes: 13 (2%) Other: 152 (28%) Total: 539 (100%) Intrapartum or postpartum transfers [n (% of transfers)]: - First stage Meconium stained amniotic fluid: 115	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(23%) Failure to progress: 97 (19%) Rupture of membranes > 12 hours: 62 (12%) Fetal heart irregularities: 31 (6%) Preterm: 22 (4%) Request for epidural: 21 (4%) Other: 61 (12%) - Second stage Failure to progress: 31 (6%) Fetal heart abnormalities: 9 (2%) Meconium stained liquor: 3 (1%) Other: 5 (1%) - Third stage Retained placenta: 21 (4%) For suturing: 1 (% NR) No reason given: 1	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(% NR) - Postpartum PPH: 6 (1%) For suturing: 5 (1%) Other: 14 (3%) Total: 505 (100%) NOTE: There is inconsistency in reporting of transfer. The authors report that 2304 women were randomised and then 539 were transferred antepartum (although this is reported as 537 in text). This leaves 1765 women; however, they report that only 1553 women were admitted to Home from Home in labour. Therefore, there appear to be missing data for over	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				200 women.	
Full citation Nove,A, Berrington,A, Matthews,Z, Comparing the odds of postpartum haemorrhage in planned home birth against planned hospital birth: results of an observational study of over 500,000 maternities in the UK, BMC Pregnancy and Childbirth, 12, 130-, 2012 Ref Id 244585 Country/ies where the study was carried out England Study type Retrospective comparative observational study Aim of the study To address the question "Is the incidence of PPH different if a home birth was intended than if a hospital birth was intended"?	Sample size N = 273,872 Characteristics Pregnancy risk status (n/total (%)) Medium: 73862/273872 (27.0) Low: 200010/273872 (73.0) Parity (n/total (%)) Nulliparous: 125963/273872 (46.0) Multiparous: 147909/273872 (54.0) Mother's age at birth (n/total (%)) < 20: 13881/273872 (5.1) 20 - 24: 51640/273872 (18.9) 25 - 29: 93757/273872 (34.2) 30 - 34: 81332/273872 (30.0) 35 - 39: 29031/273872 (10.6) 40+: 4231/273872 (1.5) Ethnic group (n/total (%)) Black African: 7516/273872 (2.7) Black Caribbean:	Interventions Planned (intended at onset of labour) home birth (n = 5998) Planned (intended at onset of labour) hospital birth (n = 267874)	Details Selection of study groups Data were extracted from the St Mary's Maternity Information System (SMMIS) - this contained information recorded by healthcare professionals contemporaneously in the woman's pregnancies, and the authors report that it has been shown to have good agreement with case notes (over 95% agreement for most variables). 15 hospitals in the North West Thames area contributed data, and they were of a wide range of location and types. Women were classed as having an intended home birth if one of the	Results Postpartum haemorrhage (n/total (%)) Home: 23/5998 (0.38) Hospital: 2785/267874 (1.04) Unadjusted odds ratio: 2.7 (confidence interval [CI] not reported; p < 0.001) Adjusted* odds ratio: 2.5 (95% CI 1.7 to 3.8; p < 0.001) [Note: 968 of these were among women of medium risk (1.31% of that group) and 1840 of these were among women of low risk (0.92% of that group)] * Adjustment was	Limitations Choice of treatment unrelated to confounders (selection bias): Unlikely; however, adjustment has been done for some confounders Groups comparable at baseline: Unclear - characteristics split by planned place of birth are not reported Groups received same/similar care (apart from intervention): No details given Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: There was no missing data for the outcome Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Data on the outcome was extracted from the database, which has been

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates 1988 to 2000 Source of funding This analysis was part of a PhD which was funded by the Economic and Social Research Council	6587/273872 (2.4) Mediterranean: 6808/273872 (2.5) Oriental: 4350/273872 (1.6) South Asian: 34674/273872 (12.7) White European: 195498/273872 (71.4) Other: 11064/273872 (4.0) Missing: 7375/273872 (2.7) Birth weight (n/total (%)) < 2500 g: 5122/273872 (1.9) 2500 - 3999 g: 241301/273872 (88.1) 4000 g +: 27449/273872 (10.0) Number of ultrasound scans in pregnancy (n/total (%)) 0: 4610/273872 (1.7) 1: 114588/273872 (41.8) 2: 99368/273872 (36.3) 3: 35376/273872 (12.9) 4: 10951/273872 (4.0) > 4: 5748/273872 (2.0) Missing: 3231/273872 (1.2) Year of birth (n/total) 1988: 20901/273872		following criteria were met: - home birth was intended at booking and the baby was delivered at home - hospital birth was intended at booking but the baby was delivered at home and SMMIS recorded the change in plan as having taken place before labour commenced - home birth was intended at booking but the baby was delivered in hospital, and SMMIS recorded the change in plan as having taken place during labour (i.e. intrapartum transfer) Women were classed as having an intended hospital birth if one of the following criteria were met: - hospital birth was intended at booking and	done for suspected macrosomia (yes/no), previous baby with birth weight > 4500 g (yes/no), mother's BMI (<30/30-34), borderline anaemia (yes/no), parity (nulliparous/multiparous), mother's age at birth (in categories as per characteristics above), ethnic group (in categories as per characteristics above), current baby's birth weight (<2500/ 2500-3999/ 4000+), sex of baby (boy/girl), number of ultrasound scans in pregnancy (in categories as per characteristics above), year of birth, hospital providing care, and time of birth (hours of day).	found to be accurate; however, there are no details about how the individual units assessed the amount of blood loss. Intention-to-treat analysis performed: Women transferred from home intrapartum were retained in planned home birth group. Indirectness: - 27% of the study population were classified as medium risk rather than low risk - these were women meeting the criteria from the 2007 guideline that are listed as "indicating individual assessment when planning place of birth." Other information Comparison: HOME vs. OU [This study is new since the 2007 guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	1989: 21939/273872 1990: 22311/273872 1991: 22108/273872 1992: 22040/273872 1993: 21077/273872 1994: 21014/273872 Inclusion criteria Exclusion criteria Pregnancy not ending in a live birth or stillbirth (i.e. miscarriages, abortions, moving out of area) High risk pregnancy: this was defined using a mixture of maternal International Classification of Disease (ICD) codes and the individual fields in the St Mary's Maternity Information System (SMMIS) database. It was based on the 2007 guidance - i.e. those characteristics "suggesting planned birth at an obstetric unit". Induction of labour		the baby was delivered in hospital - home birth was intended at booking but the baby was delivered in hospital and SMMIS recorded the change in plan as having taken place before labour commenced. Unplanned home births were excluded - these were births where a hospital birth was intended at booking but the baby was delivered at home, and SMMIS recorded the change as having taken place during labour. Unplanned home births are excluded as they would have artificially increased the risks associated with the planned hospital birth group. However, a sensitivity analysis was done with them in the	Note: - Adjusted odds ratio and CI with unplanned home births re-included did not change at all - Adjusted odds ratio with unattended births re-included was 2.5 (95% CI 1.6 to 3.7)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Elective caesarean section Gestation < 37 weeks Intended place of birth unknown Unplanned home birth Unattended in labour Baby of indeterminate sex Missing data		model and the odds ratio and confidence interval were exactly the same. Similarly, re-including unattended births made almost no difference. A total of 311,419 women were excluded from the analysis as a result of the exclusion criteria. High risk women were excluded based on the criteria from the 2007 Intrapartum Care guideline which are listed as "suggesting planned birth at an obstetric unit." Medium risk women were retained in the study - these were women meeting the criteria from the 2007 guideline that are listed as "indicating individual assessment when planning place of birth."		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Setting/care protocol No particular details are given, as the study used data from a database which contained information from 15 different units. Transfer criteria No details given. Data collection, analysis and monitoring Data were extracted from SMMIS but it is not reported who by. Adjusted analyses were performed using a logistic binary regression model with PPH as the outcome variable. It was built using manual forward selection ($p < 0.05$ as the cut-off). Covariates were identified following a literature review. Some were excluded		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			from modelling despite being associated with PPH: mode of birth, type of healthcare professional attending, type of pain relief, augmentation of labour. The authors report that this was because these factors may be mediators that explain the difference between the two birth settings - holding them constant would have been akin to controlling for the effect of place of birth on PPH. Other covariates were not included in the model as there was no significant association between them and PPH. In terms of missing data on explanatory variables - if < 0.1% of records had missing data on a variable these		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			records were deleted, if 0.1% - 12% had missing data a "missing" category was created, and if > 12% records had missing data then it was not included as a covariate in the model. Outcomes reported 1. Postpartum haemorrhage: defined as blood loss of at least 1000 ml		
Full citation Overgaard,Charlotte, Moller,Anna Margrethe, Fenger-Gron,Morten, Knudsen,Lisbeth B., Sandall,Jane, Freestanding midwifery unit versus obstetric unit: a matched cohort study of outcomes in low-risk women, BMJ Open, 1, -, 2011 Ref Id 194787 Country/ies where the study	Sample size N = 1678 Characteristics Parity (n (%)) Nulliparous FMU: 215 (25.6) OU: 215 (25.6) Multiparous FMU: 624 (74.4) OU: 624 (74.4) Smoking status (n (%))	Interventions Planned (intended at onset of labour) birth in a freestanding midwifery unit (n = 839) Planned (intended at onset of labour) birth in an obstetric unit	Details Selection of study groups Both groups of women had to be judged to be low risk and fulfil the criteria for an FMU birth at the onset of labour (see inclusion criteria). All labouring women admitted to FMUs by their midwife were included in the study. Women in the OU	Results Mode of birth (n/total (%)) a. Spontaneous vaginal birth FMU: 796/839 (94.9) OU: 751/839 (89.5) RR 1.06 (95% CI 1.03 to 1.09) b. Instrumental birth† FMU: 25/839 (3.0)	Limitations Choice of treatment unrelated to confounders (selection bias): Unlikely; however they matched women to try and control for this Groups comparable at baseline: Yes Groups received same/similar care (apart from intervention): Yes Blinding of those assessing outcomes: No details given

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
was carried out Denmark Study type Cohort study (with matched pairs) Aim of the study To compare perinatal and maternal morbidity and birth interventions in low risk women giving birth in two freestanding midwifery units (FMUs) and two obstetric units Study dates 2004 to 2008 Source of funding Grants from the Augustinus Foundation, the Obel Family Foundation, the Oticon Foundation, the University College North Jutland Research and Development Fund, and the Danish Association of Midwives Research and Development	Non-smoker FMU: 684 (81.5) OU: 684 (81.5) 1-9 cigarettes FMU: 59 (7.0) OU: 59 (7.0) 10 or more cigarettes FMU: 96 (11.5) OU: 96 (11.5) BMI (n (%)) < 18 FMU: 17 (2.1) OU: 22 (2.6) 18 - 24.9 FMU: 528 (62.9) OU: 530 (63.2) 25 - 29.9 FMU: 226 (26.9) OU: 219 (26.1) > 30 FMU: 68 (8.1) OU: 68 (8.1) Age (n (%))	(n = 839)	group were included if they were a matched to one of the women in the FMU group. They were selected from the administration system which carries information on all pregnant women; therefore, whenever a woman was included in the FMU group, a woman was selected from admitted low risk women in the nearest OU. Project staff were blinded to the identity and birth outcome of the FMU women selected the matched controls. The criteria for matching were as follows: - Low risk status [total match] - Parity [total match] - Smoking [total match] - BMI [± 5]	OU: 61/839 (7.8) RR 0.4 (95% CI 0.3 to 0.6) c. Caesarean section FMU: 19/839 (2.3) OU: 34/839 (4.0) RR 0.6 (95% CI 0.3 to 0.9) p = 0.04 † FMU midwives had authorisation to perform ventouse births in the case of acute fetal distress in the second stage; however, this only occurred once in the case of acute bradycardia Epidural (n/total (%)) FMU: 35/839 (4.2) OU: 86/839 (10.3) RR 0.4 (95% CI 0.3	Missing data/loss to follow-up: No Precise definition of outcomes: it is not reported what constituted severe maternal morbidity. Valid and reliable method of outcome assessment: Blood loss was estimated and therefore may be subject to bias Intention-to-treat analysis performed: Yes Because the government closed two FMUs, the authors had to retrospectively enrol women who had given birth the previous year in the FMUs. For these women, the outcome of the birth would have been known and the authors report that they could not rule out the possibility of bias linked to the inclusion of these women. However, they report that all OU women were enrolled

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Fund	16 - 20 FMU: 24 (2.9) OU: 25 (3.0) 21 - 35 FMU: 731 (87.1) OU: 716 (85.3) > 35 FMU: 84 (10.0) OU: 98 (11.7) Ethnicity (n (%)) Nordic or Western European FMU: 805 (96.0) OU: 809 (96.4) Eastern European or Asian FMU: 27 (3.2) OU: 22 (2.6) Arab or African FMU: 7 (0.8) OU: 8 (1.0) Education level (n (%)) No training/education qualifying for the labour market FMU: 216 (25.7)		- Age [± 5] - other factors such as ethnicity, education level, occupation and cohabitation status were matched within groups (note: it is unclear how this was done, as the proportions of women in various groups in these latter categories are not equal) Setting/care protocol Freestanding midwifery units (FMU) The units offered midwifery-led care during pregnancy and intrapartum and postnatal periods to women. They were both located in community hospitals with an intensive care unit but not an obstetric service. Women had to be transferred to the OU by ambulance. All the	to 0.6) Postpartum haemorrhage (n/total (%)) a. Over 500 ml FMU: 29/839 (3.5) OU: 68/839 (8.1) RR 0.4 (95% CI 0.3 to 0.7) p = 0.0001 b. Over 1000 ml FMU: 11/839 (1.3) OU: 14/839 (1.7) RR 0.8 (95% CI 0.4 to 1.7) p = 0.6900 Intact perineum (n/total (%)) FMU: 514/839 (61.3) OU: 466/839 (55.5) RR 1.1 (95% CI 1.02 to 1.2) p = 0.0142	prospectively and that no systematic changes occurred during the study period. They also note that a subgroup analysis comparing the 2004 FMU data with the main prospectively collected data did not detect any systematic differences or deviation of results between the two groups of data. Indirectness (these are possible sources of indirectness but are not necessarily serious): - healthy multiparous women were considered low risk regardless of BMI and age, as long as their previous pregnancies and labours were not complicated - midwives in the FMU could perform ventouse births - it is unclear how comparable this is to the situation in most FMUs in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	OU: 217 (25.9) Skilled training FMU: 255 (30.4) OU: 255 (30.4) 1 - 2.5 years of postsecondary education FMU: 84 (10.0) OU: 81 (9.6) 3 - 4 years of postsecondary education FMU: 254 (30.3) OU: 256 (30.5) 5 - 6 years of postsecondary education FMU: 30 (3.6) OU: 30 (3.6) Cohabitation status (n (%)) Living with partner FMU: 815 (97.1) OU: 819 (97.6) Not living with partner FMU: 24 (2.9) OU: 20 (2.4)		FMU midwives had at least 2 years experience and training in obstetric emergencies, included ventouse. They gave antenatal and out-of-hours postpartum care for all women in the area (whether they had booked for OU or FMU births). Obstetric maternity units One of the hospitals was a specialist hospital with a specialist OU seeing about 3500 births per year. The other is a provincial hospital which provides care for low risk, and most high risk, women and has a generalised paediatric unit (it has about 1400 births per year). Transfer criteria	Tears (n/total (%)) a. First or second degree FMU: 290/839 (34.6) OU: 337/839 (40.2) RR 0.9 (95% CI 0.8 to 0.97) p = 0.0154 b. Third or fourth degree FMU: 19/839 (2.3) OU: 24/839 (2.9) RR 0.8 (95% CI 0.4 to 1.4) p = 0.5224 c. Perineal suturing FMU: 294/839 (35.0) OU: 366/839 (43.6) RR 0.8 (95% CI 0.7 to 0.9) p = 0.0002 Maternal readmission or	the UK - the FMU is specifically referred to as that, and transfer by ambulance was required for transfer to an obstetric unit, but the unit was located at a hospital. They report that, early in the life of the FMU, an adverse event occurred against protocol - there was a cord prolapse and a gynaecologist (who had been employed at the unit before it turned into an FMU) was summoned and performed an emergency CS. Other information Comparison: FREESTANDING MIDWIFERY UNIT compared with OU [This study is new since the 2007 guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Occupation (n (%)) No paid work FMU: 160 (19.1) OU: 131 (15.6) Unskilled work FMU: 107 (12.7) OU: 119 (14.2) Skilled work FMU: 542 (64.6) OU: 557 (66.4) Academic work/manager or senior official FMU: 30 (3.6) OU: 32 (3.8) Inclusion criteria Fulfilling criteria for freestanding midwifery unit (FMU) birth at onset of labour Low risk: - Healthy - In spontaneous labour at between 37+0 and 41+6 weeks gestation - Uncomplicated pregnancy - No medical/obstetric history		Transfer was by ambulance using multidisciplinary regional criteria, and care by the midwife continued with obstetrician supervision. Data collection, analysis and monitoring The sample size calculation was based on Apgar score and caesarean section (primary outcomes). The study was originally planned to include 1027 in each group, commencing 1 January 2005. However, in October 2006, the government announced plans to close two of the FMUs, by which time only 550 FMU women had been included. In order to increase their sample size, the authors	outpatient visit at 0-28 days postpartum (n/total (%)) FMU: 24/839 (2.9) OU: 40/839 (4.8) RR 0.6 (95% CI 0.4 to 1.0) p = 0.0599 Severe maternal morbidity (n/total (%)) FMU: 0/839 (0) OU: 1/839 (0.1) RR not reported [Note: it was a uterine rupture followed by peripartum hysterectomy in multiparous woman having epidural analgesia and oxytocin augmentation] Perinatal/neonatal death (n/total (%))*	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	or conditions that would increase obstetric risk (as outlined by original Intrapartum Care guideline). Although, note that healthy multiparous women were considered low risk regardless of age and BMI if their previous pregnancies and births had been uncomplicated. Exclusion criteria 3 women were admitted to the FMU for emergency treatment without satisfying the criteria for FMU care		retrospectively included all of the 289 women who had been admitted to the FMUs since the opening of the second FMU in March 2004. These were prospectively matched with women from the nearest OU, giving a total sample size of 839 in each arm. Re-run power calculations showed that the study still retained power to detected differences in the primary outcomes. During the study period, data was collected from patient records and the patient administration system. This was done by project staff with knowledge of the field, based on written instructions. Full follow-up was obtained for all women.	FMU: 1/839 (0.1) OU: 0/839 (0) RR and p-value not reported [Note: the death was of a baby born with a severe diaphramic hernia not detected by an ultrasound scan at 19.4 weeks] Admission to NICU (n/total (%)) a. Any FMU: 28/839 (3.3) OU: 42/839 (5.0) RR 0.7 (95% CI 0.4 to 1.1) p = 0.1143 b. Stay in NICU more than 48 hours FMU: 14/839 (1.7) OU: 15/839 (1.8) RR 0.9 (95% CI 0.5 to 1.9) p = 1.00	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			All analysis was done by intention-to-treat and using STATA. McNemar's test and Wilcoxon signed-rank tests were used where appropriate. The authors also did a supplementary regression analysis adjusting for matching characteristics, to check for residual confounding. Supplementary subgroup analyses were performed on 2004 and main data separately, to check for bias introduced by the inclusion of the extra FMU women. Outcomes reported 1. Mode of birth 2. Use of epidural 3. Postpartum	[Note: 3 babies from the FMU group, born in the OU after transfer, had to remain in NICU for more than a week] Neonatal asphyxia (n/total (%)) FMU: 27/839 (3.2) OU: 41/839 (4.9) RR 0.7 (95% CI 0.4 to 1.1) p = 0.1143 Neonatal readmission at 0-28 days postpartum (n/total (%)) FMU: 26/839 (3.1) OU: 35/839 (4.2) RR 0.7 (95% CI 0.4 to 1.1) p = 0.1480 * The authors report that they did not aim to look for	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			haemorrhage: over 500 ml and over 1000 ml; blood loss was estimated not measured 4. Vaginal/perineal trauma: Intact perineum and incidence of first/second and third/fourth degree tears are reported 5. Maternal morbidity: need for readmission at 0-28 days postpartum, and severe maternal morbidity (classification not reported) 6. Perinatal/neonatal death 7. Admission to NICU 8. Neonatal morbidity: neonatal asphyxia and need for readmission at 0-28 postpartum are reported	differences in mortality or severe morbidity as the study was not powered to detect differences Transfer Actual place of birth in women planning birth in FMU: - Transit birth before reaching FMU‡: 9/839 (1.1%) - Birth in ambulance during transfer to OU: 2/839 (0.2%) - Birth in OU: 95/839 (11.3%) - Birth in at home: 20/839 (2.4) - Birth in FMU: 713/839 (85.0%) Actual place of birth in women planning birth in OU: - Transit birth before reaching OU‡: 5/839 (0.6%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Birth in OU: 834/839 (99.4%) ‡ included if the woman had contacted the FMU within 24 hours and been advised to stay at home/return home Transfer intrapartum or within 2 hours of births 124/839 women transferred either intrapartum or after birth but < 2 hours postpartum - Primiparous: 79/215 (36.7) - Multiparous: 45/624 (7.2) The reasons for transfer were as follows (as a proportion of all intrapartum transfers	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				and those within 2 hours): INTRAPARTUM (n = 97) a. Failure to progress: 55 (44.4) - Primiparous: 42 (53.2) - Multiparous: 13 (44.8) b. Meconium stained amniotic fluid: 14 (11.3) - Primiparous: 9 (11.4) - Multiparous: 5 (11.1) c. Fetal heart rate abnormality: 10 (8.1) - Primiparous: 5 (6.3) - Multiparous: 5 (11.1) d. Prolonged latent phrase/rupture of membranes over 24 hours (+ birth not	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				imminent): 7 (5.6) - Primiparous: 3 (3.8) - Multiparous: 4 (8.9) e. Request for epidural: 6 (4.8) - Primiparous: 5 (6.3) - Multiparous: 1 (2.2) f. Abnormal fetal presentation: 5 (4.0) - Primiparous: 4 (5.1) - Multiparous: 1 (2.2) AFTER BIRTH BUT < 2 HOURS POSTPARTUM (n = 27) g. Perineal trauma (complicated/3rd/4th degree): 16 (12.9) - Primiparous: 10 (12.7) - Multiparous: 6 (13.3)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				h. Retained placenta/PPH > 500 ml: 9 (7.3) - Primiparous: 1 (1.3) - Multiparous: 8 (17.8) i. Infant minor respiratory problem: 2 (1.6) - Primiparous: 0 (0) - Multiparous: 2 (4.4) Transfer > 2 hours after birth or during postpartum stay 13/839 (1.5%) of women transferred during the postpartum period. The reasons for transfer were as follows (as a proportion of all postpartum transfers): a. Neonatal cause	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(light for date, minor respiratory problem, hypoglycaemia, jaundice): 11 (84.6) - Primiparous: 6 (85.7) - Multiparous: 5 (83.3) b. Maternal cause (postpartum bleeding, infection): 2 (15.3) - Primiparous: 1 (14.3) - Multiparous: 1 (16.7)	
Full citation Pang,J.W., Heffelfinger,J.D., Huang,G.J., Benedetti,T.J., Weiss,N.S., Outcomes of planned home births in Washington State: 1989-1996, Obstetrics and Gynecology, 100, 253-259, 2002 Ref Id 174694 Country/ies where the study	Sample size N = 16,726 Characteristics Age/years (n (%)) 10-19 Home: 283 (4.60) Hospital: 1138 (10.70) 20-29 Home: 2851 (47.60) Hospital: 5924 (56.00)	Interventions Planned (intended at onset of labour) home birth (n = 6133) Planned (intended at onset of labour) hospital birth	Details Selection of study groups Planned home birth The birth certificates did not identify which births were planned; therefore, planned home births were defined as singleton newborns born at at least 34 weeks gestation who had a	Results Postpartum bleeding (n/total (%)) Home: 74/5969 (1.24) Hospital: 84/9861 (0.85) - babies ≥ 34 weeks Crude RR 1.46 (95% CI 1.07 to 1.99) Adjusted RR 1.58 (95% CI 1.17 to	Limitations Choice of treatment unrelated to confounders (selection bias): There were differences between the two groups; however, there was some attempt to adjust for these Groups comparable at baseline: Women intending to give birth at home were older, more likely to be married, white, non

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
was carried out USA Study type Retrospective cohort study Aim of the study To determine whether there was a difference between planned home births and planned hospital births in Washington state, with regard to adverse outcomes for mother any infant Study dates 1989 - 1996 Source of funding None stated	30+ Home: 2980 (48.70) Hospital: 3523 (33.30) Missing Home: 19 Hospital: 8 Prenatal care begun (n (%)) First trimester Home: 4307 (71.50) Hospital: 8248 (81.60) Second trimester Home: 1474 (24.50) Hospital: 1572 (15.60) Third trimester Home: 246 (4.10) Hospital: 282 (2.80) Missing data Home: 106 Hospital: 491 Parity (n (%)) 0 Home: 1454 (23.80) Hospital: 4466 (42.70)	(n = 10593)	home birth with a midwife, nurse or physician as the birth attendant or certifier on the birth certificate (if an attendant was not listed, then the certifier did the attending). In addition, singleton newborns with a gestational age of at least 34 weeks who were born after transfer from home to a medical facility were consider planned home births if their birth certificates indicated that delivery was initially attempted at home by a healthcare professional. Planned hospital birth group This was singleton births of at least 34 weeks gestation who were born in hospital with no indication that delivery was initially	2.14)* - babies ≥ 37 weeks Crude RR 1.39 (95% CI 1.01 to 1.89) Adjusted RR 1.52 (95% CI 1.12 to 2.05)* * adjusted for parity [Note: raw data are not split by parity, but the following relative risks are reported: - Nulliparous women: RR 2.76 (95% CI 1.74 to 4.36) - Multiparous women: RR 1.05 (95% CI 0.68 to 1.60)] Neonatal mortality (n/total (%)) Home: 20/6133 (0.33) Hospital: 18/10593	smokers and parous. They were also slightly less likely to reside in an urban area, to have initiated prenatal care during the first trimester and to give birth to infants weighing < 2500 g Groups received same/similar care (apart from intervention): unclear - it is a population based study; therefore no details are given Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: there are missing data for 2.7% of home birth arm and 7% of hospital birth arm for the outcome of postpartum bleeding Precise definition of outcomes: PPH is not defined Valid and reliable method of outcome assessment: The authors report the potential for

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	1+ Home: 4663 (76.20) Hospital: 5994 (57.30) Missing data Home: 16 Hospital: 133 Birth weight/g (n (%)) < 2500 Home: 81 (1.30) Hospital: 246 (2.30) 2500 - 4499 Home: 6033 (98.70) Hospital: 10343 (97.70) Missing data Home: 19 Hospital: 4 Inclusion criteria Singleton birth At least 34 weeks gestation Exclusion criteria Pregnancy related		attempted at home. The group were selected at random, except for frequency matching by year of birth to those intended to be born at home. The study groups were restricted to those without pregnancy complications (see exclusion criteria). Therefore, out of the 7019 home births, 6133 were included in the study population. Out of 14038 hospital births, 10593 were included. Setting/care protocol No details given. Transfer criteria No details given Data collection, analysis and monitoring Birth certificate data were linked to infant	(0.17) - babies ≥ 34 weeks Crude RR 1.81 (95% CI 0.96 to 3.41) Adjusted RR 1.99 (95% CI 1.06 to 3.73)* - babies ≥ 37 weeks Crude RR 1.89 (95% CI 0.99 to 3.59) Adjusted RR 2.09 (95% CI 1.09 to 3.97)† * adjusted for parity † adjusted for maternal age [Note: the authors report that the association between intent to deliver at home and neonatal death was particularly strong in nulliparous women, with a RR of 2.73 (95% CI 1.06 to	misclassification of outcomes in this study, due to the way that the data were collected. Intention-to-treat analysis performed: Yes, in that they attempted to compare planned home and planned hospital births. However, because planned place of birth was not formally recorded on the birth certificates, the authors were forced to make assumptions. This method of classifying planned place of birth could have resulted in misclassification of unplanned home births as planned home births, which is mentioned by the authors in their discussion of limitations. They report that they attempted to minimise this by excluding births before 34 weeks and those with complications. Indirectness:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	complications (because it is unlikely that these women would intend to deliver at home): - anaemia (haematocrit < 30% or haemoglobin < 10 mg/dl) - cardiac disease - acute or chronic lung disease - diabetes - polyhydramnios - oligohydramnios - genital herpes - hemogliobinopathy - chronic hypertension - pregnancy induced hypertension - eclampsia - incompetent cervix - previous preterm or SGA infant - macrosomia in a previous birth (> 4000 g) - renal disease - Rh sensitisation - syphilis - hepatitis B infection		death certificates to identify cases of neonatal and post-neonatal death. Other information was identified through information on the birth certificates. Secondary analyses were also performed for those weighing at least 2500 g at birth or of at least 37 weeks gestation (6052 planned home births and 10347 planned hospital births) Relative risks were calculated using stratified analysis. Variables considered as confounders were: - maternal age (10-19, 20-29, 30+) - race (white, black, Asian, other) - marital status (married, unmarried)	7.06) for all women, and RR of 2.99 (95% CI 1.12 to 7.94) when restricted to those of at least 37 weeks. The RR for multiparous women is not reported] The causes of death were as follows (n): - Brain injuries Home: 2 Hospital: 1 - Congenital heart disease Home: 5 Hospital: 5 - Respiratory distress Home: 5 Hospital: 0 - Infection/sepsis Home: 2 Hospital: 3	- 81/6133 (1.3%) of home births and 392/10593 (3.7%) of hospital births were born prior to 37 weeks (but later than 34 weeks) - 7.6% of home births were attended by physicians. Other information Comparison: HOME vs. OU [This study is new since 2007 guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- education level (high school or less, more than high school) - payer status (indigent, insured/self-paying) - smoking (yes, no) - county of birth - residence (urban, rural) - prenatal care (initial visit during first, second or third trimester) - parity (0, 1+) - birth weight (< 2500g, 2500g+) Factors were considered in the final model if they altered the crude RR by at least 10% Outcomes reported 1. Postpartum bleeding: no further definition given 2. Neonatal mortality 3. Post-neonatal	- Other major congenital anomaly Home: 3 Hospital: 6 - Other Home: 3 Hospital: 3 Post-neonatal mortality (n/total (%)) Home: 15/6133 (0.24) Hospital: 27/10593 (0.25) - babies ≥ 34 weeks Crude RR 0.96 (95% CI 0.51 to 1.80) Adjusted RR 0.96 (95% CI 0.51 to 1.80) - babies ≥ 37 weeks Crude RR 0.91 (95% CI 0.47 to 1.74) Adjusted RR 0.91 (95% CI 0.47 to 1.74)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			mortality	[Note: for this outcome of post-neonatal mortality, the adjusted RR does not appear to have been adjusted for any confounders] Transfers Out of the 6133 planned home births, 279 (4.5%) involved a transfer. Out of the 6052 planned home births of at least 37 weeks gestation, 269 (4.4%) involved a transfer	
Full citation SCUPHOLME,A., McLeod,A.G.W., Robertson,E.G., A birth center affiliated with the tertiary care center: Comparison of outcome, Obstetrics and Gynecology,Obstet.Gynecol., 67, 598-603, 1986	Sample size N = 500 Characteristics Note: for most demographic characteristics, comparative data for the two groups are not reported; however, the authors report that the groups are	Interventions Planned (intended at onset of labour) birth at a birth centre (n = 250) Planned (intended at	Details Selection of study groups Women requesting care at the birth centre were screened at the initial visit using strict protocol. Women without prior prenatal care had to register	Results Maternal mortality (n/total (%)) Birth centre: 0/250 (0) Hospital: 0/250 (0) Mode of birth (n/total (%)) a. Spontaneous	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear; however matching was done to try and control for confounders Groups comparable at baseline: Yes Groups received

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 174689 Country/ies where the study was carried out USA Study type Prospective cohort with matched pairs Aim of the study To evaluate the relative safety of a birth centre when compared to a hospital Study dates November 1st 1982 to January 31st 1984 Source of funding None stated	'identical' for age, parity, ethnic background and financial status. Age (%) 16-19: 14 20-29: 63.2 30-34: 17.6 > 35: 5.2 Race (%) White: 52 Black: 17 Hispanic: 31 Parity (%) Primigravida: 59 Multigravida: 41 Highest educational level completed (%) - Not finished high school Birth centre: 11 Hospital: 52 - Completed high school Birth centre: 39.0 Hospital: 32.4 - College for 1-4 years	onset of labour) birth in hospital (n = 250)	before 28 weeks, and those with prior care by 34 weeks. Only low risk women were considered. During the study period, 628 women presented for care of which 48 were rejected as ineligible during the first visits. 100 (17%) out of the remaining group of 580 were transfered antepartum, 23% were excluded for noncompliance, 12% for other medical reasons and 2 moved. Therefore, 250 women started care at the birth centre and were well-screened and low risk. Women arriving in labour at the birth centre were matched with a women admitted in labour to the obstetric unit at the hospital. The hospital group women	vaginal* Birth centre: 230/250 (92%) Hospital: NC (83%) b. Assisted vaginal* Birth centre: 5/250 (2%) Hospital: NC (3%) c. Caesarean section* Birth centre: 15/250 (6%) Hospital: 35/250 (14%) (p is 0.005 to 0.01 for the whole of mode of birth) * raw event rate data were calculated by the technical team based on % and denominator information reported in the study. However, for the hospital arm, it was	same/similar care (apart from intervention): Generally yes, although birth centre group also received prenatal care at the birth centre Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: For the outcome of PPH it is unclear what the denominator is (specifically stated for other outcomes), and raw event rate data is not reported for PPH or mode of birth. Precise definition of outcomes: Haemorrhage is not defined Valid and reliable method of outcome assessment: Blood loss was estimated Intention-to-treat analysis performed: Yes Indirectness: - Women in the obstetric ward were cared for by physicians, which is less

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Birth centre: 46.8 Hospital: 14.0 - College for at least 5 years Birth centre: 3.2 Hospital: 1.6 Infant birth weight / g (%) - < 2500 Birth centre: 0 Hospital: 1 - 2500-3999 Birth centre: 87 Hospital: 92.5 - > 4000 Birth centre: 12 Hospital: 6.5 Inclusion criteria Low risk women (i.e. eligible for admission to birth centre) Receiving prenatal care from 28 weeks onwards Exclusion criteria Obstetric problems (e.g.		had to have received prenatal care from 28 weeks onwards and to have been eligible for admission to birth centre. They were matched on: - age - parity - ethnic background - financial status Setting/care protocol Birth Centre This was developed as a lower cost alternative for low risk women, and was located in a high rise building outside of the main hospital complex and separated by a thoroughfare. The unit consisted of six large bedrooms (each with adjoining bathroom), two examination rooms, an education room, waiting room, staff office and storage. An ambulance	not possible to calculate all of these values definitiv ely due to rounding. There could either have been 208 spontaneous vaginal births and 7 assisted, or 207 spontaneous vaginal births and 8 assisted and both combinations would be rounded to the same %. Postpartum haemorrhage (PPH) (%) Birth centre: 5 Hospital: 1.4 [this is reported in data table; however, it is reported as 2.4% in text elsewhere] [Note: raw event rate data cannot be calculated as it is not reported what the	comparable to the UK Other information Comparison: FREESTANDING MLU vs. OU [This study was included in the 2007 guideline] This study evaluates a package of care from 28 weeks onwards.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	women were excluded for gestational diabetes and premature rupture of membranes) Non compliance [For further details, see section on 'selection of study groups' in methods in this table]		was available in the garage for transfers. The staff consisted of certified nurse midwives, a registered nurse, licensed practical nurses and secretarial staff. Medical consultation was from the obstetricians and paediatricians on staff at the nearby hospital. They consulted, and also accepted referral of women who developed complications. A physician reviewed the history when considering eligibility, and examined women during a second visits and again at around 36 weeks. The remainder of the visits were done by the nurse midwives. Childbirth education was done within the	denominator was for this outcome] Maternal readmission after discharge (n/total (%)) Birth centre: 0/250 (0) Hospital: 0/250 (0) Transfer 54/250 (21.6%) of women who arrived at the birth centre in labour were transferred intrapartum, due to (n): - Premature rupture of membranes (PROM) 12 hours, labour not established: 17 - Secondary arrest of labour: 15 - Prolonged latent phase > 18 hours: 6 - Second stage > 2 hours: 7	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			centre. Lab tests were collected and done in the hospital. The management of labour was based on a non-interventionist approach. Families stayed together and women were encouraged to ambulate, and to eat and drink as needed. No electronic fetal monitoring (EFM), or induction/augmentation with oxytocin was available. Analgesia and IV were available if needed; however, there was no regional or general anaesthesia. Women could stay for up to 24 hours in the centre, and then return for a visit the day after. Hospital It was a large tertiary care facility serving multi-ethnic population,	- Fetal distress: 1 - Placental abruption: 1 - Prolapsed cord: 1 - Pre-eclamptic toxaemia: 2 - Thick meconium stained fluid: 2 - Unstable lie: 1 - Maternal fever > 100.4 F in labour: 1 3 mothers were transferred for postpartum problems (no specifics given). 32 out of the 196 infants that were born in the birth centre were transferred for paediatric consultation and/or admission, due to (n): - Mild respiratory distress: 12 - Cardiac murmur: 4	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			and within 10000 births per year. Care was provided by attending physicians, residents and nurse-midwives. Women were only admitted once in active labour unless there was a complication. Management of labour was reported as tending to be "aggressive" and technologically oriented. Transfer criteria Any women needing operative or assisted delivery had to be transferred. If thick meconium was diagnosed, women were transferred immediately. If there was light meconium staining, women were allowed to remain at the centre as long as there were no fetal heart irregularities. When a	- Positive Coombs test: 9 - Bilateral congenital hip dislocation: 1 - Fractured clavicle: 2 - Persistent fetal circulation: 1 [this baby died at 5 weeks old] - Tracheo-oesophageal fistula: 1 - Meningocele: 1 - Jaundice: 1 The authors report that the transfer system was efficient, as a result of a hotline system between the birth centre, labour room and NICU. Once transfer was initiated, a building security officer was assigned to help and drive the ambulance. They report that	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			birth occurred with meconium present, the vocal cords were visualised and endotracheal suctioning was done if needed. If meconium stained liquor was found below the cords, the baby was transferred to hospital. Any other complications in labour resulted in transfer. Women transferred during labour were included in the birth centre group. Data collection, analysis and monitoring Matching of the two study groups was done by first identifying women from the hospital delivery book who were from the same age and parity category as the birth centre women and who delivered about the same time (average 2	entry to birth centre with cord prolapse to CS in the hospital had once been achieved in 20 minutes.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			days, maximum 2 weeks). Then, ethnicity and financial classification were obtained from records, generating a potential list. Then, birth certificate sheets were obtained to get data on education status and month when prenatal care started. This generated another list, for which medical records were obtained, and then reviewed to ensure that there were no factors precluding admission to the study. Chi-squared test was used to compare results. Outcomes reported 1. Maternal mortality 2. Mode of birth: raw event rate data are not reported; however, in		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			some cases can be calculated 3. Postpartum haemorrhage: this is not defined, and the authors report that blood loss was estimated and therefore could be subjective (raw event rate data are not reported)		
Full citation Stone,P.W., Maternity care outcomes: assessing a nursing model of care for low-risk pregnancy, Outcomes Management for Nursing Practice, 2, 71-75, 1998 Ref Id 174690 Country/ies where the study was carried out Unclear (systematic review reports USA though) Study type Prospective cohort study	Sample size N = 146 Characteristics The authors report that generally, the women were educated, married, Caucasian women in their middle to late 20s who had private insurance coverage and were generally multiparous. They also report that there were no significant differences in any sociodemographic variables measured between the two groups.	Interventions Planned (intended at onset of labour) birth in a freestanding birth centre (FSBC) (n = 69) Planned (intended at onset of labour) birth in traditional care setting (n = 77)	Details Selection of study groups Women in both study groups all met the same low-risk birth centre eligibility criteria at 34-36 weeks, based on health assessment data in the medical record. (note: criteria for judging low risk are not reported) Setting/care protocol The study was conducted in a rural region.	Results Intact perineum [vaginal births only] (n/total (%)) Birth centre: 12/54 (22) Traditional care: 4/52 (8) (p < 0.01) Presence of perineal tear [vaginal births only] (n/total (%)) a. First degree Birth centre: 26/54 (48) Traditional care: 15/52 (28*)	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear; however, the authors report that groups were not different at baseline Groups comparable at baseline: Yes, according to authors Groups received same/similar care (apart from intervention): Unclear - very few details given Blinding of those assessing outcomes: No details given Missing data/loss to follow-

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare freestanding birth centre (FSBC) model of care to traditional maternity care with regards to clinical outcomes, cost and satisfaction Study dates Not reported Source of funding NINR training grant ~F31 NR-07048-01	Inclusion criteria Low risk and birth centre eligible at 34-36 weeks English speaking, reading and writing Exclusion criteria None stated		- FSBC Certified nurse-midwives provided prenatal and childbirth care - Traditional care Physicians provided care Transfer criteria No details given Data collection, analysis and monitoring Outcomes were measured by self-report surveys at 34-36 weeks gestation and then again at 6 weeks postpartum. Other data were extracted from the prenatal and childbirth medical records. Outcomes reported Episiotomy, and measures of perineal trauma are the only	b. Second degree Birth centre: 9/54 (17) Traditional care: 1/52 (2) c. Third degree tear Birth centre: 0/54 (0) Traditional care: 2/52 (4) * as reported in the paper, but the exact % is 28.8, therefore this is a rounding error Episiotomy [vaginal births only] (n/total (%))† Birth centre: 4/54 (7%) Traditional care: 29/52 (56%) † reported in text; therefore denominators had to	up: Outcomes are only reported for women with a vaginal birth (therefore 27% of women have missing data). 2 women were missing all childbirth data (1.4%) Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: No report of transfer Indirectness: - Comparison was with traditional care provided by a physician and therefore is not particularly comparable with care in obstetric units in the UK, by midwives Other information Comparison: FREESTANDING MIDWIFERY UNIT vs. OU

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			priority outcomes reported	be assumed based on denominators for other perineal outcomes Transfer No details about any transfers are reported	[This study was included in the 2007 guideline]
Full citation van der,Kooy J., Poeran,J., de Graaf,J.P., Birnie,E., Denktass,S., Steegers,E.A., Bonsel,G.J., Planned home compared with planned hospital births in the Netherlands: intrapartum and early neonatal death in low-risk pregnancies, Obstetrics and Gynecology, 118, 1037-1046, 2011 Ref Id 164671 Country/ies where the study was carried out The Netherlands Study type Retrospective cohort study	Sample size N = 679,952 (However, for 57,935 of these women, the planned place of birth was unknown; therefore the true population of interest is 622,017) Characteristics Parity (n (%)) a. Natural prospective approach - Primiparous Home: 171986 (42.69) Hospital: 104249 (47.58) - Multiparous Home: 230926 (57.31) Hospital: 114856 (52.42)	Interventions Planned (intended at onset of labour) birth at home (n = 402912) Planned (intended at onset of labour) birth in hospital (n = 219105)	Details Selection of study groups Low risk women (see inclusion/exclusion criteria) were categorised according to their intended place of birth. For some women, this was not decided until the onset of labour, in which case it was coded as unknown. This could have been due to delayed antepartum care, or indifference by the woman. Two different analyses were done, which	Results Intrapartum death and neonatal death at 0-7 days (n/total (%)) a. Natural prospective approach Home: 594/402912 (0.15) Hospital: 403/219105 (0.18) - Crude RR 0.80 (95% CI 0.71 to 0.91) - Model 2: 'not included in equation'* - Model 3 Adjusted OR 1.05 (95% CI	Limitations Choice of treatment unrelated to confounders (selection bias): unclear; however, adjusted analyses have been done Groups comparable at baseline: No. Women planning a home birth were more likely to be multiparous, at least 25 years old, of Dutch origin and live in a privileged neighbourhood. In babies born to women planning home births, premature birth was less common, as was the prevalence of a 'Big 4' condition Groups received same/similar care (apart

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare the intrapartum and early neonatal mortality rate of planned home birth with planned hospital birth in community midwife-led deliveries after case mix adjustment Study dates 2000 to 2007 Source of funding None reported - under Financial Disclosure, the authors did not report any potential conflicts of interest	b. Perfect guideline approach - Primiparous Home: 148082 (40.73) Hospital: 88110 (46.35) - Multiparous Home: 215486 (59.27) Hospital: 101988 (53.65) Maternal age/years (n (%)) a. Natural prospective approach < 19 Home: 4036 (1.00) Hospital: 6713 (3.06) 20-25 Home: 34661 (8.60) Hospital: 32617 (14.89) 25-34 Home: 296128 (73.50) Hospital: 142597 (65.08) > 35 Home: 68087 (16.90) Hospital: 37178 (16.97) b. Perfect guideline approach		included slightly different women: - Natural prospective approach ([NPA] primary analysis) This resembled an intention-to-treat analysis, and compares planned home birth and planned hospital births in women starting birth under the supervision of a midwife. For this analysis, 679952 are included. This approach includes some spontaneous preterm labour because these women were not referred to the gynaecologist during labour or were referred late in planned home births. - Perfect guideline approach [PGA] This includes only a sub-set of women who	0.91 to 1.21) * the authors report that when adjusting for maternal factors only the intended place of birth had no significant effect on outcome and showed a similar result to the univariable (crude) analysis b. Perfect guideline approach Home: 344/363568 (0.09) Hospital: 182/190098 (0.10) - Crude RR 0.99 (95% CI 0.83 to 1.18) - Model 2 Adjusted OR 1.02 (95% CI 0.85 to 1.23) - Model 3 Adjusted OR 1.11 (95% CI 0.93 to 1.34)	from intervention): Unclear; as the study used population-based data, details of care in labour are not reported Blinding of those assessing outcomes: Unclear - no details given Missing data/loss to follow-up: 8.5% of initial study population had planned place of birth coded as 'unknown' Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: - NPA: 8.29% of planned home birth group and 10.25% of planned hospital birth group are women/babies outside the scope of the guideline (premature, congenital abnormality, SGA,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	< 19 Home: 3502 (0.96) Hospital: 5770 (3.04) 20-25 Home: 30787 (8.47) Hospital: 28669 (15.08) - 25-34 Home: 267408 (73.55) Hospital: 124071 (65.27) > 35 Home: 61871 (17.02) Hospital: 31588 (16.62) Gestational age/weeks (n (%)) a. Natural prospective approach < 34 Home: 2409 (0.60) Hospital: 1702 (0.78) 35-36 Home: 6510 (1.62) Hospital: 4064 (1.85) 37 Home: 15203 (3.77) Hospital: 9603 (4.38)		in retrospect were compliant with the guidelines, which defined low risk women at the onset of labour, and allowed them to choose between home and hospital birth under a midwife at the onset of labour. Non-compliance was present when a high risk condition was already present at the onset of labour: gestational age less than 37 weeks or more than 41 weeks, prolonged rupture of membranes (more than 24 hours), and intrauterine death with unclear timing relative to the onset of labour. 602331 women are included for this approach, which still includes undetected SGA and congenital malformations that		combination) - PGA: 6.09% of planned home birth group and 7.67% of planned hospital birth group are women/babies outside the scope of the guideline (congenital abnormality, SGA, combination) Other information Comparison: HOME vs. OU (hospital setting under the care of a midwife at the onset of labour) [This study is new since the 2007 guideline] The study population of this paper may overlap with another included study (De Jonge et al., 2009)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	38-41 Home: 368926 (91.56) Hospital: 193816 (88.46) > 41 Home: 9864 (2.45) Hospital: 9920 (4.53) b. Perfect guideline approach < 34 Home: 0 Hospital: 0 35-36 Home: 0 Hospital: 0 37 Home: 13622 (3.75) Hospital: 8468 (4.45) 38-41 Home: 349946 (96.25) Hospital: 181630 (95.55) > 41 Home: 0 Hospital: 0		emerge at birth. Data collection, analysis and monitoring Women meeting the inclusion criteria were identified from the Netherlands Perinatal Registry, which contains population based information for 96% of pregnancies. Data were collected by 95% of midwives, 99% of gynaecologists and 68% of paediatricians (100% of NICU paediatricians). The data were anonymised. Data on maternal risk factors were collected: parity (nulliparous vs. multiparous), age, ethnicity (Western vs. non-Western), and living in a deprived neighbourhood (yes or no, based on post codes).		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	'Big 4' (n (%)) a. Natural prospective approach Small for gestational age Home: 18786 (4.66) Hospital: 13114 (5.99) Premature Home: 8090 (2.01) Hospital: 5117 (2.34) Low Apgar Home: 1692 (0.42) Hospital: 1180 (0.54) Congenital abnormality Home: 4874 (1.21) Hospital: 2941 (1.34) Combination of above Home: 1648 (0.41) Hospital: 1279 (0.58) - Total Home: 35090 (8.71) Hospital: 23631 (10.79) b. Perfect guideline approach Small for gestational age Home: 17089 (4.70)		The authors report that the case mix of a population was defined by the presence of the 'Big 4', which represent a risk indicator: - Congenital abnormalities (list defined but not reported) - Intrauterine growth restriction (small for gestational age: birth weight below the 10th percentile for gestational age, gender, and parity-specific) - Low Apgar score (< 7 at 5 minutes) - Preterm birth (less than 37 completed weeks) T-tests were used to compare the NPA and PGA approaches by intended place of birth. Then, intended place of		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Hospital: 11604 (6.10) Premature Home: 0 Hospital: 0 Low Apgar Home: 1483 (0.41) Hospital: 959 (0.5) Congenital abnormality Home: 4366 (1.20) Hospital: 2531 (1.33) Combination of above Home: 693 (0.19) Hospital: 453 (0.24) Total Home: 23631 (6.50) Hospital: 15547 (8.18) In addition, the women who planned a home birth were more likely to be of Dutch origin and to live in a privileged neighbourhood. Inclusion criteria Women with a singleton		birth was investigated using predefined nested multivariable logistic regression models (stepwise analysis with inclusion $p < 0.05$ and exclusion $p > 0.10$) adding in maternal and neonatal explanatory variables. Hospital births was always set as the reference. Analyses were repeated both forward and backward, and then with forced inclusion of predictive variables. Model 2 adjusted for: - maternal factors including parity, age, ethnic background, neighbourhood Model 3 adjusted for: - maternal factors including parity, age, ethnic background, neighbourhood - gestational age		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	pregnancy under the supervision of a community midwife at the onset of labour (defined as spontaneous contractions or spontaneous rupture of membranes) Exclusion criteria Medium risk women, e.g. women with a history of postpartum haemorrhage (PPH) or obesity (BMI more than 30) Records with incomplete data [Note: higher risk women would have already been excluded because they would not be under the care of a community midwife at the onset of labour]		- presence of 'Big 4' Outcomes reported Intrapartum and early neonatal mortality: includes intrapartum death, neonatal death up to 24 hours, neonatal death from 1 to 7 days postpartum		
Full citation Waldenstrom,U., Nilsson,C.A., A randomized controlled study of birth center care versus standard maternity care: effects on women's health, Birth, 24,	Sample size N = 1860 Characteristics Age/years (average): 30 Length of gestation/years	Interventions Planned (booked) birth in a birth centre (alongside unit)	Details Setting Characteristics of birth centre: - Same premises for antenatal, intrapartum, and postpartum care	Results PERINEAL LACERATIONS Episiotomies (n/total (%)) Birth centre: 66/841 (7.9)*	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
17-26, 1997 Ref Id 125813 Country/ies where the study was carried out Sweden Study type Randomised controlled trial Aim of the study To evaluate the effect of birth centre care on women's health during pregnancy, birth, and 2 months postpartum by comparing them with women experiencing standard maternity care Study dates Expected date of birth among sample was between October 1989 and June 1993 Source of funding The Swedish National Delegation for Social	(average): 20 Length of education/years: 14 Native Swedes (%): 87 Nulliparous (%) Birth centre: 59 Control: 56 (p = 0.27) Note: At the beginning of the study (when the birth centre had just opened), women enrolled later in pregnancy than at the end, when more women were aware of it. Therefore, most women in the birth centre arm had made at least one standard antenatal care (ANC) visit before transferring to the birth centre. Only 18% received all their ANC in the birth centre. For further details of the study population, see entry in Waldenstrom et al., 1997	(n = 928) Planned (booked) birth in standard care (control group) (n = 932)	- Home-like environment - Same team of 10 midwives from early pregnancy to postpartum check-up - No doctor during labour - No pharmacological pain relief (epidural, pethidine, N20) available, no induction/augmentation, no EFM - ≤ 24 hours stay postpartum - Postpartum visits offered Characteristics of standard care: - Different premises for antenatal, intrapartum, and postpartum care - Hospital-like environment - Different midwives provide care from early pregnancy to postpartum check-up	Control: 69/815 (8.5) Difference (%): -0.6 (95% CI -3.3 to 2.0) p = 0.71 * This is as reported in the study; however, the correct % (given the numerator and denominator reported) is 7.847, therefore this is a rounding error Tears (n/total (%)) a. ALL Birth centre: 655/841 (77.9) Control: 621/815 (76.2) Difference (%): 1.7 (95% CI -2.4 to 5.7) p = 0.45 b. Clitoris/labia Birth centre: 236/841 (28.1)	Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No details given Blinding of outcome assessors: No details given Missing data/loss to follow-up: 16 of the birth centre group had a miscarriage at or before 22 weeks; 14 of the standard care group had a miscarriage at or before 22 weeks and 2 further were lost to follow-up before intrapartum care. For the 2 month questionnaire, 97% of birth centre arm and 93% of control group replied. However, it is unclear where the denominator for perineal lacerations is derived from, because it is greater than the denominator for 'vaginal births' but does not report excluding CS. Over 10% of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Research Swedish Medical Research Council Karolinska Institute Södersjukhuset, Stockholm	Inclusion criteria Willingness to participate and answer questionnaires At least one antenatal visit [Note: History of low birth weight, preterm birth, perinatal death or difficult vaginal delivery did not preclude participation. Women with previous caesarean section (CS) were accepted if their last birth was vaginal. For further details of the trial, see Waldenstrom et al., 1997] Exclusion criteria Complicating general condition (e.g. diabetes or hypertension) Drug abusers Women continuing to smoke during pregnancy		- Doctor at hand during labour - Pharmacological pain relief (epidural, pethidine, N20), induction/augmentation and EFM available The birth centre was one storey below the standard delivery ward. Recruitment and randomisation Randomisation took place at a visit to the birth centre once women had consented and completed a background questionnaire. Women were asked to pick an opaque envelope from a box; it was not possible for the woman or any member of the research team to predict allocation. Care protocol	Control: 244/815 (29.9) Difference (%) not reported c. Vagina Birth centre: 516/841 (61.3)† Control: 527/815 (64.7) Difference (%) not reported † This is as reported in the study; however, the correct % (given the numerator and denominator reported) is 61.355, therefore this is a rounding error d. Perineum Birth centre: 352/841 (41.9) Control: 351/815 (43.1)	women had data missing for this outcome, when the denominator is compared to the number randomised. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: 2.7% of birth centre arm and 4.6% of standard care arm had induction of labour; 1.9% of birth centre arm and 2.4% of standard care arm had elective CS; an unknown proportion of women had a previous CS, although they had to have a later vaginal birth to be included Other information Comparison: ALONGSIDE MLU vs. OU

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Birth centre Birth centre care was integrated antenatal, intrapartum, and postpartum care. During pregnancy, women could be referred for EFM or ultrasound scanning and then still continue with birth centre care, if the medical criteria were still fulfilled. Women were cared for in labour by midwives, who made their own decision about transfer based on the medical guidelines set up by the obstetricians with medical responsibility for the centre. - Standard care Separate teams of midwives saw women antenatally in community health centres, and during pregnancy women	Difference (%) not reported e. Anal sphincter Birth centre: 15/841 (1.8) Control: 13/815 (1.6) Difference (%) not reported Stitches (n/total (%)) a. Internal Birth centre: 514/841 (61.1) Control: 611/815 (75.0) Difference (%): -13.9 (95% CI -18.3 to -9.4) p < 0.001 b. External Birth centre: 343/841 (40.8) Control: 393/815 (48.2)	[This study reports the same trial as Waldenstrom et al., 1997; however, it has been included because it reports additional outcomes of interest. The trial was included in the 2007 guideline.] This study evaluates a package of care, from antenatal care onwards, not just intrapartum care. Women required physical transfer in the event of a complication requiring an obstetrician.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			routinely saw a doctor twice. Then different teams of midwives handled the normal births, although the obstetrician was usually available on the labour ward. Other midwives provided postnatal care. Data collection, analysis and monitoring No a priori sample size calculation is reported. The sample size was limited by the time limit for the trial, which was 3.5 years. Two women were lost to follow-up from the standard care group: 1 emigrated and the other withdrew from all participation. Eight records of intrapartum and postpartum care were also missing, 4 because of home births.	Difference (%): -7.4 (95% CI -12.2 to -2.7) p < 0.001 MATERNAL OUTCOMES IN THE FIRST 2 MONTHS AFTER BIRTH - REASONS FOR SEEKING MEDICAL CARE TOTAL SEEKING MEDICAL CARE - Outpatient Birth centre: 169/883 (19.1) Control: 154/853 (18) - Hospital care Birth centre: 12/883 (0.4) Control: 7/853 (0.8) The following detail the reasons for seeking medical care in the first 2 months. Where 'NR'	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Data about interventions and maternal/infant outcomes were extracted from case records. A questionnaire regarding maternal health was mailed at 2 months after birth. Analysis was by intention to treat; therefore, those women who were transferred or withdrew from the birth centre at their own request are included in the birth centre arm. All statistical tests were 2-sided. % differences were calculated with the normal approximation to the binomial function, with Yates' continuity correction. Student's t test was used to compare means, and this was checked with the Randomisation test for skewed data (there	is stated, this represents a gap in the table, where it is not clear whether this represents missing data or no events. Infections (n/total (%)) a. Endometritis - Outpatient Birth centre: 9/883 (1.0) Control: 11/853 (1.3) - Hospital care Birth centre: 2/883 (0.2) Control: 4/853 (0.5) b. Pyelonephritis - Outpatient Birth centre: 2/883 (0.2) Control: NR - Hospital care Birth centre: 2/883 (0.2)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			were no differences found in the results of the two tests). [Note: for further details of the trial protocol, see entry in Waldenstrom et al., 1997]	Control: NR c. Urinary tract infection - Outpatient Birth centre: 11/883 (1.2) Control: 9/853 (1.0) - Hospital care Birth centre: 1/883 (0.1) Control: NR d. Respiratory tract infection - Outpatient Birth centre: 16/883 (1.8) Control: 23/853 (2.7) - Hospital care Birth centre: NR Control: NR e. Fever - Outpatient Birth centre: 4/883 (0.5) Control: 4/853 (0.5)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Hospital care Birth centre: NR Control: NR f. Other infections - Outpatient Birth centre: 12/883 (1.3) Control: 11/853 (1.3) - Hospital care Birth centre: NR Control: NR Breast problems (n/total (%)) - Outpatient Birth centre: 26/883 (2.9) Control: 24/853 (2.8) - Hospital care Birth centre: 3/883 (0.3) Control: 1/853 (0.1) Bleeding, anaemia (n/total (%)) - Outpatient	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Birth centre: 19/883 (2.1) Control: 10/853 (1.2) - Hospital care Birth centre: NR Control: 1/853 (0.1) Problems relating to perineal or caesarean wounds (sutures, pain, infection) (n/total (%)) - Outpatient Birth centre: 13/883 (1.5) Control: 15/853 (1.8) - Hospital care Birth centre: NR Control: NR Low back problems, symphysiolysis or other orthopaedic problems (n/total (%)) - Outpatient Birth centre: 14/883	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(1.6) Control: 10/853 (1.2) - Hospital care Birth centre: NR Control: NR Anal problems, hemorrhoids (n/total (%)) - Outpatient Birth centre: 6/883 (0.7) Control: 5/853 (0.6) - Hospital care Birth centre: 1/883 (0.1) Control: NR Allergy/asthma (n/total (%)) - Outpatient Birth centre: 5/883 (0.6) Control: 4/853 (0.5) - Hospital care Birth centre: NR Control: NR	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Rest of fetal membranes/placenta (n/total (%)) - Outpatient Birth centre: 4/883 (0.5) Control: 2/853 (0.2) - Hospital care Birth centre: NR Control: NR Headache/dizziness (n/total (%)) - Outpatient Birth centre: 2/883 (0.2) Control: 1/853 (0.1) - Hospital care Birth centre: NR Control: NR Psychological problems (n/total (%)) - Outpatient Birth centre: 2/883 (0.2)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Control: 1/853 (0.1) - Hospital care Birth centre: NR Control: NR High blood pressure (n/total (%)) - Outpatient Birth centre: NR Control: 3/853 (0.3) - Hospital care Birth centre: NR Control: NR Cerebral infarction (n/total (%)) - Outpatient Birth centre: 1/883 (0.1) Control: NR - Hospital care Birth centre: 1/883 (0.1) Control: NR Herpes zoster (n/total (%))	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Outpatient Birth centre: 1/883 (0.1) Control: NR - Hospital care Birth centre: 1/883 (0.1) Control: NR Fatigue (n/total (%)) - Outpatient Birth centre: 1/883 (0.1) Control: NR - Hospital care Birth centre: 1/883 (0.1) Control: NR Surgery of bladder tumour (n/total (%)) - Outpatient Birth centre: NR Control: 1/853 (0.1) - Hospital care Birth centre: NR Control: 1/853 (0.1)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Other minor problems (n/total (%)) - Outpatient Birth centre: 21/883 (2.4) Control: 20/853 (2.3) - Hospital care Birth centre: NR Control: NR	
Full citation Waldenstrom,U., Nilsson,C.A., Winbladh,B., The Stockholm birth centre trial: maternal and infant outcome, British journal of obstetrics and gynaecology, 104, 410-418, 1997 Ref Id 104414 Country/ies where the study was carried out Sweden Study type Randomised controlled trial	Sample size N = 1860 Characteristics Age 'at confinement'/years (mean ± SD) Birth centre: 29.9 ± 4.5 Standard care: 29.9 ± 4.3 Parity (n (%)) - 1st Birth centre: 544 (58.6%) Standard care: 522 (56.0%) - 2nd Birth centre: 254 (27.4%) Standard care: 290 (31.1%)	Interventions Planned (booked) birth in a birth centre (alongside unit) (n = 928) Planned (booked) birth in standard care (n = 932)	Details Setting Characteristics of birth centre: - Same premises for antenatal, intrapartum, and postpartum care - Home-like environment - Same team of midwives from early pregnancy to postpartum check-up - 8-11 recommended visits to a midwife, with visit to a doctor only when indicated - No doctor during	Results Mode of birth (n/total (%)) a. Elective CS Birth centre: 17/912 (1.9) Standard care: 22/916 (2.4) % difference -0.5 (95% CI -1.9 to 0.8) p = 0.53 b. Emergency CS Birth centre: 48/912 (5.3) Standard care: 60/916 (6.5)	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: Not possible Blinding of staff providing care: No details given Blinding of outcome assessors: No details given Missing data/loss to follow-

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare an in-hospital birth centre with standard maternity care regarding medical interventions and maternal and infant outcome Study dates Expected date of birth among sample was between October 1989 and June 1993 Source of funding The Swedish National Delegation for Social Research Swedish Medical Research Council Karolinska Institute Södersjukhuset, Stockholm	- 3rd or more Birth centre: 130 (14.0%) Standard care: 120 (12.9%) Gestation at randomisation/weeks (mean ± SD) Birth centre: 20.1 ± 8.1 Standard care: 20.2 ± 7.9 Inclusion criteria Willingness to participate and answer questionnaires Resident of Greater Stockholm At least one partner in the couple Swedish speaking At least one antenatal visit [Note: history of low birth weight (LBW), preterm birth, perinatal death or difficult vaginal delivery did not preclude participation. Women with previous caesarean section (CS) were accepted if their last birth was vaginal]		labour - No pharmacological pain relief (epidural, pethidine, N20) available, no induction/augmentation, no electronic fetal monitoring (EFM) - Need for transfer in event of complication - ≤ 24 hours stay postpartum - Postpartum visits offered Characteristics of standard care: - Different premises for antenatal, intrapartum, and postpartum care - Hospital-like environment - Different midwives provide care from early pregnancy to postpartum check-up - 10-12 recommended visits to a midwife and 2 to a doctor - Doctor at hand during	% difference -1.2 (95% CI -3.5 to 0.9) p = 0.29 c. Vacuum extraction Birth centre: 36/912 (3.9) Standard care: 40/916 (4.4) % difference -0.5 (95% CI -2.3 to 1.4) p = 0.74 d. Forceps Birth centre: 0 Standard care: 1/916 (0.1) % difference -1.0 (95% CI NR) Episiotomy (n/total (%))* Birth centre: 66/847 (7.8) Standard care: 69/834 (8.3)	up: 16 of the birth centre group had a miscarriage at or before 22 weeks; 14 of the standard care group had a miscarriage at or before 22 weeks and 2 further were lost to follow-up. PPH, blood transfusion and episiotomy are only reported for women having a vaginal birth. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes, except method of assessing blood loss is not reported Intention-to-treat analysis performed: Yes Indirectness: 2.7% of birth centre arm and 4.6% of standard care arm had induction of labour; 1.9% of birth centre arm and 2.4% of standard care arm had elective CS; an unknown proportion of women had a previous CS,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Complicating general condition (e.g. diabetes or hypertension) Drug abusers Women continuing to smoke during pregnancy		labour - Pharmacological pain relief (epidural, pethidine, N20), induction/augmentation and EFM available - No need for transfer in event of complication - Mean 3-5 days stay postpartum - Postpartum visits offered by 2 out of 7 hospitals The birth centre was one storey below the standard delivery ward. Recruitment and randomisation Leaflets about the birth centre and the trial were distributed at the antenatal clinics in the Stockholm area. At a woman's first phone contact with the birth centre, an appointment was made and further information about the	% difference -0.5 (95% CI -3.3 to 2.0) p = 0.71 Measures of blood loss (n/total (%))* a. Postpartum haemorrhage > 600 ml Birth centre: 106/847 (12.5) Standard care: 106/834 (12.7) Difference -0.2 (95% CI -3.0 to 3.4) p = 0.96 b. Blood transfusion Birth centre: 6/847 (0.7) Standard care: 5/834 (0.6) % difference 0.1 (95% CI -0.7 to 0.9) p = 0.98	although they had to have a later vaginal birth to be included; 1.1% of birth centre arm and 1.3% of standard care arm were born premature; 2.9% of birth centre arm and 3.4% of standard care arm had malformations Other information Comparison: ALONGSIDE MLU vs. OU [This study was included in the 2007 guideline] This study evaluates a package of care, from antenatal care onwards, not just intrapartum care. Women required physical transfer in the event of a complication requiring an obstetrician. Details of possible

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			study was given. Eligible and consenting women were then asked to pick an opaque envelope from a box (note: 100 envelopes were prepared at a time, and then added to the box when there were a few left) Care protocol Birth centre Birth centre care was integrated antenatal, intrapartum, and postpartum care. During pregnancy, women could be referred for EFM or ultrasound scanning and then still continue with birth centre care, if the medical criteria were still fulfilled. Women were cared for in labour by midwives, who made their own decision about transfer	* vaginal birth only Use of epidural block (n/total (%))† Birth centre: 108/895 (12.1%) Standard care: 135/894 (15.1%) % difference -3.0 (95% CI -6.2 to 0.1) p = 0.07 † vaginal birth and emergency CS Perinatal death (n/total (%)) (defined as intrauterine death after 22 weeks and infant death within 7 days of birth) Birth centre: 8/912 (0.9%) Standard care: 2/916 (0.2%) OR 4.04 (95% CI 0.80 to 39.17)	avoidable factors in perinatal morbidity and mortality in the birth centre Morbidity Case 1: Woman was transferred from birth centre after 8 hours of labour with slow progress. EFM was deemed normal and woman received epidural block. 3 hours after transfer, vacuum extraction commenced due to signs of fetal distress and the baby was born 29 minutes later after the cup slipped twice. The baby suffered neonatal seizures and showed signs of brain damage at discharge. Early fetal scalp sampling and caesarean section might have improved outcome Case 2: Woman was transferred from the birth centre after 13 hours of labour, due to a

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			based on the medical guidelines set up by the obstetricians with medical responsibility for the centre. Standard care Approximately 75 community centres provided antenatal care, and 7 hospitals provided intrapartum and postpartum care. Women could select their own antenatal clinic and hospital. Midwives handled normal births, although the obstetrician was usually available on the labour ward. Transfer criteria If women gave birth outside of 37-43 weeks gestation, they were transferred. No further details are given. Data collection,	p = 0.11 More details about perinatal deaths in women randomised to birth centre (note: avoidable factors were identified in two of them, see 'other information'): 1. Reason for transfer was fetal death in utero before onset of labour; 26+1 weeks; birth weight 580 g; cause of death was toxoplasmosis 2. Reason for transfer was ruptured membranes; 24+4 weeks; birth weight 740 g; cause of death was immaturity, chorioamnionitis, intracranial haemorrhage grade II	deceleration. Labour had progressed very slowly. Oxytocin augmentation started 1.5 hours after transfer. Two FBS were normal. 4 hours after transfer, vacuum extraction was commenced due to maternal fatigue and weak contractions but was abandoned after four unsuccessful attempts. 10 minutes later the baby was delivered by CS. Mother and baby had convulsions, probably due to low plasma sodium. The mother recovered after 3 days in ICU, and baby after 1 month in neonatal care. Earlier transfer, earlier oxytocin, awareness of electrolyte imbalance, and possible earlier CS may have improved outcome. Case 3: In birth centre, labour progressed normally although fetal

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			analysis and monitoring No a priori sample size calculation is reported. The authors report that the project was initially funded for 2 years, and then extended for a further 1.5 years to increase power. They then report that this had 80% power to detect a reduction in CS from 10% in standard care to 6.3% in birth centre group, a reduction in epidural from 16% to 11.4% and an increase in neonatal transfers from 10% to 14.4%. Two women were lost to follow-up from the standard care group: 1 emigrated and the other withdrew from all participation. Eight hospital records were also missing, 4 because of home births.	3. Reason for transfer was fetal death in utero before onset of labour; 37 weeks; birth weight 2250 g; cause of death was unknown, suspected intrauterine growth restriction (IUGR) 4. Reason for transfer was fetal death in utero before onset of labour; 38+4 weeks; birth weight 3235 g; cause of death was cord complication 5. Reason for transfer was bradycardia, tense uterus; 39+4 weeks; birth weight 3315 g; cause of death was placental separation 6. Reason for transfer was fetal death in utero before onset of labour; 41+0 weeks;	head was not fixed in pelvic inlet on arrival. FHR was normal on auscultation. Baby was born with fine Apgar scores, but convulsions were seen within 24 hours and tomography showed a small bleed around the falx and subdurally at the tentorium edge. EFM may have given earlier information leading to a change in labour management. Mortality Case 4: Woman called birth centre in 40th week due to reduced movement in the previous 2 hours. There were no contractions or pain, but abdomen was slightly tense. The midwife advised her to call again if she continued to feel no movement. After 8 hours she called again and was advised to come in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Data about interventions and maternal/infant outcomes were extracted from case records. Information about background characteristics was collected from self-completed questionnaires completed at the first visit, prior to randomisation. Analysis was by intention to treat; therefore, those women who were transferred or withdrew from the birth centre at their own request are included in the birth centre arm. Individual cases of perinatal death and some serious morbidity are reported in more detail. The potential avoidable factors were evaluated by a	birth weight 3800 g; cause of death cord complication 7. Reason for transfer was intrapartum death in birth centre; 41+6 weeks; birth weight 3950 g; cause of death was unknown - suspected amniotic in folliculitis and urinary tract infection (UTI) 8. Reason for transfer was fetal death in utero before onset of labour; 42+2 weeks; birth weight 3330 g; cause of death was unknown, post-term More details about perinatal deaths in women randomised to standard care: 1. 37+0 weeks gestation; birth weight 2470 g;	immediately. Upon admission, fetal bradycardia and tense uterus were diagnosed and the woman was transferred Case 5: Infant died after the onset of labour in 42nd gestational week. The woman had come to the birth centre in early labour and after 3.5 hours the midwife was unable to hear a heartbeat. There was suspicion of amniotic folliculitis and UTI; EFM on admission might have altered the outcome. However, as the mother did not want the midwife to use a handheld ultrasound monitor, she might also have refused EFM.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			paediatrician and an obstetrician. All statistical tests were 2-sided. % differences were calculated with the normal approximation to the binomial function, with Yates' continuity correction. Student's t test was used to compare means, and this was checked with the Randomisation test for skewed data (there were no differences found in the results of the two tests).	cause of death was asphyxia (second twin) 2. 37 weeks gestation; birth weight 3570 g; cause of death was anencephaly Neonatal morbidity (n/total (%)) a. Serious neonatal morbidity, not caused by malformations or preterm birth Birth centre: 6/933 (0.6%) Standard care: 2/936 (0.2%) OR 3.03 (95% CI 0.54 to 30.72) p = 0.28 [Note: it is not reported what these morbidities are; however, possible avoidable factors	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				were identified in three cases, see 'other information'] b. Birth trauma Birth centre: 7/933 (0.8%) Standard care: 13/936 (1.4%) c. Intrauterine hypoxia and birth asphyxia Birth centre: 9/933 (1.0%) Standard care: 9/936 (1.0%) d. Convulsions Birth centre: 3/933 (0.3%) Standard care: 1/936 (0.1%) e. Infant respiratory distress syndrome Birth centre: 4/933 (0.4%) Standard care: 1/936 (0.1%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				f. Massive aspiration Birth centre: 1/933 (0.1%) Standard care: 3/936 (0.3%) g. Fetal and neonatal haemorrhage Birth centre: 1/933 (0.1%) Standard care: 1/936 (0.1%) h. Jaundice and/or haemolytic disease (phototherapy) Birth centre: 39/933 (4.2%) Standard care: 27/936 (2.9%) i. Feeding problems Birth centre: 4/933 (0.4%) Standard care: 4/936 (0.4%) j. Congenital	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				pneumonia Birth centre: 1/933 (0.1%) Standard care: 1/936 (0.1%) k. Other respiratory conditions Birth centre: 19/933 (2.0%) Standard care: 16/936 (1.7%) l. Suspected or confirmed septicaemia Birth centre: 9/933 (1.0%) Standard care: 6/936 (0.6%) m. Other infections Birth centre: 4/933 (0.4%) Standard care: 6/936 (0.6%) Admission to NICU in the first week after birth (n/total (%))‡	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				a. All babies Birth centre: 102/912 (11.18%) Standard care: 83/916 (9.06%) % difference 2.1 (95% CI -0.7 to 4.9) p = 0.13 ‡ this detail is reported in text, without a denominator; therefore, it has been assumed that the denominator is women randomised minus the miscarriages and two women lost to follow-up, which matches the % that have been reported in the text b. Excluding those with physiological jaundice as principal	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				diagnosis Birth centre: 76 (8.6%) Standard care: 71 (7.9%) p = 0.58 [Note: this was done because physiological jaundice in standard care was normally treated on the maternity ward] c. Subgroup analysis by parity The authors report that the pattern of transfer differed between primiparous and multiparous women. - Primiparous (%) Birth centre: 15.6 Standard care: 9.5 % difference 6.1	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(95% CI 2.1 to 10.1) p = 0.003 - Multiparous (%) Birth centre: 4.7 Standard care: 8.4 % difference -3.7 (95% CI -7.1 to 0.2) p = 0.04 Transfer Of the 928 women randomised to the birth centre, 890 remained after exclusion of early miscarriages and withdrawals. 762 women then started labour at the birth centre, and 586 women gave birth there: Withdrawals and transfers among primiparas (n = 544) and multiparas (n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				384) in the birth centre group (%): Withdrawals: 2.4% - Primiparas: 2.0 - Multiparas: 2.9 (p = 0.54) Miscarriage, abortion: 1.7% - Primiparas: 1.5 - Multiparas: 2.1 (p = 0.65) Antenatal transfer: 13.4% - Primiparas: 15.8 - Multiparas: 9.9 (p = 0.01) Home birth: 0.4% - Primiparas: 0.2 - Multiparas: 0.8 (p = 0.39) Intrapartum transfer: 19.0% - Primiparas: 29.4 - Multiparas: 4.2 (p < 0.001)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Actual birth centre birth: 63.1% - Primiparas: 51.1 - Multiparas: 80.2 (p < 0.001) Maternal postpartum transfer: 1.8% - Primiparas: 2.2 - Multiparas: 1.3 (p = 0.45) Reasons for transfer: - ANTENATAL (n (%)) Breech: 29 (3.3) High blood pressure, toxaemia: 20 (2.2) > 42 weeks: 20 (2.2) < 37 weeks: 11 (1.2) Growth retardation: 8 (0.9) Twins: 5 (0.6) Haemorrhage: 4 (0.4) Rhesus iso-immunisation: 3	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(0.3) Signs of fetal distress: 3 (0.3) Intrauterine death: 5 (0.6) Other causes: 16 (1.8) - INTRAPARTUM (n (%)) Failure to progress in labour (including 24 hours of ruptured membranes without regular contractions): 88 (9.9) Fetal distress: 45 (5.1) Analgesia; 39 (4.4) Other causes: 4 (0.4) - POSTPARTUM (n (%)) Retained placenta: 5 (0.6) Sphincter damage: 5 (0.6) Haemorrhage: 4	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(0.4) Small baby: 2 (0.2) Perineal haematoma: 1 (0.1)	
Full citation Woodcock,H.C., Read,A.W., Bower,C., Stanley,F.J., Moore,D.J., A matched cohort study of planned home and hospital births in Western Australia 1981-1987., Midwifery, 10, 125-135, 1994 Ref Id 174688 Country/ies where the study was carried out Australia Study type Retrospective cohort with matching Aim of the study To evaluate practice comparing planned home birth with planned hospital birth	Sample size N = 3904 Characteristics Parity (%)) Nulliparous Home: 41.9 Hospital: 41.9 Parity 1 or 2 Home: 48.2 Hospital: 48.1 Parity 3 or more Home: 9.9 Hospital: 10.0 Age/years (mean) Home: 28.5 Hospital: 28.4 Height/cm (mean) Home: 164.3 Hospital: 164.2	Interventions Planned (booked) home birth (n = 976) Planned (booked) hospital birth (n = 2928)	Details Selection of study groups Planned home birth A planned home birth was a birth where the mother booked antenatally with a registered midwife or medical practitioner for a home birth, regardless of whether the booking was later changed to hospital. Therefore, both antenatal and intrapartum transfers are included. The births included were singleton planned home births - 7 multiple births and 19 births with major congenital malformations were excluded, leaving 976 births.	Results Note: adjusted ORs are adjusted for birth weight and gestational age Mode of birth (n/total) a. 'Normal' vaginal Home: 865/976 Hospital: 1787/2928 Crude OR 1.00 Adjusted OR 1.00 b. Operative vaginal Home: 61/976 Hospital: 679/2928 Crude OR 0.15 (95% CI 0.11 to 0.20) Adjusted OR 0.14 (95% CI 0.10 to 0.18)	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear, because there were differences in the proportions of women with complications of pregnancy and medical conditions. The authors report in methodology that they adjusted for this difference; however, the figures are not presented. Groups comparable at baseline: Matching was generally successful. The main difference was in the proportion of women with complications or medical conditions, as a result of the fact that they were analysed by 'booked' place of birth Groups received same/similar care (apart

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates 1981 - 1987 Source of funding Australian National Health and Medical Research Council	Complications of pregnancy (%)* Home: 10.3 Hospital: 28.6 * These included minor and major conditions. 22 (2%) of women in home birth group and 310 (11%) of women in hospital group had hypertension. Medical conditions (%)† Home: 2.4 Hospital: 9.1 † These ranged from minor (e.g. carpal tunnel syndrome, allergic rhinitis) to serious (endocrine disorders, cardiovascular conditions) Breech or other non-cephalic presentation (%) Home: 2.3 Hospital: 4.6 Previous stillbirth (%) Home: 0.8 Hospital: 0.8		Planned hospital birth A birth planned to occur in hospital. The matched cohort of planned singleton hospital births was selected by computer from the births occurring during the study period, which were not home births. The aim of matching was to ensure women were as similar as possible with regard to their risk status (see below for matching criteria). Three babies were selected for each planned home birth. The hospital births were also only chosen if their gestation at birth was equal to or greater than gestation at 'booking' of home birth. This was needed because only 24% of home births had booked with a midwife	c. Emergency caesarean section (CS) Home: 36/976 Hospital: 203/2928 Crude OR 0.27 (95% CI 0.18 to 0.40) Adjusted OR 0.25 (95% CI 0.17 to 0.38) d. Elective CS Home: 6/976 Hospital: 221/2928 Crude OR 0.05 (95% CI 0.02 to 0.11) Adjusted OR 0.06 (95% CI 0.03 to 0.14) e. Assisted breech Home: 8/976 Hospital: 38/2928 Crude OR 0.37 (95% CI 0.17 to	from intervention): Unclear, as it was a population based study Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: Precise definition of outcomes: Yes. Valid and reliable method of outcome assessment: Because of the way that data were coded in the Midwives' Notification system, women that were transferred needed to be identified using the transferred form, as they would be recorded as a hospital birth. The authors report being confident that few, if any, transfers were not identified; however, this cannot be guaranteed. Similarly, the authors report that home birth and hospital birth midwives report some variables

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Previous death of live born child (%) Home: 1.5 Hospital: 1.5 Inclusion criteria Singleton births, planned either at home or in hospital Exclusion criteria Multiple birth Congenital malformations		by 20 weeks, and the authors wanted to excluded the potential bias of an excess of preterm births in the hospital groups. The following matching criteria were used: - year of birth: exact year, +/- 1 or 2 years if necessary - parity: 0, 1, 2, 3+ - previous stillbirth: yes, no - previous death of live born child: yes, no - maternal age: 5 year groups for ages 20-39, exact age if < 20 or ≥ 40 - maternal height: < 160 cm, 160-165 cm, > 165 cm - marital status: married, defacto/single - postcode: area of maternal residence in Western Australia	0.83) Adjusted OR 0.56 (95% CI 0.25 to 1.27) [Note: All of the ORs have also been converted to compare to a reference odds of normal vaginal birth; however, it is not clear how they did this conversion] Postpartum haemorrhage (PPH) (n/total) Home: 64/976 Hospital: 46/2928 Crude OR 4.29 (95% CI 2.92 to 6.30)* Adjusted OR 3.83 (95% CI 2.59 to 5.66)* * relative to a reference of	differently, such as definitions of 'normal' and PPH (method of assessing blood loss is not reported) Intention-to-treat analysis performed: Yes Indirectness: - 10.3% of home birth group and 28.6% of hospital birth group had complications of pregnancy; however, some could have been minor. 2.4% of home birth group and 9.1% of hospital birth group had medical conditions, but again, some were not serious. 2.3% of home birth group and 4.6% of hospital birth group were breech or other non-cephalic presentation - 22/976 (2.3%) of home birth group and 776/2928 (26.5%) of hospital birth group had induction of labour - 6/976 (0.6%) of home birth group and 221/2928

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			(Note: Maternal height was not recorded for 42 (4%) planned home births, so they were randomly distributed between the three height groups. Similarly, gestation at booking was unknown for 10% of home births and they were randomly assigned according to the known distribution of home births) Setting/care protocol No details given, as it is a population based study Transfer criteria No details given, as it is a population based study Data collection, analysis and monitoring Data were collected from the following sources:	absence of PPH Third degree tear (n/total) Home: 2/976 Hospital: 11/2928 Crude OR 0.55 (95% CI 0.12 to 2.46)† Adjusted OR 0.54 (95% CI 0.12 to 2.49)† † relative to absence of third degree tear Birth trauma (n/total) Home: 23/976 (2.4%) Hospital: 207/2928 (7.1%) Crude OR 0.31 (95% CI 0.20 to 0.48) Adjusted OR 0.28 (95% CI 0.18 to 0.44)	(7.5%) of hospital group had an elective CS - 34/976 (3.5%) of home birth group and 160/2928 (5.5%) of hospital birth group were preterm (not significantly different) Note: 1025/3904 (26.3%) of the study population had induction of labour or an elective CS Other information Comparison: HOME vs. OU [This study was included in the 2007 guideline]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Midwives' home birth records: kept by midwives for every woman who booked with them for a home birth. This contained details of medical history, antenatal care, labour, birth and postnatal care - Midwives' Notification of Case Attended Form 2 - statutory form completed by the midwife attending every live or stillbirth in Western Australia, regardless of location - Western Australia Maternal and Child Health Research Database: contained all data from the Midwives' Notification System, linked to birth certificates, the Birth Defects Registry, and to perinatal and infant death certificates. Cause of death coding	[Note: most cases of birth trauma were recorded as 'injuries to scalp'] Perinatal mortality (n/total) a. Stillbirth Home: 2/976 Hospital: 11/2928 b. Neonatal mortality Home: 3/975 Hospital: 1/2928 c. Total Home: 5/976 [5.1 per 1000] Hospital: 12/2928 [4.1 per 1000] Crude OR 1.25 (95% CI 0.44 to 3.55) Adjusted OR 3.00 (95% CI 0.93 to 9.66) [Note: In the planned home	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			was carried out by one person, based on death certificate, Notification Form and information on birth defects, and was done without knowledge of place of birth. Particular emphasis was placed on identifying transfers, from the Health Department of Western Australia Transfer Forms. This was because the way that data were recorded meant that, where women had been transferred, the Midwives Notification System rec orded them as a hospital birth. The records needed to be linked with the transfer data. Crude and adjusted	birth group - cause of death was unknown for one antepartum stillbirth and the other stillbirth was due to infection with Listeria monocytogenes - of the three neonatal deaths, one was due to infection, one was due to low birth weight and one was due to sudden infant death syndrome In the planned hospital group: - six of the eleven stillbirths had an unknown cause. Three were attributed to maternal hypertension, one to antepartum haeomorrhage (APH) and one to cord compression	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			odds ratios were calculated for planned home births compared with planned hospital births. Odds ratios were calculated relative to the expected 'normal value' for each outcome. Adjusted ORs were adjusted for birth weight and gestational age (as continuous variables), and further for the presence of any recorded pregnancy complications and maternal medical conditions. All analyses were by intention to treat. [Note: although the authors report that they adjusted for all of the above, they later report that presence of complications and medical conditions made only small differences to the ORs	- the cause of death for the neonatal death was recorded as obstetric trauma] Admission to special care nursery (n/total (%)) Home: 13/976 (1%) Hospital: 219/2928 (8%) Post-neonatal death (n/total) Home: 1/976 Hospital: 9/2928 Crude OR 0.33 (95% CI 0.04 to 2.63) Adjusted OR 0.44 (95% 0.55 to 3.53) [Note: Sudden infant death syndrome (SIDS) was recorded as cause of death for 7/9 hospital deaths and the other	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			and therefore the figures are not included. Therefore, the reported ORs are only adjusted for birth weight and gestational age] Outcomes reported 1. Mode of birth 2. Postpartum haemorrhage: ≥ 500 ml 3. Third degree tear 4. Perinatal death: stillbirth of at least 20 weeks gestation or 500g birth weight, or the death of a live born baby within 28 days of birth (neonatal death) [Note: babies of < 500 g (n = 1) were excluded] 5. Admission to special care nursery 6. Post-neonatal death: death of a live born	two were late infant deaths due to infection and 'other causes'. No details about the home birth death are given] Transfer Of the 976 planned home births, 791 (81%) actually occurred at home. The remainder were transferred: - antenatally: 48/976 (4.9%) - first stage of labour: 113/976 (11.6%) - second stage of labour: 24/976 (2.5%) - third stage of labour: 14/976 (1.4%) - postnatal transfers of women: 16/976 (1.6%) - postnatal transfers	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			baby between 29 days and one year of age	of baby: 16/976 (1.6%) Note: two births in the planned hospital group occurred at home.	

1.1.2 Maternal and neonatal outcomes associated with different birth settings? HEALTH ECONOMICS

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
Full citation Schroeder,E., Petrou,S., Patel,N., Hollowell,J., Puddicombe,D., Redshaw,M., Brocklehurst,P., Birthplace in England Collaborative Group., Cost effectiveness of alternative planned places of birth in woman at low risk of complications: evidence	Study dates April 2008 to April 2010 Intervention Home birth setting Alongside midwifery units Freestanding midwifery units Comparison(s)	Source of effectiveness data Birthplace in England national prospective cohort study Source of cost data Interviews were conducted with the regional lead midwives (Liverpool Women's Hospital NHS Foundation Trust, Oxford Radcliffe Hospital NHS Trust, Taunton and Somerset NHS Trust, Kings College Hospital NHS Foundation Trust, Barts and the London Trust) for 'bottom up'	Time horizon and discount rate Duration of follow-up of the Birthplace prospective cohort study. Women were identified at the start of their care in labour and follow-up was complete when the intrapartum and related postnatal care for both	Cost per patient per alternative The total mean costs per low risk woman planning birth at the start of care in labour were: £1631 for an obstetric unit £1461 for an alongside midwifery unit £1435 for a free standing midwifery unit £1067 for the home	Limitations No long term costs or benefits were included in the analysis. Therefore the results were not presented as an incremental cost per QALY. CNST insurance costs would not be considered in economic evaluations developed for NICE as

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
from the Birthplace in England national prospective cohort study, BMJ, 344, e2292-, 2012 Ref Id 273056 Economic study type Cost effectiveness analysis Country(ies) where the study was done UK Perspective & Cost Year Health system 2009/10 Source of funding National Institute for Health Research Service Delivery and Organisation programme, and the Birth at Home in	Obstetric unit	costing. 'Top down' costing was used to collect overhead costs such as management and administrative costs, operational costs, and capital costs. Proportional use of other hospital services such as screening, haematology and pathology, were also included. The authors developed a model to calculate trust overheads apportioned to intrapartum care. The Healthcare Commission's review of maternity services was used to generate running costs, bed days, occupancy rates, numbers of women delivering and intrapartum transfers. Other data sources e.g. transition probabilities none	mother and baby ended. This time horizon included higher level postnatal or neonatal care but did not include the life-long health effects due to morbidities associated with labour and birth. No discount rate needed Method of eliciting health valuations (if applicable) not applicable Modelling approach Economic evaluation with individual level data from the Birthplace national prospective cohort	The total mean costs per low risk women without complicating conditions at the start of care in labour: £1511 for an obstetric unit £1426 for an alongside midwifery unit £1405 for a free standing midwifery unit £1027 the home Effectiveness per patient per alternative Nulliparous women at low risk of complications, adverse perinatal outcome avoided Compared to the obstetric unit: Home -0.004 (-0.008 to -0.00001) FMU 0.0008 (-0.002 to 0.003) AMU 0.0005 (-0.003 to 0.003) Nulliparous women without	damages paid include legal costs as well as costs of care. Also, there may be a payment to reflect the loss of quality of life, which would lead to double counting when QALYs are also included in the model. In this analysis neither long-term costs nor effects were included and so there would not be double counting. However, the CNST costs are added to staff time and so are applied to all births regardless of whether the woman or baby experiences an adverse event. Therefore, it is not clear if adding these insurance costs will reflect the downstream obstetric litigation costs.

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
England study funded by the Department of Health Policy Research Programme			study	complications, adverse perinatal outcome avoided Compared to the obstetric unit: Home -0.006 (-0.011 to -0.002) FMU -0.001 (-0.004 to 0.0012) AMU -0.00099 (-0.0041 to 0.0013) Multiparous women at low risk of complications, adverse perinatal outcome avoided Compared to the obstetric unit: Home 0.001 (-0.0004 to 0.0025) FMU 0.0005 (-0.0015 to 0.0024) AMU 0.0007 (-0.001 to 0.003) Multiparous women without complications, adverse perinatal outcome avoided	The authors placed the results within the context of the configuration of the maternity services included in the Birthplace study and the time horizon of the study. The authors acknowledged that both costs and cost-effectiveness reported may change if maternity services are reconfigured. The authors state that planning changes to maternity services in order to maximise cost-effectiveness based on these results for intrapartum care would require commissioners to consider the resource use and related cost implications on the maternity service as a

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
				Compared to the obstetric unit: Home 0.0005 (-0.0008 to 0.0019) FMU 0.0003 (-0.0015 to 0.002) AMU -0.00009 (-0.00196 to 0.00162) All women at low risk of complications, maternal morbidity avoided Compared to the obstetric unit: Home 0.195 (0.187 to 0.204) FMU 0.172 (0.168 to 0.182) AMU 0.116 (0.106 to 0.126) All women at low risk of complications, normal birth Compared to the obstetric unit: Home 0.300 (0.290 to 0.310) FMU 0.256 (0.245 to 0.268)	whole. The economic modelling required to do this requires forecasting of occupancy rates, overheads, patient safety and transfer with consideration of fixed and variable costs, and disinvestment from one form of maternity service in preference of another. Other information

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
				AMU 0.184 (0.173 to 0.194) Incremental cost-effectiveness Nulliparous women at low risk of complications, adverse perinatal outcome avoided Compared to the obstetric unit: Home £69,761 FMU -£98,136 AMU -£47,995 Nulliparous women without complications, adverse perinatal outcome avoided Compared to the obstetric unit: Home £39,178 FMU £30,169 AMU £1631 Multiparous women at low risk of complications, adverse perinatal outcome avoided	

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
				Compared to the obstetric unit: Home -£323,037 FMU -£128,134 AMU -£119,618 Multiparous women without complications, adverse perinatal outcome avoided Compared to the obstetric unit: Home -£315,420 FMU -£92,180 AMU £47,222 All women at low risk of complications, maternal morbidity avoided Compared to the obstetric unit: Home -£3,024 FMU -£1,442 AMU -£1,322 All women at low risk of complications, normal	

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
				birth Compared to the obstetric unit: Home -£1,960 FMU -£956 AMU -£836 Other reporting of results Uncertainty At a £20,000 cost effectiveness threshold for avoiding an adverse perinatal outcome, for low risk nulliparous women without complicating conditions there was a 0.80 probability of home birth being the most cost effective option and a 0.16 probability of free standing midwifery units being the most cost effective option. For multiparous low risk women without complicating conditions planned home birth had a 100% probability of being	

Bibliographic details	Intervention and Comparison	Data sources	Time horizon & Method	Results	Reviewer comment
				the most cost effective option across all thresholds of cost effectiveness.	

1.1.3 Women's experiences and views of different birth settings

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Waldenstrom,U., Nilsson,C.A., Experience of childbirth in birth center care. A randomized controlled study, Acta Obstetricia et Gynecologica Scandinavica, 73, 547-554, 1994 Ref Id 104295 Country/ies where the study was carried out Sweden Study type Randomised controlled trial	Sample size N = 1230 Planned birth centre care n = 617 Planned obstetric care n = 613 Characteristics Age - mean (SD not reported) Birth centre care = 29.9 years Obstetric care = 29.7 years Nulliparous	Interventions The birth centre offered integrated antenatal, intrapartum and postnatal care, all in the same premises. Expectant parents were cared for by the same team of midwives from outset of pregnancy, throughout the birth and up	Details Women interested in birth centre care received an information folder from the local antenatal clinic or from the birth centre describing the trial, procedure and reasons for random allocation. At first telephone contact a midwife checked that women met the inclusion criteria. If accepted, the woman met a research	Results Recollection of birth 2 months post-birth Experience of birth: mean score (SD not reported), N 1 = very negative, 7 = very positive Nulliparous Birth centre care = 5.5 (SD not reported), 334 Obstetric care = 5.3 (SD not reported), 290 Multiparous Birth centre care = 6.3 (SD not reported), 255 Obstetric care = 6.1	Limitations Access to the birth centre was only through participation in the trial; two months after the birth 321/547 (52%) women in the control group were more or less disappointed by allocation to obstetric care (> 1 on 7-point scale) To check for bias caused by disappointment, authors compared results for these women with control group women who were not in the least disappointed (1 on 7-point scale). No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To evaluate the effects of birth centre care on women's experience of childbirth, including their behaviour regarding the use of analgesia Study dates October 1989 – January 1992 Source of funding Supported by grants from the Swedish National Delegation for Social Research, F 88/42:2 and the Swedish Medical Research Council B89-27X-8701-01A and the South Hospital	Birth centre care = 57% Obstetric care = 53.7% Inclusion criteria Willingness to participate in research project with random allocation and to answer three questionnaires, residence in greater Stockholm area and at least one member of each couple had to speak Swedish. Exclusion criteria Disease or risk factor that might significantly complicate the birth or jeopardise the baby's health, including diabetes, twin pregnancy, toxaemia, drug abuse and smoking	to two months after birth. The birth centre encouraged natural birth and pharmacological pain relief was only available in the case of transfer to standard delivery ward, located one storey above the birth centre. Electronic fetal monitoring and sonography was not available in the birth centre. During pregnancy women could be referred for fetal monitoring or ultrasound scan and continue with birth centre care. The birth centre had home-like birthing rooms with own	assistant and gave consent to participation. Randomisation was by sealed opaque envelopes. Women completed three questionnaires: on their first visit to the birth centre, before randomisation, concerning background characteristics and demographic details; one month before term, concerning antenatal care; two months after expected date of birth, concerning experiences of care received during birth and postpartum. A response rate of 93% was achieved (birth centre care =	(SD not reported), 259 Satisfaction with own achievement: mean score - 1 = very dissatisfied, 7 = very satisfied Nulliparous Birth centre care = 6.4 (SD not reported), 334 Obstetric care = 6.1 (SD not reported), 290 (p = 0.01) Multiparous Birth centre care = 6.5 (SD not reported), 255 Obstetric care = 6.5 (SD not reported), 259 Involvement in process of birth: mean score - 1 = not at all involved, 7 = very involved Nulliparous Birth centre care = 6.4 (SD not reported), 334 Obstetric care = 6.2 (SD not reported), 290	statistical differences were found, apart from women disappointed with allocation experienced less midwife support (p < 0.001) and felt less free to express their feelings during the birth (p = 0.01) than women who felt no disappointment. Other information There is a second publication of this study included in this evidence table (Waldenstrom, U., Nilsson, C.-A. 1993. Women's satisfaction with birth center care. Birth 20: 3-13). Birth centre opened October 1989 as the first in the greater Stockholm area and from opening was part of a clinical trial. It was not possible to obtain birth centre care outside of the trial. Women who had participated in the trial could

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	during the current pregnancy.	bathrooms and partners could remain at the centre. Standard obstetric care was split into antenatal care in neighbourhood antenatal clinics, intrapartum care on hospital delivery wards and postpartum care on hospital postpartum wards. Midwives assisted at all normal births, and many complicated births, under the supervision of an obstetrician.	593/617, 96%; obstetric care = 555/613, 91%).	(p = 0.03) Multiparous Birth centre care = 6.7 (SD not reported), 255 Obstetric care = 6.6 (SD not reported), 259 Freedom in expression of feelings: mean score - 1 = not at all free, 7 = completely free Nulliparous Birth centre care = 6.5 (SD not reported), 334 Obstetric care = 6.1 (SD not reported), 290 (p = 0.003) Multiparous Birth centre care = 6.5 (SD not reported), 255 Obstetric care = 6.3 (SD not reported), 259 (p = 0.01) Anxiety during birth: mean score - 1 = not at all anxious, 7 = very anxious	return to the birth centre with a subsequent pregnancy. Definition of women in obstetric care group who were disappointed with allocation and the method for assessing bias due to disappointment with allocation to obstetric care differ to that used in the second publication (Waldenstom & Nilsson, 1993). Birth centre care results comprise scores of women who gave birth in the birth centre and women who transferred out of the birth centre before, during or after birth, or who withdrew from birth centre care voluntarily. (Intention-to-treat analysis.) Transfers out of birth centre care Withdrawals at own request (primarily because they changed their mind about analgesia in labour, or

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Nulliparous Birth centre care = 2.8 (SD not reported), 334 Obstetric care = 2.9 (SD not reported), 290 Multiparous Birth centre care = 2.2 (SD not reported), 255 Obstetric care = 2.2 (SD not reported), 259 Support from midwife: mean score - 1 = none at all, 7 = much support Nulliparous Birth centre care = 6.1 (SD not reported), 334 Obstetric care = 5.3 (SD not reported), 290 ($p < 0.001$) Multiparous Birth centre care = 6.2 (SD not reported), 255 Obstetric care = 5.5 (SD not reported), 259 ($p < 0.001$)	preferred a home birth): 20/617 (3.2%); nulliiparous = 8/352 (2.3%), multiparous = 12/265 (4.5%) Antenatal transfers: 77/617 (12.5%); nulliparous = 52/352 (14.8%), multiparous = 25/265 (9.4%) Intrapartum transfers: 108/617 (17.5%); nulliparous = 96/352 (27.3%), multiparous = 12/265 (4.5%) Post-birth transfers: 7/617 (1.1%); nulliparous = 4/352 (1.1%), multiparous = 3/265 (1.1%)
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Dahlen,H.G., Barclay,L.M., Homer,C.S., The novice birthing: theorising first-time mothers' experiences of birth at home and in hospital in Australia, Midwifery, 26, 53-63, 2010 Ref Id 116217 Country/ies where the study was carried out Australia Study type Qualitative - in-depth interviews Aim of the study To explore the experience of a small group of first-time mothers giving birth at home and in hospital, and to investigate the implications of the findings for maternity services Study dates Not reported Source of funding Not reported	N = 19 Birth at home n = 8 Birth at tertiary referral public hospital n = 8 Birth at private hospital n = 1 Birth at birth centre n = 2 Characteristics Age - mean (SD not reported) All = 19–37 years Home birth = 30 years Hospital birth = 25 years Nulliparous 17/19 (89%) Inclusion criteria Not reported Exclusion criteria Not reported	Home birth and hospital birth	Women were recruited using purposive and theoretical sampling approaches. Women were identified in the postnatal ward of a large tertiary referral hospital and asked to consent to be interviewed 6 weeks later. Women who had home births were contacted by their independent midwives and asked if they could be approached to participate. Each potential participant was given information on the study and a consent form signed. Only one woman (hospital birth) who was approached chose not to participate. Interviews were conducted between 6 and 26 weeks after	Preparation Home birth midwives prepared women for all aspects of the birth experience. This helped familiarise women in ways that better equipped them to face the unknown and reduced fear. The hospital group generally felt less empowered, less familiar and less well equipped to handle the unknown and talked about fear much more as a consquence. Choice and control Importance of choice and control was often talked about by both groups of women: "Without choice there's no feeling of control or participation... your personality becomes	Women who had given birth at home were generally interviewed a few weeks later than those who had given birth in hospital, as they were more difficult to access. Only 2/19 women were multiparous. There were siginificant differences in socioeconomic status (details not reported), age and antenatal preparation between home birth and hospital birth women. Role of the researcher not adequately described. Other information One home birth woman was transferred to hospital and had a forceps delivery; all women who have birth in hospital, except for one forceps delivery, had normal vaginal births. Author reports study found to be credible by other women experincing first births and

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			the birth (mean 15 weeks), in the women's homes, and lasted from 20 minutes to 3 hours. They were audiotaped and transcribed. Open-ended questions were asked, altering as the analysis emerged. Key open-ended questions began each discussion, for example "tell me about your birth experience". Grounded theory approach was adopted, which aims to discover the dominant themes and develop a conceptual framework that underpins theorising. Transcripts were broken down in to lines, phrases and paragraphs and these	irrelevant. You're just a thing that's popping a baby out. It's all a very technical exercise... Because once your body takes over you're already losing control in one sense anyway... The last thing you need is to have everything else in your environment make you feel that way. I couldn't control anything (hospital birth)." In contrast (except for one woman) the home birth women felt in control of their births: "I suppose to put it one way, it's your turf and someone else is coming onto your ground. They respect that... At home they're just willing to do whatever you want to	their midwives.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			discrete concepts labelled. Labels consisted of words used by the women to ensure their original meaning was maintained. Similar concepts were examined, compared and grouped in to categories. Data collection and analysis continued until categories were saturated and no new concepts were obtained. The next step examined causal conditions and the context in which categories were embedded, the intervening conditions, termed "mediating factors" (these influenced activity), and the consequences.	do as long as you and your baby are fine and well. So I think you feel a lot more confident and a lot more 'at home being in your home' (home birth)". Information and communication Lack of communication was the area most negatively reported. The ability to communicate with a midwife helped develop a trusting relationship: "If we'd shown up with an emotional something happening she would have been available to us, and so for me that trust expanded into the pregnancy and into the birth and into that period afterwards	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(home birth)". Good communication reduced fear: "They explained everything to me and they sort of got me through it. So I didn't feel scared during that part at all (hospital birth". Poor communication increased fear: "The baby's heart went down and as soon as the baby's heart went down everyone came running in and it gave me a heart attack. I thought Oh God! What has happened? The baby is going into distress (hospital birth)". Two women in the home birth group made negative	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				comments about their midwives: "So if I was to make a comment on anything about the support that I received from [the midwife] it was just not fully understanding or getting an explanation of exactly sort of what happened in that area (home birth)". "I ended up going back inside. I felt very invalidated and then thought I'm not going to say any more about how I'm feeling (home/hospital birth)." Support Women valued quiet support more than technical expertise and the directive demeanour of some midwives: "It's interesting when I think back of how unobtrusive the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				midwives were, they were definitely there. But I don't feel like I got a whole barrage of directions from her at all (home birth)". Some women discussed a lack of support: "I was just sitting there looking at this machine watching the baby's heart beat. Just laying there, not knowing what was happening. Midwives would come in and out (hospital birth". Women who felt unsupported became fearful: "I sort of felt lonely. I was sort of lying there and I did not have anyone to sort of say you know, 'don't worry, this is what actually happens'... I	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				was just lying there trying to be brave. I didn't make any screaming or noises. It was just a bit sort of frightening and then if I'd had someone there with me I wouldn't have felt as sort of scared because it's more that I was on my own (hospital birth)". Midwives 'honouring' the birthing woman Birth setting was not the most important factor in women's birth experiences, rather it is the care received: "She [hospital midwife] was fantastic and she was the one who gave me every opportunity and honoured me to do exactly what I wanted to do to deliver a baby. My hospital experience was very different to what I	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				imagined and really good. When I think back to my birth, that's the part I feel good about. I felt empowered. I felt supported and I felt like I was acutally in control (home/hospital birth)."	
Full citation Christiaens,W., Gouwy,A., Bracke,P., Does a referral from home to hospital affect satisfaction with childbirth? A cross-national comparison, BMC Health Services Research, 7, 109-, 2007 Ref Id 116748 Country/ies where the study was carried out Belgium/The Netherlands Study type Prospective cohort study Aim of the study Assess the influence of the	Sample size N = 592 Expected home, actual home = 163 Expected home actual hospital = 100 Expected hospital, actual hospital = 268 Other referrals = 61 Characteristics Age - mean 31 years Nulliparous 45.8% Inclusion criteria	Interventions In the Netherlands, if pregnancy and labour take a normal course, women can give birth at home accompanied by a midwife and/or general practitioner or they may choose to have a short stay in a birth clinic or hospital under supervision of the same primary caregivers. In	Details Women were invited by their midwife or obstetrician to participate through 5 hospitals and 27 midwifery practices in two cities with comparable sociodemographics (Ghent, Belgium and Tilburg, The Netherlands). Questionnaires were completed within the first 2 weeks after delivery and were returned to the	Results When comparing women who gave birth at the place they intended to, home births were consistently more satisfying than hospital births on all dimensions of satisfaction (total and general satisfaction P < 0.001). Women who had been referred from home to hospital reported lower general satisfaction scores (P	Limitations Researchers relied on health professionals at participating hospitals to distribute questionnaires. It is unclear whether the questionnaires were selectively distributed - the authors report that not all questionnaires were distributed. Estimates of response rate, using number of questionnaires distributed as denominator, range between 68% and 19% for the hospitals and 100% and 38% for midwifery practices. Authors do not clearly describe the questionnaire used to measure

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
discrepancy between expected and actual place of delivery on satisfaction with childbirth Study dates September 2004 – September 2005 Source of funding Not reported	Speak and understand Dutch, over 18 years of age Exclusion criteria Not reported	case of difficulties during pregnancy or labour women are referred to hospital. There is a high referral rate, 70% of Dutch women start with antenatal care in primary care, only 30% actually have a home birth. Community-based midwives can continue to provide care in hospital unless specialist care is needed, hence intrapartum continuity is mostly guaranteed. In Belgium there is no formal boundary between primary and secondary	midwife or obstetrician in a closed envelope. Dutch women with a home birth returned questionnaires directly to the researcher by mail. Women who delivered in hospital for the most part completed the second questionnaire during the postpartum stay. Women with a short stay returned questionnaires by mail. The Mackey Childbirth Satisfaction Rating Scale was used to measure satisfaction (physician-related items were omitted). Authors estimated a linear regression model. Subdimensions of satisfaction were total,	= 0.001) compared with women who planned a hospital birth. However, transfer to hospital was "inconsequential" in terms of other subdimensions of satisfaction. The "disadvantage" of being referred to the hospital when a home birth was expected was smaller in Belgium than in the Netherlands. Belgian women referred to hospital during pregnancy or labour had higher satisfaction scores than Belgian women who planned to give birth in hospital and did. The opposite was true in the Netherlands.	satisfaction. Other information Table 2 details numbers for planned and actual place of birth by country and parity. Numbers add up to give a total of 592 participants (Dutch = 332, Belgian = 260). In Results authors report number of cases in analysis as 563 (605 women completed questionnaires but 42 excluded from analysis due to incomplete data).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		care, consequently the majority of of Belgian women go straight to an obstetrician for antenatal care. The percentage of hospital births is approximately 99%. Because the number of women planning a home birth is low, most hospitals do not have arrangements with independent midwives for women who are referred to hospital (as in the Netherlands), hence referred women are handed over to hospital staff and intrapartum continuity is	general, self, baby, midwife, partner.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		reduced.			
Full citation Janssen,P.A., Carty,E.A., Reime,B., Satisfaction with planned place of birth among midwifery clients in British Columbia, Journal of Midwifery and Women's Health, 51, 91-97, 2006 Ref Id 117070 Country/ies where the study was carried out Canada Study type Prospective matched cohort study Aim of the study To compare satisfaction with the birth experience among women planning birth at home versus in hospital Study dates January 1998 – December 1999	Sample size N = 800 Home birth n = 670 (550 returned questionnaires) Hospital birth n= 130 (108 returned questionnaires) Characteristics Age - mean ± SD Home birth = 30.2 years ± 5.4 Hospital birth = 31.0 years ± 5.3 Nulliparous - n/N (%) Home birth = 255/550 (47.6%) Hospital birth = 60/108 (56.1%) Inclusion criteria Eligibility requirements for planned homebirth	Interventions Planned (at the onset of labour) midwife-attended births at home compared with planned (at the onset of labour) midwife-attended births in hospital	Details All women planning a homebirth in the province of British Columbia during the study period were required by legislation to enroll in the Home Birth Demonstration Project. All midwives in British Columbia were provided with a questionnaire and pre-adressed and stamped envelope to hand to their clients after the birth. The hospital group consisted of women planning a hospital birth at the onset of labour who also met the eligibility requirements for homebirths established by the College of Midwives of	Results Satisfaction within 6 weeks postpartum "Overall, how satisfied with childbirth experience?" 5-point scale: 1 = never, 5 = always Mean ± SD, N Home birth = 4.87 ± 0.42, 550 Hospital birth = 4.80 ± 0.49, 108 Total Labour Agentry Scale score within 6 weeks postpartum 29 items in total, 7-point scale on each item therefore highest possible score = 203 Mean ± SD, N Home birth = 188.49 ± 16.85, 550 Hospital birth = 176.60 ± 23.79, 108 Labour Agentry Scale	Limitations Home birth group response rate = 64%; hospital birth group response rate = 83% Hospital birth group were only recruited during the latter 50% of the study period. Questionnaires may have been selectively distributed: in the home birth group, 670/862 (77.7%) of eligible women received a questionnaire from their midwife. In the hospital group, 130/142 eligible women received a questionnaire from their midwife. Proportion of nulliparous women was lower in the group planning home birth. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Health Transition Fund, Health Canada	(established by College of Midwives of British Columbia) included singleton fetus, cephalic presentation, term gestation (> 36 and < 42 completed weeks) and no more than one previous caeserean delivery. Women in the hospital group had to meet the eligibility requirements for planned homebirth. Exclusion criteria Pre-existing serious medical conditions (e.g. cardiac or renal disease, insulin-dependent diabetes, proteinuric pre-eclampsia or eclampsia, symptomatic placental abruption or placenta previa or		British Columbia were given questionnaires only in the last 6 months of the study period. (Only the evaluation of homebirth was funded by the Ministry of Health and the limited discretionary funds of the study authors were used to recruit the hospital comparison group.) The questionnaires were completed prior to 6 weeks postpartum and mailed to the coordinator of the Home Birth Demonstration Project if a home birth or to one of the study investigators if a hospital birth. The Labour Agentry Scale is a	within 6 weeks postpartum 7-point scale: 1=almost always, 7=rarely Mean score ± SD, N I felt competent Home birth = 1.44 ± 0.83, 550, Hospital birth = 1.98 ± 1.14, 108 p < 0.001 I felt very responsible Home birth = 1.31 ± 0.70, 550 Hospital birth = 1.85 ± 1.19, 108 p < 0.001 I felt secure Home birth = 1.35 ± 0.85, 550 Hospital birth = 1.73 ± 1.31, 108 p = 0.001 I felt relaxed	Authors state 441/550 (80.2%) of women planning home birth actually gave birth at home. They report mean Labour Agentry and satisfaction scores for 104 women who transferred from home birth to hospital. 441+104 = 545, not the 550 women who planned a home birth and returned study questionnaires. Reasons for transfer were not reported. Coding was reversed on positively worded items on the Labour Agentry Scale, so that a positive response was reflected in a higher score on all items of the scale. Authors report the observed 0.5 to 1 point changes observed on a majority of Labour Agentry Scale items is equivalent to a 7% to 14% relative difference. Authors

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	active genital herpes)		standardised 29-item scale for measurement of expectancies and experiences of personal control during childbirth. A response rate of 82% was achieved (home birth = 550/670, 82%; hospital birth = 108/130, 83%).	Home birth = 2.20 ± 1.43, 550 Hospital birth = 3.45 ± 1.87, 108 p < 0.001 I experienced a sense of success Home birth = 1.30 ± 0.85, 550 Hospital birth = 1.66 ± 1.30, 108 p = 0.002 I felt incapable Home birth = 6.59 ± 0.98, 550 Hospital birth = 6.00 ± 1.42, 108 p < 0.001 I experienced a sense of great anxiety Home birth = 6.38 ± 1.21, 550 Hospital birth = 5.89 ± 1.51, 108 p < 0.001	comment that this "may or may not be a difference of clinical relevance".

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				I felt powerless Home birth = 6.61 ± 0.94, 550 Hospital birth = 6.17 ± 1.33, 108 p < 0.001 I experienced a sense of conflict Home birth = 6.66 ± 0.98, 550 Hospital birth = 6.52 ± 0.94, 108 p = 0.21 I felt fearful Home birth = 6.33 ± 1.25, 550 Hospital birth = 5.71 ± 1.55, 108 p < 0.001 I had a sense of not being in control Home birth = 6.21 ± 1.41, 550 Hospital birth = 5.93 ± 1.52, 108 p = 0.004	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				I had a feeling of being confined Home birth = 6.73 ± 0.81, 550 Hospital birth = 6.53 ± 0.98, 108 p = 0.001 Total Labour Agentry Scale scores by acutal place of birth - mean ± SD, N 7-point scale: 1 = almost always, 7 = rarely - mean score ± SD, N Planned home, actual home = 191.67 ± [unclear in paper], 441 Planned hospital, actual hospital = 173.71 ± 24.89, 87 p < 0.001 Planned home, actual hospital = 177.58 ± 22.17, 104 Planned hospital,	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				acutal home = 188.56 ± 13.66, 20 p = 0.035 Overall satisfaction with childbirth experience by acutal place of birth 5-point Likert scale: 1 = never, 5 = always - mean ± SD, N Planned home, actual home = 4.95 ± 0.20, 441 Planned hospital, actual hospital = 4.75 ± 0.53, 87 p < 0.001 Planned home, actual hospital = 4.56 ± 0.66, 104 Planned hospital, acutal home = 5.00 ± 0, 20 p < 0.001	
Full citation Coyle,K.L., Hauck,Y., Percival,P., Kristjanson,L.J.,	Sample size Birth centre n = 17	Interventions Birth centre care compared with	Details A convenience sample of women from all	Results Birth centre themes	Limitations Sample was self-selecting - women eligible for the study

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ongoing relationships with a personal focus: mothers' perceptions of birth centre versus hospital care, Midwifery, 17, 171-181, 2001 Ref Id 125421 Country/ies where the study was carried out Australia Study type Qualitative - in-depth interviews Aim of the study To describe women's perceptions of care in Western Australian birth centres following a previous hospital birth Study dates November 1996 – April 1997 Source of funding Nurses Board of Western Australia, Edith Cowan University and the Olive Anstey Nursing Fund	Characteristics Age 22 – 34 years Nulliparous 0/17 (0%) Previous birth in hospital 17/17 (100%) Inclusion criteria (1) Attended a minimum of five antenatal visits by birth centre midwives during their pregnancy (2) Had a midwife care for them in labour who had conducted at least two of their antenatal visits (3) Experienced a normal birth (4) Had been discharged home within 24 hours of	previous hospital birth	three Western Australia birth centres was selected. In one birth centre women who met selection criteria were invited to participate, by a midwife not involved in the study, prior to discharge. Women in the other two birth centres were recruited from a larger cohort of mothers participating in a longitudinal birth study in Western Australia. Those women meeting selection criteria for the current study were telephoned and invited to particpate. Interviews were conducted by the prinicpal investigator, lasted between 45 and 90 minutes, and were conducted at 2-4 months postpartum in	Cumulative care interactions - women comfortable with carers Communication was facilitated as a result of being cared for by a familiar midwife (women were cared for in labour by a midwife they had met at least twice during pregnancy). Care provision by a 'known' midwife resulted in women being able to focus their energy and attention on the birth process instead of having to spend time developing a relationship with an unknown carer: "... with the last two babies I knew the midwives and all I had to do was concentrate on myself and the labour. I think that is what causes a lot of	chose birth centre care and by the nature of the selection criteria achieved an uncomplicated birth. Being influenced by such birth experiences may have limited the variability of data and influenced analysis of theme dimensions; women's previous hospital experiences will likely have impacted their choice for birth centre care for subsequent deliveries. Other information There is a second publication of this study included in this evidence table (Coyle, K., et al. 2001. Normality and collaboration: mothers' perceptions of birth centre versus hospital care. Midwifery 17: 182-93) which reports the themes 'beliefs about pregnancy and birth' (carer's non-interventionist/interventionish) and 'care interactions'.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	the birth (5) Had previously given birth to a baby in a hospital setting (6) Were available for interview 2 or 4 months after the birth of their baby (7) Had not had any part of their pregnancy care provided by the principal investigator Exclusion criteria Not reported		the women's homes. Interviews explored women's perceptions of both their most recent care experiences and previous hospital experiences. A semi-structured interview guide with open-ended questions and prompts was developed. This was not rigidly adhered to, allowing the interviewer to explore issues as they emerged. Modified grounded theory was adopted to guide the study, which allows important categories and themes to emerge from the data without prior assumptions. Data were analysed from transcribed interviews. Units of	pain during labour, your mind is elsewhere thinking about other things rather than what you are actually doing". Women were also more likely to trust and listen to familiar midwives. The closeness of their relationship with known carers had a positive impact on the woman's birth experience: "So I just think that besides having your mum and your husband there who you can lean on, you also feel like a closeness with the midwife as well. It is a bond. You can't explain what that feels like. I really like it I think that is the way it should be comparing	21 women were invited to participate, four declined the offer and saturation was achieved after 17 interviews. One woman had previously had a home birth, as well as a previous hospital birth. In the full guideline this study is referred to as Coyle et al., 2001b.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			analysis were sentences, phrases or paragraphs. Significant meanings of these units were then coded and categorised in to groups. Analysis began and continued through the interview process, each interview was transcribed as soon as possible after the interview and coded throughout data collection.	with other births". Cumulative care interactions - women being known Women felt they were known by their midwife (women were cared for in labour by a midwife they had met at least twice during pregnancy). Women found it beneficial to be cared for by someone who knew their history and past experiences: "She [midwife] knew what I had been going through with the first pregnancy and the birth. She knew everything, what I was scared of and all of those things. She knew exactly what I wanted, I didn't have to tell her." Known midwives were	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				able to determine how much support individual women needed. Some required minimal physical input from the midwife, other women needed a large amount of physical and psychological support. Being known by the midwife also facilitated participants' perception of their ability to be in control of their birth experience: "Having met her [midwife] before and discussing what we would like to have happen and the feeling that she was putting me back in control, that really made a big difference. Rather than the doctor being in charge".	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				For many women, control over the birth experience was directly linked to the presence of known carers. One participant described her feelings when she was facing transfer to hospital for induction of labour after having all her pregnancy care in the birth centre: "... it was an absolutely enormous issue for me that I would be transferred out... I would lose control... [being care for by] people I hadn't met and didn't know". Care structures - personalised care and 'seeing me through' Many participants described how they felt their care was adjusted to suit them individually:	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				"Everything went at its own pace. I didn't feel things were pushed on us... it was very very nuturing care... there was no such thing as the system taking over". When women felt their specific needs were being met they interpreted their care as being personalised. Women had one midwife carer for the duration of labour. Women felt this had a positive effect on their experience: "... that was what she [midwife] said to me at my visits 'whoever is with you will be with you that entire time. We are not going to leave you, there will the that same person there the whole time'. Like I say, when I look	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				at it that made all the difference in being able to concentrate..." Hospital setting themes Non-cumulative care interactions - lack of rapport Many particpants received care throughout labour from unfamiliar carers. Some women described carers they did not know as strangers whose presence was a source of anxiety: "It would have been nice to have everyone around you that you knew, not just your family... rather than all these strangers around and then they change and you get more strangers coming in. It's a bit scary...".	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Experiencing a lack of trust was also mentioned by some participants when care was provided by unfamiliar carers: "with the main hospital, when I had my first baby and the people I didn't know, I was thinking to myself: 'Did I really want to listen to them?' I wanted to do my own thing but then again they were saying 'no, no, no, you have to do this' and I really ddin't want to do that...". Non-cumulative care interactions - women being unknown Participants were often encouraged to write a birth plan, but in many cases written birth plans seemed to have minimal impact	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				as a tool to assist women inform unfamiliar carers of their birth preferences: "Actually, they sent out a questionnaire to your home and you filled it out and that allowed you to list all the choices and preferences you wanted. But when I actually went in it was never referred to and I remember thinking later, I can't remember specifically what happened, but I remember going home and thinking that they didn't even look at the care plan I had written". Care structures - systemised care and fragmented labour care Many women perceived that the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				organisational structure of the hospital setting dictated the type of care they received, they felt they were 'just a number' in a large system. The hospital's inability to offer choices resulted in women perceiving care as inflexible and impersonal: "With my first child that is what I had. This is what we've got, this is what you get. I didn't like that because I didn't have a choice. I just turned up for the experience". The hospital shift system often resulted in women being exposed to multiple carers within a short time frame: "I liked the first lot and	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				I was just starting to get used to them and then all of a sudden, I had an epidural, went to sleep a bit, woke up and I had different ones, and it was like, oh OK".	
Full citation Christiaens,W., Verhaeghe,M., Bracke,P., Childbirth expectations and experiences in Belgian and Dutch models of maternity care, Journal of Reproductive and Infant Psychology, 26, 309-322, 2008 Ref Id 164237 Country/ies where the study was carried out Belgium/The Netherlands Study type Prospective cohort study Aim of the study To assess the association between expectations and the experience of birth as	Sample size N = 611 Number of women planning home birth and planning hospital birth not reported Number of women with acutal home and actual hospital birth not reported Characteristics Age - mean 31.2 years Nulliparous 54.2% Inclusion criteria	Interventions Planned home birth and planned hospital birth	Details Women were invited by their midwife or obstetrician to participate through 5 hospitals and 27 midwifery practices in two cities with comparable sociodemographics (Ghent, Belgium and Tilburg The Netherlands). One questionnaire at 30 weeks of pregnancy and one questionnaire at 2 weeks postpartum. They were returned to the midwife or	Results Women planning to give birth at home had lower W-DEQ scores compared to women planning for a hospital birth (OR = 1.38 P < 0.001) [lower scores are better] Women with a home birth had more optimistic expecations and their birth experience was even more positive than expected. Women who did not give birth at the planned place had a	Limitations Researchers relied on health professionals at participating hospitals to distribute questionnaires. It is unclear whether the questionnaires were selectively distributed - the authors report that not all questionnaires were distributed. Estimates of response rate, using number of questionnaires distributed as denominator range between 68% and 19% for the hospitals and 100% and 38% for midwifery practices. Intention-to-treat analysis was not reported. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
determined by the kind of care and the type of caregiver chosen Study dates September 2004 – September 2005 Source of funding Not reported	Speak and understand Dutch, over 18 years of age Exclusion criteria Not reported		obstetrician in a closed envelope. Dutch women with a home birth returned questionnaires directly to the researcher by mail. Women who delivered in hospital for the most part completed the second questionnaire during the postpartum stay. Women with a short stay returned questionnaires by mail. The Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ version A and B) is a validated instrument (in Dutch) with 33 items which are 'statements concerning intensities of emotions and magnitude of cognitions regarding delivery'. Lower	more negative experience: they increased [made worse] the postnatal appraisal score of women planning a homebirth and decreased [made better] the postnatal appraisal score of women planning a hospital birth. Taking the actual instead of planned place of birth in to account lowers [improves] the postnatal W-DEQ score for women who actually had a home birth and heightens scores for women who had a hospital birth, resulting in a larger discrepancy between expectations and reality for home births and a smaller discrepancy for hostpial births.	None

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			scores indicate a positive appraisal of birth experience. Authors used a linear mixed model to explore the relationship between expectation and experience.		
Full citation Overgaard,C., Fenger-Gron,M., Sandall,J., The impact of birthplace on women's birth experiences and perceptions of care, Social Science and Medicine, 74, 973-981, 2012 Ref Id 164852 Country/ies where the study was carried out Denmark Study type Prospective cohort study with matched control group Aim of the study To compare women's birth	Sample size N = 436 Freestanding midwifery unit n = 218 Obstetric unit n = 218 Characteristics Age - n/N (%) ≤ 30 years Freestanding midwifery unit = 110/185 (59.5%) Obstetric unit = 113/190 (59.5%) ≥ 30 years	Interventions Freestanding midwifery units The two freestanding midwifery units were converted from small maternity units and in a style less home-like than typical freestanding midwifery units, although some "softening" of colours and decor had been done. Efforts were	Details All women admitted to one of the two studied freestanding midwifery units were invited to participate. For each freestanding midwifery unit participant a control was participant was identified among the low-risk women intending to give birth in the nearest obstetric unit. Women were prospectively included at the start of care in labour. Matching was done on following criteria: low-	Results Statistically significant outcomes (p < 0.0000) Mean score (SD not reported), N 1=unacceptable, 6=optimal Overall birth experience Freestanding midwifery unit = 5.5 (SD not reported), 185 Obstetric unit = 5.0 (SD not reported), 190 (Values imputed = 21%)	Limitations Non-randomised design; factors relating to women's self-selection of birth setting and potential confounding factors are unknown. Other information No differences in parity, age, and BMI were found between responders and non-responders. Smokers, women without post-secondary education, or low employment level were significantly less willing to respond. Any difference in response rates between the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
experiences, care satisfaction and perception of specific patient-centred care elements in two freestanding midwifery units versus two obstetric units and to explore the influence of specific medical and sociodemographic factors on women's birth experience Study dates January 2006 – October 2006 Source of funding Augustinus Foundation, Obel Family Foundation, Oticon Foundation, University College North Jutland Research and Development Fund, and the Danish Association of Midwives	Freestanding midwifery unit = 75/185 (40.5%) Obstetric unit = 77/190 (40.5%) Nulliparous - n/N (%) Freestanding midwifery unit = 42/185 (22.7%) Obstetric unit = 45/190 (23.7%) Inclusion criteria Low-risk women; healthy with straightforward pregnancies as outlined by NICE intrapartum care guideline (2007) Exclusion criteria Not reported	made to make women and their birth companions feel at home and use all the unit's facilities such as the kitchen and common room. Ambulation and the use of water and music for pain relief/relaxation were encouraged. The units were staffed by community midwives working in flexible shifts in a team model and generally providing one-to-one care during labour. In case of complications women/infants were transferred to the nearest obstetric unit	risk status, parity, smoking, body mass index, age, ethnicity, educational level, occupation and co-habitation status. Data were collected by postal questionnaire distributed 28 days after birth. Sociodemographic and medical data were collected from medical records. Women were introduced to the study by project staff via telephone on the day the questionnaire was mailed. Women consented to participation when returning the questionnaire. Respondents were encourage to give a chronological account	Care satisfaction Freestanding midwifery unit = 5.7 (SD not reported), 185 Obstetric unit = 5.3 (SD not reported), 190 (Values imputed = 21%) Support from midwife Freestanding midwifery unit = 5.7 (SD not reported), 182 Obstetric unit = 5.4 (SD not reported), 190 (Values imputed = 23%) Midwife present when wanted Freestanding midwifery unit = 5.7 (SD not reported), 182 Obstetric unit = 5.4 (SD not reported), 189 (Values imputed = 23%) Attention to	two groups did not result in an unequal distribution of socio-demographic characteristics in respondents. It is assumed that intention-to-treat analysis was performed, as the authors do not state that women who experienced transfer were excluded from the analysis. The authors do state, regarding transfer, "No subgroup analysis was performed due to the small number of cases." Authors used Bonferroni method to correct for multiple comparisons, level of significance adjusted to P < 0.0025. Outcomes where > 30% of missing values were imputed to allow matched data anaylsis are not presented in the evidence summary

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		located 25-30 min away. Obstetric units The two supporting obstetric units were the region's specialist maternity units, offering 24-hour service for epidural analgesia, acupuncture and use of water tub for pain relief/water birth. Birthing rooms equipped with a labour bed as a central featureand some had "soft" colours. Electronic fetal monitoring was only used in case of complications. One-to-one care and continuous	of their perceptions and to ponder all aspects of their birth experience before assessing their overall experience and satisfaction with care. Questionnaire was tested for validity and revised through pilot studies. A response rate of 86% was achieved (375/436; freestanding midwifery unit = 185/218, 85%, obstetric unit = 190/218, 87%). Groups were compared using Wilcoxon's sign-rank test for paired continuous data. For incomplete pairs, the missing part was imputed using a logistic or ordered	psychological needs Freestanding midwifery unit = 5.4 (SD not reported), 177 Obstetric unit = 4.9 (SD not reported), 180 (Values imputed = 28%) Feeling of being listened to Freestanding midwifery unit = 5.4 (SD not reported), 180 Obstetric unit = 5.0 (SD not reported), 188 (Values imputed = 24%) Level of information Freestanding midwifery unit = 5.4 (SD not reported), 183 Obstetric unit = 4.9 (SD not reported), 187 (Values imputed = 22%) Participation in	chapter. Responses in both groups skewed towards very positive scores; supplementary analysis performed where scores were dichotimised as 'optimal' (score of 6) and 'all other scores (score of 5 or less). Scores were compared using McNemar's test and multiple imputation of missing data, results were consistent with primary analysis. Transfers out of freestanding midwifery unit A total of 21 women were transferred but only 16 of those women returned questionnaires. Of those 16 returning questionnaires, 11/185 women were transferred during labour, 5/185 were transferred < 2 hours after birth.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		support were generally not provided until late in the first stage of labour.	logistic regression model on the outcome of the observed party. The findings were compared with the findings of a supplementary complete-case analysis, performed on fully observed pairs, to check for concordance. All primary ordinal outcomes were dichotomised into optimal score (6) and all other scores (1 - 5), and the two sub-groups were compared using McNemars test for for paired binary data which allowed for the calculation of odds ratios and confidence bands.	decision making Freestanding midwifery unit = 5.4 (SD not reported), 176 Obstetric unit = 5.0 (SD not reported), 180 (Values imputed = 29%) Consideration of birth wishes Freestanding midwifery unit = 5.6 (SD not reported), 107 Obstetric unit = 4.9 (SD not reported), 120 (Values imputed = 66%) Non-statistically significant outcomes Mean score (SD not reported), N Midwife's suggestions for pain relief - 6-point scale 1=unacceptable, 6=optimal (p = 0.0038) Freestanding	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				midwifery unit = 5.3 (SD not reported), 106 Obstetric unit = 4.7 (SD not reported), 120 (Values imputed = 66%) Loss of control over labour/reactions - 5-point scale 0 = no loss, 4 = control lost all through birth (p = 0.031) Freestanding midwifery unit = 0.1 (SD not reported), 179 Obstetric unit = 1.2 (SD not reported), 190 (Values imputed = 24%) Loss of control over staff actions - 5 point scale 0 = no loss, 4 = control lost all through birth (p = 0.0061) Freestanding midwifery unit = 0.2 (SD not reported), 181	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Obstetric unit = 0.5 (SD not reported), 188 (Values imputed = 24%)	
Full citation Hundley,V.A., Milne,J.M., Glazener,C.M., Mollison,J., Satisfaction and the three C's: continuity, choice and control. Women's views from a randomised controlled trial of midwife-led care, British Journal of Obstetrics and Gynaecology, 104, 1273-1280, 1997 Ref Id 168440 Country/ies where the study was carried out UK Study type Randomised controlled trial Aim of the study To compare women's satisfaction with care and delivery in a midwife-managed delivery unit with that in a consultant-led labour ward	Sample size N = 2844 Midwife-managed unit n = 1900 Consultant-led labour ward n = 944 Characteristics Age - mean (years) ± SD Midwife-managed unit = 28 ± 4.4 Consultant-led labour ward = 28 ± 4.5 Nulliparous - n/N (%) Midwife-managed unit = 929/1674 (56%) Consultant-led labour ward =	Interventions The midwife-managed unit consisted of five single rooms in a separate unit located 20 yards from the consultant-led labour ward. The philosophy of care behind the unit is to provide a safe, 'homely' environment where women can retain choice and control in the management of their labours.	Details At booking, women identified as low risk were randomised to deliver in either the midwife-managed unit or the consultant-led labour ward. Allocation of 2:1 in favour of the midwife-managed unit was used due to expected transfer of women with complications from the unit to the consultant-led labour ward. Women were given a questionnaire on discharge from the hospital. Women who did not respond by 3 weeks after delivery were sent a second copy of the	Results Overall satisfaction - median (interquartile range) Women asked to grade overall satisfaction with experience on scale of 0 to 10; 0 = thoroughly unsatisfied, nothing good to be said about it, 10 = an absolutely wonderful experience that could not have been better Midwife-managed unit = 8.0 (7 to 9) Consultant-led labour ward = 8.0 (7 to 9) Satisfaction - n/N (%) No statistically significant difference in satisfaction between groups.	Limitations Of the 2844 women randomised, 266 women did not receive questionnaires (9%), as a result of loss to follow-up, requested alternative location for delivery, omitted due to staff error, neonatal death or stillbirth, mulitple pregnancy and delivery before arrival at hospital. Other information Antenatal care of all women in the study was identical to that received by other women booking at local maternity hospital. Statistical significance was reduced from 5% to 0.1% using Bonferroni correction to take account of the large

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates October 1991 — December 1992 Source of funding Scottish Office Department of Health	451/789 (57%) Inclusion criteria Low risk women booking for delivery in general practictioner units Exclusion criteria Low risk women who requested domino deliveries (because they were a self-selecting group who had care given by one midwife throughout the antenatal and intrapartum period)		questionnaire. Women not returning questionnaires by 6 weeks after delivery were reminded by telephone. A response rate of 95% was achieved (97% in midwife-managed unit and 93% in consultant-led labour ward).	"Do you feel your labour and delivery was managed by the staff as you liked it in every way?" Midwife-managed unit = 1291/1654 (78.1%) Consultant-led labour ward = 564/768 (73.4%) "Do you feel your labour and delivery was managed by the staff as you liked it in some ways but not others?" Midwife-managed unit = 342/1654 (20.7%) Consultant-led labour ward = 193/768 (25.1%) "Do you feel your labour and delivery was managed by the staff not as you liked it at all?"	number of variables tested. Intention-to-treat analysis was performed.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Midwife-managed unit = 21/1654(1.3%) Consultant-led labour ward = 11/768 (1.4%) Control No statistically significant difference in involvment in labour management decisions (midwife-managed unit = 92.3%, consultant-led labour ward = 90.6%, p = 0.2). Statistically significant difference in decision about type of pain relief to use (p < 0.001): "How was the decision made about the type of pain relief to use?" - n/N (%) Own decision Midwife-mananged unit = 894/1616 (55.3%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Consultant-led labour ward = 384/765 (50.2%) Happy to follow staff's advice Midwife-mananged unit = 594/1616 (36.8%) Consultant-led labour ward = 275/765 (36.0%) No involvement in decision Midwife-mananged unit = 116/1616 (7.2%) Consultant-led labour ward = 100/765 (13.1%) 'Other' Midwife-mananged unit = 12/1616 (0.7%) Consultant-led labour ward = 6/765 (0.8%) Choice	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Few women in either group reported being given a choice as to the way their baby's heartbeat was monitored (midwife-managed unit = 88/1429, 6.2%, consultant-led labour ward = 73/741, 9.9%). Where women wanted to move and change position 70.7% (663/937) in the midwife-led unit and 62.8% (239/380) in the consultant-led labour ward were able to do so most of the time. Most common reasons for restricted mobility was woman attached to monitor, drip or epidural infusion (midwife-managed unit = 22.2%, consultant-led labour ward = 30.3%, p < 0.001). 34 women in the midwife-	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				managed unit reported that they were unable to move because they were told to keep still. Majority of women happy with position for delivery (midwife-managed unit = 79%, consultant-led labour ward = 79.4%).	
Full citation Stone,P.W., Maternity care outcomes: assessing a nursing model of care for low-risk pregnancy, Outcomes Management for Nursing Practice, 2, 71-75, 1998 Ref Id 174690 Country/ies where the study was carried out Unclear (likely USA) Study type Propsective cohort study Aim of the study To compare freestanding birth centre (FSBC) model of care to	Sample size N = 146 Freestanding birth centre n = 69 Traditional (physician) care setting n = 77 Characteristics The authors report that generally, the women were educated, married, Caucasian women in their middle to late 20s who had private insurance coverage and were generally multiparous. They	Interventions Planned birth in a freestanding birth centre Planned birth in traditional care setting	Details Women in both study groups all met the same low-risk birth centre eligibility criteria at 34-36 weeks, based on health assessment data in the medical record. (note: criteria for judging low risk are not reported.) The study was conducted in a rural region.	Results Satisfaction Access - 6-point scale 1 = poor 6 = excellent Mean ± SD, N Freestanding birth centre = 22.3 ± 3.2, 57 Traditional care = 19.2 ± 4.7, 55 (P ≤ 0.001) Nursing care - 6-point scale 1 = poor 6 = excellent Mean ± SD, N Freestanding birth centre = 27.8 ± 3.6, 57 Traditional care = 27.3	Limitations Postpartum questionnaires were anaylsed for 57/69 (83%) women in the freestanding birth centre group and 55/77 (71%) women in the traditional care group Characteristics of included women not adequately reported Transfer not reported Unclear how comparable 'traditional physician care' is with usual obstetric care in the UK

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
traditional maternity care with regards to clinical outcomes, cost and satisfaction Study dates Not reported Source of funding NINR training grant #F31 NR-07048-01	also report that there were no significant differences in any sociodemographic variables measured between the two groups. Inclusion criteria Low risk and birth centre eligible at 34-36 weeks English speaking, reading and writing Exclusion criteria Not reported		In the freestanding birth centre certified nurse-midwives provided prenatal and childbirth care. In the traditional care setting physicians provided care. Outcomes were measured at 34-36 weeks gestation and then again at 6 weeks postpartum. Other data were extracted from the prenatal and childbirth medical records. The Patient Judgement of Hospitality Quality (PJHQ) instrument was used to assess satisfaction with childbirth care at 6 weeks postpartum. The instrument has 28 items that ask	± 3.9, 55 Primary care provider - 6-point scale 1 = poor 6 = excellent Mean ± SD, N Freestanding birth centre = 28.8 ± 2.8, 57 Traditional care = 25.9 ± 4.7, 55 (P ≤ 0.001) Environment - 6-point scale 1 = poor 6 = excellent Mean ± SD, N Freestanding birth centre = 50.4 ± 4.9, 57 Traditional care = 47.5 ± 6.3, 55 (P ≤ 0.01)	Other information Five dimensions of Patient Judgment of Hospital Quality instrument: access, nursing care, primary care provider, environment and discharge/billing (discharge/billing dimension data not extracted).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			respondents to rank five aspects of care they received on a 6-point Likert type scale, ranging from excellent to poor. The higher the score the more satisfied the respondent was with the care they received. Response rate = 77%		
Full citation Byrne,J.P., Crowther,C.A., Moss,J.R., A randomised controlled trial comparing birthing centre care with delivery suite care in Adelaide, Australia, Australian and New Zealand Journal of Obstetrics and Gynaecology, 40, 268-274, 2000 Ref Id 174927 Country/ies where the study was carried out Australia Study type	Sample size N = 201 Birth centre n = 100 Delivery suite n = 101 Characteristics Age - mean (SD) Birth centre = 27.5 years (5.6) Delivery suite = 26.8 (4.9) Nulliparous (%) Birth centre = 47% Delivery suite = 46%	Interventions Birth centre care The birth centre consisted of two rooms set up close to the conventional delivery suite. All medical equipment was stored behind cupboards or curtains within easy reach if required. Women were cared for by	Details Women attending the antenatal clinic at the Queen Victoria Hospital were given an information sheet about the study early in pregnancy, and were eligible for randomisation from 20-36 weeks gestation. Women could choose either to: (1) enter the trial (randomisation was explained, as well as	Results Outcomes measured at 12-hours postpartum No statistically significant differences in women's perceptions of control, satisfaction and anxiety between the two groups. Felt more control - n/N (%) Birth centre = 47/73 (67%)	Limitations High rate of transfer out of birth centre care - 76%. Authors performed intention-to-treat analysis (for women where outcome data were available) but impact of transfer on results not fully considered. Unclear whether a repeat at 6 months of the satisfaction measures made at 12-hours postpartum was conducted. Consequently the effect of time on women's levels of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Randomised controlled trial Aim of the study To address the hypotheses that care of healthy pregnant women by midwives who have a philosophical commitment to the normality of the birthing process would increase maternal satisfaction with the care offered, lower intervention rates without adversely affecting outcome, and be more cost effective than conventional care. Study dates June 1993 – January 1995 Source of funding Not reported	Inclusion criteria Normal uncomplicated pregnancy Exclusion criteria Any pregnancy risk factors or they presented to the antenatal clinic later than 30 weeks gestation	a midwife committed to the normality of the birth process. The midwife recognised the women as active, conscious participants with rights to exercise informed choice and encouraged women to retain control of their birth and postpartum care. The homelike surroundings encouraged women to feel relaxed and to use own resources to cope with labour. Partners and support persons were encouraged to take an active role in both physical and	the need for transfer out of the birth centre); (2) give birth in the delivery suite; or (3) give birth in the delivery suite. Block randomisation stratified by parity, performed by a clerical officer not involved in the study, was used to randomise eligible women choosing to take part in the trial to either birth centre care or delivery suite care. Baseline demographic data were collected at entry to the trial. Outcome data were collected from case notes and questionnaires completed by women within 12 hours of delivery and again at 6 weeks postpartum. The 12-hour	Delivery suite = 50/75 (66%) Relative risk = 0.97 (95% CI 0.76 to 1.22, p = 0.77) Felt more satisfaction - n/N (%) Birth centre = 57/73 (79%) Delivery suite = 59/75 (80%) Relative risk = 0.99 (95% CI 0.84 to 1.18, p = 0.93) Felt less anxiety - n/N (%) Birth centre = 28/73 (39%) Delivery suite = 35/75 (47%) Relative risk = 0.82 (95% CI 0.56 to 1.20, p = 0.30) Happy and satisfied with care - n/N (%) Birth centre = 63/73 (89%)	satisfaction is not considered. The study was underpowered to detect differences that were considered clinically relevant when the trial was planned (episiotomy and tear rate). Unclear what is meant by 'felt more satisfaction' or 'felt less anxiety'. Other information 201/863 eligible women chose to participate in the trial. Of the 662 women who declined, 343/662 (52%) chose the birth centre and 319/662 (48%) chose the delivery suite. One woman randomised to the delivery suite group moved house and delivered at a different hospital. One woman in the delivery suite group transferred to birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		emotional support. Measures to manage pain such as bathing, hot towels, movement and massage, plus pharmacological pain relief with pethidine were available. Progress in labour was monitored according to hospital protocol. Delivery suite care Women were under the care of both a midwife and doctor. The midwife was the main caregiver, who liaised with the doctor. The midwife endeavoured to	postpartum questionnaires were collected by postnatal staff; if questionnaires were not completed by the time of discharge women were telephoned at home. A modified version of Mason's survey manual on women's experience of maternity care was used to measure maternal satisfaction. Questionnaires consisted of direct answer questions and Likert scales. A response rate of 74% was acheived for the 12-hour postpartum questionnaire (birth centre = 73%, delivery suite = 75%) and 67% for the 6-week	Delivery suite = 63/75 (86%) Relative risk = 1.03 (95% CI 0.90 to 1.18, p = 0.69) Satisfied with staff (kind and understanding) - n/N (%) Birth centre = 65/73 (90%) Delivery suite = 70/75 (93%) Relative risk = 0.95 (95% CI 0.86 to 1.06, p = 0.35) Satisfied with analgesia - n/N (%) Birth centre = 50/73 (68%) Delivery suite = 51/75 (68%) Relative risk = 1.01 (95% CI 0.80 to 1.25, p = 0.94) Outcomes measured	centre care at her request. 9/100 women in the birth centre group required Caesarean section and 67/100 women in the birth centre group actually delivered in the delivery suite (induction of labour, need for augmentation, instrumental delivery, epidural block, breech presentation and staffing problems). Thirteen women allocated to the birth centre delivered in the delivery suite due to staffing problems - due to both of the centre's birthing rooms being full, evening admissions being admitted directly to the delivery suite and managers failing to call the on-call midwife resulting in delivery in the delivery suite.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		cater for the individual needs of each woman, including offering alternative pain relief such as massage, showers, movement and hot towels. Fetal montioring, intravenous fluids and pharmalogical pain relief were used at the doctor's, midwife's and mother's discretion. Progress in labour was monitored according to hospital protocol.	postpartum questionnaire.	at 6-months postpartum More women in the birth centre group would choose their allocated place of delivery for subsequent births (60%) compared with the delivery suite group (47%) ($p < 0.007$).	
Full citation Waldenstrom,U., Nilsson,C.A., Women's satisfaction with birth center care: a randomized, controlled study, Birth, 20, 3-13,	Sample size N = 1230 Birth centre care n =	Interventions Birth centre The birth centre was located one storey below the	Details Women interested in birth centre care received an information folder from	Results Satisfaction at 2 months post-birth Women receiving birth centre care were	Limitations Access to the birth centre was only through participation in the trial; 58.7% of women allocated to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
1993 Ref Id 174931 Country/ies where the study was carried out Sweden Study type Randomised controlled trial Aim of the study To evaluate women's satisfaction with the care received at the in-hospital birth centre compared with standard antenatal, intrapartum and postnatal care Study dates October 1989 – January 1992 Source of funding Supported by grants from the Swedish National Delegation for Social Research, F 88/42:2 and the Swedish Medical Research Council B89-27X-8701-01A	617 Obstetric care n = 613 Characteristics Age - mean (SD not reported) Birth centre care = 29.9 years Obstetric care = 29.7 years Nulliparous Birth centre care = 57% Obstetric care = 53.7% Inclusion criteria Willingness to participate in research project with random allocation and to answer three questionnaires, residence in greater Stockholm area and at least one member	delivery ward. Functionally the unit was similar to a free-standing birth centre, with its own staff, facilities and medical guidelines. Continuity of care was an essential characteristic: antenatal, intrapartum and postnatal care were provided all in the same premises. Expectant parents were cared for by the same team of midwives from outset of pregnancy, during the birth and the final visit two months after birth. Electronic fetal monitoring, sonography and	the local antenatal clinic or from the birth centre describing the trial, procedure and reasons for random allocation. At first telephone contact a midwife checked that women met the inclusion criteria. If accepted, the woman met a research assistant and gave consent to participation. Randomisation was by sealed opaque envelopes. Women completed three questionnaires: on their first visit to the birth centre, before randomisation, concerning background characteristics and demographic details; one month before term, concerning	satistically significantly more satisfied with their care than women receiving obstetric care ($p < 0.001$ on all three domains of satisfaction) Satisfaction with physical aspects of intrapartum care (medical supervision and/or treament) Mean score (SD not reported), N - 1 = very unsatisfactory, 7 = very satisfactory Birth centre care = 6.5 (N = 574) Obstetric care = 6.0 (N = 534) Satisfaction with psychological aspects of intrapartum care (professional response to women's thoughts and emotions)	obstetric care reported being disappointed with their allocation at one month before term, this dropped to 29.4% two months after birth. To check for bias caused by disappointment, authors compared outcomes for birth centre care women with only those obstetric care women who expressed no or very little disappointment with allocation (≤ 3 on 7-point scale). Authors report that results "remained essentially unchanged". Interrogation of data to assess impact of transfer on results not clearly reported and differs from method used in a subsequent publication of this study. Women in both groups were asked two open-ended questions about their opinions of birth centre care.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	of each couple had to speak Swedish. Exclusion criteria Disease or risk factor that might significantly complicate the birth or jeopardise the baby's health, including diabetes, twin pregnancy, toxaemia, drug abuse and smoking during the current pregnancy.	pharmacologic pain relief were not available. During pregnancy women could be referred for fetal monitoring or ultrasound scan and then continue with birth centre care provided the unit's medical criteria were met. Parental responsibility and self-care were other characteristics. The obstetrician was responsible for the centre's medical guidelines and was available at the centre for consultation half a day per week. The midwife assessed the birth and was	antenatal care; two months after expected date of birth, concerning experiences of care received during birth and postpartum. Questionnaires included three types of question: those with a predefined alternative for answering, 7-point scales with extreme values verbally described and two open-ended questions about advantages and disadvantages of birth centre care. A response rate of 93% was achieved (birth centre care = 593/617, 96%; obstetric care = 555/613, 91%).	Mean score (SD not reported), N - 1 = very unsatisfactory, 7 = very satisfactory Birth centre care = 6.3 (N = 574) Obstetric care = 5.5 (N = 534) Satisfaction - comprehensive assessment Mean score (SD not reported), N - 1 = very unsatisfactory, 7 = very satisfactory Birth centre care = 6.5 (N = 574) Obstetric care = 5.9 (N = 534) 88.7% of birth centre care women expressed a wish to give birth at the birth centre in future, whereas half of the women receiving obstetric care (45.6%)	Women in both groups were not asked the same questions about their opinions of obstetric care. Other information There is a second publication of this study included in this evidence table (Waldenstrom, U., Nilsson, C.-A. 1994. Experience of childbirth in birth center care. Acta Obstet Gynecol Scand 73: 547-54). Birth centre opened October 1989 as the first in the greater Stockholm area and from opening was part of a clinical trial. It was not possible to obtain birth centre care outside of the trial. Women who had participated in the trial could return to the birth centre with a subsequent pregnancy. Definition of women in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		responsible for any decision regarding transfer to the delivery ward according to medical guidelines. Standard obstetric care Standard obstetric care was split into antenatal care in neighbourhood antenatal clinics, intrapartum care on hospital delivery wards and postpartum care on hospital postpartum wards. Midwives assisted at all normal births, and many complicated births, under the supervision of an obstetrician.		preferred obstetric care in the future. Opinions of birth centre care Women receiving birth centre care and also women receiving obstetric care were asked two open-ended questions regarding the advantages and disadvantages of birth centre care. Content of care was the most appreciated quality; they mentioned parental participation, responsibility, freedom, and being treated with respect and confidence by staff of the centre, who were concerned with and sensitive to their needs and consequently gave them individualised	obstetric care group who were dissapointed with allocation (women scoring > 4 on 7-point scale with 1 = not at all disappointed, 7 = very disappointed) and the method for assessing bias due to disappointment with allocation to obstetric care (comparison of birth centre group outcomes with only those women in the obstetric care women who were not disappointed, scored ≤ 3 on 7-point scale) is different to that used in the second publication (Waldenstom & Nilsson, 1994). Birth centre care results comprise scores of women who gave birth in the birth centre and women who transferred out of the birth centre before, during or after birth, or who withdrew from birth centre care voluntarily. (Intention-to-treat analysis)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				care. Women receiving obstetric care were not asked about advantages and disadvantages of obstetric care.	Transfers out of birth centre care Withdrawals at own request (primarily because they changed their mind about analgesia in labour, or preferred a home birth): 20/617 (3.2%); primiparous = 8/352 (2.3%), multiparous = 12/265 (4.5%) Antenatal transfers: 77/617 (12.5%); primiparous = 52/352 (14.8%), multiparous = 25/265 (9.4%) Intrapartum transfers: 108/617 (17.5%); primiparous = 96/352 (27.3%), multiparous = 12/265 (4.5%) Post-birth transfers: 7/617 (1.1%); primiparous = 4/352 (1.1%), multiparous = 3/265 (1.1%)
Full citation Esposito,N.W., Marginalized women's comparisons of their hospital and freestanding birth center experiences: a contrast of inner-city birthing systems, Health Care for Women	Sample size N = 29 Characteristics Age - range 16 to 33 years	Interventions Freestanding birth centre developed as a demonstration project by the Maternity Center	Details An ethnographic approach was used to develop an analytic description of the birthing centre. The women who agreed to	Results Women's perceptions of accessibility Women repeatedly emphasised the importance of being treated like a person	Limitations Unclear whether all the women in the study were multiparous, and if so whether at least one previous birth had been in hospital setting. However,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
International, 20, 111-126, 1999 Ref Id 175640 Country/ies where the study was carried out USA Study type Qualitative - open-ended ethnographic interviews plus participant observations of birth and everyday activities at the birth centre and in the immediate neighbourhood Aim of the study Describe the stories of inner-city women who have childbirth experiences in both a hospital setting and at a birthing centre Study dates 1991 – 1992 Source of funding Not reported	All except one woman met low income and "nutritional risk" designation requirements for participation in the Special Supplemental Food Program for Women, Infants and Children. Inclusion criteria Pregnancy or a recent birth centre birth Exclusion criteria Not reported	Association and funded by the Kellogg Foundation. Centre was in an inner-city neighbourhood where maternal death rate was four times higher than national average. The centre had a playroom, exam rooms, utility room, kitchenette, a family room, two birthing rooms with full size platform bed, with a bathroom with a jacuzzi, recliner, telephone and infant transporter for emergency care. Women were required to stay a minimum of 4 hours and could	participate (only one refused) were recruited in the waiting room of the birth centre. Following informed consent, women were interviewed in English. Translators were not required for the participants who spoke Spanish. Participant observation was conducted on various days of the week at various times in and around the birthing centre. Field notes were handwritten and later transcribed. Ongoing analysis guided the indexing, grouping, categorising and reanalysis of data.	and feeling respected during their health care experiences at the birth centre. They contrasted this with their experiences in other settings: "There is something like treating you like a person. No titles, a closeness, they care about you as a person... Not like a city hospital where people are rude and obnoxious, here, they remembered my name... It was an intimate thing to share my pregnancy with the ladies here, to get to know them; they're very special". "When I first came to the birthing center I was scared [of birth]. But I found out you can be scared with friendly people or scared with people	analysis presented appears to be only of those women who had previous hospital experiences. Unclear when and where interviews were conducted. Role of researcher not clearly described. Data analysis performed by single researcher and derivation of themes not clearly reported. Other information None

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
		stay up to 12 hours after birth. A nurse midwife with the help of a birth assistant facilitated all birth centre births.		you don't know. In the clinic at the hospital, people are cold, you are there, [and], you're a number. Here [you are] a person, they know you by name. At the clinic, not caring, impersonal, they just want to get the job done. Here they make you feel at home. Now my fear is that I might get transferred during labor [to hospital]". Privacy was an issue expressed by a number of women: "People don't realize how my privacy was invaded in the hospital... A whole bunch of lights, they put your legs up. Here [at birthing center] it's different, there are no big spotlights, they don't strap you down. [Here], I was calm."	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Struggling to maintain control One participant described how she refused to be hooked to an intravenous drip and hated the restrictions of the fetal monitor. She felt distanced from her providers, with a sense of diminished access to the care she desired. During her birth centre experience she felt more connected and less intruded upon: "I wasn't nervous... because I was relaxed, the labor went faster... it was mostly me and the midwife, it was just her talking to me, just telling me what to do, just her listening to the baby's heart, it wasn't a midwife here, then a	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				doctor, then another doctor... I didn't feel like a rat in a cage, I felt like a woman about to give birth". One woman's experience suggests that hospitals can be responsive to the individual woman but focusing on an attractive environment does not make a humanized birth: "The obstetrician who delivered me I never saw before. The medical care was good; the nursing care was good. But I had no control. I had to go by what they said... I didn't want to be medicated [but they medicated me] and I was groggy. Then when I was fully dilated they said 'push' and made me leave	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				the [labor-delivery-recovery room] because the doctor had a bad back and couldn't or wouldn't deliver me in a bed. I had to make it convenient for other people... doctors do good when people are sick but when you aren't sick you need people who will support you."	
Full citation Coyle,K.L., Hauck,Y., Percival,P., Kristjanson,L.J., Normality and collaboration: mothers' perceptions of birth centre versus hospital care, Midwifery, 17, 182-193, 2001 Ref Id 175750 Country/ies where the study was carried out Australia Study type Qualitative - in-depth interviews	Sample size Birth centre n = 17 Characteristics Age 22 – 34 years Nulliparous 0/17 (0%) Previous birth in hospital 17/17 (100%)	Interventions Birth centre care compared with previous hospital birth	Details A convenience sample of women from all three Western Australia birth centres was selected. In one birth centre women who met selection criteria were invited to participate, by a midwife not involved in the study, prior to discharge. Women in the other two birth centres were recruited from a larger cohort of	Results Birth centre themes Non-interventionist approach Participants' experiences revealed that birth-centre midwives did not interfere with their bodies in a physical sense, procedures were kept to a minimum and used when required rather than routinely: "I wasn't touched	Limitations Sample was self-selecting - women eligible for the study chose birth centre care and by the nature of the selection criteria achieved an uncomplicated birth. Being influenced by such birth experiences may have limited the variability of data and influenced analysis of theme dimensions; women's previous hospital experiences will likely have impacted their choice for birth centre care for

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To describe women's perceptions of care in Western Australian birth centres following a previous hospital birth Study dates November 1996 – April 1997 Source of funding Nurses Board of Western Australia, Edith Cowan University and the Olive Anstey Nursing Fund	Inclusion criteria (1) Attended a minimum of five antenatal visits by birth centre midwives during their pregnancy (2) Had a midwife care for them in labour who had conducted at least two of their antenatal visits (3) Experienced a normal birth (4) Had been discharged home within 24 hours of the birth (5) Had previously given birth to a baby in a hospital setting (6) Were available for interview 2 or 4 months after the birth of thier baby (7) Had not had any part of their pregnancy care provided by the		mothers participating in a longitudinal birth study in Western Australia. Those women meeting selection criteria for the current study were telephoned and invited to particpate. Interviews were conducted by the prinicpal investigator, lasted between 45 and 90 minutes, and were conducted at 2-4 months postpartum in the women's homes. Interviews explored women's perceptions of both their most recent care experiences and previous hospital experiences. A semi-structured interview guide with open-ended questions and prompts was developed. This was	when I came in and I was in labour, I wasn't examined at all which I really appreciated. They seemed to know where I was at and not interfere with me in anyway". Women also felt support of natural childbirth was enhanced by fact that technology (e.g. epidural, fetal monitoring) were not readily available. Midwives 'hands-off' approach was positively received by women and reinforced their belief that birth was a normal life event. Women as primary decision-makers Women felt that they were treated as autonomous	subsequent deliveries. Other information There is a second publication of this study included in this evidence table (Coyle, K., et al. 2001. Ongoing relationships with a personal focus: mothers' perceptions of birth centre versus hospital care. Midwifery 17: 182-93), which reports on the themes of 'care interactions' and 'care structures' 21 women were invited to participate, four declined the offer and saturation was achieved after 17 interviews. One woman had previously had a home birth, as well as a previous hospital birth. In the full guideline this study is referred to as Coyle et al., 2001a

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	principal investigator Exclusion criteria Not reported		not rigidly adhered to, allowing the interviewer to explore issues as they emerged. Modified grounded theory was adopted to guide the study, which allows important categories and themes to emerge from the data without prior assumptions. Data were anaylsed from transcribed interviews. Units of analysis were sentences, phrases or paragraphs. Significant meanings of these units were then coded and categorised in to groups. Analysis began and continued through the interview process, each interview was transcribed as soon as	individuals at the birth centre, the midwives provided them with information that enabled them to make informed decisions: "She [midwife] would ask me a question and say we could do it [manage labour] this way and that way and gave me suggestions, but ultimately it was my decision". Hospital setting themes Interventionist approach The use of technology was an accepted part of the process, with an assumption that women would want to use analgesia: "When I was in the hospital, when I was actually in labour, a midwife said 'it is too late to give her an	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			possible after the interview and coded throughout data collection.	epidural' and I thought, 'well, did I ask for one?' Health professional superiority Many participants felt that medical practitioners and midwives in the hospital setting had a superior attitude because they were the experts: "When I had a doctor it was his baby, we weren't allowed to talk and I had to do it his way." Women as passive participants Women did not perceive that they were encouraged to be involved in decisions affecting their care: "And they didn't seem	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to take any consideration of my feelings or what I wanted or asked me what I wanted, they just went ahead and did it. They said 'this is what we have to do, this is what we are going to do'. It wasn't 'this is what we could do, we have other options'. They didn't give me any options." Failure to provide women with enough information also resulted in women sensing a lack of involvement in the decision-making process: "but I was never really sat down and said that when we induce this is what is going to happen"	
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Littlefield,V.M., Adams,B.N., Patient participation in alternative perinatal care: impact on satisfaction and health locus of control, Research in Nursing and Health, 10, 139-148, 1987 Ref Id 175803 Country/ies where the study was carried out USA Study type Prospective cohort study Aim of the study To describe relationships among variables for women who choose alternative versus conventional perinatal care. Study dates Not reported Source of funding Not reported	N = 104 Alternative birthing unit n = 26 Delivery suite n = 78 Characteristics Age - mean (SD not reported) Alternative birth centre = 29.6 years Delivery suite = 27.1 years Women were statistically significantly older in the alternative birth centre group. Nulliparous Alternative birth centre = 29% Delivery suite = 77% Inclusion criteria 19 years of age or older, no identified	Alternative birth centre University teaching hospital had recently established an alternative birth centre adjacent to its labour and delivery suite. Decor was home-like, with a king-sized bed, lounge chairs and wallpaper. Emergency equipment for mother and newborn were concealed but immediately available. Policies and procedures included a focus on high participation in decisions about care, family involvment and non-intervention	Study subjects were women attending childbirth classes at the university hospital. Volunteers who met the study criteria completed consent forms and a Multidimensional Health Locus of Control (MHLC) scale at 30–32 weeks gestation. Two to three days post-delivery, women completed a second MHLC scale and a Patient Participation and Satisfaction Questionnaire (PPSQ), which was based on two previous questionnaires tested on perinatal populations.	Sense of participation 2-3 days post delivery Alternative birth centre women were more likely to experience high participation in labour and delivery ($p < 0.001$) PPSQ score - mean ± SD, N (possible score range for this outcome not reported) Alternative birth centre = 19.82 ± 0.6, 21 Delivery suite = 17.6 ± 3.5, 78 Satisfaction 2-3 days post delivery Satisfaction with labour and delivery nursing PPSQ score - mean ± SD, N (possible score range from 18 to 90) Alternative birth centre = 86.54 ± 6.1, 21 Delivery suite = 85.10 ± 6.76, 78 No satistically	Woman's self-selected choice determined place of delivery and philosophy of care. Women who transferred out of alternative birth centre to delivery suite due to labour complications (reasons for transfer not reported) were excluded from analysis. Interpretation of scores on Patient Participation and Satisfaction Questionnaire scale unclear; an unvalidated scale. Other information 5/26 women in the alternative birth centre group actually delivered in the delivery suite due to complications in labour. These women were excluded from the analysis. All participants appear to have returned

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	high risk status prenatally, anticipation of vaginal birth, able to read and comprehend English Exclusion criteria Not reported	in the normal process of birth. Delivery suite Family-centred but more likely to emphasise medical intervention and physician-dominated decisions concerning care options. Environment was typical of hospital labour and delivery units. The same physicians and hospital nurses provided the perinatal care for both groups.		significant difference Satisfaction with delivery environment PPSQ score - mean ± SD, N (possible score range from 5 to 25) Alternative birth centre = 24.40 ± 1.0, 21 Delivery suite = 21.10 ± 3.68, 78 p < 0.001 Satisfaction with delivery experience PPSQ score - mean ± SD, N (possible score range from 12 to 60) Alternative birth centre = 28.03 ± 3.7, 21 Delivery suite = 25.818 ± 3.24, 78 p < 0.001 Overall satisfaction PPSQ score - mean ± SD, N (possible score range from 1 to 5) Alternative birth centre	questionnaires with sufficient data for analysis. The Participation in Perinatal Care scale contains 97 items, each scored 1 to 5, 1 = very dissatisfied, 5 = very satisfied.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				= 4.95 ± 0.2, 21 Delivery suite = 4.69 ± 0.91, 78 p < 0.001 Total satisfaction PPSQ score - mean ± SD, N (possible score range from 81 to 405) Alternative birth centre = 335.73 ± 9.72, 21 Delivery suite = 326.97 ± 19.33, 78 p < 0.001 Comprehensive satisfaction PPSQ score - mean ± SD, N (possible score range from 97 to 485) Alternative birth centre = 415.18 ± 12.99, 21 Delivery suite = 397.19 ± 26.67, 78 p < 0.001	
Full citation Shaw,Irene, Reactions to transfer out of a hospital birth center: A pilot study, Birth:	Sample size 189 women completed questionnaires for	Interventions The birth centre is run by midwives as an	Details All women accepted for confinement at the birth centre during the	Results Positive response to transfer Antenatal transfer =	Limitations Aim, inclusion/exclusion criteria, participant characteristics, intervention,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Issues in Perinatal Care & Education, 12, 147-150, 1985 Ref Id 175935 Country/ies where the study was carried out Australia Study type Qualitative Aim of the study Not clearly stated. This was a pilot study to begin to answer the following questions: what are the long-term effects of transfer? Is it possible to prepare people adequately for the experience? Are there time changes with respect to feeling about transfer in the months after birth? Study dates Late 1979 to 1982 Source of funding	content analysis 8 women were interviewed Characteristics Not reported Inclusion criteria Not reported Exclusion criteria Not reported	autonomous unit within a university teaching hospital. Transfer rate is typical of centres with strict adherence to predetermined criteria for low risk.	study period were sent questionnaires about their labour and birth experience either within a week of birth or three months after birth. Content analysis of questionniare material was supplemented with eight partially structured, focused interviews, conducted by the author, carried out 10 to 14 weeks after birth. Interviewees were selected from a geographically accessible list of 31 women who had expressed interest in the research findings on their completed questionnaires. Thirteen women were approached by letter for an interview and 8 responded.	3.6% Intrapartum transfer = 45.1% Postpartum transfer = 4.5% Neutral response to transfer Antenatal transfer = 25.9% Intrapartum transfer = 39% Postpartum transfer = 27.3% Negative response to transfer Antenatal transfer = 68.2% Intrapartum transfer = 14.7% Postpartum transfer = 50% Great deal of self-criticism* Antenatal transfer = 1.2% Intrapartum transfer =	methodology, outcome measures all inadequately described. Methodology underlying content analysis not described. Women completed questionnaires either at 1 week or 3 months after birth. Results were not presented for these two different time points separately. Other information 540 women were accepted in to the birth centre during the study period. 254/540 (47%) women were transferred. Of the transferred women 74% (189/254) returned questionnaires for content analysis. 85 antenatal transfers 82 intrapartum transfers 22 postpartum transfers

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not reported				7.3% Postpartum transfer = 5% Some self-criticism* Antenatal transfer = 23.5% Intrapartum transfer = 34.2% Postpartum transfer = 5% No self-criticism* Antenatal transfer = 72.9% Intrapartum transfer = 58.5% Postpartum transfer = 90% *based on content analysis of description of labour	Findings emerging from the qualitative interviews not extracted in to evidence table as thematic exploration not clearly reported.
Full citation Sjoblom,I., Idvall,E., Radestad,I., Lindgren,H., A provoking choice--Swedish women's experiences of reactions to their plans to give	Sample size N = 1025 Characteristics Subjectively low risk	Interventions Home delivery with accompanying midwife	Details Questionnaires from 1025 women (95% response), 735 of whom answered an open-ended question:	Results Categories and sub-categories: Seen as an irresponsible person	Limitations A core assumption of the researchers was that 'low risk' is understood as meaning different things by healthcare providers and

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
birth at home, Women and Birth: Journal of the Australian College of Midwives, 25, e11-e18, 2012 Ref Id 273410 Country/ies where the study was carried out Sweden Study type Questionnaire with open-ended questions. Non comparative. Aim of the study Women's experiences of reactions to their decision to give birth at home. Study dates 1992 - 2005 Source of funding Not stated	(see Discussion) Inclusion criteria Parous women with successful deliveries. Exclusion criteria Women who answered that they avoided talking about their decision due to previous negative experiences: N = 34.		"If you think anyone has tried to influence you not to give birth at home, would you please describe that experience or the situation you are thinking of?" 34 women were excluded as they answered that they did not want to talk about it. Answers were analysed using thematic content analysis (Graneim and Lundman., 2008). This was considered to best show differences and similarities in the material due to categorisation without changing meaning of text.	“My midwife said that she was obligated to dissuade me since a home birth involved major risks.” “A selfish act” Does not take responsibility for child as child might die “The midwife said that the child could die (if born at home) and that I was irresponsible, and she scolded me…so I stopped going to the maternal health centre.” Relatives: “You should give birth in hospital, at least for our sake.” Met with emotional arguments and ignorance “It feels odd that people react so strongly without really knowing anything.” Exposed to	receivers. The women were low-risk in their own opinions, but this was not corroborated by scientific evidence. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				persuasion "You should definitely not give birth at home." Intimidation and threats "The midwife…tried everything, scare tactics, pressure, threats etc." Alienation "Lots of times I felt like an alien, I was just out of place in their system and didn't fit into the pigeonholes." To be considered as different with an alternative lifestyle "I visited a doctor who wondered if I was part of some religion that didn't allow us to use hospitals…it wasn't justified going against society like we were doing."	
Full citation Laurel,Merg, Carmoney,Pat,	Sample size n = 11	Interventions Intervention =	Details The study explored	Results Home birth vs hospital	Limitations The amount of time between

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Phenomenological Experiences: Homebirth After Hospital Birth, International Journal of Childbirth Education, 27, 70-75, 2012 Ref Id 272830 Country/ies where the study was carried out USA Study type Observational study Aim of the study To gather stories of women who have had a home birth after a previous hospital birth. Study dates Not stated Source of funding Not stated	Characteristics Participants self-identified as the following: Caucasian = 6 Jweish = 2 African-American = 1 Peruvian-American = 1 Mexican-American = 1 Age range = 30 - 51 (90% in thirties) Number with Bachelor degrees = 72.7% Inclusion criteria Women who chose a home birth after previously giving birth in a hospital.	home birth Comparitor = hospital birth	the common themes among experiences of women who chose a home birth with a midwife after a previous hospital birth. A questionnaire was developed and evaluated by an expert panel as a guide for semi-structured oral interviews. The questions explored feelings, beliefs and attitudes to the phenomenon of having a home birth after a hospital birth. Prompts included the evolution of their role as mothers, though other prompts were general and open-ended. Interviews were conducted in each woman's home or place of work. One participant responded	birth: Respect/autonomy vs disrespect/coercion "And if it wasn't clearly my call, she made it like it was, and that was the difference" Empowerment vs power struggle/powerlessness "As a result of having a homebirth, they would be able to do everything life and mothering demanded of them." Trust vs disrespect and coercion 3 women all experienced their midwives handling shoulder dystocias. They each relayed that their midwives handled those situations better ghan they would have been handled in a hospital.	giving birth and being interviewed is not given. Other information The author regards the study as unavoidably value-laden with the researcher's experience creating bias. To mitigate this, researchers' experiences were set out in brackets; facts were set aside, and concentration was given to the "structural invariants of an experience" (Dukes., 1984).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Nulliparas women or women who had never given birth in hospital.		in writing as she was ill during the time scheduled for her interview.	Accomplishment vs failure 2 women felt they had failed at their hospital births. Alllies vs Adveseries Homebirth midwives wanted the best possible birth experience. Mostly that meant staying out of the way and allowing the birth to happen while offering support. On rare occasions it meant letting the woman know that something she would not neccesarily prefer would need to happen. Avioding probable interventions 3 women experienced position changes to handle shoulder dystocias; however they all felt they would	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				have had more invasive interventions at a hospital for this same problem. 1 woman was 8 cm dilated for 12 hours. She had an intact amniotic sac and did not have any temperature problems, or anything else that indicated trouble, but she feels certain a hospital would not have been as patient with her. Healing vs boroken One participant was unable to hold her baby skin-to-skin in hospital. She came to view her daughter as, "Intense...needy...and crying all the time." 5 women felt psychological healing at their home births.	
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Tingstig,C., Gottvall,K., Grunewald,C., Waldenstrom,U., Satisfaction with a modified form of in-hospital birth center care compared with standard maternity care, Birth, 39, 106-114, 2012 Ref Id 273119 Country/ies where the study was carried out Sweden Study type Observational - retrospective questionnaire Aim of the study To compare satisfaction with modified birth centres with satisfaction of standard antenatal/intrapartum/postpartum care. Study dates July 2007 - July 2008 Source of funding Not stated	N = 1333 Characteristics Nulliparas women made up 45% of the birth centre group and 54% of the standard care group. The remainder of women was multiparas. All other stated characteristics were those defined by the inclusion and exclusion criteria. Inclusion criteria Women who gave birth 2 months previously in either the modified birth centre or the standard care unit. Exclusion criteria Diabetes	Birth at a modified birth centre (MBC) vs. birth at a standard care centre (SC).	Identical questionnaires were received from 547 women who had received them 2 months after giving birth. Questionnaire response rate 82.7% of women in modified birth centre (MBC) 71.6% of women receiving standard care (SC) Low risk status was established by MBC admission criteria/data from women's antenatal and intrapartum files. Questionnaires elicited experience of care, demographic data and obstetric history. Specific statements were pre-printed and	Women planning to give birth at the ‘modified’ centre required less counselling prior to birth because of fear of childbirth. It was more common in the modified birth center group to have a “known” midwife during labor, and the midwife was present in the birthing room “all or most of the time” in the majority of cases. The number of midwives seen during labour was almost the same for the primiparas of the two groups but fewer in multiparas in the modified birth centre group compared with the standard care group. Women were more satisfied with the relationship with the	Copy-writing errors meant that the 'Satisfaction with care' results-table needed the reviewer to make assumptions for interpretation. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Hypertension Epilepsy BMI > 29 History of CS or perinatal mortality Multiple pregnancy Age > 40 if nulliparous Smokers		women picked a number from 1 - 4 (from "Agree completely" to "Do not agree at all", or "Very satisfied" to "very dissatisfied"). Outcome variables were dichotomised with a focus on identifying women who were most satisfied.	caregiver in the modified birth centre group, Women in the modified birth centre group found the setting very calm, personal, pleasant, and not stressful to a greater extent than participants in the standard care group. Calmness was an important factor when giving birth. % Agreement with following statements: MBC primiparas n = 247 / SC primiparas n = 424 / MBC multiparas n = 300 / SC multiparas n = 362 The midwife gave me all the support I needed 72.7 / 67.1 / 81.2 / 63.8 Cared for me as a unique	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				person 74.4 / 69.9 / 80.9 / 64 Understood how I perceived my situation 68.8 / 64.6 / 79 / 61.1 Gave me opportunity to discuss my difficulties 70.2 / 61.7 / 77.2 / 57.4 Took me seriously 75.8 / 71 / 85.3 / 69 Overall satisfaction with care: MBC primiparas n = 242 / SC primiparas n = 424 / MBC multiparas n = 300 / SC multiparas n = 362 Very satisfied 70.2 / 60.8 / 84.7 / 57.2	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Satisfied 24.4 / 31.6 / 11.6 / 34.9 In between 2.9 / 4.5 / 2.7 / 3.9 Dissatisfied 2.1 / 2.6 / 1 / 2.8 Very dissatisfied 0.4 / 0.5 / 0 / 1	
Full citation Geerts,C.C., Klomp,T., Lagro-Janssen,A.L., Twisk,J.W., van,Dillen J., de,Jonge A., Birth setting, transfer and maternal sense of control: results from the DELIVER study, BMC Pregnancy and Childbirth, 14, 27-, 2014 Ref Id 301857 Country/ies where the study was carried out The Netherlands Study type Observational trial	Sample size Total women in available records: N = 5749 (2188 excluded) Eligible women: N = 3561 Study sample: N = 2112 Planned home birth: n=1279 Planned hospital birth: n=781 Characteristics	Interventions Planned midwife-attended home birth OR Planned midwife-attended hospital birth (normal in Netherlands)	Details Information on planned place of birth was obtained from LVR-1 form which women filled in during pregnancy. If complications arose, care was transferred from the midwife to an obstetrician. Level of personal control during childbirth was measured with a shortened version of	Results FIRST STAGE scores out of 11 Place (n): / Mean LAS / Difference (95%CI) Crude Nullip: Home(520): 60.7 /2.8(1-4.5) Hospital(370): 57.9	Limitations No copy of questionnaire in paper (especially as standardised form has been adapted and reverse-translated). Transfer data for 'Midwife-led hospital care' refered to transfer of care-giver rather than place of birth. I.e. the women planned midwife-led care on the obstetric unit itself (rather than an alongside unit). Transfers were reported as hospital-to-hospital.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the sense of control felt by women with planned home birth and planned hospital birth. Study dates September 2009 to December 2010 Source of funding	n (%) Characteristic: Home birth / Hospital birth / χ2(df) or Z of U / p-value Nulliparous: 528(41.3) / 382(48.9) / 11.4(1) / 0.001 Parous: 751(58.7) / 399(51.1) / 11.4(1) / 0.001 Non-western background: 45(3.5) / 81(10.4) / 54.5(2) / <0.001 1st social quartile: 342(26.8) / 222(28.6) / 1.1(3) / 0.78 2nd social quartile: 322(25.3) / 190(24.5) / 1.1(3) / 0.78 3rd social quartile: 290(22.8) / 179(23.1) / 1.1(3) / 0.78 4th social quartile:		the Labour Agentry Scale (LAS) in the postpartum period (approx 6 weeks). The LAS was translated from English to Dutch, then reverse-translated to check accuracy. Women rated 11 items on a 7-point Lickert scale: 1 (never/almost never) to 7 (almost always). A score was assigned to each response, and the sum of these gave a total LAS for each woman. Totals ranged from 11 (feeling rarely in control) to 77 (almost always in control). A difference of 5.5 points was considered clinically relevant (based on former quality of life studies). Social quartile of	Crude Parous: Home(736): 63.5 / 3.5(2.1-4.9) Hospital(390): 60 Adjusted Nullip: Home(515): 60.6 / 2.6(0.9-4.3) Hospital(365): 58 Adjusted Parous: Home(732): 63.3 / 3(1.6-4.4) Hospital(386): 60.3 SECOND STAGE Place (n): / Mean LAS / Difference (95%CI) Crude Nullip:	Other information Transfer data for 'Midwife-led hospital care' refered to transfer of care-giver rather than place of birth. I.e. the women planned midwife-led care on the obstetric unit itself (rather than an alongside unit). Transfers were reported as hospital-to-hospital.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	320(25.1) / 184(23.7) /1.1(3) / 0.78 Median (min-max): Fear of handicapped neonate: 8(4-16) / 8(4-16) / -1.6 / 0.11 Concern with appearance: 6(3-12) / 6(3-12) / -1.3 / 0.18 Fear of giving birth (nullip): 6 (3-12) / 7(3-12) / -3.1 / 0.002 Fear of giving birth (parous): 3(2-8) / 4(2-8) / -4 / <0.001 Inclusion criteria Singleton pregnancies that were in midwifery care at the onset of labour. Gestation >37 weeks Exclusion criteria		women was assessed using postcode, education, income and employment-rates.	Home(500): 59.3 / 3.1(1.2-5.1) Hospital(351): 56.2 Crude Parous: Home(726): 60.3 / 2.8(1.1-4.5) Hospital(386): 57.5 Adjusted Nullip: Home(495): 59.16 / 2.8(0.9-4.7) Hospital(346): 56.3 Adjusted Parous: Home(722): 60.1 / 2.3(0.6-4) Hospital(382): 57.8	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Women transferred for prolonged rupture of membranes. Women transferred to secondary care during pregnancy. Women with complications resulting in advice to give birth in hospital.			LAS SCORES AMONG WOMEN TRANSFERRED FROM HOME TO HOSPITAL: FIRST STAGE scores out of 11 Place (n): / Mean LAS / Difference (95%CI) Crude Nullip: Home to hospital transfer (294): 58.6 / 2.2(-0.1-4.5) Crude Parous: Home to hospital transfer (95): 59.7 / 3.1(-0.4-6.5) Adjusted Nullip: Home to hospital transfer (292): 58.4 /	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.7(-0.6-4) Adjusted Parous: Home to hospital transfer (95): 58.9 / 1.8(-1.8-5.4) SECOND STAGE Place (n): / Mean LAS / Difference (95%CI) Crude Nullip: Home to hospital transfer (275): 57.1 / 2.6(0.1-5.2) Crude Parous: Home to hospital transfer (91): 59.0 / 5.1(1.2-9) Adjusted Nullip:	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home to hospital transfer (273): 57 / 2.5(-0.1-5.1) Adjusted Parous: Home to hospital transfer (91): 58.5 / 4.3(0.2-8.4) LAS SCORES AMONG WOMEN NOTTRANSFERRED FROM HOME TO HOSPITAL: FIRST STAGE scores out of 11 Place (n): / Mean LAS / Difference (95%CI) Crude Nullip: Home to home (204): 63.8 / 3.4(-0.6-6.2) Crude Parous:	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Home to home (610): 64.2.7 / 3.6(1.8-5.4) Adjusted Nullip: Home to home (202): 63.6 / 3(0.2—5.9) Adjusted Parous: Home to home (606): 64.9 / 3.3(1.5-5.1)) SECOND STAGE Place (n): / Mean LAS / Difference (95%CI) Crude Nullip: Home to home (203): 62.2 / 3.9(0.8-7) Crude Parous: Home to home (605):	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				60.6 / 3.3(1.1-5.5) Adjusted Nullip: Home to home (201): 61.9 / 3.1(-0.1-6.3) Adjusted Parous: Home to home (601): 60.5 / 2.9(0.7-5.2))	

1.1.4 What is the appropriate staffing configuration of midwives and healthcare support staff on labour ward to support one-to-one continuous care during labour?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Ball,J., Bennett,B., Washbrook,M., Webster,F., Birthrate Plus programme: a basis for staffing standards?,	Sample size Total n = 68680 hospital births with a further n = 1520 home births	Interventions Birthrate calculation	Details Birthrate plus provides workforce planning and strategic decision making in maternity services, and has been endorsed by the RCOG	Results Ratio of hospital birth/midwife by size of units: The mean ratios and range per group of units were:	Limitations Non-comparative study. There is no evidence of validation and effectiveness of the tool

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
British Journal of Midwifery, 11, 264-266, 2003 Ref Id 166817 Country/ies where the study was carried out UK Study type Case series Aim of the study To implement a project in England to assist units in implementing Birthrate Plus. Study dates 2001-2002 Source of funding Department of Health England	Characteristics N/A Inclusion criteria N/A Exclusion criteria N/A		(1994) and the RCM (1999). Birthrate is based on a scoring system which assigns women into one of five categories (see Ball, 1992). Recorded midwife time per category is based on minimum standards of one to one throughout the labour, with increased percentages of midwife time for more complicated cases in higher categories. The category based case-mix for each hospital is then used to add the midwife time needed for postnatal care in hospital and community together with the need for all hospital and community based antenatal care and clinics, thus producing a complete staffing establishment. All staffing figures include time management, variability of work load, holiday, sickness and study leave.	Group 1: under 2500 births per annum Mean ratio of 28.36 births to 1 w.t.e. midwife range: 26.08 - 30.42 births to 1 w.t.e. midwife. Group 2: 2500 - 3500 births per annum Mean ratio of 27.92 births to 1 w.t.e. midwife. Range: 25.04 – 33.2 births to 1 w.t.e. midwife. Group 3: 3501 - 5800 births per annum Mean ratio of 28.72 births to 1 w.t.e. midwife. Range: 22.52 – 34.27 births to 1 w.t.e. midwife. The results suggest that although there are local issues that influence the number and distribution of midwives across different areas of care, the close range of ratios indicates a possible framework for large scale workforce planning, and that an initial ratio of 28 hospital birth to 1 w.t.e. midwife per annum might be appropriate. Ratio of home birth and caseload	linking staffing levels to maternal and neonatal outcomes. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Outline of the programme in England and Wales 2001 - 2002: By the end of 2002, a total of 101 maternity services spanning 117 sites were registered. n = 64 units in England had completed their studies by end of 2002. All units collected a minimum of 6 months data, gained from n = 68680 hospital births with a further n = 1520 home births. There were variety of sizes and types of units. These consisted of: Group 1: 15 units with 1100 – 2500 hospital births per annum Group 2: 14 units with 2501 – 3500 hospital births per annum Group 3: 15 units with 3501 – 5800 hospital births per annum.	based birth/w.t.e. midwives The amount of midwife time needed for women receiving home or caseload based delivery is calculated on an agreed allocation of 38 hours per woman for all antenatal, intrapartum, and postnatal care (Ball, 1996). Therefore the main differences in the ratios of such births per w.t.e midwife per annum arise from differences in allowances for travel in rural and urban settings. These range from 15% to 20%. The ratio of home/caseload based births over 43 units: Mean ratio of 35.5 births to 1 w.t.e. midwife. Range: 34 – 37.5 births to 1 w.t.e. midwife. This suggests a ratio of 35 home/case load based to 1 w.t.e. midwife per annum.	
Full citation Ball,J.A., Washbrook,M., Developing a real-time assessment of staffing needs in delivery suites,	Sample size N/A Characteristics	Interventions Acuity tool	Details The acuity tool was developed and validated within a Welsh trust in 2006 and 2007. The tool was then tested via pilot	Results	Limitations Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
British Journal of Midwifery, 18, 780-785, 2010 Ref Id 167181 Country/ies where the study was carried out UK Study type N/A Aim of the study Birth rate Plus methodology was extended to create a measure of acuity which would enable managers to assess, compare and record fluctuating labour ward workload with midwife availability in real time. Study dates 2006-2007 Source of funding Not specified	N/A Inclusion criteria N/A Exclusion criteria N/A		studies in a broader sample of five maternity services in Wales during 2008 and 2009 (annual births from the five maternity services ranged from 2220 births per annum to 4190 per annum). The tool provides an ongoing record of workload in the labour ward and subsequently the number of midwives needed to meet the workload. The tool enables midwives to prospectively assess women on admission and update the score as labour progress. Applying the tool, the number of women receiving care, their category of need (Cat I - V), the total ward acuity and the number of midwives needed to match it can be calculated. The tool consists of: 1) prospective classification of need The same clinical indicators already used by Birthrate Plus, (see Ball, 1992; Ball, 1996)		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			were used and the scoring system was changed to produce a category of need at admission, at delivery or for post-delivery emergencies (for instance a woman admitted in category I - needs 1 midwife for one-to-one care. As labour advances she might end up with an epidural and electronic fetal monitoring which would change her category from I to III needing 1.2 midwives. The woman could then have a normal delivery and a healthy baby and would remain in category III if there were no postnatal complications. 2) assessing the number of midwives required The same ratio applied as for the normal workforce planning system; one-to-one care for all women in labour and an additional allowance of midwife time for those in higher categories (1.2 midwives for category III, 1.3 midwives for category IV and 1.4 midwives for category V)		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			3) care in labour ward More categories added to normal BR+ workforce planning categories (categories X, A, R, see Ball 1992): - category A divided to categories A1) antenatal women who require some form of treatment and observation that may go home with no need of further treatment or may be admitted to antenatal ward. A2) a woman who needs specialised care e.g. severe antepartum haemorrhage, preterm labour. - Transfers out: records the time that a midwife 4) post-operative and postnatal care - PO1: women in recovery room post operation - PO2: women waiting for a bed in postnatal area - PN: women who remain in the delivery suite until they go home within a few hours of		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			birth Ward record of acuity at agreed intervals of time All women in the labour ward had their category decided at the agreed interval of times (1, 2, or 4 hourly). The results were entered on an Excel spreadsheet. This 1) calculated the ratio of midwife time per category for each woman then the total acuity and number of midwives needed and 2) compared the number of midwives present in the labour ward with the number of midwives required. Methods of assessing validity and reliability of the scoring system - Checking each woman's score and category against her hospital notes. - Comparing a random sample of acuity sheets with the normal BR+ retrospective scoring method.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Undertaking reliability checks to ensure that midwives applied the score system correctly. Details of completed Birthrate Plus acuity system The development of acuity system changed the BR+ research tool from a written material to electronic. By this system all women in labour ward were recorded in a large spreadsheet which enabled regular updates and varied analysis of data. Deciding the frequency of recording Recording of number of women and their acuity can be made at 1, 2 or 4 hourly intervals depending on the workload volume of each unit. Recording these data on a weekly record can also demonstrate how often acuity and staffing do or don't match each other.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Dealing with issues raises by acuity records To deal with on going pressures of work with in the labour ward, it was necessary to draw upon midwives from other areas of the service. This could be limited specifically at night shifts when the number of midwives from other areas of service is limited. Recomendations made: A care policy in the labour ward is needed to specify the agreed level of acuity versus staffing which is to be maintained. Some agreed procedures to address the acuity crises are also needed. A longer term policy to undertake a staffing review to assess the number of midwives needed in labour ward.		
Full citation Ball,J.A., Birthrate. Using clinical indicators to assess case mix,	Sample size N/A Characteristics	Interventions A method to assess workload in	Details The Second Report of the Social Services Committee on Perinatal and Neonatal	Results Using the data (midwife time needed per category) - At the end of 6 months, the	Limitations There is no evidence of validation and effectiveness of the tool

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
workload outcomes and staffing needs in intrapartum care and for predicting postnatal bed needs, -, 1992 Ref Id 219010 Country/ies where the study was carried out UK Study type Case series Aim of the study Examining a method to assess the variable workload in maternity units Study dates Source of funding	N/A Inclusion criteria N/A Exclusion criteria N/A	maternity units (Birthrate)	Mortality (Short, 1980) noted the lack of valid methods of assessing the variable workload in maternity units. Following that in order to fill the gap, in terms of intrapartum service, the method known as Birthrate (Ball, 1988) was developed. Birthrate was initially developed in Lincoln County Hospital (Ball, 1988) Birthrate has three main components: A score system The score system is a retrospective score and is completed when the mother and baby are ready to leave the delivery suite. It is based upon clinical indicators of the process and outcome of labour for mother and infant, and others which demonstrate increased need or any emergency intervention. Each of these indicators is	mean daily number of cases per category should be calculated - The time needed per category is based on the mean time in the labour ward per woman category plus extra midwife time needed for complicated cases (category III, IV, V) - The mean time for category III, category IV and category V increases by 20%, 30%, 40% respectively. - For categories A and R, the mean time per case should be used with no further increase. Workload ratios The workload ratios are calculating by using the mean time for a category I woman as the basic component of staffing. The mean time for other categories are divided by category I to produce the ratios: e.g. mean time in category I: 4.2 hours, mean time in category III: 9.84. Workload ratio would be 9.84/4.4 = 2.3 Calculating the staff needed	linking to maternal and neonatal outcomes. Other information Validation of Birthrate: Birthrate was developed in Lincoln County Hospital and validated blind comparative evaluation of women's records over 6 months. 95% of all score sheets were found to be accurately recorded. The validity and reliability of the method were tested further in three other hospital in 1986. In 1998 the criteria for assessment were discussed at the research and Midwife Conference. In the 1991 both Royal College of Obstetricians (RCOG) and Royal College of Midwives (RCM) recommended Birthrate to House of Commons Select Committee on Maternity Care as a

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			weighted to reflect the degree of need, and the resulting total score classifies mother and infant into one of five outcome categories (I - V). Categories - Categories I and II reflect normal labour and outcome and are predominantly midwife led care. - Categories III - V reflect increasing levels of need. Category III are women who may have had an induction of labour, continuous fetal monitoring for known or suspected risk and instrumental delivery. - Category IV might be a woman who has had a well managed elective caesarean section (CS) or one who has had a normal delivery with a healthy infant, but has had a long labour, received an epidural, and episiotomy with sutures. - Category V usually relates to emergency operative delivery,	The workload (i.e. mean number of cases per day) is multiplied by the workload ratios to produce the daily workload index. This is then multiplied by the mean time needed per category case and a further staffing formula applied to make allowances for other work (holidays, sickness etc.)	rational basis for assessing staffing needs in delivery suites.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			associated medical/obstetric problem, unexpected emergency or stillbirth. Other work in delivery suites consists of: Category X, Category A1 or A2, readmissions (Category R) - Category X are women who usually self admit, may have early signs of labour, need observation, support and care, but do not progress and go home or might be admitted overnight. - Category A1 are antenatal women who require some monitoring and possibly intervention, but do not have major problems and may then go home or be admitted to the antenatal ward - Category A2 are antenatal women with a more serious problem, e.g. premature labour, antepartum haemorrhage, raised blood pressure who require intervention and monitoring and will certainly be admitted for further care; or in some		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			cases be transferred to another maternity unit for expert neonatal care. Midwife hours When the score sheet is completed, a record is made of the length of time that the woman has received care in the delivery suite. During data collection the mean times are recorded by category. In line with intensive care practice (Intensive Care Society, British Paediatric Society) a further allowance of time is given to the categories which reflect intervention and or complications in labour, birth or with babies. Thus, such women or their infant(s) require the attention of more than one midwife at times during their labour. Allowances are also made for management and staff meetings, and for the time spent by midwives in statutory supervision as currently required.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Sickness, study leave and annual leave allowances are also added. These may vary slightly according to the local service standards. For community midwives, provision must be made for the amount of time spent travelling between the homes of clients and clinics etc. Staffing formula Converts the data into the number of midwives required to measure the workload. How to use the system: 1) a score sheet is completed at the time that woman leaves the labour ward: Scoring system provides 8 categories. There are 5 categories for women who gave birth in labour ward (categories I-V) and three other categories (X, A, R): Category I score = 6 This the most normal category: gestation > 37, length of		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			labour 8 hours or less, spontaneous vaginal birth, perineum intact, baby's apgar > 8, birth weight > 2.5 kg. Category II score = 7 - 9 This is also a normal category: Similar to category I but within addition of induction or perineal tear or length of labour in excess of 8 hours. Category III score = 10 - 13 This is in many cases a normal category following an epidural and elective CS with good outcome. Category IV score = 14 - 18 Many cases with complications for mother and baby will fall in this category. Category V score = 19 or more cases with complications for mother and baby that require a high degree of support. Category X Cases who were admitted to labour ward but following assessment were either sent home (not in labour) or sent to other wards. Category A Cases who were admitted in category X who		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			require some intervention including an intravenous infusion (e.g antepartum haemorrhage, pre-eclampsia). Category R Cases who were readmitted to labour ward for any reason Setting up the system and ensuring reliability of data - Setting up the system: ensure all staff (including agency and bank staff) are aware of the principles and the use of the system - Collating daily and monthly data - Calculating mean number of cases per category (monthly) - Calculating mean time per category (monthly); the mean time per category recorded will provide the time element in the workforce calculation. - Making allowance for flying squad/escort calls - Ensuring reliability: this can be checked by randomly selecting 10% of the birthrate data (score sheets per		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			category per month) and comparing the score given in the sheets against the case record.		
Full citation Ball,J.A., Washbrook,M, Birthrate Plus; A Framework for Workforce Planning and Decision Making in Maternity Services, , -, 1996 Ref Id 219011 Country/ies where the study was carried out UK Study type N/A Aim of the study The book is a practical guide for hospital managers and their colleagues to how to use and implement Birthrate Plus (+)	Sample size N/A Characteristics N/A Inclusion criteria N/A Exclusion criteria N/A	Interventions See Ball, 1992	Details See Ball, 1992	Results See Ball, 1992 The amount of midwife time needed for women receiving home or caseload midwifery care is calculated on agreed allocation of a total of 38 hours per woman for all antenatal, intrapartum, and postnatal care. The main differences in the ratios of births per w.t.e midwife per annum arise from differences in allowances for travel in different rural urban setting. These range from 15% to 20%. Two changes made to scoring sheet in Ball 1992: Elective anaesthetic moved from section D to section A In the section C, Paediatrician called at or after birth was deleted	Limitations Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates N/A Source of funding Not specified					
Full citation Allen,M., Thornton,S., Providing one-to-one care in labour. Analysis of âBirthrate Plusâ labour ward staffing in real and simulated labour ward environments, BJOG: An International Journal of Obstetrics & Gynaecology, 120, 100-107, 2013 Ref Id 220209 Country/ies where the study was carried out UK Study type Retrospective case series Aim of the study	Sample size n = 5800 births (1 year) Characteristics N/A Inclusion criteria N/A Exclusion criteria N/A	Interventions N/A	Details Data were obtained from the labour ward of a university hospital in Coventry. The variation in births by time and day was analysed over a 1-year period. Three months of BR+ data were analysed for variation of workload. Historical data from the labour ward regarding the number of women in the ward and workload (assessed by Birthrate plus) was compared with the recommended level of midwife support as calculated using BR+. Analysis A computer simulation model was used. The potential of alternative staffing schedules was investigated, along with an assessment of how a	Results Analysis of patterns in the 1 year births data set Average births per day over 1 year n = 16.2 (SD 4) (80% of days n = 11 - 12 birth, 10% of days had < 11 birth and 10% of days > 22 birth) Number of births per day by week varied significantly p < 0.001 (average number of births was 20% higher on weekdays than weekends). The number of births varied by hour of day; it was significantly higher between 9.00 to 12.00 weekdays where caesarean section was performed. During this 3 hour period the	Limitations Midwife staffing levels for transfer of mothers between units, supervising activities and dealing with women not in established labour (not admitted onto labour ward), was not included. Validation of the tool in matter of staffing level and clinical outcomes was not performed. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To assess the ability of the 'Birthrate Plus' (BR+) midwife staffing system to cope with variability of workload on labour wards in order to provide one to one care during labour Study dates Not specified Source of funding The author was funded by the National Institute for Health Research (NIHR) Collaboration for leadership in Applied Health Research and Care (CLAHRC) for the South West Peninsula.			changing number of births per year affects the ability to provide one to one care during labour. The main outcome measure was labour ward overloading (when either the number of women or the BR+ Workload Index exceeded the scheduled midwife availability). BR+ calculations Birthrate Plus calculates the number of midwives needed by: 1) adding up the total time women spend in labour ward 2) identifying which category the woman belongs to (from the 5 predefined categories) 3) multiplying the time spent in the labour ward by a multiplier (based on the woman's category) to allow for increased midwife time need in complicated categories. This results in the Workload index which is the total midwife staffing recommended to cope with the workload and delivering one to one care. Data over the 3 month period was used. BR+ method was	number of births was 60% higher than the rest of the day. When caesarean section was removed from the analysis the variation still reminded significantly higher ($p < 0.01$) but with a smaller magnitude. Analysis of patterns in 3 months year using BR+ formula Mean number of women that presented in labour ward: 5.9 (SD 2.5) An average workload index of: 7.4 (SD 3.1) Mean ratio of midwives to women: 1.3:1 Mean ratio of midwives to work load index: 1.1:1 For 36% of the time there was a greater workload index than the number of midwives available. For 13% of the time there were more women than midwives. The number of women exceeded the number of births 5% to 10% during the day on weekend but increased by 25% to 30% during the day on weekdays. Between 9.00 and 13.00 on	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			applied to calculate: 1) the percentage of time when there were more women than midwives 2) the percentage of time the BR+ Workload Index in any given hour exceeded the number of midwives present for that hour. Model description The simulation model separates the arrival pattern of women in two types; spontaneous birth and elective caesarean. The model allows for arrival rate of two types to be independently adjusted for day of the week and allows the time of arrival for caesarean section to be set. Women would then be assigned to a BR+ category. The length of stay in the model depends only on the BR+ category and whether they were undergoing elective section; no other data were used. The model runs an audit of the virtual labour ward every hour; total number of women on the ward are counted and	weekdays, the average workload index exceeded the allocated number of midwives approximately 65% of the time. Validation of simulation model Simulation model was compared with actual BR+ data over 3 months. In all indicators the model produced results that were similar to BR+ data (5% of the actual data) Relationship between the staffing levels and incidence of overload Using simulation to guarantee that there were more midwives than women, the midwife/woman ratio on the labour ward (6000 births per year) needed to be 1.8:1 (standard BR+ calculation: 1.4:1) if the workload index is taken as a guide to workload on labour ward then to ensure there are sufficient midwives to cover workload index 95% of the time, the average midwife:woman ratio needed to be approx 2.2:1 (significantly higher than BR+ guideline). Probability of labour	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			the current workload index will be calculated using BR+ formula.	ward overload was significantly higher during the day on weekdays. The performance of the unit could be improved by increasing resources at the time at the time of predictable increase in load: a 25% reduction in occurrence of overload could be achieved with only 4% increase in budget. Alternatively there is a no cost option with reduced staffing level on Saturday night and all Sundays and reapplied at peak load during the weekdays. In this no-cost option a 15% reduction in occurrence of overload could be achieved. Effect of size of unit on probability of labour ward overload As the size of unit increased the amount of time that labour ward was overloaded reduced. Using the BR+ calculation small units (approx. 2000 births per/year) were forecast to have more women than midwives 16% of the time. The larger units (approx. 8000 births per year) were	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				overloaded 10% of the times. The severity of potential overload was significantly worse for smaller units. In the small units the workload index could rise twice the number of allocated midwives (happening 6% of the time). This level of severe workload was very rare in the larger units (happening only 0.1% of the time).	

1.1.5 Care in the latent phase (services)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Lauzon,Leeanne, Hodnett,Ellen D., Antenatal education for self-diagnosis of the onset of active labour at term, Cochrane Database of Systematic Reviews, -, 2009 Ref Id	Sample size n = 245 Characteristics Characteristics of the included study: Bonovich (1990) Participants: n = 245 nulliparous women, > 30 week pregnancy gestation, > 16 years	Interventions Structured antenatal education	Details Search methods for identification of studies The following searches were performed for identification of the studies: 1. Quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) 2. Monthly searches of	Results Visit to labour ward before active labour Labour diagnosis education n = 104 mean 0.29 (SD 0.59) Standard care n = 104 mean 0.58 (0.72) Mean difference MD -0.29 (95% CI -0.47 to -	Limitations Unclear method of randomisation and 15% of the sample was lost to follow up. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
60408 Country/ies where the study was carried out Various Study type Systematic review Aim of the study To assess the effectiveness of teaching pregnant women a self diagnosis of active labour onset in term pregnancy Study dates Assessed as up to date: October 2007 Source of funding University of Toronto Canada	of age Intervention: Interviews were conducted with participants at the 37th week of pregnancy in order to determine women knowledge of the onset of labour. Correct information was positively reinforced and specific teaching given to women regarding the palpation of uterine fundus, differentiation between Braxton Hicks and active labour contractions, recognition of amniotic fluid and pain perception. Setting: the trial was conducted in an urban community hospital in the United States. Study population were predominately low income single African-American women.		MEDLINE 3. Hand searches of 30 journals and the proceedings of major conferences; 4. Weekly current awareness search of a further 37 journals. Trials identified through the searching activities were given a code (or codes) depending on the topic. The codes were linked to review topics. Data collection and analysis Two reviewers independently selected and assessed the single trial. Each paper was evaluated for methodological quality and appropriateness for inclusion, regardless of results, using standard Cochrane criteria. No identified trials were excluded from this review. Only one study met the	0.11)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria Randomised control trial assessing a structured antenatal education for the self diagnosis of onset of labour compared with usual care. Exclusion criteria Not specified		inclusion criteria. Intervention details Women in the study group received antenatal education regarding the palpation of uterine fundus, differentiation between Braxton-Hicks and active labour contractions, timing of contractions, recognition of amniotic fluid, and pain perception. Teaching was reinforced at subsequent weekly antenatal visits. Interviews were conducted with the participants to determine knowledge gained from family and friends regarding labour onset at 37 weeks gestation, and correct information was positively reinforced.		
Full citation Janssen,P.A., Still,D.K., Klein,M.C., Singer,J., Carty,E.A.,	Sample size Study group (allocated to home visit): n = 728	Interventions Home visit versus telephone triage	Details Seven hospitals with obstetric services in the City of Vancouver, British	Results Maternal outcomes Mode of birth (all participants) n (%)	Limitations Appropriate randomisation: yes Allocation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Liston,R.M., Zupancic,J.A., Early labor assessment and support at home versus telephone triage: a randomized controlled trial, Obstetrics and Gynecology, 108, 1463-1469, 2006 Ref Id 66487 Country/ies where the study was carried out Canada Study type Randomised control trial Aim of the study To compare the effectiveness of obstetric triage at home compared with that performed by telephone on rates of caesarean section Study dates	Control (allocated to telephone support): n = 731 Characteristics Women in two groups were comparable with respect to age, marital status, education, family income, employment status and employment of spouse, and ethnicity. No difference observed in study groups with respect to obstetric characteristics including mean pre-pregnant weight, weight gain, maternal height, attendance at prenatal classes, use of a doula, reported contractions of greater than 24 hours before hospital admission, receipt of narcotics before randomisation, and status of membranes.		Columbia took part. Standard care As part of standard practice in the participating hospitals, women experiencing painful uterine contractions at term were advised by their physician and in antenatal classes to contact the labour and delivery suite by telephone to seek advice as to when to come to hospital. Women seeking advice by telephone were verbally assessed for eligibility for the study and also women who arrived at the hospital without prior telephone contact (those who were not in labour and were about to be discharged, were also assessed for eligibility for the study). Study group Women randomised to the telephone triage group	Vaginal birth Home visit n = 336 (46.2) Telephone triage n = 329 (45.0) RR 1.03 (95% CI 0.92 to 1.15) Forceps or vacuum birth Home visit n = 184 (25.3) Telephone triage n = 216 (29.5) RR 0.86 (95% CI 0.73 to 1.02) Caesarean delivery Home visit n = 208 (28.6) Telephone triage n = 186 (25.4) RR 1.12 (95% CI 0.94 to 1.32) Mode of birth (all participants) Vaginal birth Home visit n = 319 (46.4) Telephone triage n = 312 (45.8) RR 1.00 (95% CI 0.89 to 1.12) Forceps or vacuum birth Home visit n = 177 (25.7)	concealment: No Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: no Blinding of staff providing care: no Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis: yes Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Between November 2001 and October 2004 Source of funding Funded by Canadian Institutes of Health Research	Inclusion criteria Lived within a 30-minute drive of the hospital Were between the ages of 16 and 42 year Had completed 37–41 weeks of gestation Were nulliparous Were carrying a singleton fetus in the vertex position Spoke English, Cantonese, Mandarin, Punjabi, Korean, or Farsi. Women with their labour being induced on an outpatient basis with prostaglandins, were also included. Exclusion criteria		were assessed over the phone by study nurses about their contractions (frequency, duration, and strength), the presence of bloody show, the status of their membranes, colour of amniotic fluid (if present), the presence of bleeding per vagina, the nature (normal, increased, or decreased) of fetal movements, and their own assessment of how they were coping. Women's responses were documented on standard hospital forms. Women with coloured amniotic fluid, vaginal bleeding, and/or decreased fetal movements were advised to come to hospital. Those who were no longer able to cope with contractions, or if the contractions were more frequent than every 5 minutes or lasting longer than 1 minute, were also advised to come to hospital. Suggestions for	Telephone triage n = 203 (29.8) RR 0.88 (95% CI 0.74 to 1.04) Caesarean delivery Home visit n = 192 (27.9) Telephone triage n = 166 (24.4) RR 1.14 (95% CI 0.96 to 1.41) Number of visit to assessment room No visit Home visit n = 260 (35.7) Telephone triage n = 194 (26.5) RR 1.54 (95% CI 1.23 to 1.92) One visit Home visit n = 331 (45.5) Telephone triage n = 368 (51.8) RR 0.82 (95% CI 0.67 to 1.01) Two to five visits Home visit n = 137 (18.8) Telephone triage n = 169	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Type 1 diabetes Cardiovascular disease Third-trimester bleeding Fetal anomalies Abnormal fetal biophysical profile Any other existing conditions that contraindicated with home birth Women whose primary caregivers were midwives were excluded because midwives routinely visit their clients in early labour at home.		coping with contractions were made over the phone. Control group Women randomised to the nurse visit were told that a nurse would be leaving the hospital immediately. The nursing assessment at home was the same as to that over the phone but, in addition, women were assessed for vital signs, abdominal palpation, auscultation of the fetal heart rate. Randomisation Computer-generated randomisation was achieved by using a centralised randomisation service accessed via a dedicated telephone line. Randomisation was stratified within participating hospitals, with randomly generated block sizes of 6, 8, and 10. Randomisation took	(23.1) RR 0.77 (95% CI 0.60 to 0.99) Not coping with contractions on admission Home visit n = 146 (20.9) Telephone triage n = 197 (28.3) RR 0.74 (95% CI 0.62 to 0.99) Cervical dilatation on admission, 3 cm or less Home visit n = 324 (44.7) Telephone triage n = 385 (52.8) RR 0.85 (95% CI 0.76 to 0.94) Use of narcotic analgesia IM or IV Home visit n = 304 (41.8) Telephone triage n = 310 (42.5) RR 0.97 (95% CI 0.79 to 1.12) Use of epidural analgesia	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			place when women phoned the hospital, uncertain as to whether or not to come in. Data analysis Sample size calculations were based on the objective of detecting a 20% relative reduction in caesarean delivery rate from 28% to 22% with a type I error, two-sided, set at P< 0.05, and a type II error, set at P = 0.20. To obtain 80% power to detect a RR less than 0.78 or greater than 1.27 for caesarean delivery, 817 women needed to be enrolled per group for a total of 1,634 women. Intention to treat data analysis was performed.	Home visit n = 476 (65.4) Telephone triage n = 499 (68.3) RR 0.95 (95% CI 0.98 to 1.01) Augmentation of labour with prostaglandins/oxytocin (spontaneously labouring participants) Home visit n = 421 (61.2) Telephone triage n = 439 (64.5) RR 0.95 (95% CI 0.88 to 1.04) Neonatal outcomes Apgar < 7 at 5 min Home visit n = 9 (1.2) Telephone triage n = 6 (0.8) RR 1.52 (95% CI 0.54 to 4.23) Suction with endotracheal tube Home visit n = 56 (7.7) Telephone triage n = 62 (8.5) RR 0.91 (95% CI 0.64 to 1.28)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Intermittent positive pressure with endotracheal tube Home visit n = 13 (1.8) Telephone triage n = 5 (0.7) RR 2.62 (95% CI 0.93 to 7.31) Admit to level II nursery Home visit n = 45 (6.2) Telephone triage n = 48 (6.6) RR 0.93 (95% CI 0.63 to 1.37) Admit to level III nursery Home visit n = 14 (1.9) Telephone triage n = 6 (0.8) RR 2.35 (95% CI 0.90 to 6.08)	
Full citation Janssen,P.A., Iker,C.E., Carty,E.A., Early labour assessment and support at home: a randomized controlled trial, Journal of Obstetrics and Gynaecology Canada: JOGC, 25, 734-741,	Sample size Home care n = 117 Telephone triage n = 120 Characteristics No significant differences observed between the two groups in maternal	Interventions Home visit by an obstetric nurse versus telephone triage.	Details Study took place at BC Women's Hospital in Vancouver, British Columbia. Standard care As part of standard practice, women experiencing painful uterine contractions at	Results Home visit n = 728 Telephone triage n = 731 Maternal outcomes Cervical dilatation < 3 cm on admission n (%) Home visit n = 23 (19.7) Telephone triage n = 43 (35.8) OR 0.37 (95% CI 0.19 to	Limitations Appropriate randomisation: yes Allocation concealment: No Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
2003 Ref Id 114708 Country/ies where the study was carried out Canada Study type Randomised control trial Aim of the study To compare childbirth outcomes of women prospectively randomised to receive early labour assessment and support either through a home visit or by telephone triage. Study dates Not specified Source of funding Funded by BC Health research Foundation, The BC Medical Services Foundation,	age, marital status, race/ethnicity, employment and smoking status, antenatal care, parity, previous caesarean section, pre-pregnant weight, weight gain during the pregnancy, maternal hight, gestational age at delivery and baby's birth weight. Significantly more women had post secondary school degrees or diplomas in the home care group compared with telephone triage group. Inclusion criteria Lived within a 30-minute drive of the hospital Were between the ages of 16 and 42 years		term were advised by their physician and in antenatal classes to contact the labour and delivery suite by telephone to seek advice as to when to come to hospital. Women were assessed over the phone by a labour ward nurses about their contractions (frequency, duration, and strength), the presence of bloody show, the status of their membranes, colour of amniotic fluid (if present), the presence of bleeding per vagina, the nature (normal, increased, or decreased) of fetal movements, and their own assessment of how they were coping. Women's responses were documented on standard hospital forms. Based on their responses a decision was made about whether or not the women need to be admitted to the hospital. Women with	0.72) Augmentation of labour with oxytocin n (%) Home visit n = 27 (23.5) Telephone triage n = 32 (26.7) OR 0.76 (95% CI 0.39 to 1.47) Continuous electronic feta monitoring n (%) Home visit n = 42 (36.5) Telephone triage n = 54 (45.8) OR 0.63 (95% CI 0.35 to 1.12) Narcotics in labour (intravenous or intramuscular) n (%) Home visit n = 31 (27.0) Telephone triage n = 48 (40.0) OR 0.55 (95% CI 0.32 to 0.96) Epidural analgesia n (%) Home visit n = 40 (34.8) Telephone triage n = 59 (49.2)	no Blinding of staff providing care: no Missing data/loss to follow-up: unclear Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis: unclear Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
the BC Women's foundation and BC women's Hospital	Had completed 37–41 weeks of gestation Were nulliparous Were carrying a singleton fetus in the vertex position Spoke English or had an interpreter in the home Exclusion criteria Type 1 diabetes Cardiovascular disease Antepartum bleeding Fetal anomalies Any other existing conditions that contraindicated home birth.		coloured amniotic fluid, vaginal bleeding, and/or decreased fetal movements were advised to come to hospital. Those who were no longer able to cope with contractions, or if the contractions were more frequent than every 5 minutes or lasting longer than 1 minute, were also advised to come to hospital. Women with cervix 3 cm or more dilated were encourage to come to the hospital when they felt that they would like additional support for pain management and did not wish to stay at home longer. Women in early labour, who phoned the hospital between 7 am and 11.30 pm, seeking telephone advice on whether or not they were ready to be admitted to BC Women's Hospital (as was standard hospital practice) were told about the study and	OR 0.64 (95% CI 0.36 to 1.16) Intravenous therapy n (%) Home visit n = 61 (52.1) Telephone triage n = 78 (65.5) OR 0.63 (95% CI 0.37 to 1.09) Caesarean delivery n (%) Home visit n = 21 (17.9) Telephone triage n = 20 (16.7) OR 1.30 (95% CI 0.62 to 2.73) Neonatal outcomes 5 min Apgar < 7 n (%) Home visit n = 0 Telephone triage n = 1 (0.8) OR 0.47 (95% CI 0.22 to 1.02) Admission to level II nursery n (%) Home visit n = 2 (1.7) Telephone triage n = 14 (11.7) OR 0.13 (95% CI 0.03 to 0.60)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			their eligibility to the study inclusion was assessed. Randomisation Randomisation was achieved by opening consecutively numbered opaque envelope containing treatment allocation. Intervention Home visit was carried out by an experienced obstetrics nurse from triage or assessment area at the BC Women's Hospital. Control group Women randomised to the nurse visit were told that a nurse would be leaving the hospital immediately. The nursing assessment at home was the same as to that over the phone but, in addition, women were assessed for vital signs,		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			abdominal palpation, and auscultation of the fetal heart rate. In all cases, the nurse advised the physician of the woman's labour status. Information related to the home visit assessment was documented on a standard hospital sheet. The time spent by nurses at participants' homes ranged from 60 to 90 minutes. After birth and before hospital discharge women were asked to complete a short questionnaire consisting of question about their satisfaction with information given, and their decision about timing of arrival at hospital. Data analysis Demographic and pregnancy related data were downloaded from the hospital database by health information		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			analysts, and a research assistant (a registered nurse) extracted the data that were not available electronically. Data from both sources were merged and imported into SPSS (Statistical Package for Social Sciences) for analysis.		
Full citation Maimburg,R.D., Vaeth,M., Durr,J., Hvidman,L., Olsen,J., Randomised trial of structured antenatal training sessions to improve the birth process, BJOG: An International Journal of Obstetrics and Gynaecology, 117, 921-928, 2010 Ref Id 116350 Country/ies where the study was carried out Denmark Study type	Sample size Total n = 1193 Ready for child programe n = 603 Normal antenatal care n = 590 Characteristics Age (years) mean (SD) Intervention 28.9 (3.7) Control 29.2 (3.7) Body mass index (kg/m2) mean (SD) Intervention 23.0 (4.7) Control 23.1 (4.3) Smoking n (%)	Interventions Antenatal training (Ready for child programe) or no structured training	Details Randomisation Randomisation was obtained by a computer-assisted voice response system. Women were assigned with an average ratio of 1:1. Intervention details The intervention group received the 'Ready for Child' programme conducted by four midwives. The programme consisted of three modules, each lasting 3 hours. The	Results Cervix > 3 on arrival at the maternity ward Intervention n = 307/ 587 (52.3) Control n = 207/575 (36%) RR 1.45, (95% CI 1.26 to 1.65) P < 0.01 Women’s ability to cope with Fear (measured on DFS) on arrival Women in the two groups had similar ability to cope with fear at their arrival to maternity ward and there were no significant differences observed in the single item	Limitations Appropriate randomisation: yes Allocation concealment: unclear Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: no Blinding of outcomes assessors: unclear Blinding of staff providing care: yes Missing data/loss to follow-up: reported Precise definition of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Randomised control trial Aim of the study To compare the birth process in nulliparous women enrolled in a structured antenatal training programme, the 'Ready for Child' programme, with women allocated to routine care. Study dates From May 2006 to May 2007 Source of funding Supported by grants from The Egmont Foundation, The Health Insurance Foundation, The National Board of Health, The Augustinus Foundation and The Danish Midwifery Association.	In pre-pregnancy Intervention 92 (17) Control 83 (16) In 20 weeks of pregnancy intervention 10 (2) Control 15 (3) In relationship with partner n (%) Intervention 529 (99) Control 505 (99) 0–5 years Intervention 293 (56) Control 296 (59) > 5 years Intervention 234 (44) Control 206 (41) Living together with partner n (%) 0–5 years Intervention 396 (75) Control 386 (77) >5 years Intervention131 (25) Control 117 (23) Education level n (%) 7–10 years		training sessions were given to women between 30 and 35 weeks of gestation, and the woman's partner could participate. The birth module included lessons and discussion of labour onset, the birth process, the attending father, pain relief, birth interventions, fear of childbirth, and a film on giving birth. The newborn module consisted of lessons and discussions of care of the newborn, breastfeeding, childhood diseases, vaccination, and equipment and children safety. The parent module included sessions on transition to parenthood, maternity leave, sexual relations, conflicts in the parental relationship, the role of the grandparents, family and friends, and postnatal depression. The instructors (four	score or overall scores on DFS.	outcomes: yes Valid and reliable method of outcome assessment: unclear Intention-to-treat analysis: yes High number of women in the control group (45%) received other kinds of antenatal education (not provided by the hospital) and this was 4% in intervention group. Other information Received the full allocated intervention Intervention group n = 435/603 (72%) Attended the delivery session Intervention group 85% Newborn session Intervention group 80%

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Intervention 42 (7) Control 38 (7) > 11 years Intervention 533 (93) Control 523 (93) Psychiatric history n (%) Intervention 61 (11) Control 59 (12) Inclusion criteria Nulliparous women registered at the Aarhus Midwifery Clinic Age > 18 years old Singleton pregnancy Ability to speak and understand Danish Exclusion criteria Not specified		midwives) were trained to run the courses. They all followed a detailed teaching manual describing the content of the educational programme. Parents were assessed by the end of each course sessions to ensure that they received the instructions on all subjects. The control group received standard care offered by the antenatal clinic, which did not include any antenatal training programmes. The antenatal training programmes in the control group were mainly organised by relaxation therapists. Most of these programmes had a visiting midwife providing approximately 3 hours of lessons on the birth process. Data collection Data were collected by		Parenthood session Intervention group 79% Partners participation in the three sessions Intervention group 72%, 66%, 67% respectively Attended other kinds of antenatal class (not provided by their hospital) Intervention group 4% Control group 45%. Lost to follow up Intervention n = 15 Control n = 16 Follow-up rate until the birth 97% (1162/1193) in both groups Response rates for the DFS Intervention group 56% Control group and 67%

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			questionnaires sent to the women's email addresses or by regular mail. Questionnaires were sent out in weeks 24 and 36 of gestation and again 6 weeks and 1 year postpartum. Trained midwives collected and validated the data. Data on cervix dilatation at the time the women arrived for delivery (the contact which ended with admission for birth) were collected specifically for this study. The midwife who examined the woman on arrival registered information on cervix dilatation and the Delivery Fear Scale (DFS). The DFS consisted of 10 statements that the midwife read to the woman and asked them to rate each with a number between 1 (do not agree at all) and 5 (agree totally) [modified from 10 points in the original scale].		Information on cervix dilatation was available for 99% (1157/1162) and scores for DFS on arrival for birth were available for 62% (718/1162) of the women.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Midwives were blinded to the randomisation and women were asked not to reveal this to the midwife. Sample size calculation Based on the assumption that 80% of nulliparous women would arrive at the maternity ward with a cervix dilatation < 3 cm, a total of 585 needed to be randomised to detect the decrease from 80% to 70%, using a statistical significance level of 5% and having 80% power to detect this difference. Statistical analysis Intention-to-treat analyses performed. Continuous data were assessed using Mann–Whitney U test. Categorical data were analysed using the chi-square test. Data management and statistical analysis were performed using stata		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Statistical Software, version 9 (STATA-Corp,College Station, TX, USA, 2006).		
Full citation Lauzon,Leeanne, Hodnett,Ellen D., Labour assessment programs to delay admission to labour wards, Cochrane Database of Systematic Reviews, -, 2010 Ref Id 150766 Country/ies where the study was carried out Various Study type Systematic review Aim of the study To examine the effect of the labour assessment program to delay hospital admission until labour	Sample size One randomised control trial n = 209 participants Characteristics One included study: MvNiven 1998 Participants: n = 209 women Inclusion criteria: low risk nulliparous women, singleton pregnancy, > 37 weeks, spontaneous onset of labour Exclusion criteria: not reported here Intervention: women in the intervention group received labour assessment consisted of checking: fetal heart rate, uterine test,	Interventions A hospital or community based programme aim to delay hospital admission until active labour	Details Search methods for identification of studies The following searches performed for identification of the studies: 1. Quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) 2. Monthly searches of MEDLINE 3. Hand searches of 30 journals and the proceedings of major conferences; 4. Weekly current awareness search of a further 37 journals. Trials identified through the searching activities were given a code (or codes) depending on the topic. The codes were	Results Discharged undelivered Treatment: 19/105 Control: 17/104 OR1.13 (95% CI 0.55 to 2.31) Length of time from hospital admission to delivery Treatment: n = 105 mean 8.3 (SD 5.6) Control: n = 104 mean 13.5 (SD 7.9) Mean Difference -5.20 (95% CI -7.06 to 3.34) Artificial rupture of membranes Treatment: 49/105 Control: 56/104 OR 0.75 (95% CI 0.44 to 1.29) Intrapartum oxytocics Treatment: 24/105	Limitations No major limitations. Randomisation methods were clear and adequately controlled. Only one subject was excluded after randomisation because of gestational age < 37 weeks Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
is in the active phase. Study dates Assessed up to date: January 2004 Source of funding University of Toronto, Canada	maternal blood pressure, status of amnion membranes and presence of bloody show. A vaginal examination performed and women with cervix dilatation > 3 cm and regular painful contractions were determined to be in active labour. Participants not in active labour were given information and advice, and asked to walk outside or return home. Control: women in the control group were admitted directly to the labour ward and received routine care including discharge if they were not in labour Setting: A teaching hospital in Ontario, Canada Inclusion criteria		linked to review topics. Data collection and analysis Two reviewers independently selected and assessed the single trial. Each paper was evaluated for methodological quality and appropriateness for inclusion, regardless of results, using standard Cochrane criteria. No identified trials were excluded from this review.	Control: 42/104 OR 0.45 (95% CI 0.25 to 0.80) Any intrapartum analgesia Treatment: 84/105 Control: 96/104 OR 0.36 (95% CI 0.16 to 0.78) Epidural analgesia Treatment: 83/105 Control: 94/104 OR 0.42 (95% CI 0.20 to 0.89) Intrapartum narcotic/inhalation analgesia Treatment: 1/105 Control: 2/104 OR 0.51 (95% CI 0.05 to 4.91) Forceps/vacuum extraction Treatment: 32/105 Control: 37/104 OR 0.79 (95% CI 0.45 to 1.41) Caesarean section	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Randomised control trials comparing labour assessment programme with direct admission to labour ward Exclusion criteria Not specified			Treatment: 8/105 Control: 11/104 OR 0.70 (95% CI 0.27 to 1.79) Perceived control Treatment: n = 99 mean 158 (SD 27) Control: n = 102 mean 142 (SD 34) Mean Difference 16.0 (95% CI 7.53 to 24.47) 5-minute Apgar < 7 Treatment: 1/105 Control: 0/104 OR 7.32 (95% CI 0.15 to 368.87) Neonatal resuscitation Treatment: 4/105 Control: 5/104 OR 0.79 (95% CI 0.21 to 2.98)	
Full citation Hodnett,E.D., Stremler,R., Willan,A.R., Weston,J.A.,	Sample size Structured care: n = 2497	Interventions One to one structured care in the labour assessment unit	Details The study was a multi-centre, randomised controlled trial. A group of nurses or midwives at	Results Maternal death Structured care n = 1* Usual care n = 0 OR not reported	Limitations Appropriate randomisation: unclear Allocation concealment: unclear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Lowe,N.K., Simpson,K.R., Fraser,W.D., Gafni,A., Effect on birth outcomes of a formalised approach to care in hospital labour assessment units: International, randomised controlled trial, BMJ, 337, 618-622, 2008 Ref Id 150929 Country/ies where the study was carried out Canada Study type Multi-centred randomised control trial Aim of the study To examine if a complex nursing and midwifery intervention in hospital labour assessment units would increase the likelihood of	Usual care: n = 2499 Characteristics Not specified Inclusion criteria Inclusion criteria for hospitals Had to have a pre-existing, geographically distinct labour assessment unit A spontaneous vaginal birth rate of 75% or less Inclusion criteria for women Nulliparous Had a live singleton fetus in the cephalic position Had no contraindications to labour	compared with usual nursing or midwifery care	each hospital were trained in the structured approach, before the trial commencing. In the North American hospitals the two day training programme was carried out by a nurse expert in antenatal education. In the UK hospitals the training programme was carried out by an expert midwife instructor after consultation with the Canadian trainers, using an adaptation of the North American curriculum. Each participant was given a manual at the end of the training session. The manual consisted of the course content and provided opportunities for the techniques to be practised before the onset of the trial. Intervention Women who approached the labour ward were assessed for trial	Mode of birth n (%) Spontaneous vaginal birth Structured care n = 1597 (64.0) Usual care n = 1533 (61.3) OR 1.12 (95% CI 0.96 to 1.27) Instrumental birth Structured care n = 341 (13.7) Usual care n = 362 (14.5) OR not reported Vacuum (n/total instrumental delivery) Structured care n = 231/341 Usual care n = 240/362 OR not reported Forceps (n/total instrumental delivery) Structured care n = 110/341 Usual care n = 122/362 OR not reported Caesarean birth Structured care n = 559 (22.4) Usual care n = 604 (24.2) OR 0.90 (95% CI 0.71 to 1.10)	Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: no Blinding of staff providing care: no Missing data/loss to follow-up: not reported Precise definition of outcomes: yes Valid and reliable method of outcome assessment: unclear Intention-to-treat analysis: yes Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
spontaneous vaginal birth and improve other maternal and neonatal outcomes Study dates May 2003 to March 2007 Source of funding Funded by Canadian Institutes of Health Research	Were competent to give informed consent or had a parent or guardian who was competent to give informed consent Were experiencing contractions but did not meet labour ward criteria for admission Exclusion criteria With gestational age less than 34 weeks With an induction of labour or caesarean delivery planned With complications that necessitated hospital admission If they were likely to be transferred to the labour ward within one hour		eligibility. Basic assessment of labour (duration and frequency of contractions, status of membranes, status of the fetal heart rate, and assessment of cervical dilation as per hospital protocol) were carried out. Immediately after randomisation women assigned to the experimental group received one to one care by a nurse or midwife trained in structured care. The following components were taught in the training programme and used in the structured care group: Normalise the environment Palpate to assess fetal position Encourage maternal positions that promote fetal head rotation or relieve pain (standing and leaning forward) Assessing labour pain	Perineal trauma requiring suturing n (%) Structured care n = 1336 (53.3) Usual care 1350 (54.0) OR 0.98 (95% CI 0.82 to 1.13) Haemorrhage > 1000 n (%) Structured care n = 51 (2.0) Usual care n = 49 (2.0) OR not reported Blood transfusion n (%) Structured care n = 13 (0.5) Usual care n = 7 (0.2) OR not reported Length of postnatal hospital stay n (%) Structured care median 50.1 (41.4 to 63.5) Usual care median 50.3 (41.2 to 64.1) p = 0.75 Reginal analgesia or anaesthesia n (%) Structured care n = 2112 (84.6)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	If they had a doula or midwife providing continuous support		using a visual analogue scale and asked women to describe their thought during the last contraction Demonstrating interventions to manage labour pain (be present continuously; encourage comfort measures, including breathing and relaxation, application of heat and cold, massage, shower or bath, movement; encourage visualisation techniques, suggesting music and rhythmic techniques) Assessing maternal emotional status If hospital admission was not planned, the importance of carrying on normal activities of daily living was discussed with women, and anticipatory guidance about coping with labour pain offered. If the woman was sent home without having given birth and if	Usual care 2159 (86.4) OR 0.85 (95% CI 0.62 to 1.08) Intramuscular or intravenous opioid n (%) Structured care n = 1126 (45.1) Usual care n = 1078 (43.2) OR not reported * Maternal death was unrelated to the trial. The cause of death was the undetected haemorrahge from uterine artery after caesarean.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			circumstances permitted, the provider was to telephone her later to check on her progress. When the woman returned, efforts were made to repeat structured care. Control: The care for the women in the control group, was provided by a nurse or midwife who had not been trained in structured care. Each nurse or midwife often provided care to more than one woman. Many factors were involved in providing the usual care including the provider's knowledge of fetal assessment, her workload, and her familiarity with appropriate interventions. Women who were sent home were asked to telephone the unit with any questions or concerns.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			The length of time women received structured care or usual care was the usual time spent by women in labour assessment units (1-4 hours). The decision on whether to admit women to the labour ward or to send them home in both groups was based on usual hospital policy. Apart from the nature of the nursing or midwifery care in the labour assessment unit that was offered to the groups; all other care in the labour assessment unit and labour ward was based on usual hospital practices and policies. In both groups the decision to send the woman home or admit her to the labour ward was made based on usual hospital policy. Randomisation:		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Was centrally controlled and concealed, using an internet-based service. The nurse or midwife accessed the trial website to obtain the participant's study group Sample size calculation: To detect a 4% absolute difference in spontaneous vaginal birth rate a sample size of 4932 was needed. The target sample size was 5000. Statistical analysis Intention to treat analysis was performed. For binary outcome variables the groups were compared using a logistic regression model with a random hospital effect for the intercept and slope. A similar logistic regression model was used to explore the interaction effects between baseline variables and treatment		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			group on the primary outcome. For length of hospital stay data was analysed using a linear regression model with a random hospital effect for the intercept and slope, using the log of length of stay as the dependent variable. Statistical procedures were done using SAS version 9.1.		
Full citation Paz-Pascual,C., Pinedo,I.A., Grandes,G., de Gamboa,G.R., Hermosilla,I.O., de la Hera,A.B., Gordon,J.P., Garcia,G.M., de Pedro,M.U., Design and process of the EMA Cohort Study: the value of antenatal education in childbirth and breastfeeding, BMC Nursing, 7, 5-, 2008	Sample size n = 616 Characteristics There was statistically significant difference between three study groups (Group A [0 AE session], Group B [1-4 sessions], Group C [≥ 3 sessions]) in nationality, educational level, social class and age. Women in group C were significantly older, had higher	Interventions Antenatal education	Details The study was designed to follow up a cohort of pregnant women from the Biscay health area attending midwife offices of the public Basque Health Service/Osakidetza. Thirty-four centres collaborated in the project. Antenatal education (AE) was given in all collaborating primary care centres. This was consisted of at least 8 sessions. Breathing	Results Group A (no antenatal education): total n = 45 Group B (1 -4 antenatal education sessions): total n = 62 Group C (≥ 5 antenatal education sessions): total n = 509 Anaesthesia in the latent phase Group A (no antenatal education): 39% Group B (1 -4 antenatal education sessions): 30%	Limitations Unclear how the education programme across the centres were similar and what measures were taken to achieve this. Power calculation for the study size was based on the assumption that 40% of women choosing not to attend the antenatal care. However only 7% of women did not attend the antenatal care and this affected

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 159273 Country/ies where the study was carried out Spain Study type Prospective cohort study Aim of the study To examine the effect of attendance to AE sessions on childbirth outcome and on the start and continuation of breastfeeding during the first year Study dates September 2005 to May 2006 Source of funding Supported by the Department of Health of the Basque Government and by the Carlos III Institute of Health of the	educational level and higher social status. Inclusion criteria - nulliparous pregnant women - 18 to 42 years old - from 36 weeks gestation Exclusion criteria - Multiple pregnancy - Pathological pregnancy: - Clinically and/or radiographically documented pelvic abnormality - Prior uterine malformation - Uterine tumour in current pregnancy - Prior uterine surgery - Prior genital tract abnormality - Positive cytologic testing for malignant		techniques, pushing, and relaxation were taught and practised Topics such as labour and birth, postpartum period, baby care, and breastfeeding were also covered. The two hospitals of the public Basque Health Service with a delivery suites collaborated in the study. Thirty primary care midwives collaborated in the study by proposing participation to all pregnant women eligible for inclusion, discussing with them the whole study process, providing informed consent, and collaborating in the initial measurements. 616 women were recruited during the study period. Women were divided to three groups based on their antenatal education attendance: (Group A [0 AE session], Group B [1-4 AE	Group C (≥ 5 antenatal education sessions): 20% Visited the Hospital in false labour Group A (no antenatal education): 31% Group B (1 -4 antenatal education sessions): 22% Group C (≥ 5 antenatal education sessions): 14%	the statistical power of the trial Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ministry of Health of Spain co-financed by FEDER funds of the European Union.	cells - Prior severe medical or surgical disease (maternal heart disease restricting physical capacity of the woman, neuropathy, coagulopathy, diabetes, etc.) - Late cerclage, performed after 16 weeks - Active toxoplasmosis during pregnancy - German measles during pregnancy - Sexually transmitted infection during current pregnancy - Gestational diabetes		sessions], Group C [≥ 3 AE sessions]) Statistical analysis The estimated sample size was 657 women. study assumed that if 40% of these women did not attend AE, this size provided a statistical power greater than 95% for detecting as significant 15% differences in false labour, anaesthesia in latent stage, instrumental deliveries and breastfeeding after one and a half months, and 20% differences in anxiety and episiotomy, and for detecting equivalence in the duration of the dilation and expulsion periods. Relative and absolute measures of association with 95% confidence intervals was calculated and tested by chi-square and t tests.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Green,Josephine M., Spiby,Helen, Hucknall,Clare, Foster,Helen Richardson, Converting policy into care: Women's satisfaction with the early labour telephone component of the All Wales Clinical Pathway for Normal Labour, Journal of Advanced Nursing, 68, 2218-2228, 2012 Ref Id 278659 Country/ies where the study was carried out UK Study type Survey Aim of the study To examine women's experiences of, and satisfaction with, early	Sample size n = 47 Characteristics - Mean maternal age: 28.8 yr (SD 5.2 range 16 - 40) - Educated to degree level: n = 27/47 - Spontaneous birth: n = 24/47 Inclusion criteria - Women who gave birth to their first baby during the study period - Low risk at the onset of labour and through the labour - Women phoned maternity unit at least once when they thought their labour had started Exclusion criteria	Interventions 'The pathway' (The All Wales Clinical Pathway for Normal Labour): telephone assessment and communications with women to encourage them remaining at home until labour is established	Details The Pathway was introduced throughout Wales over 2003-2004. The aim was to encourage women to remain at home until labour is established with assessment by telephone, unlike the more common set-up where the phone call is a basis for admission and face-to-face assessment. During the study period, telephone interviews were carried out with 46 low-risk first-time mothers in Wales. Analysis Study was a mixed-method with quantitative and qualitative analysis. Frequencies were generated from CATI database using SPSS and lines were drawn up from all women showing their	Results Total n = 46 Spontaneous vaginal birth n = 24 Instrumental birth n = 14 Caesarean section n = 6 The sum of the above reported numbers do not equals 46 (total n). No further explanation given Satisfaction Very satisfied: n = 16 (35%) Satisfied: 17 (37%) Dissatisfied: n = 13 (28%) Women aged > 30 were significantly more likely than the younger women to be very satisfied (OR = 25.9 CI 3.0 to 223.8) Satisfaction More strongly related to interpersonal interactions with midwives Dissatisfaction	Limitations - No detailed information about the 'Pathway' - Incomplete data reported - Selection criteria not reported hence high risk of selection bias Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
labour telephone communications within the All Wales Clinical Pathway for Normal Labour ('the pathway') Study dates 2005 to 2006 Source of funding National Co-ordinating centre for NHS Service Delivery and Organisation R & D (NCCSDO)	Not specified		sequence of contacts and their follow-up. Data were defined in terms of satisfaction score: very satisfied (5 out of 5), satisfied (4 out of 5), and dissatisfied (a score of 0-3). Binary logistic regression performed in order to report confidence intervals.	Dissatisfied women reported in relation to: - unclear and inadequate advice and information - unmet needs for support (ill-defined criteria for what to do next/when to call back or attend the unit) - unaddressed fears or anxieties - negative midwife manner - short length of call (more who reported call < 5 min were significantly dissatisfied OR 7.0 CI 1.7 to 29.1) - Being sent home from maternity unit (Women who were sent home after attending maternity unit were significantly more dissatisfied compared with those who were not sent home OR 5.8 CI 1.3 to 25.4) Very satisfied Women were distinguished by - feeling welcome to attend the maternity unit - by the perceived adequacy of the advice given	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Antenatal awareness and preparation about the 'Pathway' little difference observed between the satisfied and dissatisfied group. Satisfied group were more likely to have seen the leaflet, discussed the 'pathway' with the midwife and to have expected to stay at home in early labour but there was no strong relation between the preparation and high satisfaction; less than half the women who had had the antenatal preparation were very satisfied	
Full citation Weavers,Annette, Nash,Kate, Setting up a triage telephone line for women in early labour, British Journal of Midwifery, 20, 333-338, 2012 Ref Id 273171 Country/ies where the	Sample size n = 121 Characteristics Not specified Inclusion criteria - All women who used the triage service and gave birth within 24	Interventions Labour triage telephone line	Details A 6-month labour triage line (as a pilot) was set up on October 2010 and completed at the end of March 2011. Following that a tool was developed to survey women's views of the labour triage during the month of January 2011. All women who	Results Total n = 121 Women response rate 72% (n = 88) Results from survey of women used triage line (n = 88): Women's view of triage service Excellent: 69%	Limitations - Women's characteristics not reported - Data analysis and its validity not reported - No data for early labour admissions reported Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study was carried out UK Study type Survey Aim of the study To examine efficacy of a collaborative service improvement project and to seek women's view on the telephone triage Study dates October 2010 to March 2011 Source of funding Not specified	hours of the contact Exclusion criteria Not specified		accessed the triage service and gave birth within 24 hours of the contact were given a form in the postnatal period and a collection point made available within the unit. Those women who gave birth at home and were eligible for the inclusion in the study were provided with a stamped addressed envelope. The 6-month pilot labour triage line was live for a 12 hours period, 7 days a week. It was ensured that a private room for the triage service was available to minimise the distraction and ensure confidentiality. The triage room was allocated opposite the midwifery care led unit (MLU). Intranet access was available for the triage midwife in case she needed to check women's maternity and pathology results. One of the labour	Good: 29% Average: 2% Women's answer to the following questions: - Was the information given by the midwife reassuring and helpful? Yes: 100% No: 0% - Were you advised about coping strategies? (if the judgement was that the woman should remain at home) Yes: 92% No: 8% - Did you feel confident with the plan of care discussed over the phone? Yes: 97% No: 3% Birth outcomes 6 months before and 6 months after introduction of the triage line in MLU (women in both groups had low risk	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			ward's telephone numbers was used for the triage line and transferred to the triage office during the triage hours. Data for birth outcomes was obtained from the hospital's maternity database.	pregnancies and first birth. Women in 'after triage' group accessed the triage line): Mode of birth Spontaneous vaginal birth (the percentages [%] are approximate measure as were calculated from a graph) Before triage: 59% After triage: 70% Assisted vaginal birth Before triage: 25% After triage: 23% Caesarean section Before triage: 15% After triage: 10% Author claims that there was reduction in early labour admissions and telephone calls to labour wards but no data for these outcomes reported	

1.1.6 Care in the latent phase (pain)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Smith,Caroline A., Collins,Carmel T., Crowther,Caroline A., Aromatherapy for pain management in labour, Cochrane Database of Systematic Reviews, - , 2010 Ref Id 155831 Country/ies where the study was carried out Various Study type Systematic review of RCTs Aim of the study To examine the effect of aromatherapy in labour on maternal and perinatal morbidity Study dates	Sample size Two studies are included in this systematic review, but for the purpose of this review only one study with relevant intervention is included (Burns 2007 n = 513 women) Characteristics Burns 2007 Participants: N = 513 women Inclusion criteria: women recruited on presentation to delivery suite. No further detail provided. Exclusion criteria: < 36 weeks gestation, multiple pregnancy, breech presentation or elective caesarean	Interventions Intervention: aromatherapy Control: standard care	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by the Trials Search Coordinator. CENTRAL, MEDLINE and EMBASE were searched, and hand searching of 30 journals and conference proceedings was done. No language restrictions were applied. Weekly current awareness alert for a further of 44 journals was also performed plus monthly BioMed Central email alert was considered. Ongoing clinical trials were searched up to 30 June 2011 in: Australian and New Zealand Trial Registry; Chinese Clinical Trial register; Current Controlled Trials; Clinical Trial. Gov: ISRCTN Register: National Centre for Complementary and Alternative Medicine (NCCAM); and the WHO International Clinical Trials Registry Platform	Results Assisted vaginal birth Intervention: n = 12/251 Control: n = 12/262 RR 1.04 (95% CI 0.48 to 2.28) Caesarean birth Intervention: n = 15/251 Control: n = 16/262 RR 0.98 (95% CI 0.49 to 1.94) Admission to NICU Intervention: n = 0/251 Control: n = 6/262 RR 0.08 (95% CI 0.00 to 1.42) Use of Pharmacological analgesia Intervention: n = 1/251 Control: n = 3/262 RR 0.35 (95% CI 0.04 to 3.32)	Limitations Burns 2007 Random sequence generation (selection bias): low risk (computer generated sequence) Allocation concealment: low risk (sealed envelope) Incomplete outcome data (attrition bias): low risk (no missing data) Selective reporting (reporting bias): unclear risk (protocol unavailable but appears) Blinding of participants and personnel (performance bias): high risk (no participants or other study personnel were blind to group allocation) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Assessed as up-to-date on April 2011 Source of funding University of Western Sydney, Women's and Children's Health Research Institute, Child, Youth and Women's Health Services, Australia. National Institute for Health Research, UK	section Setting: Delivery suite at San Gerardo Hospital, Italy in 2003. Intervention: aromatherapy (one of five essential oil; Roman chamomile, clay sage, frankincense, lavender and mandarin). Decision as to which oil to used was reached between women and midwife. Modes of application were acupuncture point, taper, foot-bath, massage or birthing pool. Control: standard care, no other details provided. Inclusion criteria Randomised control		(ICTRP) Selection of studies Two of the reviewers independently assessed all potential identified studies for inclusion. Data extraction and management Two reviewers extracted the data using the the form designed by the Review Group for this purpose. It was analysed in RevMan. Where information was unclear, the original authors were contacted for further details. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Sequence generation - Allocation concealment - Blinding (participants and outcome assessor)	Spontaneous vaginal birth Intervention: n = 224/251 Control: n = 234/262 RR 1.00 (95% CI 0.94 to 1.06) Augmentation Intervention: n = 92/251 Control: n = 84/262 RR 1.14 (95% CI 0.90 to 1.45)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	trials only Exclusion criteria Non randomised trials and quasi randomised trials		- Incomplete outcome data - Selective reporting bias - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, mean difference and standardised mean difference were used, depending on whether trials had measured outcomes on the same or different scales. Ordinal data Data measured on scale (e.g. pain measured with visual analogue scale) were analysed as continuous data and other ordinal data (e.g. satisfaction with pain relief) were analysed as dichotomous data. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			to-treat basis as far as possible. The denominator being set as the number randomised minus any participants whose outcomes were known to be missing. Analysis Heterogeneity was regarded high if I2 > 30 and either T2 > 0 or there was a low P value (< 0.10) in the Chi2 test for heterogeneity. A fixed-effect model was used for combining data where studies were assumed estimating the same underlying treatment effect. If substantial clinical or statistical heterogeneity detected, random effects meta analysis was used. Fixed-effect meta-analysis was used where trials were comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			heterogeneity was present or suspected. If substantial heterogeneity was detected, it was investigated using subgroup and sensitivity analysis.		
Full citation Smith,Caroline A., Collins,Carmel T., Cyna,Allan M., Crowther,Caroline A., Complementary and alternative therapies for pain management in labour, Cochrane Database of Systematic Reviews, - , 2010 Ref Id 155854 Country/ies where the study was carried out Various Study type Systematic review of RCTs	Sample size Fourteen studies are included in this systematic review, but for the purpose of this review only two studies with relevant intervention and the right population are included (Chung 2003, Chang 2002) Characteristics Chang 2002 Participants: n = 83 Inclusion: between 37 and 42 weeks pregnant, with a normal pregnancy, the partner was expected to be present during labour and cervical dilatation	Interventions Complementary and alternative therapies used in labour with or without concurrent use of pharmacological or non-pharmacological interventions compared with placebo, no treatment or pharmacological forms of pain management.	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by the Trials Search Coordinator. CENTRAL, MEDLINE and EMBASE were searched, and hand searching of 30 journals and conference proceedings was done. No language restrictions were applied. Weekly current awareness alert for a further of 44 journals was also performed plus monthly BioMed Central email alert was considered. Ongoing clinical trials were searched up to 30 June 2011 in: Australian and New Zealand Trial Registry; Chinese Clinical Trial register; Current Controlled Trials; Clinical Trial.	Results Acupressure Chung 2003: n = 97 Length of first stage of labour Mean (SD) Acupressure: n = 43 mean 6.33 (2.55) Control: n = 42 mean 8.45 (4.39) MD -2.12 (95% CI -3.65 to -0.59) p = 0.006 Women's perception of pain experienced The trial reported on pain during the first stage of labour, latent, active and transitional. No difference between groups in labour pain	Limitations Chung 2003 Random sequence generation (selection bias): low risk (tossing a coin) Allocation concealment: unclear Incomplete outcome data (attrition bias): high risk (18% withdrawn) Blinding of participants and personnel (performance bias): high risk (no blinding of participants but the outcome assessor were blind) No intention to treat analysis performed

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To examine the effects of complementary and alternative therapies for pain management in labour on maternal and perinatal morbidity Study dates Assessed as up-to-date: June 2006 Source of funding The University of Adelaide, Adelaide, Australia. Child Health Research Institute, Australia.Child, Youth and Women's Health Services, Adelaide, Australia.	was no more than 4 cm Exclusion: not specified setting: women were recruited from a regional hospital in Taiwan between 1999-2000 Intervention: The primary researcher gave the massage during uterine contractions and taught the method to the woman's partner. Women received firm rhythmic massage lasting 30 minutes comprised of effleurage, sacral pressure and shoulder and back kneading. Women were encouraged to select their preferred technique. The 30-minute massage was repeated in phase 2 and in the transitional phase 3. Control: received		Gov: ISRCTN Register: National Centre for Complementary and Alternative Medicine (NCCAM); and the WHO International Clinical Trials Registry Platform (ICTRP) Selection of studies Two of the reviewers independently assessed all potential identified studies for inclusion. Data extraction and management Two reviewers extracted the data using the the form designed by the Review Group for this purpose. It was analysed in RevMan. Where information was unclear, the original authors were contacted for further details. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for	was found during the transitional and latent phases between groups (no overall measure reported). Pain in the active labour Weighted mean difference (WMD) between the acupressure and control group WMD -2.12 (95% CI 3.65 to -0.59) Other outcomes included uterine contractions (raw data not provided) and no differences were found between groups. Massage Chang 2002 Length of first stage of labour Mean (SD) Massage: n = 30 mean 10.96 (4.81) Control: n = 30	Chang 2002 Random sequence generation (selection bias): unclear risk (not reported) Allocation concealment: unclear Incomplete outcome data (attrition bias): high risk (27% missing data) Blinding of participants and personnel (performance bias): high risk (no blinding) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	standard nursing care and 30 minutes of the researcher's attendance and casual conversation Chung 2003 Participants: n = 127 Inclusion: between 37 and 42 weeks pregnant, a low-risk pregnancy, singleton pregnancy and able to speak Chinese Exclusion: Women who were induced with oxytocin, or received an epidural block or who planned a caesarean section were excluded from the study setting: The trial was undertaken in Taiwan, no other details were reported Intervention: Trained midwives administered the acupressure to women. The intervention lasted 20		Systematic Reviews of Interventions: - Sequence generation - Allocation concealment - Blinding (participants and outcome assessor) - Incomplete outcome data - Selective reporting bias - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, mean difference and standardised mean difference were used, depending on whether trials had measured outcomes on the same or different scales. Ordinal data Data measured on scale (e.g. pain measured with visual analogue scale) were analysed as continuous data and other ordinal data (e.g. satisfaction with pain relief) were analysed as dichotomous data.	mean 9.61 (4.4) MD 1.35 (95% CI -0.98 to 3.68) p = 0.26 Satisfaction with birth Mean (SD) Massage: n = 30 mean 3.7 (1.32) Control: n = 30 mean 4.17 (1.05) MD -0.47 (95% CI -1.07 to 0.13) p = 0.13	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	minutes, consisting of 5 minutes pressure to points LI4 and BL67. Five cycles of acupressure were completed in 5 minutes, with each cycle comprising 10 seconds of sustained pressure and 2 seconds of rest without pressure. A protocol was established to control finger pressure, accuracy of points and accuracy of technique. For the effleurage group, the left and right upper arms were massaged for 10 minutes. control: midwife stayed with the participant for 20 minutes, taking notes or talking with the participant or family members Inclusion criteria All published and		Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis as far as possible. The denominator being set as the number randomised minus any participants whose outcomes were known to be missing. Analysis Heterogeneity was regarded high if I2 > 30 and either T2 > 0 or there was a low P value (< 0.10) in the Chi2 test for heterogeneity. A fixed-effect model was used for combining data where studies were assumed estimating the same underlying treatment effect. If substantial clinical or statistical heterogeneity was detected, random effects meta analysis was used. Fixed-effect meta-analysis was used where trials were		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	unpublished randomised and quasi-randomised controlled trials. Exclusion criteria		comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where heterogeneity was present or suspected. If substantial heterogeneity was detected, it was investigated using subgroup and sensitivity analysis		
Full citation Smith,Caroline A., Levett,Kate M., Collins,Carmel T., Crowther,Caroline A., Relaxation techniques for pain management in labour, Cochrane Database of Systematic Reviews, - , 2011 Ref Id 155997 Country/ies where the study was carried out Various	Sample size N = 11 studies are included in the systematic review. For the purpose of this review n = 6 studies with the right intervention and population were selected. Characteristics Almedia 2005 Participants: n = 65 women Women recruited from	Interventions Relaxation technique: 1. Breathing techniques 2. Tensing and relaxing muscles 3. Yoga 4. Breathing techniques and massage 5. Music	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by the Trials Search Coordinator. CENTRAL, MEDLINE and EMBASE, were searched, and hand searching of 30 journals and conference proceedings was done. No language restrictions were applied. Weekly current awareness alert for a further of 44 journals was also performed plus monthly BioMed Central email alert was considered. Ongoing	Results 1. Breathing techniques (Almedia 2005,Durham 1986) Length of labour Breathing group: mean 445.26 (SD 158.05) Control: 339.7 (SD 168.45) MD 105.56 (95% CI -1.50 to 212.62) p = 0.053 Use of pharmalogical pain relief No differences observed	Limitations Almedia 2005 Random sequence generation (selection bias): high risk (tossing a coin) Allocation concealment: low risk Incomplete outcome data (attrition bias): high risk (n = 29 (44%) post randomisation exclusion; n = 12 for use of exogenous oxytocin, n = 2 for forceps delivery and n =

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Systematic review of RCTs Aim of the study To examine the effects of relaxation methods for pain management in labour on maternal and perinatal morbidity. Study dates Assessed as up-to-date May 2011 Source of funding The University of Western Sydney, Australia. Women's and Children's Health Research Institute, Flinders Medical Centre South Australia, Australia. Children, Youth and	antenatal ward, obstetric ward and postnatal ward of a public hospital. Inclusion criteria: primiparous with normal labour, low risk and in latent phase (≤ 4 cm dilation), not having previously participated in preparation course for childbirth. Exclusion criteria: dystosia, fetal distress, multiple pregnancy, breech presentation or elective caesarean section, required forceps delivery and use of analgesia Setting: delivery suite in a public hospital, located in Goias, Brazil. Intervention: individualised nursing care with advice and encouragement on the use of breathing techniques and relaxation.		clinical trials were searched up to 30 June 2011 in: Australian and New Zealand Trial Registry; Chinese Clinical Trial register; Current Controlled Trials; Clinical Trial. Gov: ISRCTN Register: National Centre for Complementary and Alternative Medicine (NCCAM); and the WHO International Clinical Trials Registry Platform (ICTRP) Selection of studies Two of the reviewers independently assessed all potential identified studies for inclusion. Data extraction and management Two reviewers extracted the data using the the form designed by the Review Group for this purpose. It was analysed in RevMan. Where information was unclear, the original authors were contacted	between breathing group and control groups (Chi2 6.17 p > 0.05) 2. Tensing and relaxing muscles (Bagharpoosh 2006) Intensity of pain during latent phase Relaxation instruction: 4.6 Usual care: 6.3 P = 0.001 Intensity of pain during active phase Relaxation instruction: 7.03 Usual care: 9.12 P = 0.0001 Intensity of pain during second stage of labour Relaxation instruction: 6.96 Usual care: 9.64 P = 0.001	15 for casarean birth) Selective reporting (reporting bias): unclear risk (protocol unavailable but appears) Blinding of participants and personnel (performance bias): high risk (not clear if the outcome assessors were blinded to group allocation) Bagharpoosh 2006 Random sequence generation (selection bias): unclear (no data provided) Allocation concealment (selection bias): unclear (no data provided) Incomplete outcome data (attrition bias): unclear (no data provided) Selective reporting (reporting bias): unclear (no data provided) Blinding of participants

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Women's Health Services, Adelaide, Australia. The University of Adelaide, Adelaide, Australia.	Control: standard care, no other details provided. Bagharpoosh 2006 Participants: n = 62 Inclusion: primiparous with no obstetric complications Exclusion: not reported Setting: Fatemieh Hospital, Hamadan, Iran Intervention: the relaxation intervention followed a standard method involving tensing and relaxing muscles in the toes, feet, ankles, calves, knees, thighs, lower abdomen, upper abdomen, shoulders, arms, hands, fingers, neck, face and head Control: standard care Chuntharapat 2008 Participants: n = 74		for further details. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Sequence generation - Allocation concealment - Blinding (participants and outcome assessor) - Incomplete outcome data - Selective reporting bias - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, mean difference and standardised mean difference were used, depending on whether trials had measured outcomes on the same or different scales. Ordinal data Data measured on scale (e.g.	3. Yoga (Chuntharapat 2008) Pain intensity Yoga group: mean 51.79 (SD 10.46) Control: 57.91 (SD 12.83) MD -6.12 (95% CI -11.77 to -0.47) p = 0.03 Satisfaction with pain relief in labour Yoga group: mean 52.88 (SD 13.57) Control: 45 (SD 12.84) MD 7.88 (95% CI 1.51 to 14.25) p = 0.01 Satisfaction with childbirth experience Yoga group: mean 156.7 (SD 13.43) Control: 150.36 (SD 11.7) MD 6.34 (95% CI 0.26 to 12.42) p = 0.01	and personnel (performance bias): high risk (no participants or other study personnel were blind to group allocation, no data provided about blinding of outcome assessor) Chuntharapat 2008 Random sequence generation (selection bias): low risk (computer generated sequence) Allocation concealment (selection bias): unclear risk (not reported) Incomplete outcome data (attrition bias): unclear risk (not reported) Selective reporting (reporting bias): unclear risk (protocol unavailable) Blinding of participants and personnel (performance bias):

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion: primiparous women without serious illness, low risk pregnancy; receiving antenatal care from the beginning, or at least 2nd trimester of pregnancy; and, without previous experience of practising yoga; > 18 years old; competent in Thai language Exclusion: not reported Setting: 2 public hospitals in Southern Thailand Intervention: participants in the experimental group received a series of 7 60-minute yoga practice sessions at the 26th, 28th, 30th, 32nd, 34th, 36th, and 37th week of pregnancy. The yoga programme was a combination of: (a) educational activities: a short explanation of basic		pain measured with visual analogue scale) were analysed as continuous data and other ordinal data (e.g. satisfaction with pain relief) were analysed as dichotomous data. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis as far as possible. The denominator being set as the number randomised minus any participants whose outcomes were known to be missing. Analysis Heterogeneity was regarded high if I2 > 30 and either T2 > 0 or there was a low P value (< 0.10) in the Chi2 test for heterogeneity. A fixed-effect model was used for combining data where studies were assumed estimating the same underlying treatment effect. If	Apgar score < 7 at 5 min Yoga group: n = 0/33 Control: n = 0/33 RR 0.00 Use of pharmalogical pain relief Yoga group: n = 14/33 Control: n = 17/33 RR 0.82 (95% CI 0.49 to 1.38) Length of labour Yoga group: mean 519.88 (SD 185.68) Control: 659.79 (SD 272.79) MD -139 (95% CI -252.50 to -27.32) p = 0.01 Augmentation with oxytocin Yoga group: n = 13/33 Control: n = 17/33 RR 0.76 (95% CI 0.45 to 1.31) 4. Breathing	high risk (no participants or other study personnel were blind to group allocation) Durham 1986 Random sequence generation (selection bias): low risk (random number table) Allocation concealment (selection bias): unclear risk (not reported) Incomplete outcome data (attrition bias): unclear (unclear whether data collection were complete) Selective reporting (reporting bias): unclear risk (not reported) Blinding of participants and personnel (performance bias): high risk (no participants or other study personnel and study assessor were blind to group

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	anatomical structures related to pregnancy and birth and (b) yoga, explaining the theories linked to each session. The women were given a booklet and tape cassette, for self-study. Women were asked to retain a record, in diary format Control: standard care. Control group participants were seen by researchers at each of their hospital visits. They engaged in casual conversation for 20-30 minutes. To ensure compliance with the research protocol, weekly telephone calls were made by investigators to each woman in both groups Durham 1986 Participants: n = 30 Inclusion: not specified		substantial clinical or statistical heterogeneity detected, random effects meta analysis was used. Fixed-effect meta-analysis was used where trials were comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where heterogeneity was present or suspected. If substantial heterogeneity was detected, it was investigated using subgroup and sensitivity analysis	techniques and massage (Yildirim 2004) Pain intensity during latent phase Total n = 40 Breathing and massage: mean 1.75 (SD 0.71) Control: 3 (SD 1.48) MD -1.25 (95% CI -1.97 to -0.53) Pain intensity (active phases of labour) Breathing and massage: mean 5.8 (SD 1.15) Control: 8.35 (SD 1.08) MD -2.48 (95% CI -3.13 to -1.83) Satisfaction with pain relief in labour Breathing and massage: n = 8/20 Control: n = 1/20 RR 8.00 (95% CI 1.10 to 58.19)	allocation) Liu 2010 Random sequence generation (selection bias): low risk (lot drawing) Allocation concealment (selection bias): low risk (coded balls) Incomplete outcome data (attrition bias): high risk (n = 51 initially allocated to each group. 40% loss of data although no difference between groups. Post randomisation exclusions: intervention group: prolonged labour and caesarean delivery n = 5, use of epidural n = 15 Control group: prolonged labour and caesarean delivery n = 4, use of epidural n = 18) Selective reporting (reporting bias): unclear risk (protocol

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion: not specified Setting: primiparous couples recruited from the Kansas medical centre, USA Intervention: all groups received instruction on Lamaze breathing techniques. During stage I, phase I (latent) labour, slow chest breathing was used. With phase 2 labour, shallow chest breathing was used to assist the woman cope with the increasing strength of the contractions. During phase 1 music was slow 4/4 tempo with a distinct drum beat. During phase 2, the tempo of the music increased as well as the volume of music. The music was tape recorded and couples had the option of using headphones Control: standard care			5. Music (Liu 2010) Pain intensity latent phase Music group: mean 6.43 (SD 2.57) Control: 6.6 (SD 2.34) MD -0.17 (95% CI -1.41 to 1.07) p = 0.79 Pain intensity active phase Music group: mean 9.17 (SD 1.02) Control: 9.35 (SD 1.02) MD -0.18 (95% CI -0.70 to 0.34) p = 0.49 Caesarean section Music group: n = 5/30 Control: n = 4/30 RR 1.25 (95% CI 0.37 to 4.21) Use of pharmalogical pain relief Music group: n = 15/30 Control: n = 18/30 RR 0.83 (95% CI 0.53	unavailable but appears) Blinding of participants and personnel (performance bias): high risk (no participants or other study personnel were blind to group allocation) Yildirim 2004 Random sequence generation (selection bias): unclear risk (not reported) Allocation concealment (selection bias): unclear risk (not reported) Incomplete outcome data (attrition bias): low risk (no missing data reported) Selective reporting (reporting bias): unclear risk (protocol unavailable) Blinding of participants and personnel (performance bias):

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Liu 2010 Participants: n = 60 Inclusion: criteria: normal pregnancy; primiparous, at term; planned vaginal delivery; singleton; no intention to use pharmacological analgesic during labour Exclusion: not specified Setting: participants were recruited from 2 hospitals in southern Taiwan Intervention: participants could choose 1 of the following types of relaxing, anxiety reducing music: classical, light, popular, crystal children's or Chinese religious music. In addition to receiving standard nursing care, the experimental participants listened to			to 1.32) Length of labour Music group: mean 26.53 (SD 13.32) Control: 29.13 (SD 21.27) MD -2.60 (95% CI -11.58 to -6.38) p = 0.57 Anxiety (latent phase) Music group: mean 6.38 (SD 2.98) Control: 5.2 (SD 2.15) MD 1.18 (95% CI -0.13 to 2.49) p = 0.07 Anxiety (active phase) Music group: mean 8.22 (SD 2.26) Control: 7.68 (SD 2.1) MD 0.54 (95% CI -0.56 to 1.64) p = 0.34	high risk (no participants or other study personnel were blind to group allocation, unclear whether the outcome assessor was blinded to the group allocation) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	1 of these types of music for at least 30 minutes during the latent phase (2-4 cm cervical dilation) and active phase (5-7 cm cervical dilation) of labour. Participants were allowed to choose whether or not to use headphones. Participants in the control group were not aware that they had not had the opportunity to listen to music, but they received routine care after admission Control: standard care Yildirim 2004 Participants: n = 40 Inclusion: primiparous, 38-42 weeks pregnant, at low risk, expecting normal vaginal delivery Exclusion: not stated. Setting: women were recruited from SKK Bakirkoy Hospital,				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Istanbul, Turkey intervention: investigators provided information about labour, breathing techniques and massage in the latent phase of labour, and accompanied these women during labour. The women received nurse-administered massage and were encouraged to perform breathing exercises and self-administered massage. They were also instructed to change their positions and to relax. Slow, deep inhalations were encouraged in the latent phase and rapid, shallow breathing was encouraged in the active phase. The pant blow abdominal breathing technique was applied in the 2nd stage of labour. Plus				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	lower and upper back massages were administered by a nurse. Women were also instructed to give themselves a soft massage in the abdominal area using their fingers. Control: standard care Inclusion criteria Randomised controlled trials (RCTs) only. Exclusion criteria Quasi RCTs in the analyses				
Full citation Smith,Caroline A., Levett,Kate M., Collins,Carmel T., Jones,Leanne, Massage, reflexology and other manual methods for pain management in labour, Cochrane Database of	Sample size The systematic review consisted of six trials (6), but for the purpose of this review outcomes from only three trials with the right intervention (intervention applied in the latent phase) reported here.	Interventions Massage versus usual care	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by the Trials Search Coordinator. CENTRAL, MEDLINE and EMBASE, were searched, and hand searching of 30 journals and conference proceedings was done. No language	Results Pain intensity First stage of labour no. of studies: 2 Intervention n = 62 Control n = 60 RR -1.05 (95% CI -1.43 to -0.67) p < 0.00001 Second stage of labour	Limitations Abasi 2009 Random sequence generation (selection bias): high risk Allocation concealment (selection bias): unclear risk (no details reported) Incomplete outcome data (attrition bias):

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Systematic Reviews, - , 2012 Ref Id 159572 Country/ies where the study was carried out Various Study type Systematic review of RCTs Aim of the study To assess the effect of massage and reflexology and other manual healing methods of pain management in labour, on maternal and perinatal morbidity Study dates Assessed as up-to-date on December 2011 Source of funding	Total participants from the three studies n = 90. Characteristics Abasi 2009 Participants: n = 62 primiparous women Inclusion Gestational age of 37-42 weeks with a singleton pregnancy, vertex presentation, spontaneous onset of labour, cervical dilatation 2-3 cm and planning Exclusion criteria: fever, infection, disc injury, skin condition, broken bones Setting: Fentolhoda maternity hospital, Bojnord, Iran, in 2005 Intervention: back massage for 30 minutes during each phase of labour. Massage applied from sacral spine upward to		restrictions were applied. Weekly current awareness alert for a further of 44 journals was also performed plus monthly BioMed Central email alret was considered. Ongoing clinical trials was searched up to 30 June 2011 in: Australian and New Zealand Trial Registry; Chinese Clinical Trial register; Current Controlled Trials; Clinical Trial. Gov: ISRCTN Register: National Centre for Complementary and Alternative Medicine (NCCAM); and the WHO International Clinical Trials Registry Platform (ICTRP) Selection of studies Two of the reviewers idependently assessed all potential identified studies for inclusion. Data extraction and management Two reviewers extracted the data using the the form	no. of studies: 2 Intervention n = 62 Control n = 62 RR -0.98 (95% CI -2.23 to 0.26) p = 0.12 Third stage of labour no. of studies: 2 Intervention n = 62 Control n = 60 RR -1.03 (95% CI -2.177 to 0.11) p = 0.08 Labour pain no. of studies: 1 Intervention: mean 3.5 Control: mean 5 RR not calculable Satisfaction with pain relief mean (SD) no. of studies: 1 Intervention: mean 4.17 (1.05) Control: mean 3.7 (1.32) RR: not calculable	unclear risk (unclear from paper) Selective reporting (reporting bias): unclear risk (protocol unavailable but appears free of selective reporting) Blinding of participants and personnel (performance bias): high risk (no participants or other study personnel were blind to group allocation) Blinding of outcome assessment (detection bias): low risk (the assessor was blinded) Chang 2002 Random sequence generation (selection bias): low risk Allocation concealment (selection bias): unclear risk (no details reported) Incomplete outcome

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
University of Western Sydney,Women's and Children's Health Research Institute, Child, Youth and Women's Health Services, Australia. National Institute for Health Research, UK	the lumbar spine, then back down to the sacrum. Control: standard care, no other details provided. Chang 2002 Participants: n = 60 women Date: September 1999 and January 2000 Setting: regional hospital in southern Taiwan Inclusion criteria: primiparous; 37-42 weeks pregnant; normal pregnancy and childbirth to date; partner present during labour; dilation no more than 4 cm Exclusion criteria: not reported Intervention: the primary researcher gave massage during uterine contractions in each phase of labour		designed by the Review Group for this purpose. It was analysed in RevMan. Where information was unclear, the original authors were contacted for further details. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Sequence generation - Allocation concealment - Blinding (participants and outcome assessor) - Incomplete outcome data - Selective reporting bias - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, mean difference and standardised mean difference were used, depending on whether trials	Depressed mood no. of studies: 1 Intervention: mean 6.9 Control: mean 14.9 RR: not calculable Stress level no. of studies: 1 Intervention: mean 5.2 Control: mean 3.5 RR: not calculable Use of pharmacological pain relief no. of studies: 1 Intervention n = 2/30 Control n = 0/30 RR 5.0 (95% CI 0.25 to 99.95) p = 0.29 Augmentation no. of studies: 1 Intervention n = 18/30 Control n = 13/30 RR 1.38 (95% CI 0.84 to 2.29) p = 0.20	data (attrition bias): low risk (clear from paper) Selective reporting (reporting bias): unclear risk (protocol unavailable but appears free of selective reporting) Blinding of participants and personnel (performance bias): high risk (no participants or other study personnel were blind to group allocation) Blinding of outcome assessment (detection bias): high risk (blinding not possible) Field 1997 Random sequence generation (selection bias): low risk Allocation concealment (selection bias): unclear risk (no details reported)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	and taught the method to the partner. After the 30-minute massage at each stage, pain and anxiety states were evaluated. The partners repeated the massage at each phase of labour, then a massage assessment form was completed by the researcher. Control: standard care and 30 minutes of the researcher's attendance and casual conversation Field 1997 Participants: n = 28 subjects recruited from Lamaze classes during the last trimester of pregnancy. Setting: The study was undertaken in Florida, USA. No inclusion or exclusion criteria reported		had measured outcomes on the same or different scales. Ordinal data Data measured on scale (e.g. pain measured with visual analogue scale) were analysed as continuous data and other ordinal data (e.g. satisfaction with pain relief) were analysed as dichotomous data. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis as far as possible. The denominator being set as the number randomised minus any participants whose outcomes were known to be missing. Analysis Heterogeneity was regarded high if I2 > 30 and either T2 > 0 or there was a low P value (< 0.10) in the Chi2 test for	Length of laour no. of studies: 1 Intervention mean 10.96 (4.81) Control mean 9.61 (4.24) RR 0.29 (95% CI -0.22 to 0.80) p = 0.26 Emotional experience Anxiety first stage no. of studies: 1 Intervention mean 37.2 (20.3) Control mean 53.47 (22.18) RR -16.27 (95% CI -27.03 to -5.51) p = 0.003 Anxiety second stage no. of studies: 1 Intervention mean 64.9 (24.07) Control mean 73.87 (22.64) RR -8.97 (95% CI -20.79 to 4.90)	Incomplete outcome data (attrition bias): low risk (no losses were reported) Selective reporting (reporting bias): unclear risk (protocol unavailable but full range of outcomes reported) Blinding of participants and personnel (performance bias): high risk (unable to blind) Blinding of outcome assessment (detection bias): low risk (the assessor was blinded) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Intervention: massage therapy plus breathing exercises learned in antenatal classes. Massage taught to birth partner for a mean of 10 minutes by massage therapist. At approximately 3-5 cm dilation, subjects received 20 minutes of head, shoulder/back, hand and foot massage, respectively. Moderate pressure and smooth movements specifically to relax stressed areas of labouring body. Repeated every hour for 5 hours Control: practicing breathing exercises learned in antenatal classes Inclusion criteria Randomised control trials and cluster randomised. Only the		heterogeneity. A fixed-effect model was used for combining data where studies were assumed estimating the same underlying treatment effect. If substantial clinical or statistical hetrogenity detected, random effects meta analysis was used. Fixed-effect meta-analysis was used where trials were comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where heterogeneity was present or suspected. If substantial heterogeneity was detected, it was investigated using subgroup and sensitivity analysis	p = 0.14 Anxiety third stage no. of studies: 1 Intervention mean 80.6 (19.11) Control mean 85.17 (18.29) RR -4.57 (95% CI -14.04 to 4.90) p = 0.34	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	abstracts with the additional information on the method and results (provided by author), are included. Exclusion criteria Non randomised studies and quasi randomised trials				
Full citation Parsons,M., Bidewell,J., Nagy,S., Natural eating behavior in latent labor and its effect on outcomes in active labor, Journal of Midwifery and Women's Health, 51, e1-e6, 2006 Ref Id 159613 Country/ies where the study was carried out USA Study type Prospective	Sample size Eating Group n = 82 Non-eating group n = 94 Characteristics There were no statistically significant differences observed between the two groups in ethnicity and mean gestational age at birth. Women in non-eating group were significantly younger in age compared with the eating group.	Interventions Food consumption during latent phase of labour	Details Women were recruited from four maternity hospitals in Sydney over a 7 month period. Women were recruited for the research with the last 4 weeks of their pregnancy. At the time of recruitment each woman was given a form to fill out while in labour, they were also asked to record the time when the first contraction started and also to record the food and fluid consumed. The effects of a eating only at the latent phase were assessed here as there was an assumption that women are not eating or not allowed by midwife to eat	Results Eating n = 82 Non-eating n = 94 Duration of the latent phase mean (SD) Eating group: 8.52 (8.31) Non-eating group: 4.05 (6.79) P < 0.001 Duration of the active phase mean (SD) Eating group: 9.75 (4.40) Non-eating group: 7.40 (2.97) P < 0.001	Limitations Woman had to self-report and complete the survey form during her labour, had to self-record the time when the first regular contraction commenced, and had to record her food and fluid intake during the latent phase. All of these depended on the mother's retrospective assessment. Women also self-reported the start of the latent phase by

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
observational study Aim of the study To examine the effect of eating during latent phase of labour on the hospital-estimated labour duration and on maternal and neonatal outcomes Study dates Not specified Source of funding university of Westeren Sydney and the New South Wales Midwives Association.	Inclusion criteria Nulliparous women, English speaking, low risk pregnancy Exclusion criteria Induction of labour, Oxytocin infusion, caesarean section delivery		during the active phase of labour. The onset of labour was self diagnosed and recorded by women and active phase was identified by midwife through women's retrospective account of her labour and not by the cervical assessment Twenty three (23%) percent of women in the eating group consumed a full meal (meat, vegetable, pasta, fish and chips) during the latent phase and 77% consumed a light meal (toast, cereal and sandwiches). Women in the non-eating group consumed fluids such water, fruit juice, tea and coffee.	Hospital estimated labour mean (SD) Eating group: 9.75 (4.40) Non-eating group: 7.40 (2.97) P < 0.001 Medical augmentation n (%) Eating group: 25 (30%) Non-eating group: 17 (18%) P = Not reported Epidural Eating group: 10 (12%) Non-eating group: 11 (12%) P = Not reported Pethidine Eating group: 46 (56%) Non-eating group: 49 (52%) P = Not reported	recording the regular contractions and it is not clear how the end of the latent phase was assessed as some women arrived at the hospital in their active phase. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Forceps or ventous Eating group: 19 (23%) Non-eating group: 15 (16%) P = Not reported SCN admission Eating group: 4 (5%) Non-eating group: 7 (7%) P = Not reported 5 min apgar score mean (SD) Eating group: 8.99 (0.60%) Non-eating group: 8.97 (0.69%) P = Not reported Intravenous hydration Eating group: 13 (16%) Non-eating group: 11 (12%) P = Not reported	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Vomiting Eating group: 10 (12%) Non-eating group: 20 (21%) P = Not reported Maternal blood loss, ml, mean (SD) Eating group: 241.98 (148.84) Non-eating group: 234.57 (121.16) P = Not reported	

1.1.7 What is the effectiveness of continuous electronic fetal monitoring compared with intermittent auscultation ON ADMISSION?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation	Sample size	Interventions	Details	Results	Limitations
Mitchell,K., The effect of the labour electronic fetal monitoring admission test on operative delivery in low-risk women: a randomised controlled	See entry in systematic review by Devane et al. (2012) Characteristics	Admission CTG Intermittent auscultation	Care during labour Following the admission CTG, the decision to end tracing and start intermittent monitoring was left up to the	All priority outcomes of interest were reported by the authors of the systematic review.	See entry in systematic review by Devane et al. (2012) Other information MOST STUDY DETAILS ARE

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
trial, Evidence Based Midwifery, 6, 18-26, 2008 Ref Id 66879 Country/ies where the study was carried out England Study type Randomised controlled trial Aim of the study To test the relationship between the labour electronic fetal monitoring (EFM) admission test and obstetric intervention Study dates 15th December 2002 to 30th June 2006 Source of funding Initial grant from the Buckinghamshire Hospitals NHS Trust's Research Department and establishment of a	Parity (n (%)) - 0 cardiotocograph (CTG): 203 (70) Auscultation: 199 (68) - 1 or more CTG: 95 (30) Auscultation: 85 (32) Inclusion criteria See entry in systematic review by Devane et al. (2012) Exclusion criteria See entry in systematic review by Devane et al. (2012)		midwives and clinicians caring for the woman. The CTG was stopped when it was considered normal (as defined by the 2001 NICE guideline). This meant that the length of CTG could vary between the 15 minute admission test and the whole labour period. Women allocated to auscultation were intermittently monitored during labour. However, regardless of allocation, if the woman was considered to have become higher risk, continuous EFM was offered and recommended as per unit policy. Analysis was by intention to treat.		REPORTED IN DEVANE ET AL. (2012). THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
research midwife role in the unit					
Full citation Cheyne,H., Dunlop,A., Shields,N., Mathers,A.M., A randomised controlled trial of admission electronic fetal monitoring in normal labour, Midwifery, 19, 221-229, 2003 Ref Id 158779 Country/ies where the study was carried out Scotland Study type Randomised controlled trial Aim of the study To test the hypothesis that admission electronic fetal monitoring (EFM) for healthy pregnant women in spontaneous labour would lead to an increase	Sample size See entry in systematic review by Devane et al (2012) Characteristics Women having artificial rupture of membranes (n (%)) cardiotocgraph (CTG): 65 (44%) Auscultation: 60 (36%) Primiparous women (n (%)) CTG: 65 (44%) Auscultation: 76 (46%) Inclusion criteria See entry in systematic review by Devane et al (2012) Exclusion criteria See entry in systematic review by Devane et al	Interventions Admission EFM Intermittent auscultation with a hand-held Doppler device	Details Care during labour Following randomisation, women received either a routine 20 minute period of EFM at the time of admission to the Midwives Birth Unit, or to receive auscultation immediately following a contraction for a minimum of 60 seconds. With the exception of the randomised intervention, women received the same admission assessment, i.e. history taking, blood pressure measurement, temperature recording, abdominal palpation, and vaginal examination. Subsequently, all women were monitored using	Results All priority outcomes of interest reported in trial are reported in the systematic review (Devane et al., 2012)	Limitations See Devane et al. (2012) for risk of bias assessment Other information MOST STUDY DETAILS ARE REPORTED IN DEVANE ET AL. (2012). THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
in continuous EFM when compared to women who have no admission EFM Study dates Not reported Source of funding North Glasgow University Hospitals NHS Trust	(2012)		intermittent auscultation, at 15 minute intervals in the first stage of labour and at 5 minute intervals, or after a contraction, during the second stage of labour. EFM was used, where required, in accordance with the guidelines for the unit. However, it should be noted that in addition to the women who received continuous EFM during labour (as reported in the systematic review), a further 125 (84%) of women in the CTG arm and 61 (37%) of the auscultation arm received additional EFM during labour. The reasons were (n (%)): - Admission EFM not discontinued CTG: 80 (64)		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Auscultation: 1 (2) - FHR abnormalities noted CTG: 29 (23) Auscultation: 13 (21) - EFM commenced on transfer to labour ward CTG: 10 (8) Auscultation: 33 (54) - Meconium stained liquor CTG: 2 (2) Auscultation: 9 (15) - Other CTG: 4 (3) Auscultation: 5 (8)		
Full citation Devane,D., Lalor,J.G., Daly,S., McGuire,W., Smith,V., Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward	Sample size Trials: N = 4 Women: N = 13296 Characteristics Cheyne (2003) - Inclusion criteria: Healthy	Interventions Admission CTG: Defined as a commonly used screening test, comprising a short, usually 20 minute long,	Details Searching for studies The Trials Search Co-ordinator was contacted on 17 May 2011, and asked to search the Cochrane Pregnancy and Childbirth Group's	Results Mode of birth (number/total) a. Caesarean section CTG: 248/5657 Auscultation: 207/5681	Limitations The systematic review did not have any serious limitations. Impey (2003) included women with an early amniotomy, and only included women with clear amniotic fluid. The study

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
for assessment of fetal wellbeing, Cochrane Database of Systematic Reviews, 2, CD005122-, 2012 Ref Id 157062 Country/ies where the study was carried out Included trials were conducted in England, Scotland and Ireland Study type Systematic review of randomised controlled trials Aim of the study To compare the effects of admission cardiotocograph (CTG) with intermittent auscultation of the fetal heart rate (FHR) on maternal and infant outcomes for pregnant women without risk factors for intrapartum hypoxia.	women with a normal pregnancy, presenting in spontaneous labour and who were eligible for admission to the Midwives Birth Unit - Exclusion criteria: Women with risk factors - N = 344 women randomised on admission in labour - Admission CTG: Routine 20 minute period at time of admission - Intermittent Auscultation: Fetal heart was auscultated during and immediately following a contraction for a minimum of 60 seconds Impey (2003) - Inclusion criteria: Admitted in labour, singleton pregnancy, less than 42 completed weeks gestation, no suspicion or evidence of antenatal fetal compromise, no adverse	recording of the FHR and uterine activity Intermittent auscultation: Intermittent surveillance of the FHR using a hand-held Doppler or a Pinard stethoscope Both tests were performed upon the mother's admission to the labour ward.	Trials Register. In addition, CENTRAL, MEDLINE, CINAHL and Dissertation Abstracts were searched. The reference list of identified studies was also searched, and any studies assessed for eligibility. No language restrictions were applied. No studies were excluded. Data collection and analysis Two review authors independently assessed studies for inclusion. They then extracted data into a pre-designed form and resolved discrepancies through discussion. Data were entered into RevMan and checked for accuracy. If there was any unclear information, the authors were	RR 1.20 (95% CI 1.00 to 1.44) Heterogeneity: I2 = 0.0% Test for overall effect: Z = 2.00, p = 0.045 [4 trials: Cheyne 2003, Impey 2003, Mires 2001, Mitchell 2008] b. Instrumental vaginal birth CTG: 782/5657 Auscultation: 716/5681 RR 1.10 (95% CI 0.95 to 1.27) Heterogeneity: I2 = 38% Test for overall effect: Z = 1.28, p = 0.20 [4 trials: Cheyne 2003, Impey 2003,	also included some women (< 5%) who had a previous caesarean section (CS) and who went into labour prior to 37 weeks completed gestation. However, the authors of the review contacted the study authors, who provided data for those 37-42 and without a previous CS, and the data for these women are what have been used in the main analysis. Mires (2001) randomised women in the third trimester, and between randomisation and admission in labour, 37% of women developed a complication, so that only 2367 were judged to be low risk in labour. The low risk subgroup data were provided by the authors, and these is what have been used in the analysis for this systematic review. The following represents the review author's risk of bias for the included studies. Overall, all studies were assessed as being

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Content was assessed as up-to-date on 14 November 2011 Source of funding Health Research Board, Ireland	obstetric history, clear amniotic fluid, maternal temperature of 37.5 degrees or less at admission - N = 8628 women randomised on admission in labour - Admission CTG: 20 minute admission CTG immediately after early amniotomy done on diagnosis of labour in women presenting to delivery ward - Intermittent Auscultation: Done for 1 minute after a contraction every 15 minutes in the first stage and every 5 minutes in the second stage of labour. It was done after early amniotomy on diagnosis of labour in women presenting to the delivery ward. Mires (2001) - Inclusion criteria: Booked		contacted to provide details. Quality assessment Risk of bias was assessed independently by two authors using the The Cochrane Collaboration's tool for assessing risk of bias. The following criteria were considered: - Sequence generation - Allocation concealment - Blinding: due to the intervention, it would not be possible to blind participants or those providing care; however, the authors report that they did consider whether outcome assessors were blinded - Incomplete outcome data: low risk was defined 20% or less missing data, and high risk as more than 20% missing data - Selective reporting	Mires 2001, Mitchell 2008] Fetal and neonatal deaths (number/total) CTG: 5/5658 Auscultation: 5/5681 RR 1.01 (95% CI 0.30 to 3.47) Heterogeneity: I2 = 0.0% Test for overall effect: Z = 0.02, p = 0.98 [4 trials: Cheyne 2003, Impey 2003, Mires 2001, Mitchell 2008] Major neonatal morbidity (number/total) a. Hypoxic ischaemic encephalopathy	at low risk of bias: Cheyne 2003 - Random sequence generation: low risk of bias - Allocation concealment: low risk of bias - Blinding of outcome assessors: high risk of bias. They were not blinded. - Incomplete outcome data: low risk of bias. The trial publication reports that 22 women (7%) were excluded from the analysis (21 not in labour, 1 missing randomisation card); however, the review authors contacted the trial authors and received data for 21/22 of them - Selective reporting: low risk of bias Impey 2003 - Random sequence generation: low risk - Allocation concealment: low risk of bias - Blinding of outcome assessors: low risk of bias - data were entered and neonatal

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	for hospital delivery, attended a hospital or community based consultant led clinic in the third trimester, and had no obstetric complications at that visit that would warrant continuous monitoring of FHR (pre-eclampsia or hypertension in previous or current pregnancy, essential hypertension, diabetes, suspected intrauterine growth restriction (IUGR), placental abruption or praevia or bleeding of unknown origin, multiple pregnancy, fetal malformation, previous caesarean section, breech presentation, or rhesus isoimmunisation - N = 3752 women randomised during third trimester. - Admission CTG: 20 minute CTG on admission in spontaneous		bias: established by cross checking the outcomes reported in the methods and results sections of the publication - Other sources of bias Missing data Levels of attrition were noted for the studies. Sensitivity analysis was done to explore the effect of including studies with high attrition. All analyses were carried out on an intention-to-treat basis. Denominators were the number randomised, minus any women whose outcomes were known to be missing. Analysis Statistical analysis was done in RevMan. A random effects model was used. This was because the authors felt	CTG: 6/1186 Auscultation: 5/1181 RR 1.19 (95% CI 0.37 to 3.90) Heterogeneity: NA Test for overall effect: Z = 0.29, p = 0.77 [1 trial: Mires 2001] b. Neonatal seizures CTG: 10/4017 Auscultation: 14/4039 RR 0.72 (95% CI 0.32 to 1.61) Heterogeneity: I2 = Test for overall effect: Z = , p = [1 trial: Impey 2003]	assessment was done without knowledge of treatment allocation - Incomplete outcome data: low risk of bias. Loss to follow-up was 0.5% in CTG arm and 0.6% in Auscultation arm - Selective reporting: low risk of bias Mires 2001 - Random sequence generation: low risk of bias - Allocation concealment: low risk of bias - Blinding of outcome assessors: low risk of bias. Data analysts were blind to randomisation code - Incomplete outcome data: low risk of bias. - Selective reporting: low risk of bias - Other bias: Between randomisation (third trimester) and admission in labour, 1384 women (37%) developed a complication that warranted continuous FHR monitoring in labour. The authors provided

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	uncomplicated labour - Intermittent Auscultation: Auscultation of the fetal heart with hand held Doppler device during and immediately after 1 contraction Mitchell (2008) - Inclusion criteria: Labouring women considered to be at 'low risk' of fetal or maternal complications on admission - Exclusion criteria: Any minor maternal medical complication (e.g. diabetes or essential hypertension), previous caesarean, preterm labour (less than 37 completed weeks), multiple pregnancy, prolonged pregnancy (more than 42 weeks), prolonged membrane rupture (more than 24 hours), induction of labour, meconium-stained liquor,		that there was sufficient clinical heterogeneity to expect that the underlying treatment effect would differ. In Impey et al. (2003), only women whose liquor was known to be clear were included. In the other trials, membrane rupture and clear liquor were not inclusion criteria.	Admission to NICU (number/total) CTG: 219/5656 Auscultation: 213/5675 RR 1.03 (95% CI 0.86 to 1.24) Heterogeneity: I2 = 0.0% Test for overall effect: Z = 0.32, p = 0.75 [4 trials: Cheyne 2003, Impey 2003, Mires 2001, Mitchell 2008]	data for the low risk women separately and these are used for the analysis in the review. Mitchell 2008 - Random sequence generation: low risk of bias - Allocation concealment: low risk of bias - Blinding of outcome assessors: unclear risk of bias - no details given - Incomplete outcome data: low risk of bias - Selective reporting: low risk of bias Other information The authors identified one trial which was on-going - the ADCAR trial. It is unclear when this trial will be published. Monitoring during labour 3 trials reported the number of women having continuous EFM in labour and in 2 of the trials, the difference was significant: Cheyne 2003:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	maternal pyrexia, rhesus sensitisation, polyhydramnios, oligohydramnios, pre-eclampsia or blood pressure over 140/90 mmHg, abnormal presentation or lie (e.g. breech, transverse), high head (5/5ths palpable per abdomen), antepartum or intrapartum haemorrhage, known or suspected IUGR, any known or suspected fetal medical complication, abnormal Doppler artery velocimetry, known fetal malformation, poor obstetric history (e.g. history of stillbirth), un-booked - N = 582 women randomised on admission in labour - Admission CTG: 15-minute CTG on admission in spontaneous uncomplicated labour - Intermittent Auscultation:				- CTG: 10/157 (6.4%) - Auscultation: 10/177 (5.6%) (NS) [Note: a further 125 women from the CTG arm and 61 women from the auscultation arm received additional EFM during labour] Impey 2003: - CTG: 2341/4017 (58.3%) - Auscultation: 1686/4039 (41.7%) (p < 0.00001) Mires 2001: - CTG: 672/1185 (56.7%) - Auscultation: 551/1178 (46.8%) (p < 0.00001) Total: - CTG: 3023/5359 - Auscultation: 2247/5394 (RR 1.30 [95% CI 1.14 to 1.48])

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Auscultation of the fetal heart for one continuous minute using a Pinard stethoscope or Doppler ultrasound device, after a contraction, at least every 15 minutes in the first stage of labour and every 5 minutes in the second stage of labour Inclusion criteria Randomised and quasi-randomised trials comparing admission CTG with intermittent auscultation of the FHR Exclusion criteria None reported				
Full citation Impey,L., Reynolds,M., MacQuillan,K., Gates,S., Murphy,J., Sheil,O., Admission cardiotocography: A randomised controlled trial, Lancet, 361, 465-	Sample size See entry in systematic review by Devane et al. (2012) Characteristics The following relate to the	Interventions Admission CTG Intermittent auscultation	Details Care during labour In the intermittent auscultation group, auscultation was done for 1 minute after a contraction, every 15 minutes in the first stage	Results All priority outcomes were reported in the systematic review (see Devane et al., 2012)	Limitations There is indirectness of population due to the proportion of women who had induction of labour. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
470, 2003 Ref Id 60264 Country/ies where the study was carried out Ireland Study type Randomised controlled trial Aim of the study To compare the effect on neonatal outcomes of admission CTG versus intermittent auscultation of the fetal heart rate Study dates August 1997 to April 2001 Source of funding Research Committee of the National Maternity Hospital, Dublin	whole study population, not the low risk sub-group from the systematic review. Induction of labour (n/total (%)) Cardiotocograph (CTG): 765/4298 (18) Auscultation: 749/4282 (17) Major congenital anomaly (n/total (%)) CTG: 27/4298 (1) Auscultation: 18/4282 (<1) Parity (n/total (%)) - 0 CTG: 2093/4298 (49) Auscultation: 2077/4282 (49) - 1 to 3 CTG: 2121/4298 (49) Auscultation: 2115/4282 (49) - ≥ 4 CTG: 81/4298 (2) Auscultation: 90/4282 (2)		and every 5 minutes in the second stage. EFM was used only if any of the following occurred: a deceleration in fetal heart rate or persistent tachycardia on auscultation; meconium in liquor or heavily blood stained liquor; maternal temperature of 38 degrees or higher; labour lasting longer than 8 hours. In the CTG group, the CTG was reviewed by the admitting midwife after 20 minutes. If the baseline FHR was 110-160 bpm, variability was visually assessed as more than 5 per minutes, decelerations were absent, and if there was more than one acceleration, it was classified as normal. Subsequent care was then the same as the		All women appear to have had an early amniotomy. MOST STUDY DETAILS ARE REPORTED IN DEVANE ET AL. (2012). THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria See entry in systematic review by Devane et al. (2012) Exclusion criteria See entry in systematic review by Devane et al. (2012)		intermittent auscultation group. If the criteria for normal were not met, CTG was continued until delivery. 58% of the CTG arm and 42% of the Auscultation arm had continuous EFM during labour - this is reported as an outcome in the systematic review.		
Full citation Mires,G., Williams,F., Howie,P., Randomised controlled trial of cardiotocography versus Doppler auscultation of fetal heart at admission in labour in low risk obstetric population, BMJ, 322, 1457-1460, 2001 Ref Id 97907 Country/ies where the study was carried out Scotland Study type	Sample size See entry in systematic review by Devane et al. (2012) Characteristics Women having artificial rupture of membranes (n/total) a. All women Cardiotocograph (CTG): 1065/1864 Auscultation: 1031/1879 b. Low risk women CTG: 640/1185 Auscultation: 614/1175	Interventions Admission CTG Intermittent auscultation with Doppler	Details The reasons for which women were excluded from the 'low risk' subgroup analysis are listed here. Some women could have more than one reason (n (%)): - Antepartum haemorrhage: 159 (4.2) - Raised blood pressure: 271 (7.2) - Suspected small for dates: 56 (1.5) - Preterm labour: 48 (1.30) - Gestational diabetes: 2	Results Metabolic acidosis at birth (defined as umbilical cord pH < 7.20 with a base deficit of > 8.0 mmol/l) a. All women CTG: 252/1370 Auscultation: 262/1378 b. Low risk women CTG: 159/876 Auscultation: 154/860	Limitations For the outcome of metabolic acidosis, 1003/3751 (26.7%) of the whole study population, corresponding to 641/2367 (27.1%) of the low risk women, had no outcome data available. Power calculation and sample size estimate were changed as the trial went along, once after the interim analysis and once following an audit of the data available. A significantly higher proportion of women randomised to CTG

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Randomised controlled trial Aim of the study To compare the effect of admission CTG and Doppler auscultation of the fetal heart on neonatal outcome and level of obstetric intervention in a low risk obstetric population Study dates Not reported Source of funding Chief Scientists Office of the Scottish Executive	Proportion of nulliparous and multiparous women in the trial is not reported. Inclusion criteria See entry in systematic review by Devane et al. (2012) Exclusion criteria See entry in systematic review by Devane et al. (2012)		(0.1) - Fetal anomaly: 2 (0.1) - Reduced fetal movements and suspected fetal compromise: 63 (1.7) - Meconium stained liquor: 99 (2.6) - Intrauterine death: 3 (0.1) - Persistent breech: 67 (1.8) - Membranes ruptured before labour: 164 (4.4) - Induction of labour: 833 (22.2) - Baby born before arrival at hospital: 19 (0.5) - Elective CS: 61 (1.6) - Women withdrew from trial: 31 (0.8) - Other: 44 (1.2) Total: 1384 (36.9) In the confirmed low risk women, 21.5% of those randomised to CTG were considered to have an abnormal fetal heart		had an abnormal FHR pattern at the start of labour, when compared to women randomised to auscultation. Part of the reason that the original trials needed to be accessed was to establish what the trial protocol for monitoring in labour was. No details are provided above those that were reported in the Cochrane review, therefore it cannot be established whether the admission CTG compared with intermittent auscultation on admission was the only way in which monitoring during labour differed. The following data for the number of women receiving continuous monitoring in labour are reported: Continuous fetal heart rate monitoring in labour (n/total (%)) a. All women CTG: 1246/1865 (66.8) Auscultation: 1128/1882 (59.9) b. Low risk women

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			trace at the onset of labour, compared with 3.6% in the Doppler group (p < 0.0001)		CTG: 672/1186 (56.7) Auscultation: 551/1178 (46.8) Other information MOST STUDY DETAILS ARE REPORTED IN DEVANE ET AL. (2012). THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS

1.1.8 What is the effectiveness of continuous electronic fetal monitoring compared with intermittent auscultation DURING ESTABLISHED LABOUR?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation	Sample size	Interventions	Details	Results	Limitations
Grant,A., O'Brien,N., Joy,M.T., Hennessy,E., MacDonald,D.,	N = 13079 (number of children live	Intermittent auscultation (n = 6552	All 30 of the children from the original trial, who survived following neonatal	Cerebral palsy (n/total) Auscultation: 10/6552 (0.15) EFM: 12/6527 (0.18)	Appropriate randomisation: Yes Allocation concealment:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Cerebral palsy among children born during the Dublin randomised trial of intrapartum monitoring, Lancet, 2, 1233-1236, 1989 Ref Id 164086 Country/ies where the study was carried out Ireland Study type Randomised controlled trial Aim of the study To confirm that the absence of neonatal signs (such as seizures) suggestive of intrapartum asphyxia is strong evidence that asphyxia was not the cause of later cerebral palsy To estimate the proportion of all cases of cerebral palsy that might possibly be	born during the trial) Characteristics See entry of MacDonald et al., 1985 for details Inclusion criteria See entry of MacDonald et al., 1985 for details Exclusion criteria See entry of MacDonald et al., 1985 for details	babies) Electronic fetal monitoring (EFM) (n = 6527 babies)	seizures, and 125 (91%) of the further 138 children whose neurological status was judged to be abnormal, were considered. They underwent a general physical and detailed neurological examination by an experienced paediatrician who was blind to both the monitoring method and the nature of the neonatal neurological abnormality. In order to identify other cases, not originally identified as having abnormal neurological signs, data were sought from specialist remedial clinics in Ireland. Once a child was identified, information about the pregnancy, labour, delivery and neonatal period was extracted from the hospital case-record or trial data sheet. Then the children were divided based on allocation.	Details of the cases Note: - Auscultation group 3 were from the 21 babies with seizures that survived during the neonatal period 7 were identified via clinic notification - EFM group 4 were from the 9 babies with seizures that survived during the neonatal period 8 were identified via clinic notification a. Children with abnormal neurological signs during neonatal period 30 out of the 39 babies with neonatal seizures survived to be discharged from hospital. 3 from each group were then judged to have cerebral palsy at 4 years old. 4 children (2 in each arm) had "spastic quadriplegia	Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: Yes Missing data/loss to follow-up: Possible because apart from those babies with seizures/other symptoms after birth, other children were identified through specialist clinics in Ireland. This would not have covered any children who had moved away or possibly any who died Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: in the original

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
associated with intrapartum asphyxia Study dates Recruitment into the original trial began on March 31st 1981 and ended on April 10th 1983 Follow-up was at age 4 Source of funding See entry on MacDonald et al., 1985 for details of the trial				with severe mental retardation." There had been signs suggestive of asphyxia in 3 which were apparent both during labour and after delivery. The fourth child was born at 34 weeks gestation with a 5 minute Apgar of 8, then had severe respiratory distress syndrome following intraventricular haemorrhage and then post haemorrhage hydrocephalus. The other 2 children had mild spastic hemiplegias, and had sequence of signs suggestive of asphyxia during labour and after birth. A seventh child with mild spastic hemiplegia was identified from among the 125 children who were formally reassessed because of neonatal neurologic abnormalities other than seizures. There had been transient	trial 22.5% of women were considered 'high risk' Other information This is a follow-up to MacDonald et al., 1985

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				abnormalities of tone, reflexes and behaviour, but they had resolved within 48 hours of birth. b. Identified from clinics In 12 out of the 15 cases (of which one was a twin), labour delivery and the neonatal period seemed normal. Of the 3 others, 1 (allocated EFM) had respiratory distress syndrome and pneumonia following spontaneous rupture of the membranes and birth at 30 weeks. One (allocated auscultation) had an emergency caesarean section (CS) because of failed induction at 43 weeks and suspected intrauterine infection. The third (allocated auscultation) was discharged apparently well but later had severe gastroenteritis that had been complicated by cerebral oedema with seizures and later meningitis.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Kelso,I.M., Parsons,R.J., Lawrence,G.F., Arora,S.S., Edmonds,D.K., Cooke,I.D., An assessment of continuous fetal heart rate monitoring in labor. A randomized trial, American Journal of Obstetrics and Gynecology, 131, 526-532, 1978 Ref Id 164097 Country/ies where the study was carried out England Study type Randomised controlled trial Aim of the study To compare the usefulness of continuous fetal heart	Sample size N = 504 Characteristics Maternal age/years (mean ± SD) Auscultation: 25.6 ± 5.0 EFM: 26.0 ± 4.9 (NS) Gestation/weeks (mean ± SD) Auscultation: 39.75 ± 1.18 EFM: 39.67 ± 1.32 (NS) Nulliparous (n/total) Auscultation: 134/251 EFM: 116/253 Cervical assessment using Bishop score (n/total) 1 - 4 Auscultation: 43/251 EFM: 38/253 5 - 8	Interventions Auscultation (n = 251) EFM (n = 253)	Details All women under the care of the University Department at the Jessop Hospital for Women, Sheffield, admitted to the labour ward during the study period had their labours analysed. Women were admitted in spontaneous labour or to be induced. The study authors wanted to evaluate a non high-risk population; therefore, the exclusion criteria aimed to exclude high risk women. All other women were allotted a sealed envelope when they were admitted, containing treatment allocation. Women allocated to continuous monitoring had a fetal scalp electrode attached, with or without an intrauterine pressure catheter, at the earliest convenient time. Oxytocin was given to all women when indicated.	Results Mode of birth (n/total) a. Spontaneous vaginal birth Auscultation: 162/251 EFM: 158/253 b. Forceps or ventouse delivery Auscultation: 78/251 EFM: 71/253 c. Caesarean section Auscultation: 11/251 (3 for fetal distress) EFM: 24/253 (4 for fetal distress) Perinatal death (n/total) Auscultation: 1/251 EFM: 0/253 (Note: the mother was multiparous, admitted at 41 weeks in spontaneous labour. The labour was slow despite an oxytocin infusion, and there were at least two separate episodes of fetal	Limitations Appropriate randomisation: Unclear - method of randomisation is not reported Allocation concealment: Yes Groups comparable at baseline: Yes; however, there was a significantly shorter first and second stage of labour in the EFM arm. Groups received same care (apart from intervention): Monitoring was internal; therefore, in order to fit the scalp electrode, the EFM arm are likely to have received an amniotomy to fit the electrode in cases where the membranes had not ruptured. This would not be necessary in the other arm of the trial. Blinding of participants: Not reported Blinding of staff providing care: Not reported

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
rate monitoring in labour using the dip area as a measure of fetal distress with or without intrauterine pressure recordings Study dates July 1976 to June 1977 Source of funding The first author received a British Commonwealth Medical Fellowship. Financial assistance was also gained from Pye Dynamics Ltd and Devices, Ltd	Auscultation: 154/251 EFM: 151/253 9 - 12 Auscultation: 54/251 EFM: 64/253 (NS) Type of labour (n/total) - Spontaneous Auscultation: 120/251 EFM: 132/253 - Accelerated Auscultation: 69/251 EFM: 51/253 - Induced Auscultation: 62/251 EFM: 70/253 (NS) Intra or postpartum pyrexia (n/total) Auscultation: 7/251 EFM: 8/253 (NS) Birth weight / grams (mean ± SD) Auscultation: 3349 ±		In women allocated to intermittent auscultation, the FHR was counted every 15 minutes (or more frequently if indicated) during or immediately after a contraction. A Pinard fetal stethoscope was used, and the rate was counted for 1 full minute. If there was any difficulty hearing the sounds, an Ultrasonic Doppler was used intermittently. A double clamped section of the cord was collected at delivery before the baby's first breath. Arterial and venous blood gas measurements were taken. Augmentation, using amniotomy alone or amniotomy with oxytocin infusion, was performed it the progress of the labour fell to the right of the nomogram. Decisions to perform caesareans or instrumental deliveries were up to the duty staff.	tachycardia [170 - 190 bpm]. After 12 hours and 45 minutes, meconium stained liquor was noted. The FHR was 190 bpm and the cervix was dilated. Forceps were applied to rotate the vertex. After birth, the baby was transferred to SCBU and intubated. The baby died of meconium aspiration at 4 hours) Abnormal neurologic signs (n/total) Auscultation: 3/251 EFM: 2/253 (Note: All of the 5 babies had depressed Apgar scores and were admitted to SCBU: - in the EFM group: both babies were hypertonic at birth, but there were no symptoms at day 9 or week 6. - in the auscultation group: The first baby was jittery and irritable for 3 days, but there were no abnormal neurologic findings on day 6 or week 6.	Blinding of outcome assessors: Not reported Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: 26% of women had induction of labour. Other information CTG: internal 2 other perinatal deaths are detailed in the text, but they were born to women excluded from the trial due to breech presentation. Length of labour (mean ± SD) a. First stage / hours Auscultation: 6.63 ± 3.88 EFM: 5.94 ± 3.36 ($p < 0.05$)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	430 EFM: 3335 ± 459 Inclusion criteria Admitted to the labour ward during the study period Exclusion criteria Breech presentation Multiple pregnancy Maternal age of 40 years or greater Previously mentally disabled or spastic child resulting from delivery Previous perinatal death - cause unknown Previous severe fetal distress - Apgar score of 3 or less Hypertension with diastolic pressure 100		Outcomes reported: 1. Mode of birth: rate of spontaneous delivery, forceps or ventouse, and caesarean section are reported 2. Perinatal death 3. Admission to special care baby unit (SCBU) 4. Abnormal neurological signs	The second baby had a cyanotic attack and a left sided convulsion at 6 hours after delivery. The baby was treated with phenobarbitone for 3 days, and there were no further convulsions, and no issues at day 12 or week 6. The third baby was "stiff and irritable" at 11 hours and received phenobarbitone for 3 days, after which time there were no abnormal neurologic findings) Admission to SCBU (n/total) Auscultation: 43/251 EFM: 45/253 Note: the indications for admission were as follows (n): -- infant depressed at delivery Auscultation: 12 EFM: 9 -- less than 2500 grams birth weight or considered preterm by attending paediatrician	b. Second stage / minutes Auscultation: 32.35 ± 25.23 EFM: 28.01 ± 21.00 (p < 0.05) c. Third stage / minutes Auscultation: 6.66 ± 10.32 EFM: 6.19 ± 8.13 (NS)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	mmHg or 100 mmHg with proteinuria Two consecutive estrogen estimations outside 2 SD from the normal Anaemia of 8 g/dl or less Insulin dependent diabetes Admitted fully dilated and ready for birth Missed			Auscultation: 7 EFM: 6 -- jaundiced - admitted for phototherapy Auscultation: 10 EFM: 16 -- treated maternal thyrotoxicosis euthyroid at time of labour Auscultation: 4 EFM: 0 -- maternal thrombocytopenia Auscultation: 1 EFM: 0 -- maternal pyrexia > 38 degrees Auscultation: 1 EFM: 0 -- meconium aspiration Auscultation: 3 EFM: 2 -- congenital anomalies Auscultation: 1 EFM: 2 -- hypothermia Auscultation: 1 EFM: 4 -- other Auscultation: 3 EFM: 6	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Cord blood gas values The authors report that cord arterial and venous blood gas analysis was done on 37 patients in each arm. There were no statistically significant differences in the proportion of infants with pH of 7.25 or less, or base deficit of 10 mmol/l or more. No further details are given; therefore, this is not reported in the GRADE table.	
Full citation Leveno,K.J., Cunningham,F.G., Nelson,S., Roark,M., Williams,M.L., Guzick,D., Dowling,S., Rosenfeld,C.R., Buckley,A., A prospective comparison of selective and universal electronic fetal monitoring in 34,995 pregnancies, New	Sample size N = 34,995 (However, the population of interest for this review is 14,618) Characteristics The following represent characteristics of the entire study population. Details of the low risk sub-group are not	Interventions Selective monitoring: intermittent auscultation for low risk women and EFM for high risk women (n = 7330) Universal monitoring: all women	Details This was a trial comparing the policy of all women being monitored using EFM (universal monitoring) with a policy of only monitoring high risk women with EFM (selective monitoring). The trial employed these different policies during alternating months, and compared the results. The standard policy in the	Results Caesarean section for fetal distress (n/total (%)) Selective/auscultation: 28/7330 (0.4) Universal/EFM: 64/7288 (0.9) (p < 0.01) Mortality (n/total (%)) a. Intrapartum fetal death Selective/auscultation: 0/7330 (0) Universal/EFM: 0/7288 (0)	Limitations Appropriate randomisation: No - low risk women received auscultation or EFM on alternating months Allocation concealment: No Groups comparable at baseline: Unclear - there were no significant differences in the selective vs. universal groups, but this detail is not reported for low risk women Groups received same

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
England Journal of Medicine,N Engl J Med, 315, 615-619, 1986 Ref Id 164091 Country/ies where the study was carried out USA Study type Quasi-randomised trial Aim of the study To compare the differences in perinatal outcome between universal and selective electronic fetal monitoring (EFM) in 34,995 deliveries Study dates October 1st 1982 onwards, for a 36 month period Source of funding None reported	reported separately. Parity (%) - Nulliparous Selective: 39 Universal: 40 - Multiparous Selective: 61 Universal: 60 Prenatal care (%) Selective: 81 Universal: 82 Birth weight / grams (%) - 500-999 Selective: 0.8 Universal: 0.8 - 1000-1500 Selective: 1.2 Universal: 1.1 - 1501-2000 Selective: 2.3 Universal: 2.5 - 2001-2500 Selective: 7.2	monitored with EFM (n = 7288)	unit (Parkland Memorial Hospital) was a policy of only using EFM in high risk pregnancies (see details listed in inclusion criteria above). Women who had complications were transferred into a labour intensive unit with 5 beds (this continued throughout both parts of the trial). Most electronic monitoring was done in this unit. A maximum of seven portable electronic monitors were available during selective monitoring months. During universal monitoring months, 12 additional monitors were made available and installed in labour rooms. Therefore, a total of 19 monitors were available for a 20 bed unit. The policy during these months was to use EFM for every pregnancy in which the baby was viable. Other than the policy of	(NS) b. Neonatal death Selective/auscultation: 5/7330 (0.1) Universal/EFM: 4/7288 (0.1) (NS) Admission to intensive care nursery (n/total (%)) Selective/auscultation: 17/7330 (0.2) Universal/EFM: 25/7228 (0.3) (NS) Neonates with seizures (n/total (%)) Selective/auscultation: 3/7330 (0.4) Universal/EFM: 1/7288 (0.01) (NS) Note: non-significant p-values are not reported	care (apart from intervention): Yes Blinding of participants: Unclear, but unlikely considering the intervention Blinding of staff providing care: No Blinding of outcome assessors: Unclear - no details are reported Missing data/loss to follow-up: Unclear Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Unclear at what point seizures were assessed and the reasons for admission to NICU Intention-to-treat analysis performed: Unclear Overall, this study is not well reported for our comparison and population of interest. The data for low risk women are reported for the comparison of selective vs. universal

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Universal: 7.2 - ≥ 2501 Selective: 88.5 Universal: 88.4 There were no significant differences identified between the two groups Inclusion criteria Not reported for the study; however, the following definitions are used to describe the different parts of the study population: High risk: - induction or augmentation of labour - dysfunctional labour (not defined) - abnormal fetal heart rate - presence of meconium in the amniotic fluid - other complications of pregnancy, including		selective or universal monitoring, there were no differences in care during the alternate months. Nursing personnel were in a ratio of 2 patients to one nurse. Oxytocin was administered according to a strict protocol. Women admitted to single bed labour rooms were visited every 30 minutes, and had the fetal heart rate measured using intermittent auscultation with a Doppler device or visual inspection of the trace. Nurses attending each birth completed a perinatal data sheet, and research nurses assessed the data for consistency and completeness before it was stored electronically. Statistical analysis was done using chi-squared test or Fisher's exact test. Two sided p-values of 0.05 were considered significant.		monitoring, and therefore, the technical team have made the assumption that this represents auscultation vs. EFM, because according to the trial protocol, in 'selective' months low risk women should all have received auscultation and in 'universal' months they should have received EFM. This assumption is corroborated by the assumption of a Cochrane review (Alfirevic et al., 2008) who reported this trial for the same comparison. Other information Cardiotocograph (CTG): not reported whether monitoring was internal or external. Abnormal fetal heart rates were identified in 2.7% of selective/auscultation women and 7.6% of universal/EFM women (low risk). This was significantly

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	hypertension, vaginal bleeding, prolonged pregnancy, diabetes, twins, breech presentation and preterm labour Low risk: - single baby - cephalic presentation - spontaneous, uncomplicated labour - birth weight exceeding 2500g Exclusion criteria Not reported				different ($p < 0.01$).
Full citation MacDonald,D., Grant,A., Sheridan-Pereira,M., Boylan,P., Chalmers,I., The Dublin randomized controlled trial of intrapartum fetal heart rate monitoring, American Journal of Obstetrics and Gynecology, 152, 524-	Sample size N = 12,964 Characteristics Nulliparous n (%)) Auscultation: 1964 (39.3) Electronic fetal monitoring (EFM): 2015 (40.4) Receiving induction of	Interventions Intermittent auscultation (n = 6490) EFM (n = 6474)	Details Sample size calculation A sample size calculation was based on adverse outcomes for babies, and the anticipated population of 10,000 had 80% power to detect a statistically significant difference if the rate was reduced by half through more intensive monitoring. An interim	Results Mode of birth and primary indication (n (%)) a. Caesarean section Auscultation: 144 (2.2) - Failure to progress in labour: 88 (1.3) - Fetal distress: 10 (0.2) - Other: 46 (0.7) EFM: 158 (2.4) - Failure to progress in	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes (because clear liquor had to be demonstrated to enter the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
539, 1985 Ref Id 164093 Country/ies where the study was carried out Ireland Study type Randomised controlled trial Aim of the study To compare continuous electronic intrapartum fetal heart monitoring with a policy of intermittent auscultation Study dates March 31st 1981 to April 10th 1983 Source of funding Medical Research Council of Ireland National Maternity Hospital Research Fund	labour (n (%)) Auscultation: 475 (9.5) EFM: 434 (8.7) Giving birth earlier than 37 weeks gestation (n (%)) Auscultation: 133 (2.7) EFM: 156 (3.1) Considered high risk at the start of labour (n (%)) Auscultation: 1137 (22.7) EFM: 1106 (22.2) (Note: this was defined as maternal age of 40 years or more, diabetes mellitus, pre-eclampsia, chronic hypertension, renal disease, cardiac disease, previous stillbirth or neonatal death, previous child with neurological abnormality, previous low birth weight baby, bleeding in pregnancy requiring admission to		analysis, after 4,000 cases, determined that recruitment should be extended to 13,000 to assess the difference on the most unambiguous set of outcomes (deaths and seizures). This would have 75% power to to detect a 50% reduction. For practical reasons, data on umbilical venous acid-base status were limited to 1000 consecutive babies. The trial protocol pre-specified stratification by risk status and by time interval between entry to trial and birth (< 1 hour, > 1 hour). Study population During the study period, 17381 women gave birth. 4356 were ineligible due to having an elective caesarean section (CS), suffering a fetal death before labour, delivering so rapidly after arrival (< 1 hour from admission) that presence of meconium stained liquor and	labour: 84 (1.3) - Fetal distress: 25 (0.4) - Other: 49 (0.7) b. Forceps delivery Auscultation: 407 (6.3) - Failure to advance: 313 (4.8) - Fetal distress: 75 (1.2) - Other: 19 (0.3) EFM: 528 (8.2) - Failure to advance: 323 (5.0) - Fetal distress: 190 (2.9) - Other: 15 (0.2) Admission to SCN (n/total (%)) Auscultation: 543/6554 (8.3) EFM: 547/6530 (8.4) (Note: in an analysis based only on the first 10,000 women recruited, it was reported that 2.7% of babies were admitted for reasons that might have been affected by intrapartum care)	trial; therefore, extra amniotomy was not required for EFM arm) Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: Yes for neonatal outcomes Missing data/loss to follow-up: For cord blood gas values, there are limited data; for other outcomes, more detail was collected in the first part of the trial when compared to the second (i.e the last 3,000 women) i.e. for 'other neurological abnormality' data were only collected for 10,094/13,084 (77%) of study babies. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: 22.5% of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Wellcome Trust Department of Health and Social Security (supports the National Perinatal Epidemiology Unit [NPEU])	hospital after the first trimester, induction of labour for pregnancy of more than 42 weeks' completed gestation, multiple pregnancy, breech presentation in labour, and gestational age less than 34 completed weeks.) Inclusion criteria Live fetus of at least 28 weeks gestation with no evidence of gross abnormality Diagnosis of labour made Amniotic fluid without significant meconium staining had been positively demonstrated, either at spontaneous rupture of membranes or early amniotomy Exclusion criteria		hence eligibility could not be assessed, less than 28 weeks, gross fetal abnormality, or meconium staining or no fluid. Out of the remaining 13,025 women eligible for inclusion, 12,964 were entered into the trial and gave birth to 13,084 babies. Randomisation Randomisation was done after eligibility had been confirmed through assessment of liquor. Allocation was done by opening of the next envelope in a series of serially numbered, sealed opaque envelopes. Monitoring in EFM arm Following randomisation, an electrode was applied to the fetal scalp and an external tocodynamometer was attached. If it was not possible to get a signal from the electrode, an external transducer was used. If the	Umbilical cord venous pH (n/total (%)) < 7.05 Auscultation: 2/535 (0.4) EFM: 2/540 (0.4) 7.05-7.09 Auscultation: 9/535 (1.7) EFM: 3/540 (0.6) 7.10-7.20 Auscultation: 40/535 (7.5) EFM: 41/540 (7.6) > 7.20 Auscultation: 484/535 (90.4) EFM: 494/540 (91.4) Neonatal morbidity (n/total (%)) a. Need for intubation Auscultation: 54/5058 (1.1) EFM: 58/5035 (1.2) b. Neonatal seizures (all women) Auscultation: 27/6554 (0.4) EFM: 12/6530 (0.2) (Note: in 10/12 cases in the EFM arm and 24/27 in the	women were considered 'high risk' Other information CTG: monitoring was internal Rates of successful fetal blood sampling were 3.5% in the auscultation group and 4.4% in the EFM group. 97.7% of those allocated to auscultation received it throughout labour. In the EFM group, 80.7% received EFM throughout, because delivery was too rapid in 10.5%, 6.6% refused monitoring, and there were technical problems in 1.1% of cases.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Elective caesarean section Fetal death prior to the onset of labour		midwife was concerned about the trace, they first checked it using auscultation and then informed the nurse-midwife in charge of the labour ward. If the latter considered the trace to be abnormal, an obstetrician was called. The following fetal heart rate (FHR) patterns were considered to be suspicious: - marked tachycardia or bradycardia - moderate tachycardia or bradycardia with reduced variability - minimal variability (absent beat-to-beat variation, flat tracing) - late deceleration pattern - moderate and severe variable deceleration patterns - other confusing patterns with varying baselines which could not be clearly interpreted If any of these patterns had	auscultation arm, seizures were first noted within 48 hours of birth. In 4 out of the 5 later cases, the cause is unlikely to be due to birth event [meningitis at 28 weeks, 2 cases of complications of hyaline membrane disease, and 1 case of hypoglycemia] and in the fifth, the seizures were first noted at 56 hours of age) c. Neonatal seizures (women without pregnancy risk factors)* Auscultation: 19/5015 (0.4) EFM: 7/5038 (0.1) d. Other neurological abnormality Auscultation: 25/5058 (0.5) EFM: 16/5035 (0.3) (Note: This is abnormalities other than seizures and is only reported in survivors. In the auscultation group, 5 babies had 'simultaneous abnormalities of tone and	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			been present for at least 10 minutes and did not respond to measures like changing position, adjusting transducers, then clinical action was taken. This was the taking of fetal scalp blood pH in the first stage of labour, and immediate delivery in the second stage of labour. If the fetal scalp blood pH was less than 7.20 delivery was actioned as soon as possible. If the pH was 7.20 - 7.25 and the FHR pattern remained suspicious, delivery was also done as soon as possible. If the FHR reverted to a normal pattern, the case was managed expectantly. If the pH was over 7.25 and the trace stayed suspicious, scalp blood pH was measured 30 minutes to an hour later. Throughout the trial, tracings were reviewed by a single experienced observer, who	reflex' and 20 babies had 'other abnormal neurological signs persisting for at least a week.' In the EFM arm, the numbers were 4 and 12 respectively) e. Neonatal trauma Auscultation: 66/5058 (1.3) EFM: 71/5035 (1.4) (Note: In decreasing order of prevalence: scalp laceration, abrasion or bruising; facial bruising, suffusion, forceps marks and conjunctival haemorrhage; cephalhematoma; other bruising; motor deficit in right arm; fractured clavicle; subdural haemorrhage and death; facial nerve injury) * Data from low risk women are reported in the GRADE table Perinatal death (n/total (%)) a. Total	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			was blinded to the outcome of the baby following delivery. The trace was classified according to whether the observer felt that it should or should not have prompted clinical action. Monitoring in auscultation arm Women randomised to receive auscultation were managed by the hospital's standard policy. The FHR was auscultated with a Pinard stethoscope for 60 seconds following a contraction. This was done at least every 15 minutes in the first stage and during ever interval between contractions in the second stage. If there was an issue detecting the FHR with auscultation, intermittent Doppler ultrasound was used. If the FHR was < 100 or > 160 bpm during three	Auscultation: 14/6554 EFM: 14/6530 b. Intrapartum stillbirth Auscultation: 2/6554 EFM: 3/6530 c. Neonatal deaths Auscultation: 12/6554 EFM: 11/6530 The following details are given about the primary causes of the deaths (n): -- Asphyxial conditions developing in labour Auscultation: 7 EFM: 7 -- Conditions associated with immaturity Auscultation: 4† EFM: 1 -- Birth trauma Auscultation: 1 EFM: 3* -- Other Auscultation: 2 EFM: 3 † in one of the babies in each of these groups,	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			contractions, and the abnormality did not respond to measures such as a change in posture, or treatment of pyrexia, then clinical action was taken as above; i.e in the first stage of labour scalp pH was taken and a scalp clip attached, and in the second stage of labour, delivery was expedited. Outcomes reported 1. Mode of birth 2. Mortality: intrapartum deaths and deaths within 28 days (neonatal deaths) were examined by a pathologist blinded to allocation. Each case was classified by primary cause of death, and in cases where the primary cause was not 'asphyxial conditions developing during labour' they were reviewed to see if the conditions may have contributed 3. Neurological	asphyxial conditions developing during labour may have been contributing factors but were not primary cause of death Stratified analyses a. By risk status 22.5% of women met the criteria for being high risk. Compared to the other participants of the trial, these women were 2.7 times more likely to have a caesarean section, and their babies were more than three times more likely to have an Apgar < 4 at one minute, to be admitted to SCN or to die. Within the risk groups, there was little evidence of a differential effect of the two policies on outcome. In the case of neonatal seizures, the effect of EFM in preventing neonatal seizures was stronger in women without risk factors when compared to women with risk factors. However, the effect of	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			abnormalities: Neurological assessments were made by a blinded neonatologist. The babies were considered to have had seizures if the neonatologist felt there was evidence of seizures of the following types: generalised tonic, multifocal clonic, focal clonic, or myoclonic. This did not included babies with 'subtle seizure activity' or 'jitteriness'. - During the first 10,000 women recruited, serial standardised assessments were made on all babies admitted to the special care nursery (SCN) and any babies on the ward who staff were concerned about. Any babies identified in these ways were examined within 48 hours of life, then at 72 hours, at 7 days, and at discharge. Assessment of tone, movement, reflexes and behaviour was done, to classify babies into one of the following categories: simultaneous abnormalities	monitoring on neonatal seizures that resulted in survival was not different in the two risk groups. Neonatal seizures (rate per 1000) - Pregnancy risk factors present Auscultation: 5.2 EFM: 3.4 Risk difference (RD): -1.8 per 1000 - Pregnancy risk factors not present Auscultation: 3.8 EFM: 1.4 RD: - 2.4 per 1000 b. By duration of labour The longer labours demonstrated a protective effect of EFM, whereas in the shorter labours, the risk of seizures was similar in the two monitoring arms. Neonatal seizures (rate per 1000)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			of both tone and reflexes, other neurological abnormalities persisting 1 week after birth, and other transient abnormalities resolved by 7 days - During the last 3,000 cases, the identification protocol was simplified, and neonatologists only identified babies who had seizures in the neonatal period. 4. Admission to special care nursery 5. Umbilical cord blood gas values: Collection of blood samples only occurred during a 2 month period of the trial. A 15 cm section of cord was double clamped at birth and 3 ml of venous blood was aspirated anaerobically into a heparinised syringe. Follow-up and statistical analyses Babies who survived	- Labour < 5 hours Auscultation: 1.8 EFM: 1.6 RD: - 0.2 per 1000 - Labour > 5 hours Auscultation: 8.5 EFM: 2.4 RD: - 6.1 per 1000	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			neonatal seizures or other abnormalities of tone and reflexes were followed up for at least a year, and seen by senior paediatricians not involved in the trial and blinded to allocation. Chi-squared tests or t-tests of statistical significance were used to compare groups.		
Full citation Vintzileos,A.M., Antsaklis,A., Varvarigos,I., Papas,C., Sofatzis,I., Montgomery,J.T., A randomized trial of intrapartum electronic fetal heart rate monitoring versus intermittent auscultation, Obstetrics and Gynecology, 81, 899-907, 1993 Ref Id 164083 Country/ies where the	Sample size N = 1428 Characteristics Maternal age/years (mean ± SD) Auscultation: 26.6 ± 5.1 EFM: 26.2 ± 5.1 (NS) Nulliparous (n (%)) Auscultation: 340 (50%) EFM: 408 (54.7%) (NS) Gestational age	Interventions Electronic fetal monitoring (n = 746) Intermittent auscultation (n = 682)	Details The study was done in two university hospitals (total of 3000 deliveries per year across the sites). Prior to the study, standard practice was intermittent auscultation, with only approximately 20% of women receiving continuous EFM. Intensive training sessions were given to all personnel, although most were familiar with the use of EFM already. The sample size calculation was based on showing a 2/3	Results Mode of delivery (n (%)) a. Spontaneous vaginal Auscultation: 561 (82.2) EFM: 571 (76.5) b. Vacuum extraction Auscultation: 58 (8.5) EFM: 101 (13.5) c. Low forceps Auscultation: 2 (0.3) EFM: 3 (0.4) d. Mid forceps Auscultation: 2 (0.3) EFM: 0 (0)	Limitations Trial was stopped after the third periodic review due to increasing mortality rates. Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes. There were significant differences between the two groups in the proportion of women having spontaneous labour (higher in auscultation arm) augmented labour (higher

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study was carried out Greece Study type Randomised controlled trial Aim of the study To determine whether the use of continuous electronic fetal monitoring (EFM) alone during labour is associated with decreased perinatal mortality and morbidity when compared to intermittent auscultation, in a population with a relatively high perinatal mortality rate Study dates October 1st 1990 to June 30th 1991 Source of funding Advanced Medical Systems provided	distribution/weeks (n (%)) 26-37 Auscultation: 57 (8.3) EFM: 48 (6.4) (NS) 37-42 Auscultation: 608 (89.1) EFM: 686 (91.9) (NS) > 42 Auscultation: 17 (2.4) EFM: 12 (1.6) (NS) Antepartum risk factors (n (%)) Auscultation: 94 (13.7) EFM: 89 (11.9) (NS) (Note: antepartum risk factors are: hypertension, diabetes, premature rupture of membranes, suspected fetal growth restriction, oligohydramnios, vaginal bleeding)		decreased in perinatal mortality. This was based on background mortality rates and reported prevalence of perinatal asphyxia in the year prior to the study. It was calculated that 2210 patients in total were needed (based on alpha of 0.05 and 80% power). Eligible patients were randomised using a coin toss. Patients in both arms had IV access secured after admission and labour in lateral or semi-Fowler position. There was one nurse for each patient in both groups. External fetal monitoring was done using a tocodynamometer for recording uterine contractions and a Doppler ultrasound to monitor fetal heart rate. External monitoring was done for as long as satisfactory tracings were obtained. Direct	e. Caesarean Auscultation: 59 (8.6) - for fetal distress: 16 - reasons other than suspected fetal distress: 43 EFM: 71 (9.5) - for fetal distress: 40 - reasons other than suspected fetal distress: 31 Admission to NICU (n (%)) a. Total Auscultation: 102 (14.9) EFM: 104 (13.9) b. Unrelated to prematurity Auscultation: 69/625 (11) EFM: 72/698 (10.3) Cord arterial pH < 7.10 (n/total (%)) Auscultation: 18/680 (2.6) EFM: 31/739 (4.1) Neonatal complications (n (%)) a. None Auscultation: 594 (87.1) EFM: 639 (85.6)	in EFM arm) and induction of labour (higher in EFM arm). The length of labour was also significantly longer in the EFM arm. However, the authors report that this should have put the EFM arm at a disadvantage. Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No for maternal outcomes, yes for neonatal outcomes, unclear for cord blood gas values (but unlikely to cause bias for this outcome, because it is biochemical) Missing data/loss to follow-up: Generally not. 0.6% of women had missing data for cord arterial pH Precise definition of outcomes: Yes Valid and reliable method of outcome assessment:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
financial support for the study	Meconium stained liquor (n (%)) Auscultation: 84 (12.3) EFM: 112 (15) (NS) Presentation (n (%)) - Vertex Auscultation: 670 (98.3) EFM: 733 (98.2) (NS) - Breech Auscultation: 11 (1.6) EFM: 12 (1.6) (NS) - Other Auscultation: 1 (0.1) EFM: 1 (0.1) (NS) Labour - Spontaneous Auscultation: 374 (54.8) EFM: 238 (31.9) (p = 0.0001)		monitoring, by the insertion of a fetal scalp electrode, was indicated if the quality of the trace was not satisfactory. If the EFM trace was satisfactory, the decision to use internal monitoring was left to the managing clinician. The initial FHR trace was assessed at least every 15 minutes during the first stage of labour and every 5 minutes during the second stage. Women assigned to auscultation were monitored using a Doppler ultrasound device. The baseline heart rate was counted between contractions and then auscultated every 15 minutes during the first stage and every 5 minutes during the second stage. The FHR was measured during and immediately after the contraction, for at least 30 seconds afterwards. The auscultation last 1 minute.	b. Hypoxic ischaemic encephalopathy Auscultation: 2 (0.3) EFM: 1 (0.1) c. Intraventricular haemorrhage Auscultation: 1 (0.1) EFM: 0 (0) d. Seizures Auscultation: 2 (0.3) EFM: 0 (0) e. Respiratory distress Auscultation: 40 (5.8) EFM: 55 (7.3) f. Hypotonia* Auscultation: 3 (0.4) EFM: 3 (0.4) g. Necrotizing enterocolitis* Auscultation: 0 (0) EFM: 2 (0.2) h. Sepsis* Auscultation: 2 (0.3) EFM: 3 (0.4) i. Hyperbilirubinemia*	Yes Intention-to-treat analysis performed: Yes Indirectness: This was not a completely low risk population: 12.8% of women had antepartum risk factors, 7.4% were preterm and 12% were induced. (As these conditions are not mutually exclusive, the total proportion was considered low enough not to exclude the study) Other information CTG: monitoring was external for as long as traces were satisfactory Duration of labour (mean ± SD) a. First stage / hours Auscultation: 5.5 ± 3.7 EFM: 6.1 ± 4.3 (p = 0.006) b. Second stage / minutes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	- Augmented* Auscultation: 260 (38.1) EFM: 391 (58.4) (p = 0.0001) - Induced Auscultation: 48 (7) EFM: 117 (15.6) * The higher use of oxytocin for augmentation in the EFM group was related to the longer labours in the EFM arm. Inclusion criteria Singleton living fetus Gestational age of 26 or more weeks Admitted in spontaneous labour or for induction of labour Exclusion criteria Known fetal congenital or chromosomal		Uterine contraction was evaluated using palpation. In the EFM group, non-reassuring heart rate patterns were defined as: - late decelerations unrelated to supine hypotension or regional anaesthesia, which failed to respond to conservative measures - persistent prolonged decelerations of less than 80 beats per minute [bpm] lasting more than 2 minutes - severe variable decelerations (70 bpm or fewer lasting 60 seconds or more - variable decelerations with a rising baseline and loss of variability - persistent fetal tachycardia (more than 160 bpm) associated with decreased variability (less than 5 bpm) - persistent decreased variability - sinusoidal FHR pattern	Auscultation: 26 (3.8) EFM: 31 (4.1) j. Hypoglycemia* Auscultation: 4 (0.6) EFM: 5 (0.6) k. Other (including congenital abnormalities)* Auscultation: 2 (0.3) (Note: Congenital heart disease; gastroschisis) EFM: 7 (0.9) (Note: Congenital heart disease (n = 2); cleft lip/palate (n = 1; duodenal atresia (n = 1); no further details given) * reported here as morbidities, as reported in the paper, but not reported in the GRADE table as they are unlikely to be affected by method of intrapartum monitoring Need for neonatal resuscitation (n (%)) Auscultation: 65 (9.5) EFM: 63 (8.4)	Auscultation: 26.9 ± 16.9 EFM: 29.4 ± 18.6 (p = 0.01)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	abnormalities		(three to five cycles per minute, amplitude five to 15 bpm) In the auscultation group, non-reassuring heart rate patterns were defined if one or more of the following was present: - FHR during and immediately after a contraction repeatedly below 100 bpm, even if there was recovery to 120-160 before the next contraction (moderate decelerations when FHR was 80-99 and severe when it was less than 80) - persistent baseline rate (between contractions) of less than 100 bpm - persistent baseline rate of more than 160 bpm In the presence of non-reassuring patterns, groups were managed similarly. Management was initially conservative, for example,	Death of baby (n (%)) a. Intrapartum fetal death Auscultation: 2 (0.3) EFM: 0 (0) b. Neonatal death Auscultation: 7 (1) EFM: 2 (0.26) c. Total perinatal death† Auscultation: 9 (1.3) EFM: 2 (0.26) † of these, 6 in the auscultation group and 0 in the EFM group are reported as being due to fetal hypoxia [Note: - The 2 deaths in the EFM group could not have been prevented by monitoring: one baby died of complex congenital heart disease and the other of haemorrhage and DIC due to trauma at the base of the tongue during intubation attempt for meconium suctioning - In the 9 deaths in the auscultation group,	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			stopping oxytocin, administering maternal oxygen, changing position, or increasing IV fluids. Fetal scalp pH, or crossing patients over from one group to another were not used. If the non-reassuring pattern persisted after 20 minutes of trying conservative methods, a surgical intervention (forceps, vacuum extraction or caesarean) was performed. A data sheet was completed by the attending physicians which recorded maternal characteristics, and outcomes for mother and baby. Most neonatal outcomes were collected by neonatologists blinded to allocation. Obstetric records and FHR data of both arms of the trial were reviewed throughout by two authors blinded to monitoring method. This was aimed at determining whether interpretation and	there was compliance with trial protocol and vaginal delivery in all 9. Details of deaths are reported below] Clinical characteristics of the nine perinatal deaths in the auscultation group: Intrapartum (n = 2) - Both women were at term (39 weeks; 41 weeks) - Neither women had risk factors and both were vertex presentation - One had meconium staining Neonatal (n = 7) - 2 out of 7 were preterm (26.3 weeks; 30 weeks) - Risk factors were present in 6 out of 7 (prematurity [2], PROM [3], gastroschisis [1]) and the remaining baby was breech. - 3 had meconium staining - The two premature babies and the case of gastroschisis are considered to be deaths that are not related to hypoxia	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			management of FHR had been appropriate. If there was delayed or absent intervention after persistent non-reassuring patterns, or surgical intervention in the presence of reassuring patterns, this was recording as 'failure to comply with protocol'. Data were periodically reviewed every 3 months to detect trends in mortality. The continuing trend of increasing death in auscultation group was compared with the year before the study, which did not show any peaks, and the study was stopped after the third review. Statistical analysis was done using chi-squared, Fisher's exact test, Student's t tests, ANOVA, and Mann-Whitney tests, where appropriate. $p < 0.05$ was considered significant.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Outcomes reported 1. Mode of delivery: recorded on a data sheet by attending physician 2. Admission to NICU: data collected by neonatologists blinded to allocation 3. Neonatal morbidity: data collected by neonatologists blinded to allocation on development of complications such as neonatal death, ischaemic encephalopathy, neurologic abnormalities, seizures, intraventricular haemorrhage, sepsis, necrotizing enterocolitis, respiratory distress syndrome (need for supplemental oxygen for over 24 hours), hyperbilirubinemia, hyperglycemia, and metabolic or other problems 4. Cord blood gas values: Following delivery, the cord was clamped and blood		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			gases were measured from the artery and vein within 10 minutes of delivery. It is unclear who collected these data		
Full citation Wood,C., Renou,P., Oats,J., Farrell,E., Beischer,N., Anderson,I., A controlled trial of fetal heart rate monitoring in a low-risk obstetric population, American Journal of Obstetrics and Gynecology, 141, 527-534, 1981 Ref Id 164094 Country/ies where the study was carried out Australia Study type Randomised controlled trial Aim of the study To determine the	Sample size N = 989 Characteristics There were no significant differences in maternal age, parity, injections of opiate, use of other drugs, or ketones between the two groups. Inclusion criteria None of the exclusion criteria Exclusion criteria Past history of stillbirth or neonatal death Antepartum haemorrhage in more than one pregnancy	Interventions Standard care (n = 482) Electronic fetal monitoring (n = 507)	Details Randomisation was by randomised cards. In one of the study sites, this did not work, because a significantly higher proportion of low parity patients were in the EFM group compared to the auscultation group. Cards were not in sealed envelopes. Parity was corrected by random elimination, leaving 927 of the original 989 patients in the trial. Results were analysed for both 927 and 989 patients, and the results were the same, so the former are reported by the study authors. Control patients were managed by staff in the standard way. Patients	Results Mode of birth (n/total (%)) a. Normal Standard: 371/482 (77.0) EFM: 307/445 (69.0) b. Forceps Standard: 101/482 (21.0) EFM: 120/445 (27.0) c. Caesarean section Standard: 10/482 (2.1) EFM: 18/445 (4.0) Neonatal death Standard: 0/482 EFM: 1/445 (Note: the authors report the following details: normal labour (9 hours), type 1 dips present in contractions for a couple of hours before delivery with the FHR	Limitations Appropriate randomisation: Allocation was by randomised cards Allocation concealment: No, cards were not in sealed envelopes Groups comparable at baseline: This is reported for the denominator of most of the outcomes, but for neurological symptoms/signs, due to issues with randomisation, there may be a difference in the proportion of primigravidas Groups received same care (apart from intervention): Yes (according to study) Blinding of participants: Not reported

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
effects of fetal heart rate monitoring in low risk patients Study dates Not reported Source of funding None reported	Eclampsia Previous delivery before 37 weeks gestation Clinical signs of fetal distress of meconium stained liquor and fetal heart rate above 160 or below 12 between contractions Medical and obstetric complications of hypertension (145/90 mmHg) Proteinuria (on boiling) Proven renal disease, cyanotic heart disease, rhesus isoimmunisation, diabetes, jaundice of hepatosis, anaemia (Hb 9g/100 ml) at any stage of pregnancy Antepartum		randomised to EFM were managed in a similar way, with the addition of fetal monitoring. Management of labour and delivery was the decision of the attending medical staff. If complications in labour indicated the need for monitoring among those randomised to standard care, it was done, but they remained in the standard care group for the analysis. Following randomisation, external CTG was done until the time at which either an amniotomy was done for obstetric reasons, or vaginal examination was done after the membranes had ruptured. At that point, a scalp electrocardiographic electrode was applied. FHR tracings were examined by a skilled, unbiased observer who reported on their type and significance to the medical	slowing to 100 bpm. The baby was delivered by forceps, with the head being rotated when the cord prolapsed. The baby was born in poor condition, with Apgars of 1 and 3, and died after 2 days in the intensive care. Cause of death was shown to be hypoxic brain damage) Neurological symptoms and/or signs (n/total (%)) Standard: 3/495 (0.6) EFM: 1/479 (0.2) (Note: the data reported for this outcome appear not to exclude the women that the authors reported that they would, because N = 974) Care of the baby (n/total (%)) a. Need for isolette* Standard: 29/480 (6.0) EFM: 40/443 (9.0) b. Need for nursery* Standard: 48/474 (10.1) EFM: 59/443 (13.3)	Blinding of staff providing care: Not reported Blinding of outcome assessors: Not reported Missing data/loss to follow-up: There are small amounts of missing data (< 2%) for need for isolette, need for nursery. and neurological signs and symptoms. Precise definition of outcomes: type of neurological signs or symptoms are not reported (and the denominator does not match what the authors stated that they would analyse/report in the methods section) Valid and reliable method of outcome assessment: unclear for neurological signs and symptoms as no details are given Intention-to-treat analysis performed: yes No details of what standard care involved are reported. However, judging by the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	haemorrhage Low estriol excretion Polyhydramnios Multiple pregnancy Breech presentation Premature labour (37 weeks) Prolonged pregnancy (42 weeks) Prolonged labour (24 hours) Known fetal malformation		staff, who then made the final decision concerning management of the patient. All staff were trained in the recognition and significance of FHR abnormalities, but there were very few incidences of abnormal traces.	c. Need for phototherapy Standard: 4/480 (0.8) EFM: 16/443 (3.6) * the papers reported the proportion of babies spending 0, 1, 2 and ≥3 days in isolette/nursery; therefore, proportion of babies not spending 0 days is reported above	discussion, this has been assumed to be by intermittent auscultation. This is supported by assumptions made by Cochrane reviewers, who included this study in a review of intermittent auscultation compared with EFM. Other information CTG was external until membranes ruptured, and then internal. 49 patients in the standard care group received EFM due to meconium in the amniotic fluid or FHR abnormality detected by auscultation. No caesarean sections were prompted by the results of the traces. Babies with early, mid or late dips were delivered by forceps.

1.1.9 What is the effectiveness of continuous electronic fetal monitoring compared with intermittent auscultation when there is meconium-stained liquor?

Study Details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Alfirevic,Zarko, Devane,Declan, Gyte,Gillian ML, Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour, Cochrane Database of Systematic Reviews, -, 2013 Ref Id 200781 Country(ies) where the study was done Various Study type Systematic review Aim of the study To evaluate the effectiveness of continuous cardiotocography during labour.	Sample size n = 500 from two studies (Pakistan 1989, Melbourne 1976) Characteristics Twelve studies included in the systematic review but only two studies consisted of right population for this review: Pakistan 1989 Randomisation: women selecting sealed unnumbered envelopes Participants: High risk women all with meconium stained liquor Intervention: cardiotocography (CTG) versus intermittent auscultation Outcomes: neonatal mortality, mode of birth,	Intervention Intermittent auscultation: intermittent monitoring undertaken either by listening to the baby's heart rate using a fetal stethoscope (pinard) or a hand-held Doppler Continuous fetal monitoring: electron fetal heart rate monitoring by means of cardiotocograph.	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by contacting the Trials Search Co-ordinator. CENTRAL, MEDLINE were searched, and hand searching of 30 journals and conference proceedings was done. No language restrictions were applied. Selection of studies Two review authors independently assessed the full text of all potential studies for inclusion and methodological quality. Data extraction and management Two authors extracted the data separately and double checked it for discrepancies. Statistical analysis was done using RevMan. Where information was	Results Caesarean section Continuous fetal monitoring: n = 74/275 (26.9%) Intermittent auscultation: n = 36/275 (13.1%) RR 2.11 (1.19 to 3.74) Caesarean section for abnormal FHR pattern and/or acidosis Continuous fetal monitoring: n = 47/275 (17.1%) Intermittent auscultation: n = 21/275 (7.6%) RR 2.24 (1.38 to 3.64) Instrumental vaginal birth Continuous fetal	Limitations Pakistan 1989: - data extracted from unpublished trial lodged with Cochrane centre - no allocation concealment Other information

Study Details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Assessed as up-to-date: Januray 2013 Source of funding Not reported	Apgar score Study period: 1988 - 1989 Melbourne 1976 Randomisation: cards in sealed numbered envelopes Participants: High risk women (40% with meconium stained liquor) Intervention: continuous CTG versus intermittent auscultation Outcomes: mode of birth, oxytocin use, analgesia use, maternal infection, neonatal mortality and morbidity, umbilical cord blood gas Study period: April 1974 - April 1975 Inclusion criteria Randomised and quasi randomised control trials		unclear, the reviewers attempted to contact the original authors. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Selection bias - Allocation concealment - Blinding - Incomplete outcome data - Sequence generation - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, weighted mean differences were used. Fixed-effect analysis was performed in the absence of significant heterogeneity. In the presence of heterogeneity sensitivity analysis followed by random effects analysis was performed.	monitoring: n = 108/275 (39.3%) Intermittent auscultation: n = 94/275 (34.2%) RR 1.16 (0.88 to 1.54) Spontaneous vaginal birth not achieved Continuous fetal monitoring: n = 182/275 (66.2%) Intermittent auscultation: n = 130/275 (47.3%) RR 1.4 (1.2 to 1.63) Perinatal death Continuous fetal monitoring: n = 5/275 (1.8%)* Intermittent auscultation: n = 6/275 (2.2%)*	

Study Details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Not specified		Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis, with the denominator being set as the number randomised minus any participants whose outcomes were known to be missing. Analysis If high levels of heterogeneity (> 50%) were identified, pre-specified sensitivity analysis was done according to the quality of the trials. Planned subgroup analyses: 1. low risk (absence of identified risk factors) 2. high risk of perinatal mortality and morbidity 3. spontaneous onset of labour 4. induction of labour 5. preterm 6. term 7. singleton/twin pregnancy 8. with and without FBS 9. parity	RR 0.83 (0.26 to 2.67) NICU admission Continuous fetal monitoring: n = 11/175 (6.3%) Intermittent auscultation: n = 30/175 (17.1%) RR 0.37 (0.19 to 71) Infection/damage from scalp electrode Continuous fetal monitoring: n = 11/175 (1%) Intermittent auscultation: n = 0/100 (0%) RR NC Neonatal seizure Continuous fetal monitoring: n = 0/175 (0%) Intermittent	

Study Details	Participants	Interventions	Methods	Outcomes and Results	Comments
				auscultation: n = 4/175 (2.3%) RR 0.11 (0.01 to 2.05)	

1.1.10 What are the appropriate definitions and interpretation of the features of an electronic fetal heart rate (FHR) trace?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Cibils,L.A., Clinical significance of fetal heart rate patterns during labor. II. Late decelerations, American Journal of Obstetrics and Gynecology, 123, 473-494, 1975 Ref Id 195117 Country/ies where the study was carried out USA Study type Cohort Aim of the study	Sample size n = 1304 records reviewed: n = 598 had no accelerations, n = 147 had late decelerations Characteristics Women in the no decelerations group were younger than women in the late decelerations group (22.8 yr vs. 25.1 yr). Gestational age and duration of FHR recording were similar in the two groups.	Interventions 60 minutes of FHR trace analysis (available prior to second stage of labour)	Details During the study period n = 1,304 records were reviewed manually and coded (details provided in a previously published paper). n = 598 (46%) had no decelerations of FHR which could be correlated in time with uterine contractions. n = 147 (11%) had FHR late decelerations.	Results There is low likelihood of neonatal problems when there is no deceleration of FHR: Neonatal morbidity and/or death* Late decelerations group: 7% No decelerations group: 0.5% p < 0.0001 * no more details on neonatal mortality provided High numbers of mortality and morbidity present in neonates with low birth	Limitations Limited outcome data No exclusion criteria specified hence high risk of selection bias Women's demographic characteristics not reported Unclear how and by whom data were analysed No statistical analysis of data provided Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To evaluate fetal heart rate (FHR) changes and patterns in two groups (with decelerations, no decelerations) in order to predict fetal condition at birth. Study dates June 1970 to 1974 Source of funding Not specified	Inclusion criteria Single pregnancy Cephalic presentation Direct or internal monitoring Minimum of 60 minutes recording prior to 2nd stage/decision to perform a caesarean section Exclusion criteria Not specified			weight with late decelerations: Neonatal morbidity and/or death in low birthweight babies < 2500g Late decelerations group: 15% No decelerations group: 5% p = ns A high percentage of babies with FHR late decelerations (50%) were distressed during labour and 33% born depressed (clinical distress defined as presence of meconium stained liquor, tachycardia, markedly irregular heat beat, no definition for "depressed" babies given).	Normal baseline FHR defined as 120 to 150 beats per minute (bpm) Tachycardia: > 150 beats per minute
Full citation Cibils,L.A., Clinical significance of fetal heart rate patterns during labor. V. Variable decelerations, American Journal of Obstetrics and Gynecology, 132,	Sample size n = 1304 records reviewed. n= 598 had no decelerations, n = 312 had variable decelerations Characteristics	Interventions FHR: variable decelerations variable decelerations with late component	Details From n = 1,304 records that were reviewed manually and coded (details provided in a previously published paper): n = 598	Results Cases with variable decelerations n = 312 Cases with no deceleration n = 598 Association between variable deceleration and baseline	Limitations Limited outcome data No exclusion criteria specified hence high risk of selection bias Women's demographic

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
791-805, 1978 Ref Id 195119 Country/ies where the study was carried out USA Study type Cohort Aim of the study To evaluate fetal heart rate (FHR) changes and patterns in two groups (with decelerations, variable decelerations) in order to predict fetal condition at birth Study dates Not specified Source of funding Not specified	Women in the no decelerations group were significantly younger than women in the late decelerations group (22.8 yr vs. 24.4 yr), had higher gestational age (39.4 wk vs. 38.6 wk) and longer duration of FHR recording (252 minutes vs. 223 minutes). Fetal weight was significantly higher in the no decelerations group compared with the variable decelerations group (3236 g vs. 2988 g). There were fewer normal and hypertensive women in the variable decelerations group, but there was a higher rate of women with other pathological conditions such as premature rupture of membranes. Inclusion criteria	('variable with hypoxic component')	(46%) had no decelerations of FHR which could be correlated in time with uterine contractions; n = 312 had FHR variable decelerations (n = 18 women had variable decelerations with a component of late deceleration in the recovery period, all of these cases had umbilical cord problems). The maternal condition and neonatal outcomes were compared in order to ascertain the clinical value of observed changes in FHR pattern.	alterations (tachycardia, saltatory or fixed FHR baselines): Saltatory fixed No deceleration: 39% Variable decelerations: 25% p = ns Tachycardia No decelerations: 5% Variable decelerations: 21% p < 0.0005 Sustained No decelerations: 8% Variable decelerations: 21% p < 0.0005 Fetal distress No decelerations: 4% Variable decelerations: 23% p < 0.0005 Neonatal death No decelerations: 0.2% Variable decelerations: 2.2% p < 0.0005 Significant association	characteristics not reported Unclear how and by whom data were analysed Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Singleton labours 60 minutes of FHR trace available prior to second stage Exclusion criteria Not specified			between variable decelerations (with a hypoxic [late] component) and baseline alterations (tachycardia, saltatory or fixed FHR baselines): Saltatory fixed Variable decelerations with late component: 39% Variable decelerations: 25% p < 0.0005 Tachycardia Variable decelerations with late component: 61% Variable decelerations: 21% p < 0.0005 Sustained Variable decelerations with late component: 67% Variable decelerations: 21% p < 0.0005 Fetal distress Variable decelerations with late component: 78% Variable decelerations: 23% p < 0.0005	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Neonatal death Variable decelerations with late component: 11% Variable decelerations: 2.2% p = ns	
Full citation Cibils,L.A., Clinical significance of fetal heart rate patterns during labor. VI. Early decelerations, American Journal of Obstetrics and Gynecology, 136, 392-398, 1980 Ref Id 195120 Country/ies where the study was carried out USA Study type Cohort Aim of the study To evaluate fetal heart rate (FHR) changes and patterns in two groups (no decelerations, early	Sample size n = 1304 records reviewed. n= 598 had no accelerations, n = 247 had early decelerations Characteristics Women in the no decelerations group were younger than women in the early decelerations group (22.8 yr vs. 23.6 yr), had similar gestational ages (39.4 wk vs. 38.2 wk) and longer durations of FHR recording (252 minutes vs. 231 minutes). Fetal weight was significantly higher in the no decelerations group	Interventions FHR: No decelerations Early decelerations	Details From n = 1,304 records that were reviewed manually and coded (referred to a previous published paper): n = 598 (46%) had no decelerations of FHR which could be correlated in time with uterine contractions; n = 247 had FHR early decelerations prior to 2nd stage of labour. The maternal condition and neonatal outcomes were compared in order to ascertain the clinical value of observed changes in	Results Transient tachycardia Early decelerations group: 10% No decelerations groups: 5% Fetal distress (no definition provided) Early decelerations group: 5% No decelerations groups: 4% Neonatal death Early decelerations group: n = 1 (congenital heart disease) No decelerations groups: n = 1 (congenital malformation)	Limitations Limited outcome data No exclusion criteria specified hence high risk of selection bias Women's demographic characteristics not reported Unclear how and by whom data were analysed Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
decelerations) in order to predict fetal condition at birth Study dates Not specified Source of funding Not specified	compared with the early decelerations group (3236 g vs. 3129 g). Inclusion criteria Singleton labours 60 minutes of FHR trace available prior to second stage Exclusion criteria Not specified		FHR pattern.		
Full citation Cibils,L.A., Votta,R., Clinical significance of fetal heart rate patterns during labor. IX: Prolonged pregnancy, Journal of Perinatal Medicine, 21, 107-116, 1993 Ref Id 195122 Country/ies where the study was carried out USA	Sample size 707 post-term pregnancies (> 14 days post estimated date of delivery [EDD]) Characteristics No characteristics specified. It is specified that the relevant clinical informations has been reported in a previously published paper.	Interventions Fetal heart rate records	Details n = 707 pregnancies that passed the estimated date of delivery by 14 days were included in the study. This was assessed in women with good menstrual histories, who had dating examinations or confirmed by an ultrasound in the first trimester of	Results No significant correlation between abnormal FHR patterns and pH: n = 598 no decelerations n = 147 traces with late decelerations Deceleration pattern Variable decelerations: 55% No or early decelerations: 23% Late deceleration: 17%	Limitations No exclusion criteria specified hence high risk of selection bias Women's demographic characteristics not reported Unclear how and by whom data were analysed Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Case series Aim of the study To evaluate fetal heart rate (FHR) changes and patterns in women with prolonged labour in order to diagnose early fetal compromise Study dates July 1980 to December 1984 Source of funding Not specified	Inclusion criteria Post-term pregnancies (> 14 days post EDD) Exclusion criteria Not specified		pregnancy. All women had either internal or external continuous fetal monitoring. Data for this study were gathered prospectively. The observation was based on the interpretation of fetal heart rate and uterine contraction and their value as a tool to diagnose early fetal compromise or to prevent fetal deterioration by early intervention. Statistical analysis was performed using χ2 method.	Baseline frequency Normal: 71% Tachycardia: 26% Bradycardia: 4% Baseline pattern Normal: 75% Fixed: 8% Saltatory: 17% Acidemia (pH ≤ 7.20) could not be predicted from deceleration patterns in FHR trace: FHR and umbilical cord pH pH ≤ 7.20 Total n = 46 pH ≥ 7.21 Total n = 108 No or early decelerations pH ≤ 7.20 n = 11 (23%) pH ≥ 7.21 n = 25 (23%) Variable decelerations pH ≤ 7.20 n = 17 (36%) pH ≥ 7.21 n = 48 (44%) Late decelerations pH ≤ 7.20 n = 18 (39%) pH ≥ 7.21 n = 35 (32%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Low,J.A., Cox,M.J., Karchmar,E.J., McGrath,M.J., Pancham,S.R., Piercy,W.N., The prediction of intrapartum fetal metabolic acidosis by fetal heart rate monitoring, American Journal of Obstetrics and Gynecology, 139, 299-305, 1981 Ref Id 195666 Country/ies where the study was carried out Canada Study type Case series Aim of the study To evaluate the fetal heart rate (FHR) characteristics in predicting the presence of a metabolic acidosis Study dates	Sample size n = 200 term infants with significant metabolic acidosis (base buffer < 36.1 mEq/l) n = 200 term infants without metabolic acidosis (base buffer > 36.1 mEq/l) Characteristics Not specified Inclusion criteria Women admitted and monitored in the intrapartum intensive-care unit. Exclusion criteria Not specified	Interventions All FHR variables	Details FHR characteristics during the 8 hours prior to delivery were studied in 200 women in whom the baby had evidence of a metabolic acidosis at birth (base buffer < 36.1 mEq/l), and compared to those in 200 women in whom the baby had a normal acid-base at birth (base buffer > 36.1 mEq/l). Fetal heart rate records were scored for each 20 minute period for a maximum of 24 twenty-minute cycles (8 hours) prior to birth. All records were assessed by one of the two authors. The assessment was performed without knowledge of the clinical or laboratory data. In each 20	Results There was no statistically significant difference between the two groups in regard to decrease frequency or absence of FHR accelerations in the 12 FHR trace cycles (4 hours before birth) indicating that fetal heart rate accelerations (as an independent variable) were not predictive of fetal acidosis (no synthesis of the statistical data provided). Total decelerations and variable decelerations in last hour prior to birth were significantly associated with acidosis. Late decelerations in the last hour prior to birth were significantly associated with neonatal acidosis. Variable decelerations only in last 20 minutes prior to birth were significantly associated with acidosis:	Limitations No analysis on combining factors for prediction. Other information Baseline heart rate classified as normal: 120 to 160 beats per minute (bpm) Bradicardia: < 120 bpm Tachycardia: > 160 bpm Baseline variability: amplitude of oscillation as normal (6 to 25 bpm), decreased (3 to 5 bpm) and absent (< 3 bpm) Accelerations: at least 15 bpm above the baseline. Normal (≥ 2 acceleration in 20 min), decreased (1 acceleration in 20 min), absent (no accelerations in 20 min) Decelerations: fall in FHR in excess of 15 bpm. Total deceleration patterns were classified on the basis of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not specified Source of funding Not specified			minute cycle the following characteristics were scored: baseline fetal heart rate, baseline FHR long term variability, FHR accelerations, FHR variable decelerations and FHR late decelerations.	Cycle 1 (20 min FHR trace 20 min before birth) Total decelerations: Index: n = 51/200 Control: n = 33/200 p = 0.001 Cycle 1 (20 min FHR trace 20 min before birth) Variable decelerations: Index: n = 38/200 Control: n = 30/200 p = 0.01 Cycle 1 (20 min FHR trace 20 min before birth) Late decelerations: Index: n = 78/200 Control: n = 23/200 p = 0.001 Cycle 2 (20 min FHR trace 40 min before birth) Total decelerations: Index: n = 42/200 Control: n = 30/200 p = 0.001 Cycle 2 (20 min FHR trace 40 min before birth)	frequency of contraction in 20 minute period. None (0% or 4% contractions associated with a deceleration), moderate (5% to 30% contractions associated with a deceleration), marked (> 30% contractions associated with a deceleration)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Variable decelerations: Index: n = 30/200 Control: n = 26/200 p = 0.2 Cycle 2 (20 min FHR 40 min trace before birth) Late decelerations: Index: n = 59/200 Control: n = 21/200 p = 0.001 Cycle 3 (20 min FHR trace 60 min before birth) Total decelerations: Index: n = 35/200 Control: n = 26/200 p = 0.006 Cycle 3 (20 min FHR trace 60 min before birth) Variable decelerations: Index: n = 26/200 Control: n = 24/200 p = 0.3 Cycle 3 (20 min FHR 60 min trace before birth) Late decelerations: Index: n = 42/200 Control: n =21/200	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				p = 0.01	
Full citation Low,J.A., Pancham,S.R., Piercy,W.N., Intrapartum fetal asphyxia: Clinical characteristics, diagnosis, and significance in relation to pattern of development, American Journal of Obstetrics and Gynecology, 129, 857-872, 1977 Ref Id 196822 Country/ies where the study was carried out Canada Study type Case series Aim of the study To examine clinical circumstances related to development of intrapartum fetal asphyxia	Sample size Total n = 587 n = 122 with significant metabolic acidosis (base buffer < 36.1 mEq/l) n = 465 without metabolic acidosis (base buffer > 36.1 mEq/l) Characteristics Parity 0 Normal group: 61% Asphyxia terminal: 67% Asphyxia/one hour: 55% Asphyxia/two hours: 72% Parity ≥ 1 Normal group: 39% Asphyxia terminal: 33% Asphyxia one/hour: 45%	Interventions All FHR variables	Details Fetal heart rate records (obtained via a scalp electrode) were reviewed for each two hour period prior to birth in n = 587 women. Based on the serial acid base observations (maternal venous blood acid base, lactate, and pyruvate characteristics during the labour and birth, fetal acid base characteristics during the last half of labour and fetal acid base, lactate and pyruvate characteristics during the labour and birth), women were divided into the normal group or the asphyxia group. FHR observations were made on the total	Results There were no statistically significant differences between the two groups (asphyxia and normal group) at mid-labour (> 2 hours prior to birth) in regard to pH, buffer base, and oxygen or carbon dioxide tension. However, the maternal pH, buffer base, and oxygen tension in the asphyxia group were all significantly lower compared to the normal group at two hours, one hour and 5 minutes prior to birth. The umbilical artery and vein buffer base was also significantly lower in the asphyxia group when compared with the normal group. Normal group n = 465 Asphyxia group n = 122 (terminal n = 46, one hour n = 40, two hours n = 36)	Limitations Unclear how and by who the records were assessed. Other information Baseline heart rate classified as normal: 120 to 160 beats per minute (bpm) bradycardia: < 120 bpm, tachycardia: > 160 bpm Baseline variability: amplitude of oscillation as normal (6 to 25 bpm), decreased (3 to 5 bpm) and absent (< 3 bpm) Accelerations: at least 15 bpm above the baseline. Normal (≥ 2 accelerations in 20 min), decreased (1 acceleration in 20 min), absent (no accelerations in 20 min) Decelerations: fall in FHR in excess of 15 bpm. Total

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Not specified Source of funding Supported by Ministry of Health grant	Asphyxia two/hours: 28% Preterm neonates Normal group: 11% Asphyxia terminal: 0% Asphyxia one/hour: 15% Asphyxia two/hours: 3% Preterm neonates Normal group: 10% Asphyxia terminal: 0% Asphyxia one/hour: 15% Asphyxia two/hours: 3% Post term gestation Normal group: 10% Asphyxia terminal: 13% Asphyxia one/hour: 20% Asphyxia two/hours: 14% Medical complication (hypertension,		decelerations, and late decelerations in relation to the contractions in each two hour period. The baseline FHR was observed at six 20-minute intervals in a two hour period. The normal acid base group as determined by a serial acid base study during birth included n = 465 women with a fetus with capillary blood buffer base of > 1 SD below the normal mean, i.e. ≥ 40 mEq/l, and umbilical artery buffer base at delivery of > 1 SD below the normal mean, i.e. ≥ 38.6 mEq/l. The fetal asphyxia group included n = 122 women in whom the baby at delivery had	Perinatal death Normal group: n = 29/465 (16%) Asphyxia terminal: n = 1/46 (2%) Asphyxia one/hour: n = 0/40 (0%) Asphyxia two/hours: n = 1/36 (3%) Mode of birth Spontaneous low forceps Normal group: n = 270/465 (58%) Asphyxia terminal: n = 14/46 (30%) Asphyxia/one hour: n = 14/40 (35%) Asphyxia/two hours: n = 11/36 (30%) Mid-forceps Normal group: n = 133/465 (29%) Asphyxia terminal: n = 28/46 (61%) Asphyxia/one hour: n = 14/40 (35%) Asphyxia/two hours: n =	deceleration patterns were classified on the basis of frequency of contractions in 20 minute period. None (0% or 4% contractions associated with a deceleration), moderate (5% to 30% contractions associated with a deceleration), marked (> 30% contractions associated with a deceleration) Total decelerations defined as percentage of contractions associated with a deceleration in each two-hour period. It was classified as moderate (5% to 29% of contractions were associated with a deceleration) and marked (> 30% of contractions were associated with a deceleration) Late decelerations defined as percentage of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	diabetes, other) Normal group: 15% Asphyxia terminal: 12% Asphyxia one/hour: 9% Asphyxia two/hours: 33% Meconium stained liquor Normal group: 33% Asphyxia terminal: 35% Asphyxia one/hour: 45% Asphyxia two/hours: 50% Regional or local anaesthesia Normal group: 90% Asphyxia terminal: 85% Asphyxia one/hour: 75% Asphyxia two/hours: 80% Inclusion criteria Women admitted and monitored in the intrapartum intensive-care unit. The criteria		an umbilical artery buffer base of < 2 SD below the normal mean, i.e. < 36.1 mEq/L. Duration of metabolic acidosis during labour were determined by the available serial fetal acid base observation in the second half of labour for each case. The criteria of developing metabolic acidosis during labour were a capillary blood buffer base of < 1 SD below the normal mean in the last hour of labour, i.e. < 40 mEq/l. The asphyxia group were divided into three groups based on the acid base characteristics during labour and delivery: terminal asphyxia (just before birth);	8/36 (22%) Caesarean section Normal group: n = 55/465 (12%) Asphyxia terminal: n = 3/46 (6%) Asphyxia/one hour: n = 9/40 (22%) Asphyxia/two hours: n = 16/36 (44%) Marked patterns of total decelerations (8 hours prior to birth) Normal group: 9% Asphyxia terminal: 29% Asphyxia/one hour: not reported Asphyxia/two hours: 20% Marked patterns of total decelerations (6 hours prior to birth) Normal group: 13% Asphyxia terminal: 21% Asphyxia/one hour: 14% Asphyxia/two hours: 20% Marked patterns of total	contractions associated with a late deceleration in each two-hour period. It was classified as moderate (< 10% of contractions were associated with a late deceleration) and marked (≥ 10% of contractions were associated with a late deceleration)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	for admission were maternal, fetal, or labour risk factors that could have been predictive of fetal asphyxia. Exclusion criteria Not specified		asphyxia/one hour (one hour before birth); asphyxia/two hours (two hours before birth).	decelerations (4 hours prior to birth) Normal group: 19% Asphyxia terminal: 30% Asphyxia/one hour: 37% Asphyxia/two hours: 39% Marked patterns of total decelerations (2 hours prior to birth) Normal group: 34% Asphyxia terminal: 54% Asphyxia/one hour: 52% Asphyxia/two hours: 61% Moderate or marked patterns of late decelerations (8 hours prior to birth) Normal group: 15% Asphyxia terminal: 9% Asphyxia/one hour: not reported Asphyxia/two hours: not reported Moderate or marked patterns of late decelerations (6 hours prior to birth)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Normal group: 18% Asphyxia terminal: 31% Asphyxia/one hour: 8% Asphyxia/two hours: 16% Moderate or marked patterns of late decelerations (4 hours prior to birth) Normal group: 21% Asphyxia terminal: 26% Asphyxia/one hour: 26% Asphyxia/two hours: 27% Moderate or marked patterns of late decelerations (2 hours prior to birth) Normal group: 31% Asphyxia terminal: 59% Asphyxia/one hour: 59% Asphyxia/two hours: 68%	
Full citation Maso,G., Businelli,C., Piccoli,M., Montico,M., De,Seta F., Sartore,A., Alberico,S., The clinical interpretation and significance of electronic	Sample size n = 198 Characteristics Not specified	Interventions Intrapartum electronic fetal monitoring	Details Data collected (retrospective for 6 months) from a labour database of Maternal and Child Institute Burlo	Results Umbilical artery pH value of 7.20 chosen as the cut off to define neonatal acidemia. Three EFM groups: normal,	Limitations - Women characteristics not reported - Selective data reported Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
fetal heart rate patterns 2 h before delivery: an institutional observational study, Archives of Gynecology and Obstetrics, 286, 1153-1159, 2012 Ref Id 275105 Country/ies where the study was carried out Italy Study type Case series Aim of the study To evaluate the clinical significance of intrapartum fetal heart rate (FHR) monitoring in low-risk pregnancies Study dates Not specified Source of funding Not specified	Inclusion criteria - Singleton - Term - Spontaneous and operative vaginal birth - External continuous FHR monitoring during the last 2 hours of labour was available - Short term neonatal outcomes were available - Low risk pregnancy (defined as cases without risk factors for the development of acidosis, cerebral palsy, perinatal death, and neonatal encephalopathy) Exclusion criteria Cases with risk factors for the development of acidosis, cerebral palsy, perinatal death, and neonatal encephalopathy		Garofolo in Italy. Based on the inclusion criteria, all cases with the last 2 hours continuous electronic fetal monitoring (EFM) before birth were included in the study. An obstetrician, blinded to neonatal outcomes, retrospectively reviewed the included cases. The tracings were interpreted as normal, suspicious or pathological, according to specific guidelines of EFM and by grouping the different FHR patterns considering baseline, variability, presence of decelerations and bradycardia (see 'Other information' section).	suspicious, pathological Normal If all four FHR variables (baseline, variability, decelerations, accelerations) fells into reassuring category (see 'Other information') Suspicious If one of the variables presented non reassuring characteristics and the reminder variables were reassuring (see 'Other information') Pathological If more than two non-reassuring or more than one abnormal variable was respectively (see 'Other information') Mean pH values in the three EFM groups: Normal pH 7.30 (95% CI 7.28 to 7.32) Suspicious pH 7.25 (95% CI 7.23 to 7.27)	Categorisation of FHR: Reassuring Baseline: 100-180 Variability: ≥ 5 Decelerations: none Accelerations: present Non-reassuring Baseline: 110 -160 Variability: < 5 for ≥ 40 but < 90 min Decelerations: - repetitive (≥ 3) typical variable decelerations with over 50% of contractions - single prolonged < 3 min Accelerations: the absence of accelerations with an otherwise normal FHR tracing is of uncertain significance Abnormal Baseline: - 161 - 180 - < 100 - >180 - sinusoidal pattern - ≥ 10 min Variability: < 5 for ≥ 40 to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Analysis: Comparisons between groups were performed with Kruskal-Wallis test. Differences among categorical variables were evaluated using Fisher's exact test.	Pathological pH 7.20 (95% CI 7.17 to 7.13) p < 0.001 (for all pairwise comparisons) Mean BD mmol/L values in the three EFM groups: Normal -3.35 (95% CI -4.19 to -2.50) Suspicious -5.62 (95% CI -6.43 to -4.81) Pathological -7.50 (95% CI -8.50 to -6.50) p < 0.001 (for all pairwise comparisons) Composite dverse outcomes*: Normal n = 0/51 (0%) Suspicious n = 5/88 (5.7%) Pathological n = 6/59 (10.1%) p = 0.005 (normal vs.	≥ 90 min Decelerations: - either repetitive (≥ 3) atypical variable decelerations or late decelerations, with over 50% of contractions - single prolonged deceleration > 3 min Accelerations: the absence of accelerations with an otherwise normal FHR tracing is of uncertain significance Normal, suspicious, pathological Normal If all four FHR variables (baseline, variability, decelerations, accelerations) fells into reassuring category Suspicious If one of the variables presented non reassuring characteristics and the reminder variables were reassuring Pathological If more than two non-

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				pathological) Normal variability: pH < 7.20 n = 3/51 (5.9%) pH < 7.10 n = 0/51 (0%) PH < 7.00 n = 0/51 (0%) BD mmol/l 0/51 (0%) Normal variability and typical variable decelerations: pH < 7.20 n = 18/63 (28.6%) pH < 7.10 n = 6/63 (9.5%) PH < 7.00 n = 1/63 (1.6%) BD mmol/l 5/63 (7.9%) Normal variability and atypical variable decelerations: pH < 7.20 n = 13/27 (48.2%) pH < 7.10	reassuring or more than one abnormal variable was respectively FHR features definitions: Atypical variable Defined in the presence of at least one of the following conditions: loss of primary or secondary rise in the baseline rate; slow return to baseline FHR after the contraction; prolong secondary rise in the baseline rate; biphasic deceleration; loss of variability during deceleration; continuation of baseline rate at lower level Bradycardia Defined as moderate or severe if persistent fall of baseline between 100 and 109 bpm was respectively observed over a time period of 5 to 10 min.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				n = 2/27 (7.4%) PH < 7.00 n = 0/27 (0%) BD mmol/l 0/27 (0%) Moderate bradycardia pH < 7.20 n = 6/17 (35.3%) pH < 7.10 n = 0/17 (0%) PH < 7.00 n = 0/17 (0%) BD mmol/l 0/17 (0%) Severe bradycardia pH < 7.20 n = 7/15 (46.7%) pH < 7.10 n = 4/15 (26.7%) PH < 7.00 n = 1/15 (6.7%) BD mmol/l 2/15 (13.3%) *Composite neonatal outcomes: umbilical artery pH < 7 and/or APGAR score < 7 at 5 min and/or neonatal resuscitation in delivery room and admission to neonatal intensive care unit for distress at birth.	
Full citation Cahill,A.G.,	Sample size Terminal deceleration:	Interventions Electronic fetal	Details Data collected from	Results Terminal deceleration and	Limitations - Uneven number of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Caughey,A.B., Roehl,K.A., Odibo,A.O., Macones,G.A., Terminal fetal heart decelerations and neonatal outcomes, Obstetrics and Gynecology, 122, 1070-1076, 2013 Ref Id 298858 Country/ies where the study was carried out USA Study type Retrospective cohort study Aim of the study To examine the incidence and characteristics of terminal fetal heart rate decelerations and to estimate their association with acidemia Study dates Between 2004 and	n = 951 No terminal deceleration n = 4,437 Characteristics Groups were similar with respect to: - maternal age and race - body mass index - gestational age at delivery - use of regional anesthesia - induction in labour Women with a terminal deceleration were more likely to be nulliparous and, they were less likely to have a spontaneous vaginal birth. The mean BMI in both groups was > 31. Inclusion criteria - singleton - vertex gestation at term (at or after 37 0/7 weeks),	monitoring	all consecutive births at Washington University in St. Louis Medical Center during the study period. The institutional policy is one of universal EFM during labor and arterial umbilical cord gas pH level birth. Women's EFM trace from 30 minutes before birth was interpreted by two formally trained obstetric research nurses certified in EFM interpretation and blinded to clinical data and outcomes.. Electronic fetal monitoring was interpreted using the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the American College of Obstetricians and	neonatal outcomes Arterial umbilical cord pH level of 7.10 or less Terminal deceleration n = 12/951 (1.3%) Not terminal deceleration n = 45/4437 (1.0%) Adjusted* OR 1.2 (95% CI 0.6 to 2.3) P = 0.49 Arterial umbilical cord pH level of 7.05 or less Terminal deceleration n = 4/951 (0.4%) Not terminal deceleration n = 13/4437 (0.3%) Adjusted* OR 1.4 (95% CI 0.5 to 4.4) P = 0.52 Arterial umbilical cord pH level of 7.10 or less and base excess < -8.0 Terminal deceleration n = 11/951 (1.2%) Not terminal deceleration n = 39/4437 (0.9%) Adjusted* OR 1.3 (95% CI 0.7 to 2.6) P = 0.45 Apgar score less than 7 at 5	participants in two groups - 30 min EFM traces just before birth were analysed - if trace was lost or discontinuous after the initiation of the terminal deceleration, it was assumed that duration of terminal deceleration was until birth Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
2008 Source of funding Not specified	- labored, and reached complete dilation. Exclusion criteria - Multiple gestation - Fetus with a known congenital anomaly - Did not have sufficient electronic fetal monitoring (EFM) recording during the 30 minutes before birth (less than 10 minutes of EFM during the 30 minutes before birth).		Gynecologists three-tiered category system. Terminal deceleration, defined as a prolonged deceleration (15 bpm or more below baseline for 120 seconds (2 min) or more and fewer than 10 minutes) or bradycardia (< 110 bpm for 10 minutes or more). The comparison made between women who had a terminal deceleration and those who did not. Interval interobserver reliability was performed. For presence of terminal decelerations, kappa coefficient was consistently more than 0.9. Detailed maternal and	minutes Terminal deceleration n = 4/951 (0.4%) Not terminal deceleration n = 51/4437 (1.2%) Adjusted* OR 0.4 (95% CI 0.1 to 1.1) P = 0.05 Special care or NICU admission Terminal deceleration n = 42/951 (4.4%) Not terminal deceleration n = 228/4437 (5.2%) Adjusted* OR 0.8 (95% CI 0.6 to 1.2) P = 0.35 Abruption composite Terminal deceleration n = 10/951 (1.1%) Not terminal deceleration n = 18/4437 (0.4%) Adjusted* OR 2.6 (95% CI 1.2 to 5.6) P = 0.2 Terminal deceleration characteristics by acidemia: Number of babies born with acidemia.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			pregnancy data including obstetric history, pregnancy course and complications, medication exposure and acute events (including placental abruption, umbilical cord prolapse, and uterine rupture), physical examination, anesthesia type, delivery, and neonatal outcomes were also extracted.Use of internal monitors for fetal heart rate monitoring and contractions and umbilical cord gas arterial pH level, as well as CO2 and base excess, also were recorded. The primary outcome was acidemia, defined as arterial umbilical cord gas pH level of 7.10 or less.	n = 12/951 (1.3%) Number of babies born with no acidemia. n = 939/951 (1.3%) Median time to birth (min SD) Acidemia 6.7 (SD 3.7 to 12.7) No academia 3.2 (SD 2.5 to 4.6) P<.01 For every additional 120 seconds of duration of the terminal deceleration beyond the first 120 seconds, there was a corresponding decrease in arterial umbilical cord pH level by 0.042 (95% CI 0.040 to 0.048; P<.01). However, terminal deceleration characteristics, such as median or greatest depth and variability within the nadir, were not associated with risk of acidemia Baradicardia and terminal deceleration Risk associated with	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Secondary outcomes included arterial umbilical cord gas pH level 7.05 or less, base excess more than −8, metabolic acidemia (pH level 7.10 or less and base excess more than −8), admission to the neonatal intensive care unit (level IV) or admission to the special care unit (level II), and Apgar score less than 7 at 5 minutes. Analysis: For continuous variables Student t tests and Mann-Whitney U tests were used and χ2 and for dichotomous variables Fisher exact tests were used as appropriate.Stratified analyses were performed to identify	Bradycardia among women with terminal deceleration: Bradycardia duration of 10 minutes or more n = 31/951 Bradycardia duration of < 10 minutes n = 930/951 Risk of acidemia (pH level of 7.10 or less): Bradycardia duration of 10 minutes or more n = 4/31 (12.9%) Bradycardia duration of < 10 minutes n = 8/920 (0.9%) Adjusted OR 18.6 (5.0 to 68.9) P < 0.01 Risk of acidemia (pH level of 7.05 or less): Bradycardia duration of 10 minutes or more n = 2/31 (6.5%) Bradycardia duration of < 10 minutes n = 2/920 (0.2%) Adjusted* OR 46.0 (5.7 to 373.0) P < 0.01	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			potentially confounding factors, which were considered in multivariable analyses. To refine estimates of association between terminal decelerations and acidemia by eliminating nonsignificant factors, multivariable logistic regression was performed. To explore the risk of acidemia and other adverse outcomes among women with terminal bradycardia a secondary analysis was performed. Linear regression was then used to estimate the incremental association between increasing terminal deceleration duration	Apgar score < 7 at 5 min: Bradycardia duration of 10 minutes or more n = 2/31 (6.5%) Bradycardia duration of < 10 minutes n = 2/920 (0.2%) Adjusted* OR 67.0 (8.4 to 536.6) P < 0.01 Special care and NICU admission: Bradycardia duration of 10 minutes or more n = 3/31 (10%) Bradycardia duration of < 10 minutes n = 8/920 (0.9%) Adjusted* OR 11.4 (3.2 to 40.7) P < 0.01 * Adjusted for nulliparity Presence of bradycardia (10 minutes or more) was poorly predictive of acidemia, with a sensitivity of 33.3%, a specificity of 97.0%, and a positive predictive value of only 12.9%.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			beyond 2 minutes and decreasing arterial umbilical cord pH level. To estimate the predictive ability of terminal deceleration duration and risk of acidemia, Receiver-operator characteristic curve analysis was used. STATA 10 special edition was used for the all analysis.	Duration of terminal deceleration Predictive value of duration of terminal deceleration beyond 2 minutes for academia (pH level of 7.10 or less) AUC (area under the curve) 0.78 (95% CI 0.60–0.94) Predictive value of duration of terminal deceleration cut-off of 4 minutes or more for academia (pH level of 7.10 or less) Sensitivity: 75.0% (95% CI 74.2 to76.3%) Specificity: 64.0% (95% CI 62.8–65.1%)	
Full citation Berkus,M.D., Langer,O., Samueloff,A., Xenakis,E.M., Field,N.T., Electronic fetal monitoring: what's reassuring?, Acta	Sample size n = 2200 consecutive singleton term pregnancies n = 484/2200 (26%) with normal FHR	Interventions Normal Baseline 120–160 bpm Variability > 5 bpm Presence of accelerations	Details A cohort of n = 2200 consecutive birth was examined and the fetal heart rate tracings analysed. Arterial blood gas	Results Association between abnormal FHR tracing patterns and immediate adverse outcome (1st stage n = 224) Mild or moderate variable	Limitations No separate data for Apgar and pH Other information Reassuring (normal) trace defined as:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Obstetricia et Gynecologica Scandinavica, 78, 15-21, 1999 Ref Id 196611 Country/ies where the study was carried out USA Study type Cohort Aim of the study To determine which combinations of fetal heart rate (FHR) pattern abnormalities are associated with normal outcome in term pregnancies Study dates From March to August 1991 Source of funding Not specified	trace during the last 30 minutes prior to delivery Characteristics There were no significant differences observed between the reassuring and non-reassuring group in fetal gestational age, sex, birth weight, and fetal complications. Women with non-reassuring tracing were significantly older, more often primigravida, had more maternal illness (cardiovascular, thyroid, kidney disease or diabetes) and more caesarean section and instrumental birth. However, there was no statistically significant differences in pregnancy complications (hypertension, infection, post-date, substance abuse,	No variable or late decelerations Abnormal Baseline 90–120 bpm or > 160 bpm Variability < 5 bpm No accelerations Any decelerations Prolonged bradycardia or any combination	was collected from 97.5% of the study population. Blood sample was drawn immediately after birth and analysed within 30 minutes of birth. Every women entering the delivery room had FHR trace performed. The last 30 minutes of trace segment prior to delivery was analysed. All traces were obtained by scalp electrocardiography, and observers that analysed the data were blinded to birth outcomes.	deceleration: not significant (ns) Decreased variability: ns Mild bradycardia: ns Tachycardia: ns Prolonged bradycardia: OR 1.9 (95% CI 1.3 to 3.7) Severe variable deceleration: ns late deceleration: ns Association between abnormal FHR tracing patterns and cord pH < 7.15 & 5 min apgar score < 7 (first stage n = 224) Mild or moderate variable deceleration: ns Decreased variability: ns Mild bradycardia: ns Tachycardia: ns Prolonged bradycardia: ns Severe variable deceleration: ns Late deceleration: ns Association between abnormal FHR tracing patterns and immediate adverse outcome (second stage n = 1635)	Any tracing with acceleration Had mild variables Had decreased variability Had mild bradycardia Had any above combination Non-reassuring (abnormal) trace defined as: No acceleration Severe or late deceleration Prolonged bradycardia Tachycardia any above combination Neonates were assessed to have immediate adverse outcomes if they: were admitted to level III, neonatal intensive care unit for > 24 hours and required oxygen support (intubation > 6 hrs, or > 24 hrs of > 40% oxygen supplementation) had significant

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	meconium stained liquor). Inclusion criteria Term pregnancy (> 36 weeks or birth weight > 2500g) Live birth Singleton pregnancy Exclusion criteria Choriamnionitis Major congenital abnormalities			Mild or moderate variable deceleration: ns Decreased variability: ns Mild bradycardia: ns Tachycardia: OR 1.9 (95% CI 1.2 to 2.8) Prolong bradycardia: ns Severe variable deceleration: ns Late deceleration: ns Association between abnormal FHR tracing patterns and cord pH < 7.15 & 5 min apgar score < 7 (second stage n = 1635) Mild or moderate variable deceleration: ns Decreased variability: ns Mild bradycardia: ns Tachycardia: ns Prolonged bradycardia: OR 3.6 (95% CI 1.2 to 11) Severe variable deceleration: OR 2.4 (95% CI 1.2 to 4) Late deceleration: OR 6.9 (95% CI 2.1 to 23) Decreased variability: ≤ 5 bpm	complications (intracranieal haemorrahge, neonatal death) experienced neurological sequelae (seizure, persistent hypotonia at discharge)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Mild bradycardia: 90 < FHR < 120 bpm Tachycardia: 120 < FHR< 160 bpm Prolonged bradycardia: < 90 bpm, > 2.5 min	
Full citation Cardoso,C.G., Graca,L.M., Clode,N., A study on second-stage cardiotocographic patterns and umbilical blood acid-base balance in cases with first-stage normal fetal heart rates, Journal of Maternal-Fetal Investigation, 5, 144-147, 1995 Ref Id 197264 Country/ies where the study was carried out Portugal Study type Cohort Aim of the study To examine the	Sample size n = 293 singleton term pregnancies. Normal 1st stage traces, analysed on all of second stage. Classified on modified Melchior and Barnard classification. n = 103 type 0 used as controls. Characteristics Instrumental vaginal birth performed in 10 cases of 0 type (9.7%), n =11 of type 1a (11.8%), n = 6 of type 1b (31.5%), n = 6 of 2a (16.6%), n = 9 of type 2b (69%), n = 10 of type 3 (71%) and n = 2	Interventions Type 0 Stable FHR during entire second stage Type 1a Mild variable decelerations Type 1b Moderate to severe variable decelerations or late decelerations with each contraction, returning to baseline inbetween Type 2a Baseline 90–120 bpm with decelerations	Details n = 293 cases in which FHR monitoring was obtained during the last hour of the 1st stage and entire 2nd stage were evaluated. Arterial and venous umbilical blood was obtained in all cases. n = 103 cases were included in type 0 (absence of FHR abnormalities during the 2nd stage) were used as a control group. FHR tracing was recorded via a spiral electrode applied to the fetal head and uterine contractions were	Results Umbilical artery acid base pH (2nd stage CTG types) Type 0 7.24 ± 0.06 Type 1a 7.15 ± 0.07 p = ns Type 1b 7.19 ± 0.07 p = 0.0001 Type 2a 7.19 ± 0.06 p = 0.0001 Type 2b 7.06 ± 0.07 p = 0.0001 Type 3 7.09 ± 0.06 p = 0.0001 Type 4 7.19 ± 0.07 p = 0.01	Limitations Unusual scoring system. Analysis not based on specific FHR abnormalities. Small numbers in more severe categories (2b: n = 13, 3: n = 14). Other information Beginning of 2nd stage: Defined as the moment of the initiation of pushing effort and full cervical dilatation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
correlation between fetal heart rate (FHR) patterns during the 2nd stage of labour and umbilical blood acid based parameters Study dates Not specified Source of funding Not specified	of type 4 (13.4). No other characteristics specified. Inclusion criteria Singleton pregnancy Term pregnancy (37-42 weeks gestation) No maternal and fetal pathology Vertex birth Spontanous or instrumental vaginal birth Normal fetal monitoring trace during the last hour of 2nd stage (FHR between 120 and 160 beats/min, variability > 5 beats/min, and absence of periodic pattern) Exclusion criteria	Type 2b Basal FHR below 90 bpm, usually with reduced variability Type 3 Basal FHR below 90 bpm, low variability, accelerations with contractions Type 4 Basal FHR below 90bpm during final moments of 2nd stage only	measured by tocodynametery. Paper speed of the monitor was 1cm/min. Analysis Analysis of the tracing was independently interpreted and classified by two investigators that were blinded to the information regarding umbilical cord pH and cases. Acidemia was diagnosed when pH levels were more than one standard deviation below the mean level obtained in the control group. The 2nd stage of labour never exceeded 45 min	Umbilical vein acid base pH (2nd stage CTG types) Type 0 7.30 ± 0.06 Type 1a 7.29 ± 0.07 p = ns Type 1b 7.22 ± 0.07 p = 0.0001 Type 2a 7.26 ± 0.06 p = 0.001 Type 2b 7.12 ± 0.07 p = 0.0001 Type 3 7.15 ± 0.06 p = 0.0001 Type 4 7.24 ± 0.06 p = 0.004 Early neonatal morbidity was found in n = 3 neonates: Case 1 CTG pattern 1b Arterial pH 7.07 Morbidity: resuscitation Days in NICU: 2	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Not specified			Case 2 CTG pattern 2b Arterial pH 7.00 Morbidity: grunting Days in NICU: 7 Case 3 CTG pattern 2b Arterial pH 7.09 Morbidity: resuscitation Days in NICU: 4 Arterial and venous pH values significantly lower in types 1b and below compared with controls. Mean pH only < 7.20 in types 2b and 3.	
Full citation Dellinger,E.H., Boehm,F.H., Crane,M.M., Electronic fetal heart rate monitoring: early neonatal outcomes associated with normal rate, fetal stress, and	Sample size n = 898 Normal pattern n = 627 Stress pattern n = 263 Distress pattern n = 8	Interventions Normal pattern 110–160 bpm, minimal to moderate variability, with or without accelerations	Details Fetal heart rate data from all labouring women monitored at 2 institutions were examined. Tracings in the final hour before delivery were defined as normal,	Results Total normal n = 627 Total stress n =236 Total distress n = 8 Umbilical pH < 7.00 Normal n = 0/627 Stress n = 2/263 (1.6%) Distress n = 2/8 (28.5%)	Limitations Underpowered cohort due to imbalance between groups. Analysis between distress and normal for pH and Apgar highly specific but interpret with caution in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
fetal distress, American Journal of Obstetrics and Gynecology, 182, 214-220, 2000 Ref Id 170635 Country/ies where the study was carried out USA Study type Cohort Aim of the study To examine the ability of well-defined classification system for electronic fetal heart rate (FHR) tracing to predict early neonatal outcome Study dates One hospital: July 1993 to February 1994 One hospital: February to June 1995 Source of funding Not specified	Characteristics Comparative characteristics not reported Inclusion criteria Singleton pregnancy > 32 weeks gestation Exclusion criteria Presence of anomalies or arrhythmias Multiple pregnancy Gestational age < 32 weeks Caesarean section before onset of labour Inability to obtain an adequate FHR tracing Traces were excluded from the study if ≥ 15	Stress pattern > 160 bpm for > 5 minutes, minimal to moderate variability, moderate to severe variable decelerations, late decelerations or sinusoidal pattern Distress pattern < 110 bpm for > 5 minutes, moderate to severe variable decelerations with absent variability, late decelerations with absent variability, 110–160 bpm with absent variability and no accelerations	fetal stress, or fetal distress. Based on the standard care of the hospital all labouring women received electronic fetal heart monitoring. All tracings were stored after birth and reviewed at the later date by an observer blinded to the birth outcomes. The FHR tracing was evaluated for the one hour period preceding the birth.	p > 0.001 NICU admission Normal n = 29 Distress/Stress n = 25 LSCS rate Normal n = 75 Distress/Stress n = 4 Stress/distress vs. normal Sensitivity 68% Specificity 71% PPV 5% NPV 99%. Umbilical cord pH < 7.00 Stress/distress vs. normal Sensitivity 100% Specificity 66% PPV 3% NPV 100% Results also on distress vs. normal NPV for all outcomes > 98%	view of numbers in each group. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	min during the final hour went untraced				
Full citation Ellison,P.H., Foster,M., Sheridan-Pereira,M., MacDonald,D., Electronic fetal heart monitoring, auscultation, and neonatal outcome, American Journal of Obstetrics and Gynecology, 164, 1281-1289, 1991 Ref Id 164084 Country/ies where the study was carried out Ireland Study type Retrospective cohort study Aim of the study To examine the relationship between a number of maternal, labour and delivery variables (including fetal	Sample size Original cohort from Dublin RCT. Two groups of FHR traces: electronic fetal monitoring (EFM) alone n = 2362 and EFM plus neurological examination n = 135 Characteristics Not specified Inclusion criteria Not specified Exclusion criteria Heavily stained meconium liquor Decreased amniotic fluid Abnormal heart rate on admission	Interventions All FHR variables	Details Data in this study are from a randomised control trial conducted in Dublin (comparing the effectiveness of electronic fetal monitoring and auscultation in improving the health of fetus during delivery and birth). For the purpose of this review only data on electronic fetal monitoring will be reported. Data for electronic fetal heart monitoring were available for both the 1st and 2nd stages of labour. The fetal heart rate monitoring was interpreted by an obstetrician who was blinded to the	Results Correlation of specific fetal heart patterns to neonatal convulsions (n = 135): 1st stage of labour Late deceleration r = 0.38, p < 0.001 Severe variable deceleration r = -0.04, p = ns Marked tachycardia r = -0.02 Moderate variable decelerations r = -0.02 Early decelerations r = 0.01 Normal baseline and variability r = -0.05 2nd stage of labour Late decelerations r = 0.38, p < 0.001 Early decelerations r = 0.01	Limitations No specifics of scoring for neurological examination specified Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
heart rate [FHR] patterns) to neonatal outcomes Study dates March 1981 to April 1983 Source of funding Not specified			women's characteristics and neonatal birth outcomes. All newborns were examined physically and neurologically by a physician. FHR patterns were recorded separately. Analysis Frequencies were reviewed for all variables, as well as distributions and skews. Pearson correlation and biserial correlations for dichotomous variables were obtained and reviewed for each sample.		
Full citation Gaffney,G., Flavell,V., Johnson,A., Squier,M., Sellers,S., Cerebral palsy and neonatal	Sample size 141 case of cerebral palsy; UK hospital Characteristics	Interventions Ominous FHR pattern	Details Children with cerebral palsy born during the study period were identified	Results Findings on cardiotocograph (CTG) in mothers of children with cerbral palsy with or without	Limitations Other information Neonatal encephalopathy defined as:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
encephalopathy, Archives of Disease in Childhood Fetal and Neonatal Edition, 70, F195-F200, 1994 Ref Id 196440 Country/ies where the study was carried out UK Study type Retrospective cohort study Aim of the study To test the hypothesis that children born at term with cerebral palsy with signs of neurological dysfunction preceded by depression at birth (termed neonatal encephalopathy) differ from those without such signs in the frequency of antenatal and perinatal factors, and in the severity and characteristics of their impairment and disability	No significant differences observed between the two groups (with neonatal encephalopathy [NE] and without neonatal encephalopathy) marital status, maternal disease, recurrent abortion, poor obstetric history, previous preterm birth, maternal smoking habit, and maternal age. More women in the 'without NE' group were primigravida compared with the 'with NE' group. Half the mothers of infants with neonatal encephalopathy (51/100) and mothers of infants with neonatal encephalopathy (20/41), had one or more complicating factors (antenatal infection, premature rupture of membranes, pre-eclampsia, severe pre-eclampsia,		from the Oxford health regional register of childhood impairment. The children with cerebral palsy were divided into those with signs of neonatal encephalopathy (with NE) and those without (without NE). This was based on the information recorded in the neonatal case notes. The clinical characteristics of the children in the study were described in terms of distribution of tone changes, as walking and non walking, and with or without intellectual deficit, vision loss, seizures, involuntary movement, or bulbar signs such as difficulty in swallowing.	neonatal encephalopathy Ominous first stage CTG Without NE: n = 4/48 (8%) With NE: n = 13/27 (48%) OR 10.2 (2.9 to 36.4) Ominous second stage CTG Without NE: n = 19/45 (42%) With NE: n = 21/25 (84%) OR 7.2 (2.1 to 24.4) Median duration of first stage abnormality (min) Without NE: 48.5 (38 to 287) With NE: 200.0 (15 to 480) p = 0.3 Median duration of second stage abnormality (min) Without NE: 38 (8 to 287) With NE: 100.0 (12 to 480) p = 0.003 Follow-on data: significant association with major and minor impairment in encephalopathy group.	Depression at birth, based on a one minute apgar score of less than or equal to 6. Followed by evidence of neonatal neurological abnormality such as lethargy, coma, impaired respiration, seizures, and/or tone change

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates 1984 to 1987 Source of funding Funded by Oxford Regional Health Authority	antepartum haemorrhage, previous infertility, induced conception, raised maternal serum alpha fetoprotein, polyhydramnios, reduced fetal movement, or complicated antenatal course). More women in the neonatal encephalopathy group had post-date pregnancy (> 41 weeks), induction of labour, 2nd stage of labour exceeding > 2 hours, meconium stained liquor, caesarean section or instrumental birth. There was no significant difference in augmentation use between the two groups. Inclusion criteria Singleton pregnancy			Quadraplegia (OR 4.8; 95% CI 2.2 to 10.5) Hemiplegia (OR 0.3; 95% CI 0.1 to 0.8)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Term pregnancy Exclusion criteria Children with major congenital abnormality Children in whom there was a definite postnatal cause for cerebral palsy such as meningitis or trauma				
Full citation Giannubilo,S.R., Buscicchio,G., Gentilucci,L., Palla,G.P., Tranquilli,A.L., Deceleration area of fetal heart rate trace and fetal acidemia at delivery: A case-control study, Journal of Maternal-Fetal and Neonatal Medicine, 20, 141-144, 2007 Ref Id 158821 Country/ies where the	Sample size Total n = electronic fetal monitoring (EFM) traces of 236 pregnancy n = 56 pregnancies met the inclusion criteria (Acidemia n = 26, Control = 30) Characteristics Maternal There were no significant differences observed between the two groups (normal and	Interventions EFM traces	Details From n = 410 third trimester cardiotocograph (CTG) tracings performed at the department of obstetrics and gynaecology, Belcolle Hospital during the study period, n = 236 with performed cord gas analysis were selected for inclusion. n = 56 pregnancies met the	Results Number of decelerations (> 15bpm/15s) during the second stage of labour Acidemia: 8.03 ± 3.77 Control: 4.64 ± 3.84) Total deceleration area/cm2/hour Acidemia: 35.56 ± 11.87 Control: 17.81 ± 9.38	Limitations Small study with a large drop out Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study was carried out Italy Study type Retrospective cohort Aim of the study To assess the correlation between the total deceleration area of the fetal heart rate (FHR) pre-delivery trace and intrapartum fetal acid-base status in a low risk population. Study dates January to August 2004 Source of funding Not reported	abnormal pH at birth) in maternal age, gestational age at delivery, primiparity, length of second stage of labour or operative delivery rate. The length of first stage of labour was statistically significantly longer in controls compared with acidemic group p < 0.001. Neonatal There were also no significant differences observed in birth weight, baby's sex, apgar score 1 min < 7 and apgar score 5 min < 7, or cord arterial pH. Cord base deficit was significantly higher in the acidemic group compared with controls p < 0.001. CTG parameter (Acidemic n = 26,		inclusion criteria (Acidemia n = 26, Control = 30). CTG was performed during second stage of labour at least one hour without interruption. Umbilical blood gas performed by collecting blood samples from cord artery and the pH < 7.2 was considered abnormal. A base deficit ≥ 12 mmol/l was considered the threshold of the fetal metabolic acidosis at delivery. Hospital records of each newborn were evaluated for Apgar, weight and neonatal complication. Analysis The deceleration area was calculated, after digital analysis,		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Control n = 30) Baseline heart rate Acidemic 131.25 ± 9.19 Control 136.25 ± 10.14 Number of decelerations > 15 bpm/15 Acidemic 8.03 ± 3.77 Control 4.64 ± 3.84 Fetal deceleration area cm2/h Acidemic 17.81 ± 9.38 Control 35.56 ± 11.87 Inclusion criteria Normal FHR pattern (normal variability, presence of accelerations) Singleton pregnancy Caucasian race Vertex presentation Vaginal birth, no labour		with Autocad System 2004. Statistical analysis performed with SPSS version 0.8 statistical package. Chi-square or Fisher's exact tests were used for comparison of proportions. Student's t-test was applied for comparisons of means.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	augmentation Term birth > 37 wks Exclusion criteria Technically uninterpretable trace Required emergency caesarean section (CS) because of maternal or fetal conditions (such as sign of placental insufficiency, cephalo-pelvic distribution) Previous CS Pre-existing heart or lung disease Carrying a baby with growth restriction or malformation				
Full citation Gilstrap,L.C.,III, Hauth,J.C., Hankins,G.D.,	Sample size n = 277 cases with known arterial cord pH samples and	Interventions Uncomplicated bradycardia or	Details Cord pH was determined within 5 minutes of birth and	Results Correlation of normal and abnormal traces and cord pH (mean ± SD)	Limitations Unclear for how long abnormalities were

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Beck,A.W., Second-stage fetal heart rate abnormalities and type of neonatal acidemia, Obstetrics and Gynecology, 70, 191-195, 1987 Ref Id 195342 Country/ies where the study was carried out USA Study type Cohort study Aim of the study To examine the incidence and type of acidaemia, degree of buffer base deficit, and immediate neonatal outcome in relation to baseline second stage fetal heart rate (FHR) patterns before delivery Study dates June 1985 to April 1986	satisfactory second stage traces Characteristics White race: 83% Maternal age 20-29 years old: 71% Primiparous: 51% Inclusion criteria Term birth Vaginal birth Vertex presentation Exclusion criteria Women with complication such as: Diabetes Chronic hypertension Preeclampsia	tachycardia	specimens were obtained from either the umbilical artery or vein. Acidosis defined as a arterial cord pH of less than 7.20. Fetal heart rate tracings were obtained during the second stage via a scalp electrode. The tracing during the 2nd stage (before expulsion of head) was evaluated for baseline FHR abnormality and variability. Only women with either a normal FHR pattern or obvious baseline changes, consisting of bradycardia or tachycardia, were included. Analysis The FHR trace was independently analysed by both authors without	Normal (n = 129) 7.29 ± 0.6 Tachycardia (n = 32) 7.25 ± 0.5 p < 0.05 Mild bradycardia (n = 53) 7.23 ± 0.7 p < 0.05 Moderate or severe bradycardia (n = 63) 7.22 ± 0.7 p < 0.05	present for Not consecutive cases, hence subject to selection bias Other information Uncomplicated bradycardia: Mild (90–119 bpm) Moderate (60–89 bpm) Severe (< 60 bpm) Tachycardia (> 160 bpm)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not specified	Acute chorioamnionitis Significant medical illness Women with abnormal FHR such as late decelerations, moderate or severe variable decelerations, bradycardia and tachycardia		knowledge of blood gas results. Traces were only included if the interpretation was in agreement (there was disagreement in < 2% of the traces)		
Full citation Gilstrap,L.C.,III, Hauth,J.C., Toussaint,S., Second stage fetal heart rate abnormalities and neonatal acidosis, Obstetrics and Gynecology, 63, 209-213, 1984 Ref Id 195341 Country/ies where the study was carried out USA	Sample size n = 833 cases with cord pH samples and interpretable traces in the last 10 minutes of labour Characteristics Demographic characteristics: White race: 75% Maternal age 20-29 years old: 65%	Interventions Uncomplicated bradycardia Uncomplicated tachycardia	Details All infants during the study period, whose delivery was by forceps, were included in the study. Cord pH was determined within 5 minutes of birth and specimens were obtained from either the umbilical artery or vein. Acidosis was defined as a pH of less than 7.20. Fetal heart rate tracings	Results Correlation of n = 833 normal and abnormal traces and cord pH Acidosis: Normal n = 19/430 (4%) Abnormal n = 80/403 (20%) p < 0.001 Association of mild bradycardia and umbilical cord pH Acidosis: Normal n = 19/430 (4%) Abnormal (with mild bradycardia [present 1-3	Limitations Not consecutive cases, high risk of selection bias Unclear how and by whom data were analysed Blood for cord pH was taken from umbilical artery or vein. Other information Uncomplicated bradycardia: Mild (90–119 bpm)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Prospective cohort study Aim of the study To examine the correlation of baseline fetal heart rate (FHR) abnormalities in the last 10 minutes of the second stage of labour with neonatal acid-base status Study dates August 1979 to January 1983 Source of funding Not specified	Primiparous: 85% Term pregnancy: 98% Inclusion criteria If a cord pH was obtained If there was satisfactory fetal heart tracing during the last minutes of 2nd stage Exclusion criteria Women with significant FHR abnormalities during the 1st stage of labour such as: Decelerations Persistent pattern of bradycardia Tachycardia Women with significant FHR abnormalities, such as late or		were obtained during the second stage via a scalp electrode. The tracing during the last 10 mins of delivery (before expulsion of the head) was evaluated for FHR abnormalities. Only women with either a normal FHR pattern or obvious baseline changes, consisting of bradycardia or tachycardia, were included.	min in 17% and > 3 in 20%]) n = 30/165 (18%) p < 0.001 Association of moderate bradycardia and umbilical cord pH Acidosis: Normal n = 19/430 (4%) Abnormal (with mild bradycardia [present 1-3 min in 25% and > 3 in 29%]) n = 33/121 (27%) p < 0.001 Association of tachycardia (mild and marked) and umbilical cord pH Acidosis: Normal n = 19/430 (4%) Abnormal (with mild or marked tachycardia) n = 17/117 (18%) p < 0.001 Umbilical artery pH < 7.20 Mild tachycardia: < 3 minutes: 4/42 (10%) > 3 minutes: 9/54 (17%)	Moderate (60–89 bpm) Severe (< 60 bpm) Uncomplicated tachycardia Mild (160–179 bpm) Marked (> 180 bpm)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	moderate or severe variable decelerations were excluded from the analysis			Marked tachycardia: < 3 minutes: 2/5 (40%) > 3 minutes: 2/16 (13%) Mild bradycardia: < 3 minutes: 19/110 (17%) > 3 minutes: 11/55 (20%) Moderate to severe bradycardia: < 3 minutes: 19/72 (26%) > 3 minutes: 14/49 (29%)	
Full citation Hadar,A., Sheiner,E., Hallak,M., Katz,M., Mazor,M., Shoham-Vardi,I., Abnormal fetal heart rate tracing patterns during the first stage of labor: Effect on perinatal outcome, American Journal of Obstetrics and Gynecology, 185, 863-868, 2001 Ref Id 169256 Country/ies where the	Sample size n = 601 FHR tracing (pregnancies); n = 301 abnormal pattern, n = 300 normal pattern Characteristics Women with abnormal tracing were more often nulliparous and delivered infants with significantly lower birth weight, compared with women with normal tracing. There were no significant differences	Interventions Fetal heart rate tracing (normal vs. abnormal)	Details The perinatal outcomes of 301 infants born at 37 to 42 weeks of gestation with pathologic fetal heart rate patterns during the first stage of labour were compared with 300 infants with normal fetal heart rate tracing patterns. Data were collected prospectively and demographic	Results Arterial pH 7.2 Abnormal FHR n = 48/301 (16%) Normal FHR n = 14/300 (4.7%) p < 0.001 Arterial pH 7.1 Abnormal FHR n = 10/301 (3.3%) Normal FHR n = 2/300 (0.7%) p < 0.02 Base deficit ≥ 12 Abnormal FHR n = 25/301	Limitations Other information Tracings were interpreted with the use of National Institute of Child Health Development Research Planing Workshop Guideline (NICHD) Abnormal pH was defined as: pH 7.2 in 2 separate analyses Base deficit of ≥ 12 mmol/l was considered to be

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study was carried out Israel Study type Cohort Aim of the study To evaluate perinatal outcomes of infants who had pathologic fetal heart rate (FHR) tracings during the first stage of labour, in comparison with pregnancies with normal tracings. Study dates January to June 2000 Source of funding Not specified	observed in FHR patterns in maternal age, ethnic origin, gravidity, gestational age and sex of the baby. Women with abnormal tracing had a significantly higher rate of oligohydramnios and oxytocin augmentation in labour. Women with abnormal FHR patterns had a significantly longer duration of 1st stage labour, and a higher incidence of thick meconium stained amniotic fluid. Inclusion criteria Low risk women Fetus at vertex presentation Normal FHR pattern Women with interpretable external		information was obtained on each woman's admission to the hospital. The labour room team evaluated each woman's FHR tracing hourly and documented the results. The same obstetrician collected the data after assessing the FHR tracing and the delivery chart. The data were collected prospectively. Tracings were interpreted with the use of the National Institute of Child Health and Human Development fetal heart rate monitor guidelines. Umbilical cord blood was collected immediately after birth and all blood gas analysis performed within 10	(8.3%) Normal FHR n = 7/300 (2.3%) p = 0.001 Admission to NICU Abnormal FHR n = 4/301 (1.3%) Normal FHR n = 4/300 (1.3%) p < 0.343 Vacuum birth Abnormal FHR n = 33/301 (11.0%) Normal FHR n = 12/300 (4%) Caesarean birth Abnormal FHR n = 46/301 (15%) Normal FHR n = 20/300 (6.3%) Spontaneous vaginal birth Abnormal FHR n = 222/301 (73.8%) Normal FHR n = 268/300 (89.3%)	diagnostic of fetal metabolic acidosis at birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	fetal monitoring tracing during the labour and birth Cases with values taken immediately after birth Exclusion criteria Congenital abnormalities Preexisting maternal heart or lung disease Fetuses with intrauterine growth retardation Women in need of emergency caesarean section Previous Caesarean section		minutes of birth. Analysis SPSS version 8.0 package was used for the analysis. Chi square test used for comparison between the two groups for the categorical variable and Student's t-test was used for continuous variables with normal distribution. Multiple logistic regression was used to investigate the independent contribution of obstetric factors to abnormal fetal heart patterns and to investigate the contribution of those factors to the occurrence of fetal acidosis (pH 7.2 and base deficit ≥ 12)	Factors associated with pathologic fetal heart rate monitoring during the first stage of labour in a multivariable analysis Hydramnios: odds ratio 7.68 (95% CI, 1.75% to 33.63%), Oligohydramnios: odds ratio 2.74 (95% CI, 1.01% to 7.39%), Presence of meconium-stained amniotic fluid: odds ratio 1.91 (95% CI, 1.03% to 3.3%) Pathological fetal heart patterns during the 1st stage of labour (compared with normal tracing n = 300 associated with fetal acidosis (pH < 7.2 and base deficit ≥ 12) Late deceleration (yes/no): odds ratio 17.5 (95% CI, 1.6 to 185.7) p = 0.01 Variable deceleration < 70 bpm (yes/no): odds ratio 3.9 (95% CI, 1.3 to 11.7) p = 0.01 Pathologic FHR during the 1st stage of labour (yes/no): odds ratio 2.86 (95% CI, 0.3	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 24.4) p = 0.336	
Full citation Heinrich,J., Elective fetal monitoring and obstetrical operative frequency, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 14, 143-152, 1982 Ref Id 196602 Country/ies where the study was carried out Germany Study type Cohort Aim of the study To evaluate the influence of fetal monitoring on obstetric operation rates with emphasis on fetal heart frequency (FHF). Study dates 1977 to 1978 and 1979	Sample size n = 2694 unselected deliveries n = 5000 elective monitored women (additional group) Characteristics Unclear gestation range/risk range Inclusion criteria Not specified Exclusion criteria Not specified	Interventions All FHR variables. Grouped into scoring system Normal Baseline 120–160 bpm; constant mild bradycardia; variability 10– 25 bpm; sporadic variable declarations; accelerations; mild variable deceleration Warning Tachycardia; variability < 10 bpm or > 25 bpm; periodic accelerations; moderate variable decelerations; early decelerations Severe	Details Digital display fetal monitors were used recording several tocometric parameters such as amplitude, frequency, base tonus and Montevideo units of labor. If the measured values exceeded an upper limit, an automatic alarm signal was activated. Arterial umbilical pH was carried out for all liveborns. The collected data included identification of the patient, results of medical history as well as of clinical and laboratory examinations and a final review of the course of pregnancy, delivery and post-	Results Umbilical artery pH Significant difference at pH < 7.20 between severe and hypoxic categories compared to warning and normal categories. FHF parameter in the 2nd stage of labour (30 min antepartum) and pH of umbilical arteria Normal classification (n = 1080) Normal pH (pH > 7.20): 1043/1080 (96.6%) Preacidosis (pH 7.25 - 7.20): 27/1080 (2.5%) Acidosis (pH < 7.20): 10/1080 (0.9) Warning symptoms (n = 1133) Normal pH (pH > 7.20): 1095/1133 (96.7%) Preacidosis (pH 7.25 - 7.20): 27/1133 (2.4%)	Limitations Small numbers in hypoxic category Not possible to determine gestation or risk categories Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
to 1981 (additional group) Source of funding Not specified		Transient bradycardia; severe variable decelerations; prolonged decelerations Hypoxia Final bradycardia; variability 0–5 bpm; typical late decelerations	partum period. The validity of the FHF-classification was demonstrated in 2694 unselected deliveries (June 1977/1978) by comparison with postnatal measurement of acid-base balance and Apgar scoring. The relation of obstetric operation rate, values of acid-base balance in umbilical arteria and FHF-parameters were also studied in an additional group of 5000 elective monitored patients (November 1979-1981). Data analysis The automated data analysis was made by means of a digital computer system (ES 1040).	Acidosis (pH < 7.20): 11/1133 (0.9) Severe functional hemodynamic (n = 431) Normal pH (pH > 7.20): 357/431 (93.0%) Preacidosis (pH 7.25 - 7.20): 48/431 (11%) Acidosis (pH < 7.20): 26/451 (6.0%) Hypoxia (n = 50) Normal pH (pH > 7.20): 30/50 (60.0%) Preacidosis (pH 7.25 - 7.20): 11/50 (22%) Acidosis (pH < 7.20): 9/50 (18%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Honjo,S., Yamaguchi,M., Umbilical artery blood acid-base analysis and fetal heart rate baseline in the second stage of labor, Journal of Obstetrics and Gynaecology Research, 27, 249-254, 2001 Ref Id 195455 Country/ies where the study was carried out Japan Study type Cohort Aim of the study To evaluate the correlation between umbilical arterial acidemia and second-stage baseline fetal heart rate (FHR) abnormalities in Japanese newborn	Sample size n = 365 Characteristics All subjects in the study were Japanese, no further characteristics were specified Inclusion criteria Term pregnancy (37 - 42 weeks) Vertex presentation Vaginal birth Exclusion criteria Women with complication such as: Diabetes Pre-eclampsia Multiple gestation	Interventions FHR tracing with either normal or baseline abnormality consisting of bradycardia or tachycardia during the 2nd stage of labour	Details Data were collected from n = 365 newborns, born during the study period in maternity ward of a hospital in Takasaki city. Based on the hospital policy, umbilical cord artery blood was taken from all newborns for blood gas determinations within 5 minutes of birth. FHR monitoring was performed in the second stage. Fetal heart rate tracings were obtained for as long as possible during the second stage of labour. Babies with marked periodic FHR abnormalities were excluded from the analysis. Therefore, in this study FHR tracings with either	Results Umbilical arterial acidemia occurred in 54.1% of the newborns with moderate to severe bradycardia, in 27.3% with mild bradycardia, and in 19.3% with tachycardia, compared with only 1.3% of those with a normal FHR ($p < 0.001$). Umbilical cord pH and blood gas analysis in newborn with normal and abnormal FHR tracing pH Normal (n = 236) 7.31 ± 0.05 Tachycardia (n = 57) 7.22 ± 0.11 ($p < 0.001$ as compared with normal) Mild bradycardia (n = 11) 7.25 ± 0.06 ($p < 0.01$ as compared with normal) Moderate to severe bradycardia (n = 61) 7.18 ± 0.06 ($p < 0.001$ as compared with normal) Base excess	Limitations Other information The FHR definition proposed by the National Institue of Child Health and HUman Development Research Planing Workshop was used: Abnormal tracing: - Baseline 110 - 160 bpm - Variability < 5 bpm - No periodic deceleration - The baseline FHR was taken as approx. mean FHR rounded to increments of 5 bpm duing a 10 minute segment The baseline tachycardia and bradycardia was defined as: - Mild bradycardia: baseline FHR between 90 - 109 bpm for ≥ 10 minutes - Moderate to severe bradycardia: baseline FHR < 90 bpm for ≥ 10 minutes - Tachycardia: baseline

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
infants. Study dates 1998 to 1999 Source of funding Not specified	Chronic hypertension Chorioamnionitis Significant medical illness Other pregnancy complications Newborns with fetal heart rate abnormality during the 1st stage of labour including: Late deceleration Moderate or severe variable deceleration Any presistant nonperiodic patterns of bradycardia, or tachycardia		normal or baseline abnormality consisting of bradycardia or tachycardia were evaluated. The cord was clamped immediately after birth, and the blood samples were taken as soon afterwards as possible.	Normal (n = 236) - 5.2 ± 2.8 Tachycardia (n = 57) - 9.5 ± 4.5 (p < 0.001 as compared with normal) Mild bradycardia (n = 11) - 8.7 ± 4.4 (p < 0.05 as compared with normal) Moderate to severe bradycardia (n = 61) -10.2 ± 3.5 (p < 0.001 as compared with normal) Number of newborns with an umbilical arterial pH < 7.2 in different FHR patterns Normal FHR pattern n = 3/236 (1.3%) Tachycardia n = 11/57 (19.3%) Mild bradycardia n = 3/11 (27.3%) Moderate to severe bradycardia n = 33/61 (54.1%) p < 0.001 (all 3 groups compared with normal group)	FHR of 160 bpm for ≥10 minutes The decrease from the baseline was taken as ≥ 15 bpm, lasting ≥ 2 minutes, but < 10 minutes. Newborn acidemia was defined as umbilical cord pH < 7.2, a pCO2 65 mmHg or lower, and bicarbonate 17.3 mmol/l or lower Metabolic acidemia was defined as an umbilical pH < 7.2, a pCO2 49.2 mmHg or lower, and bicarbonate 17.3 mmol/l, or lower
Full citation Krebs,H.B., Petres,R.E.,	Sample size n = 1996 fetal heart	Interventions Periodic variable	Details Fetal tracings were	Results Mode of birth:	Limitations Unbalanced cohort with

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Dunn,L.J., Smith,P.J., Intrapartum fetal heart rate monitoring. VI. Prognostic significance of accelerations, American Journal of Obstetrics and Gynecology, 142, 297-305, 1982 Ref Id 159500 Country/ies where the study was carried out USA Study type Cohort study Aim of the study To assess the prognostic value of accelerations in early labour and just prior to delivery Study dates January 1975 to June 1977 Source of funding	rate (FHR) traces Characteristics Not specified Inclusion criteria Term, singleton pregnancies > 34 weeks gestation Exclusion criteria Not specified	and uniform accelerations	obtained from women in labour during the study period. The time of monitoring exceeded 2 hours and included at least 30 minutes of the first stage of labour. The FHR tracings were reviewed by the senior author. The average monitoring time was 6.2 hours. Indications for monitoring were preeclampsia and eclampsia (10.2%), meconium stained liquor (14.2%), premature rupture of membranes (16.8%), and other high risk factors such as post-datism, intrauterine growth retardation, diabetes (7.1%), and oxytocin for indicated induction or augmentation (23%). Monitoring was	Caesarean section: 16.2% (n = 241 in the 1st stage of labour, n = 83 in the second stage of labour) Prognostic significance of sporadic accelerations in the first 30 minutes of monitored labour: ≥ 3 accelerations per 30 minutes Perinatal mortality Elective n = 2 (0.2%) Non elective (with high risk factors) n = 4 (0.4%) P > 0.5 Prognostic significance of sporadic accelerations in the first 30 minutes of monitored labour: < 3 accelerations per 30 minutes Perinatal mortality Elective n = 3 (2.8%) Non elective (with high risk factors) n = 12 (9.8%) P < 0.05	only 86 (4%) adverse outcomes. Not clear if the outcome assessors were blinded to outcomes. Unclear data analysis. Other information FHR scoring for internal FHR monitoring; for each of the criteria 0 to 2 points may be given so that a score of 0 to 10 may be obtained Baseline FHR < 100, > 180 = 0 score 100 - 119, 161 - 180 = 1 score 120 - 160 = 2 score Variability (oscillatory amplitude [bpm]) < 3 = 0 score 3 - 5 > 25 = 1 score 6 - 25 = 2 score Variability (frequency [bpm])

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not reported			elective in 46% of the women. The first and last 30 minutes of FHR tracing obtained from women in labour were evaluated.		< 3 = 0 score 3 - 6 = 1 score > 6 = 2 score Acceleration/30 min 0 = 0 score period, 1 - 4 sporadic = 1 score ≥ 5 sporadic = 2 score Deceleration/30 min Late, severe variable, atypical variable = 0 score Mild variable, moderate variable = 1 score None, early deceleration, dip 0 = 2 score Acceleration defined: Transient increase in the FHR bpm above the baseline FHR. Sporadic accelerations occur independently from uterine contractions. Uniform sporadic accelerations have a rounded configuration, whereas variable sporadic accelerations differ from one another and abruptly

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					leave and return to the baseline FHR. Periodic accelerations occur during the uterine contractions and are called uniform periodic accelerations. Variable accelerations are varied in shape and often develop notching, which widen, deepen, and progress into variable decelerations.
Full citation Larma,J.D., Silva,A.M., Holcroft,C.J., Thompson,R.E., Donohue,P.K., Graham,E.M., Intrapartum electronic fetal heart rate monitoring and the identification of metabolic acidosis and hypoxic-ischemic encephalopathy, American Journal of Obstetrics and Gynecology, 197, 301-308, 2007	Sample size Cases n = 107 Control n = 107 Characteristics The gestational age distribution: Born ≥ 37 weeks: 64% Born 29 - 36 weeks: 30% Born 24 - 28 weeks: 6 % Born by caesarean section: 71%	Interventions Electronic fetal monitoring	Details Infants who were born with metabolic acidosis born in a single university were identified. The cases were 107 non anomalous chromosomally normal fetuses with an umbilical arterial pH < 7.0 and base excess < or = 12 mmol/l. Controls were the subsequent delivery that was matched by	Results Cases had a significant increase in late and prolonged decelerations/hour and late decelerations/contractions. Those fetuses with HIE had significant increases in bradycardia, decreased variability, and non reactivity but no difference in late or variable decelerations/hour. Identification of HIE (FHR parameters during the last hour before delivery) Time baselines < 110	Limitations Other information Fetal metabolic acidosis and HIE are associated with significant increases in electronic fetal monitoring abnormalities, but their predictive ability to identify these conditions is low.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 121224 Country/ies where the study was carried out USA Study type Case controlled study Aim of the study To determine whether electronic fetal monitoring (EFM) can identify fetuses with metabolic acidosis and hypoxic-ischemic encephalopathy Study dates April 1991 to February 2006 Source of funding Not specified	Inclusion criteria All infants born with metabolic acidosis Exclusion criteria Not specified		gestational age and mode of delivery. The last hour of the electronic fetal monitoring before delivery was evaluated by 3 obstetricians who were blinded to the outcome using a guideline developed by National Institute of Child Health and Human Development (NICHD) research planning workshop. Within the case group, n = 13 neonates had neurological complications (including 8 with seizures, n = 1 with grade 3 intra ventricular haemorrhage, n= 4 died). All 13 infants had clinical features that were consistent with at least Sarnat stage 2 (moderate	beats/min Area under receiver operating characteristic curve: 0.56 Sensitivity: 15.4% Specificity: 98.9% Positive predictive values (PPV): 66.7%, Negative predictive values (NPV): 89.4% Baseline variability < 5 beats/min Area under receiver operating characteristic curve: 0.69 Sensitivity: 53.8% Specificity: 79.8% PPV: 26.9% NPV: 92.6% Non-reactive Area under receiver operating characteristic curve: 0.65 Sensitivity: 92.3% Specificity: 61.7% PPV: 2.7% NPV: 82.9% all 3 abnormalities	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			hypoxic ischemic encephalopathy [HIE]). The EFM tracings of these 13 infants were compared with those of the other 94 infants with metabolic acidosis who had no neurologic injury.	Area under receiver operating characteristic curve: 0.82 Sensitivity: 7.7% Specificity: 98.9% Positive predictive values: 50.0% Negative predictive values: 88.6%	
Full citation Low,J.A., Pickersgill,H., Killen,H., Derrick,E.J., The prediction and prevention of intrapartum fetal asphyxia in term pregnancies, American Journal of Obstetrics and Gynecology, 184, 724-730, 2001 Ref Id 197178 Country/ies where the study was carried out Canada Study type Cohort	Sample size n = 166 term pregnancies with confirmed fetal asphyxia Characteristics Inclusion criteria Term pregnacies base deficit > 12mmol/l Exclusion criteria	Interventions Fetal heart rate patterns	Details The outcomes of n = 166 term pregnancies with biochemically confirmed fetal asphyxia (umbilical artery base deficit at delivery, > 12 mmol/l) were examined. The population included n = 83 women who delivered by caesarean section matched with 83 women delivered vaginally. Antepartum and intrapartum clinical	Results Fetal asphyxial exposures were as follows: mild, n = 140; moderate, n = 22; and severe, n = 4. Mode of birth in mild feta asphyxia Caesarean section n = 67 (n 24/67 had meconium stained amniotic fluid) vaginal birth n = 73 (n = 32/67 had meconium stained amniotic fluid) Mode of birth in moderate or severe fetal asphyxia Caesarean section n = 16 (n = 4/16 had meconium	Limitations Other information Fetal asphyxia was classified as mild, moderate, or severe on the basis of umbilical artery base deficit (cutoff > 12 mmol/l) and neonatal encephalopathy and other organ system complications FHR criteria predictive of fetal asphyxia: Absent or minimal baseline variability and late or prolong decelerations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To examine the roles of clinical risk scoring, electronic fetal heart rate monitoring, and fetal blood gas and acid-base assessment in the prediction and prevention of intrapartum fetal asphyxia in term pregnancies. Study dates Not reported Source of funding Not specified			risk factors and neonatal complications were documented. Fetal assessments included fetal heart rate patterns in the fetal heart rate record and fetal capillary blood gas and acid-base assessments. Each caesarean birth was matched with a vaginal birth on the basis of gestational age (± 1 week), birth weight (± 100g) and umbilical artery acid base deficit > 12 mmol/l in the same year. The assessment of electronic FHR record was the interpretation of clinician in charge (outlined by medical record). Analysis Statistical analysis	stained amniotic fluid) vaginal birth n = 10 (n = 4/10 had meconium stained amniotic fluid) Predictive and non-predictive FHR patterns according to mild fetal asphyxia vrsus moderate or severe fetal asphyxia Mild asphyxia predictive pattern n = 89 Nonpredictive FHR pattern n = 25 No record n = 26 Moderate or severe asphyxia predictive pattern n = 20 Nonpredictive FHR pattern n = 4 No record n = 2 Classification of FHR patterns in 26 pregnancies with moderate or severe asphyxia Predictive n = 13 Suspect n = 7 Nonpredictive n = 3 No FHR monitoring record n	The FHR patterns are based on the findings in six 10 minute cycle of FHR recording: - Absent baseline variability, usually with repretitive cycles (≥ 2) of the late or prlonged deceleration - Repretitive cycles (≥ 2) of both minimal baseline variability and late or prolong decelerations - Repretitive cycles (≥ 2) of either minimal baseline variability or late or prolonged deceleration - One cycle of either mimnimal baseline variability or late or prolong decelerations - no cycle of either minimal baseline variability or late or prolonged decelerations Criteria for classification of FHR as predictive, suspect, and nonpredictive of fetal asphyxia on the basis of a 10 minute cycle

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			included Student's t test. No further details provided	= 3	of FHR recordings Predictive Absent (cycle) ≥ 1 and late or prolong decelerations ≥ 2 or Minimal (cycle) ≥ 2 and late or prolong decelerations ≥ 2 Suspect Minimal (cycle) ≥ 2 and late or prolong decelerations ≥ 0/1 or Minimal (cycle) ≥ 0/1 and late or prolong decelerations ≥ 2 Nonpredictive Minimal (cycle) 1 and late or prolong decelerations 0 or Minimal (cycle) 0 and late or prolong decelerations 1 or Minimal (cycle) 0 and late or prolong decelerations 0 Classification of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					intrapartum fetal asphyxia Mild asphyxia Metabolic acidosis (base deficit ≥ 12): present Encephalopathy: minor* present or not present Cardiovascular, repiratory and renal complications: minor† present or not present Moderate asphyxia Metabolic acidosis (Base deficit ≥ 12): present Encephalopathy: moderate** present Cardiovascular, repiratory and renal complications: moderate †† or severe††† present or not present Severe asphyxia Metabolic acidosis (Base deficit ≥ 12): present Encephalopathy: severe* present** Cardiovascular, repiratory and renal complications: moderate †† or severe†† present

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					* Irritability or jitteriness ** Profound lethargy or abnormal tone *** Coma or abnormal tone with seizure † Cardiovascular: with bradycardia (≤ 100 beats/min) or tachycardia (≥ 100 beats/min), repiratory: supplementary oxygen was required, †† Cardiovascular: with hypertention or hypotention, respiratory: if positive pressure or ventilation > 24 hours were required, renal: elevation of serum creatinine level (> 100 mmol/l) ††† With abnormal electrocardiographic or echocardiographic findings, respiratory: if mechanical ventilation >24 hours were required, renal: anuria or oliguria (< 1 ml/kg per hour)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Low,J.A., Victory,R., Derrick,E.J., Predictive value of electronic fetal monitoring for intrapartum fetal asphyxia with metabolic acidosis, Obstetrics and Gynecology, 93, 285-291, 1999 Ref Id 196968 Country/ies where the study was carried out Study type Case control study Aim of the study To examine the predictive value of each fetal heart rate (FHR) variable and of patterns of FHR variables for fetal asphyxia during labour Study dates May 1984 to May 1996	Sample size n = 71 term infants with base deficits > 16 mmol/l n = 71 term infants with base deficits < 8 mmol/l Studied over 4 hours prior to delivery (divided into 10-minute cycles) Characteristics No significant differences between the asphyxia and control group observed in maternal age, parity, medical and obstetric history or birth characteristics. Higher rate of meconium stained liquor in the asphyxia group compared with the control group (23/71 vs. 12/71 p = 0.05). Mean birth weight Asphyxia group 3,412 ± 472	Interventions All FHR variables	Details A matched case control study conducted during the study period. n = 142 term infants who had the blood gas and acid base assessment at delivery were selected. Each case in the asphyxia group (infants with umbilical artery > 16 mmol/l) was matched with a control infant whose umbilical artery base deficit was < 8 mmol/l. Matching was performed based on the birth weights (± 150 g) and gestational age (± 1 week). The control infant was the next one after the asphyxia case that met the criteria. The severity of asphyxia was classified as mild (n = 41),	Results Predictive value of abnormal FHR variables for acidosis Absent baseline variability (> 10 minutes) with late and/or prolonged decelerations: sensitivity - 17% specificity - 98% positive predictive value (PPV) - 18 negative predictive value (NPV) - 98.3 Minimal baseline variability (> 20 minutes) and late and/or prolonged decelerations (> 20 minutes): sensitivity - 46% specificity - 89% PPV - 8 NPV - 98.7 Minimal baseline variability (> 20 minutes) or late decelerations and/or prolonged decelerations (>	Limitations Good NPV for all features individually. Poor specificity in combination. Baseline tachycardia, variable and early decelerations not discriminative features Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not specified	Control group 3,426 ± 459 Caesarean section rate Asphyxia group 23/71 Control group 11/71 p = 0.01 Inclusion criteria For infants in the asphyxia group: - Umbilical artery base deficit > 16 mmol/l Infants in control group: - Umbilical artery base deficit < 8 mmol/l Exclusion criteria Not specified		moderate (n = 17) or severe (n = 13) on the basis of short term outcome or expressed by newborn encephalopathy and other newborn organ system complications.	20 minutes): sensitivity - 75% specificity - 57% positive predictive value - 3.5 negative predictive value - 99.1 Minimal baseline variability (10 minutes) and/or late and/or prolonged decelerations (10 minutes): sensitivity - 93% specificity - 29% PPV - 2.6 NPV - 99.5	
Full citation Menihan,C.A., Phipps,M., Weitzen,S., Fetal heart rate patterns and sudden infant death syndrome, JOGNN - Journal of Obstetric, Gynecologic, and	Sample size Cases n = 29 Controls n = 98 Characteristics There were no significant differences	Interventions Electronic fetal heart monitoring (EFM)	Details Data were obtained from 127 infants born during the study period at Women and Infants Hospital in Rhode Island. Thirty two infants (n = 32)	Results FHR measures among foetuses ≥ 32 weeks Baseline variability in 1st hour of tracing Increased or moderate Cases n = 15 (57%)	Limitations Other information Statistical differences were found in demographic characteristics between sudden infant death syndrome mother-infant

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Neonatal Nursing, 35, 116-122, 2006 Ref Id 117077 Country/ies where the study was carried out USA Study type Retrospective case control study Aim of the study To determine differences in electronic fetal monitoring patterns between infants who died of sudden infant death syndrome (SIDS) and controls. Study dates Between 1990 and 1998 Source of funding Association of Women's Health, Obstetrics, and neonatal Nurses Philips Grant	observed between the two groups in previous live birth, any obstetric and medical conditions (mixed population), maternal surgeries, medication and vitamins taken during pregnancy and prior infant birth weight < 2500g. Compared with controls (n = 98), the mothers whose infants subsequently died of SIDS (n = 29), were younger (22 vs. 28 years; p < 0.01), were more likely to receive Medicaid health insurance (odds ratio 4.6; confidence interval 1.9 to 11.2), were more likely to be unmarried (odds ratio 5.2; confidence interval 2.1 to 12.8), had less intention to breastfeed (26% vs. 57%), and were more likely to		who had been born at the hospital were chosen as potential cases and and the control infants for each of 32 SIDS cases were selected by computer, matching the day of birth for each case (unclear if mode of birth was matched). A total of 96 infants were identified for the control group. The birth certificates of each of 32 SIDS babies were reviewed by one of the researchers for confirmation of autopsy result. 29/32 infants were confirmed as SIDS and included in the study. The reasons for death in three other infants were unclear - SIDS was listed as a possible diagnosis in their	Controls n = 56 (78%) Unadjusted OR: not reported (NR) Minimal or absent Cases n = 5 (45%) Controls n = 16 (23%) Unadjusted OR 1.2 (95% CI: NR) Baseline variability in last hour of tracing Increased or moderate Cases n = 9 (45%) Controls n = 35 (49%) Unadjusted OR: NR Minimal or absent Cases n = 11 (55%) Controls n = 36 (51%) Unadjusted OR 1.2 (95% CI 0.4 to 3.2) Fetal sleep cycles during tracing Present throughout tracing Cases n = 1 (5%) Controls n = 14 (20) Unadjusted OR: NR 50% -75% of tracing	couples and their controls. However, no differences were detected in the intrapartum electronic fetal monitoring records, specifically in variability and sleep/wake cycles.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	smoke (odds ratio 4.6; confidence interval 9 to 11.2). Inclusion criteria Infants born between 1990 and 1998 who subsequently died of sudden infant death syndrome (SIDS) and controls. Exclusion criteria Not specified		death certificate. Sample size For the sample size calculation it assumed 50% of SIDS victims would have minimal or absent variability in the EFM readings, and 20% of controls would have minimal or absent variability in their EFM readings. Therefore 3 control per case incorporated and an alpha error of 0.05 and beta error of 20 included. Based on these assumptions, a sample size of 112 (28 cases and 84 controls) was needed for the study. Data analysis Data were analysed using Student's t test for continuous variables and chi-	Cases n = 7 (35%) Controls n = 24 (34%) Unadjusted OR 4.1 (95% CI 0.5 to 52.3) 25% - 49% of tracing Cases n = 4 (20%) Controls n = 11 (16%) Unadjusted OR 5.1 (95% CI 0.5 to 43.4) < 25% of tracing Cases n = 6 (30%) Controls n = 18 (26%) Unadjusted OR 4.7 (95% CI 0.6 to 139.6) Not present during tracing Cases n = 2 (10%) Controls n = 3 (5%) Unadjusted OR 9.3 (95% CI: NR) Fetal sleep cycles (dichotomised) 50% - 100% of tracing Cases n = 8 (40%) Controls n = 38 (54%) Unadjusted OR: NR 0% - 49% of tracing	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			square and Fisher's exact test for categorical variables.	Cases n = 12 (60%) Controls n = 32 (46%) Unadjusted OR 1.8 (95% CI 0.6 to 4.0)	
Full citation Murphy,K.W., Russell,V., Collins,A., Johnson,P., The prevalence, aetiology and clinical significance of pseudo-sinusoidal fetal heart rate patterns in labour, British Journal of Obstetrics and Gynaecology, 98, 1093-1101, 1991 Ref Id 122221 Country/ies where the study was carried out UK Study type Prospective Cohort Aim of the study To investigate the prevalence of sinusoidal and pseudo-sinusoidal	Sample size n = 1520 women who had fetal monitoring during labour for various reason were reviewed Intervention n = 230 Control n = 100 Characteristics The reasons for monitoring were (high risk and low risk population): Oxytocin (31%) Hypertensive disorder and intrauterine growth retardation (22%) Epidural analgesia (15%) Breech (4%)	Interventions Sinusoidal and pseudo-sinusoidal patterns	Details Study conducted in John Radcliffe Hospital, Oxford, over a 6 month period in which all women who had continuous FHR monitoring in labour had their intrapartum CTGs inspected for the presence of sinusoidal or pseudo-sinusoidal FHR patterns. Control: Every tenth women who was monitored during the study period and who did not have a sinusoidal or pseudo-sinusoidal FHR pattern was selected as a control.	Results Intervention n = 230 with pseudo-sinusoidal patterns (n = 219 were minor and n = 11 intermediate patterns) Control n = 100 with no sinusoidal pattern Minor pseudo-sinusoidal n = 65/219 (30%) Control group n = 26/100 (26%) Frequency distribution of minor pseudo sinusoidal patterns in the study group Number of pseudo sinusoidal episodes per subject n = 1 Number of subjects n = 94 (42%) Number of pseudo sinusoidal episodes per subject n =2 Number of subjects n = 71	Limitations Unclear how and by whom data were analysed and if the assessor was blinded to the outcomes Other information Pseudo-sinusoidal pattern classification: - Minor when the amplitude of the oscillations was 5-15 beats/min - Intermediate at 16-24 beats/min - Major when the amplitude was ≥ 25 cycle frequency was 2-5 cycles/min for minor and intermediate patterns and 1-2 cycles/min for major patterns CTG classified as normal or abnormal according to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
fetal heart rate (FHR) patterns in labour and the relation between the characteristics of the FHR pattern and fetal outcome. Study dates September 1987 to February 1988 Source of funding Not specified	Irregular FHR on auscultation (3%) Others (16%) Inclusion criteria All women who had fetal monitoring in labour during the study time (49% of all labours were monitored). Only cardiotocographs (CTG) with pseudo-sinusoidal pattern which persisted ≥ 10 min were included Exclusion criteria Not specified		Intrapartum ultrasonography was undertaken in a small pseudo-sinusoidal episode in order to look for fetal sucking or mouth movements. Analysis: Both internal (electrocardiographic) and external (ultrasonic) recordings of FHR were analysed. The intrapartum CTGs were reviewed immediately after recordings were made. To compare the results between the study group and the control group univariate analyses were performed. The reviewers examined the association between the presence of pseudo-sinusoidal patterns	(32%) Number of pseudo sinusoidal episodes per subject n = 3 Number of subjects n = 38 (17%) Number of pseudo sinusoidal episodes per subject n > 4 Number of subjects n = 18 (8%) Caesarean section rates Minor pseudo-sinusoidal n = 22/219 (10%) Control group n = 12/100 (12%) p = ns Instrumenal vaginal birth Minor pseudo-sinusoidal n = 65/219 (30%) Control group n = 26/100 (26%) p = ns Fetal sleep pattern present Minor pseudo-sinusoidal n = 125/219 (57%) Control group n = 51/100	the criteria suggested by Steer et al. (1989) Uterine hyper-stimulation: - When more than 15 contractions were present during a 30 min period Data on pseudo sinusoidal traces divided into minor, moderate and severe categories depending on amplitude of oscillations and frequency of cycles. CTGs were classified as normal or abnormal according to criteria suggested by Steer et al. (1989)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			and some variables. Multivariate analyses (logistic regression analysis) were performed.	(51%) p = ns Umbilical artery pH < 7.12 (measured in 67% of intervention group and 57% of the control group) Minor pseudo-sinusoidal n = 20/147 (14%) Control group n = 5/57 (9%) p = ns Admission to special care Minor pseudo-sinusoidal n = 19 (9%) Control group n = 4 (4%) p = ns Significant association with epidural analgesia (RR 1.84; 95% CI 1.24 to 2.76) and pethidine administration (RR 1.84; 95% CI 1.31 to 2.59) from multivariate analysis.	
Full citation	Sample size	Interventions	Details	Results	Limitations
Nelson,K.B., Dambrosia,J.M., Ting,T.Y., Grether,J.K.,	n = 95 infants with cerebral palsy (CP) at aged 3 years with n	Continuous electronic fetal monitoring (EFM)	Data were collected from singleton children born during	Heart rate patterns according to presence (n = 78) or absense of cerebral	The findings on fetal monitoring record were those noted in the birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Uncertain value of electronic fetal monitoring in predicting cerebral palsy, New England Journal of Medicine, 334, 613-618, 1996 Ref Id 171881 Country/ies where the study was carried out USA Study type Case control study Aim of the study To investigate the usefulness of fetal monitoring as interpreted by the obstetrician at the time of birth of infants who were diagnosed with cerebral palsy Study dates From 1983 to 1985 Source of funding	= 378 matched controls Characteristics Maternal parity (nulliparous) Children with CP: n = 42 (54%) Controls: n = 144 (48%) Maternal gestational age (means) Children with CP: 40 weeks Controls: n = 40 weeks Maternal age (mean) Children with CP: 28 yr Controls: 27 yr Induction of labour Children with CP: n = 13 (17%) Controls: n = 48 (16%) Internal monitoring Children with CP: n = 45 (58%) Controls: n = 170 (57%)	(except in 9% of CP cases and 13% of controls)	the three-year study period in four counties in the San Francisco area. All weighed 2500 g or more at birth, survived to the age of three years, and had moderate or severe cerebral palsy. The inclusion or exclusion of each identified child was determined by means of a standardised clinical examination or extensive review of the medical records. Controls were randomly selected from the singleton children who met all the criteria for the case children except the diagnosis of cerebral palsy. Demographic data were extracted by nurses working at the California Birth	palsy (n = 300) Tachycardia > 160 bpm Children with CP: n = 22 (28%) Control: n = 85 (28.3)% Odds ratio 1.0 (0.6 to 1.7) Tachycardia > 180 bpm Children with CP: n = 5 (6.4%) Control: n = 16 (5.3%) Odds ratio 1.3 (0.4 to 3.4) Bradycardia < 100 bpm Children with CP: n = 27 (34.6%) Control: n = 75 (25%) Odds ratio 1.5 (0.9 to 2.5) Bradycardia < 80 bpm Children with CP: n = 13 (16.7%) Control: n = 35 (11.7%) Odds ratio 1.5 (0.8 to 3) Mutiple late decelerations Children with CP: n = 11 (14.1%) Control: n = 12 (4.0%) Odds ratio 3.9 (1.7 to 9.3)	records, as indicated by the physicians attending the deliveries. No monitoring strips were available for this study. No actual definition of reduced beat-to-beat variability or multiple late decelerations. Duration of monitoring or specific heart-rate patterns not specified in the analysis. Other information Cerebral palsy defined as chronic disability originating from central nervous system, characterised by aberrant control of movement or posture, appearing in early life, and not resulting from progressive disease

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Supported in part by a cooperative agreement with the Center for Environmental Health and Injury Control, Centers for Disease Control and Prevention, in part by funds from the Comprehensive Environmental Response, Compensation, and Liability Act Trust Fund through an interagency agreement with the Agency for Toxic Substances and Disease Registry, Public Health Service, and in part by a training grant from the Department of Health and Human Services, Maternal and Child Health Bureau.	Inclusion criteria Singleton infants with birth weight of 2500 grams or more Exclusion criteria Children in whom cerebral palsy was acquired after the first 28 days of life or through non-accidental head trauma in the first month and children with mild involvement or isolated hypotonia were not included.		Defects Monitoring Program who did not know whether the records were those of case or control children and did not know that the study was about cerebral palsy. The findings on fetal monitoring record were those noted in the birth records, as indicated by the physicians attending the deliveries. No monitoring strips were available for this study. Data collected on the highest fetal heart rate above 160 or 180 beats per minute, the lowest fetal heart rate below 100 or 80 beats per minute, and the presence or absence of multiple late decelerations (commonly defined	Decreased beat to beat variability Children with CP: n = 13 (16.7%) Control: n = 21 (7%) Odds ratio 2.7 (1.1 to 5.8) MLD/DV Children with CP: n = 21 (26.9%) Control: n = 28 (9.3%) Odds ratio 3.6 (1.9 to 6.7) Association between multiple late decelerations, decreased variability or both with cerebral palsy in high and low risk populations Low Sensitivity: 13.8 Specificity: 91.3 PPV: 0.05 High Sensitivity: 13.8 Specificity: 89.1 PPV: 0.25	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			as bradycardia occurring well after the onset of uterine contractions, although in this study the term was recorded as used by the clinicians involved) and decreased beat-to-beat variability in heart rate. Multiple late decelerations and decreased beat-to-beat variability were then combined into a single variable indicating the occurrence of either or both during labor.		
Full citation Ozden,S., Demirci,F., Significance for fetal outcome of poor prognostic features in fetal heart rate traces with variable decelerations, Archives of Gynecology and	Sample size 167 'randomly' selected FHR traces Study group n = 76 with variable decelerations. Divided to two groups poor cases with poor prognostic features (PPFs) (n = 45) and	Interventions Variable deceleration classified into 7 subtypes according to PPFs 1. Loss of primary acceleration 2. Loss of secondary	Details Data for the study were collected from n = 167 randomly selected women with a singleton pregnancy at term. n = 96 women who had an FHR trace without	Results Mode of birth Vaginal birth Study group: poor (PPFs) n = 25/45 (55.6%); poor (-PPFs) n = 18/31 (58%) Control group n = 65/91 (71.4%) P = ns	Limitations Complex analysis Small sample size Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Obstetrics, 262, 141-149, 1999 Ref Id 197028 Country/ies where the study was carried out Turkey Study type Cohort Aim of the study To determine the clinical significance of the existence of poor prognostic features in fetal heart rate (FHR) traces with variable decelerations. Study dates From January 1995 to January 1996 Source of funding Not specified	poor cases without PPFs (n = 31) Control group n = 91 normal traces Characteristics No significant differences observed between the two group in maternal age, gravidity, parity, and cervical dilatation. Inclusion criteria Singleton Term pregnancy Exclusion criteria Poorly documented gestational age Premature birth Multiple pregnancy	acceleration 3. Loss of variability during deceleration 4. Slow return to baseline 5. Biphasic deceleration 6. Prolonged secondary acceleration 7. Prolonged deceleration	pathological features were selected as a control group. The remaining 76 women had variable decelerations and their FHR traces were analysed for the existence of poor prognostic features. All the traces were analysed by one study author. Umbilical cord pH were taken for included women and pH < 7.20 were defined as acidemia. Analysis Statistical analysis performed using SPSS. Kruscall Wallis one way ANOVA was used to compare cord blood gas value among the three groups.	Caesarean section Study group: poor (PPFs) n = 20/45 (44.4%); poor (- PPFs) n = 13/31 (41.9%) Control group n = 26/91 (28.6%) P = ns pH Study group: poor (PPFs) n 7.18 - 0.08 poor (- PPFs) 7.24 - 0.08 Control group 7.27 - 0.06 P = 0.00001 Comparison of vriable deceleration subgroups to the number of poor prognostic features for the neonatal outcomes Vaginal birth Study group: PPF0 n = 18/31 (58%); PPF1 n = 9/13 (69%); PPF2 n = 7/12 (58%); PPF3 n = 5/8 (62%); PPF 4 4/12 (33%) p = ns (comparison between the group without PPF n = 31 and with PPF n = 45) Caesarean section	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Study group: PPF0 n = 13/31 (42%); PPF1 n = 4/13 (31%); PPF2 n = 5/12 (42%); PPF3 n = 3/8 (37%); PPF 4 8/12 (67%) Caesarean section PH Study group: PPF0 7.24 - 0.08; PPF1 7.20 - 0.06; PPF2 7.15 - 0.09; PPF3 7.18 - 0.08; PPF 4 7.18 - 0.01 p = 0.02	
Full citation Powell,O.H., Melville,A., MacKenna,J., Fetal heart rate acceleration in labor: excellent prognostic indicator, American Journal of Obstetrics and Gynecology, 134, 36-38, 1979 Ref Id 196676 Country/ies where the study was carried out USA Study type	Sample size n = 1677 monitored labours Characteristics Not specified Inclusion criteria Not specified Exclusion criteria Not specified	Interventions Uniform accelerations (> 3 in 15 minutes > 15 beats for > 15s)	Details Infants born during the study period in a teaching hospital of the Eastern Virginia Medical school, who met the inclusion criteria, were included in the study. All labouring women had electronic fetal monitoring (EFM) routinely. 65% of the study population gave birth in the private section	Results Mortality rate of the hospital during the study period: 18.6/1000 Mortality rate of group of monitored women during the study period: 14.9/1000 Acceleration present in 935 women who were monitored Perinatal mortality Acceleration present: n = 4 per 1000 Acceleration not present: n = 20 per 1000	Limitations No population data presented. Unclear how and by whom the data were analysed. No inclusion/exclusion criteria specified. Unclear what percentage of premature labour and high risk pregnancies were included. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Cohort study Aim of the study To examine correlation between fetal heart rate (FHR) acceleration and neonatal outcomes Study dates January 1976 to December 1976 Source of funding Not specified			and 35% in the usual section of the clinic. Only traces with uniform FHR acceleration patterns were included. The accelerations occurring in association with decelerations were excluded.	The 4 deaths in the "acceleration" group were due to pneumonia in one case (a term infant), due to intracranial haemorrhage in one case (a 37 week infant delivered by midforceps), and due to respiratory distress syndromes in two babies. In the 20 babies who died in the "no accelerations" group, the deaths were often associated with hypoxia (such as: diabetes, post maturity, sepsis, preeclampsia) that were demonstrable in 16 babies. Two (n = 2) died from respiratory distress syndrome and two died with congenital abnormality syndrome. There was no difference in the presence of accelerations in vertex and non vertex presentations. n	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				= 91 women had breech presentation. n = 76 were monitored and only n = 2 failed to show acceleration in labour. There was one death among breech births which was due to severe hypoxia in a vaginal birth and there were no accelerations present during labour for this baby.	
Full citation Roy,K.K., Baruah,J., Kumar,S., Deorari,A.K., Sharma,J.B., Karmakar,D., Cesarean section for suspected fetal distress, continuous fetal heart monitoring and decision to delivery time, Indian Journal of Pediatrics, 75, 1249-1252, 2008 Ref Id 60814 Country/ies where the study was carried out India Study type	Sample size Total n = 217 Characteristics Not specified Inclusion criteria Gestational age ≥ 36 No fetal anomalies Non reassuring CTG not responding to conservative management (including changing the maternal position, intravenous	Interventions Caesarean section for non reassuring fetal heart rate (FHR) detected by cardiotocograph (CTG)	Details During the study period, a total of 3,148 women delivered in a maternity unit of whom 217 (6.8%) women underwent cesarean section for non-reassuring fetal heart trace in labor. The percentage of caesarean sections for various indications was 16.2%. The maternal demographic profile, specific types of	Results Various fetal heart abnormalites indicated by CTG and its relation to immediate adverse neonatal outcomes Persistent bradycardia n = 106/217 (48.8%) 5 minutes Apgar < 7 n = 16/106 Umbilical cord pH < 7.10 n = 4/106 NICU admission n = 16/106 Recurrent late deceleration n = 56 (25.8%) 5 minutes Apgar < 7 n = 10/56	Limitations No definition for bradycardia, deceleration and non reassuring CTG provided. Unclear if the outcome assessors were blinded to the study groups allocation. Women's demographic characteristics not reported. Other information Non-reassuring fetal heart

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Prospective observational study Aim of the study To find out the efficacy of continuous fetal heart monitoring by analysing the cases of ceasarean section for non reassuring fetal heart in labour, detected by cardiotocography (CTG) and correlating these cases with perinatal outcome. Study dates March 2002 to March 2007 Source of funding Not specified	hydration, and oxygen administration) Exclusion criteria Abnormal presentation Multiple pregnancy Intrauterine growth restriction (IUGR) Caesarean section for other primary indications		abnormal fetal heart rate tracing and the decision to delivery time interval were noted. The decision time to perform a caesarean section was defined as when the senior resident on duty took the decision to perform the caesarean and exact delivery time. The adverse immediate neonatal outcomes in terms of Apgar score < 7 at 5 minutes, umbilical cord pH < 7.10, neonates requiring immediate ventilation and NICU admissions were recorded. The correlation between non-reassuring fetal heart, decision to delivery interval and neonatal outcome were analysed.	Umbilical cord pH < 7.10 n = 5/56 NICU admission n = 10/56 Variable deceleration n = 38/217 (17.5%) 5 minutes Apgar < 7 n = 7/38 Umbilical cord pH < 7.10 n = 4/38 NICU admission n = 7/38 Decreased variability n= 17/217 (7.8%) 5 minutes Apgar < 7 n = nil Umbilical cord pH < 7.10 n = nil NICU admission n = nil Overall findings for non-reassuring CTG and its relation to the neonatal outcomes Decision to delivery interval (DDI): DDI ≤ 30 min n = 121/217 DDI > 30 min n = 96/217 5 minutes apgar < 7 DDI ≤ 30 min n = 18/121 (14.8%)	rate detected by CTG did not correlate well with adverse neonatal outcome.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Data analysis Statistical analysis was done using Student's t-test and chi square test where appropriate.	DDI > 30 min n = 15/96 (15.6%) p = ns Arterial cord pH < 7.10 DDI ≤ 30 min n = 8/121 (6.6%) DDI > 30 min n = 5/96 (5.2%) p = ns NICU admission for suspected birth asphyxia DDI ≤ 30 min n = 26/121 (21.4%) DDI > 30 min n = 7/96 (7.2%) p < 0.05 Fresh stillbirth DDI ≤ 30 min n = 1*/121 (0.8%) DDI > 30 min n = nil p < 0.05 *Death was due to placental abruption Born healthy n = 184 (84.7%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Salim,R., Garmi,G., Nachum,Z., Shalev,E., The impact of non-significant variable decelerations appearing in the latent phase on delivery mode: a prospective cohort study, Reproductive Biology and Endocrinology, 8, 81-, 2010 Ref Id 109319 Country/ies where the study was carried out Israel Study type Prospective cohort Aim of the study To estimate the impact of non-significant variable decelerations (NSV) appearing during the latent phase of labour on delivery mode and neonatal outcome.	Sample size Category I n = 251 Category II NSV n = 186 Category II SV n = 76 Characteristics There were no significant differences observed between the three groups in maternal age, parity and polyhydramnios. Inclusion criteria Term pregnancy (≥ 37) In the latent phase of labour (defined as interval between the start of regular contractions combined with any cervical dynamics [dilating > 4 cm]) Singleton pregnancy	Interventions Electronic fetal monitoring (EFM)	Details Variable deceleration was defined according to 2008 National Institute of Child Health and Human Development workshop. Variable decelerations were categorised as significant (SV) if fetal heart rate (FHR) reached 70 beats/min for one minute or more but less than 2 minutes, otherwise they were categorised as non-significant (NSV) Women were divided into three groups. All had a fetal heart rate tracing with normal baseline and variability: Study group (Category II NSV): women who had Category II tracing	Results Total n = 1005 Category II-NSV tracings (study group) n = 186 Category II-SV n = 76 Category I tracings n = 251 Mode of birth There was a statistically significant differences observed between the three groups in method of birth (category II-SV versus category I and category II-NSV) (p = 0.0001) Spontaneous vaginal birth Control group (Category I): n = 238 (94.8%) Study group (Category II NSV): n = 166 (89.2%) Second control group (Category II SV): n = 40 (52.6%) Vacuum Control group (Category I): n = 6 (2.4%) Study group (Category II NSV): n = 8 (4.3%)	Limitations Other information Fetal Heart interpretation categorisation from National Institute of Child Health and Human Development workshop 2008 (Macones et al., 2008): Category I Category I fetal heart rate (FHR) tracings include all of the following: Baseline rate: 110–160 beats per minute (bpm) Baseline FHR variability: moderate Late or variable decelerations: absent Early decelerations: present or absent Accelerations: present or absent Category II Category II FHR tracings include all FHR tracings

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates January to April 2009 Source of funding Not specified	Exclusion criteria Fetal heart tracing abnormalities during the latent phase Caesarean section without a trial of labour Women gave birth to infants with major malformation		based on Institute of Child Health and Human Development (NICHD) categorisation system; women with NSV, episodic or recurrent, and normal base line and moderate variability Control group (Category I): women who had category I tracing based on NICHD categorisation Second control group (Category II-SV): women who had category II-SV tracing based on NICHD categorisation; women with significant variables (SV) Sample size In order to show a	Second control group (Category II SV): 11 (14.5%) Caesarean Control group (Category I): n = 7 (2.8%) Study group (Category II NSV): n = 12 (6.5%) Second control group (Category II SV): n = 25 (32.9%) Reasons for vacuum or caesarean delivery There was a statistically significant difference observed between the three groups in reasons for vacuum or ceasarean delivery (category II-SV versus category I and category II-NSV) (p = 0.0001) Indication for CS (not reassuring FHR monitoring) Control group (Category I): n = 3 (23.1%) Study group (Category II	not categorized as Category I or Category III. Category II tracings may represent an appreciable fraction of those encountered in clinical care. Examples of Category II FHR tracings include any of the following: Baseline rate Bradycardia not accompanied by absent baseline variability Tachycardia Baseline FHR variability Minimal baseline variability Absent baseline variability not accompanied by recurrent decelerations Marked baseline variability Accelerations Absence of induced accelerations after fetal stimulation Periodic or episodic decelerations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			difference of 10% in the rate of operative birth between the category I and category II-NSV tracing with an alpha of 0.05 and a power of 80% a sample size of 160 per group was required Analysis One-way analysis of variance was used to compare the continuous demographic and clinical variables of the three groups. Significant group differences were tested (post-hoc). Backwards stepwise logistic regression using significant invariables was performed to determine which predicted operative delivery. P < 0.05 was considered	NSV): n = 5 (25%) Second control group (Category II SV): n = 20 (55.6%) Indication for CS (failure to progress in the active or second stage) Control group (Category I): n = 10 (76.9%) Study group (Category II NSV): n = 15 (75.0%) Second control group (Category II SV): n = 16 (44.4%) Neonatal outcomes Neonatal weight (g) Control group (Category I): mean 3329 ± 392 Study group (Category II NSV): mean 3397 ± 439 Second control group (Category II SV): mean 3130 ± 487 p = 0.002 (category II-SV versus category I and category II-NSV) Neonatal born < 2500 g	Recurrent variable decelerations accompanied by minimal or moderate baseline variability Prolonged deceleration ≥ 2 minutes but ≤ 10 minutes Recurrent late decelerations with moderate baseline variability Variable decelerations with other characteristics, such as slow return to baseline, "overshoots," or "shoulders" Category III Category III FHR tracings include either: Absent baseline FHR variability and any of the following: Recurrent late decelerations Recurrent variable decelerations Bradycardia Sinusoidal pattern

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			significant. Assessment All traces were assessed by two obstetricians at the same time, both were blinded to the groups allocation and neonatal outcomes.	Control group (Category I): n = 2 (0.8%) Study group (Category II NSV): n = 1 (0.5%) Second control group (Category II SV): n = 4 (5.3%) p = 0.0001 (category II-SV versus category II-NSV) Apgar score at 5 min (out of 10) Control group (Category I): mean 9.96 ± 0.23 Study group (Category II NSV): mean 9.90 ± 0.31 Second control group (Category II SV): mean 9.86 ± 0.39 p = 0.01 Mean cord PH Control group (Category I): 7.31 ± 0.07 Study group (Category II NSV): 7.31 ± 0.07 Second control group (Category II SV): 7.30 ± 0.08 p = 0.5	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Cord pH between 7.0 to 7.1 Control group (Category I): n = 2 (0.8%) Study group (Category II NSV): n = 7 (3.8%) Second control group (Category II SV): n = 4 (5.3%) Meconium stained amniotic fluid Control group (Category I): n = 22(8.8%) Study group (Category II NSV): n = 26 (14%) Second control group (Category II SV): n = 15 (19.7%) Nuchal cord or true knot Control group (Category I): n = 23 (9.2%) Study group (Category II NSV): n = 19 (10.2%) Second control group (Category II SV): n = 12 (15.8%) p = 0.3 Neonatal death Control group (Category I):	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				n = 0 Study group (Category II NSV): n = 0) Second control group(Category II SV): n = 0	
Full citation Sameshima,H., Ikenoue,T., Predictive value of late decelerations for fetal acidemia in unselective low-risk pregnancies, American Journal of Perinatology, 22, 19-23, 2005 Ref Id 157246 Country/ies where the study was carried out Japan Study type Retrospective cohort study Aim of the study To evaluate the clinical significance of late decelerations (LD) of	Sample size Carditocograph (CTG) trace of n = 5522 women with low-risk pregnancies Characteristics Average maternal age No decelerations 28.4 ± 4.8 Occasional LD 30.0 ± 4.9 Recurrent LD 38.8 ± 2.0 p = ns Avarage gestational age No decelerations 38.5 ± 1.8 Occasional LD 38.8 ± 2.0 Recurrent LD 38.1 ± 2.5	Interventions FHR via cardiotocograph (CTG) trace	Details Cliinical significance of late decelerations (LD) of intrapartum fetal heart rate (FHR) monitoring to detect low pH (< 7.1) in low-risk pregnancies was evaluated. Data collected from two secondary and two tertiary-level institutions where 10,030 women delivered. Among them, 5522 were low-risk pregnancies. The last 2 hours of FHR patterns before delivery were interpreted according to the guidelines of the National Institute of Child Health and	Results Occasional LD n = 301/5522 Recurrent LD n = 99/5522 Recurrent LD n = 99 Moderate variability and acceleration n = 64/99 Moderate variability without acceleration n = 16/99 Acceleration with minimal variabiliy n = 3/99 Minimal variability without accelerations n = 16/99 Blood gases and pH values deteriorated as the incidence of LD increased and as baseline accelerations or variability decreased. Positive predictive value for low pH (< 7.1) was exponentially elevated from 0% at no	Limitations Poor reporting of results Unclear if the outcome assessor was blinded to the outcomes Other information In low-risk pregnancies, information on LD combined with acceleration and baseline variability enables us to predict the potential incidence of fetal acidemia.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
intrapartum fetal heart rate (FHR) monitoring to detect low pH (< 7.1) in low-risk pregnancies. Study dates 1995 to 2000 Source of funding Supported in part by Grant-in-Aid for Scientific Research from Ministry of Education, Japan	Average parity of the three groups 0.6 ± 0.9 Inclusion criteria Low risk pregnancies Cases with recurrent and occasional late deceleration (LD) Exclusion criteria Premature birth < 32 wk Multiple pregnancy Hypertensive disorders Pre-eclampsia or eclampsia Chronic hypertension Collagen diseases Diabetes mellitus Thyroid dysfunction		Human Development. The correlation between the incidence of LD (occasional, < 50%; recurrent, ≥ 50%) and severity (reduced baseline FHR accelerations and variability) of LD, and low pH (< 7.1) wasevaluated. Statistical analyses Included a contingency table with chi2 and Fisher's exact test, and one-way analysis of variance with the Bonferroni/Dunn test.	decelerations, 1% in occasional LD, and > 50% in recurrent LD with no baseline FHR accelerations and reduced variability.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Cardiac, repiratory, renal disease Epilepsy Placenta praevia Coagulation disorders Intrauterine infection and chorioamnionitis Intrauterine growth restriction Fetal abnormalities Anomalies Hydrops fetalis Metabolic disorders Known congenital syndromes				
Full citation Samueloff,A., Langer,O.,	Sample size n = 2220 consecutive	Interventions Scoring FHR	Details Data were collected	Results pH ≥ 7.20, <7.20	Limitations Variability not single useful

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Berkus,M., Field,N., Xenakis,E., Ridgway,L., Is fetal heart rate variability a good predictor of fetal outcome?, Acta Obstetricia et Gynecologica Scandinavica, 73, 39-44, 1994 Ref Id 196845 Country/ies where the study was carried out USA Study type Cohort Aim of the study To investigate whether fetal heart rate (FHR) variability serves as a reliable single predictor of fetal outcome Study dates During 1991 Source of funding	deliveries Characteristics Maternal age (mean ± SD) 27.4 ± 6.04 Complication in pregnancy (hypertension, diabetes, abrupto placenta, placenta previa, chorioamnionitis, previous caesarean section): 27. 34% Epidural: 47.3% Inclusion criteria Not specified Exclusion criteria < 37 weeks gestation Twins Fetal malformation Stillbirth	variability using 5 scoring systems: A. FHR amplitude variability ≥ 3 bpm < 3 bpm B. FHR amplitude ≥ 5bpm < 5 bpm C. FHR frequency of oscillations ≥ 3 bpm < 3/min D. FHR frequency of oscillations ≥ 5 bpm < 5/min E. Combination of (amplitude frequency)/2. Value < 3 scored as low and ≥ 3 as high	from follow up of n = 2200 consecutive births during 1991 from a teaching hospital. Based on the hospital policy, every women entering the labour ward was connected to a fetal heartt monitor. Fetal heart variability data were obtained from n = 1816 women (the missing 7.8% of variability data was due to either imminent birth in which obtaining a trace was not possible or lost tracing). Analysis Three sections of the trace were analysed: 1. early in labour for a period of 30 minutes, 2. 30 minutes of	Scoring method A: sensitivity 10.99%, specificity 93.80%, positive predictive value (PPV) 25.20%, negative predictive value (NPV) 84.74% Scoring method B: sensitivity 26.24%, specificity 78.93%, PPV 19.12%, NPV 84.93% Scoring method C: sensitivity 6.78%, specificity 95.18%, PPV 23.17%, NPV 84.48% Scoring method D: sensitivity 25.35%, specificity 90.52%, PPV 19.72%, NPV 85.11% Scoring method E: sensitivity 7.44%, specificity 96.30%, PPV 27.63%, NPV	predictor of outcome. Division of cases into normal and abnormal not balanced as non-matched. Hence, performance of tests affected. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
not specified			tracing in the active phase 3. throughout the entire 2nd stage in segments of 30 minutes (a maximum of three segments). In all deliveries with 2nd stage longer than 90 minutes, the last tracing prior to the delivery was analysed. A total of 4361 tracing segments were analysed by five maternal-fetal faculty members blinded to the maternal and neonatal outcomes.	84.58% Both amplitude and frequency methods poorly sensitive at lower limits (< 3). Sensitivity increased by increasing limit to 5 in both scores but consequent drop in specificity. Combination method has low sensitivity.	
Full citation Sheiner,E., Hadar,A., Hallak,M., Katz,M., Mazor,M., Shoham-Vardi,I., Clinical significance of fetal heart rate tracings during the second stage of labor, Obstetrics and	Sample size n = 601 Characteristics Women with abnormal FHR patterns were of significantly lower birth order and more often carried male fetuses	Interventions Abnormal fetal heart rate tracing	Details Women were examined at the delivery suite. Based on the hospital policy, all labouring women had continuous fetal monitoring and the	Results Pathologic FHR patterns during 2nd stage of labour (compared with normal tracing) associated with pH < 7.2 (n = 57) and base deficit of ≥ 12 (n = 28) Variable decelerations ≥ 70	Limitations Unclear if the assessors were blinded to the outcomes Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Gynecology, 97, 747-752, 2001 Ref Id 196075 Country/ies where the study was carried out Israel Study type Cohort Aim of the study To examine the importance of abnormal FHR patterns during the second stage of labor in terms of pregnancy outcome Study dates January to June 2000 Source of funding Not specified	compared with women with normal FHR patterns. The women with abnormal FHR tracings during the second stage of labour had a significantly higher rate of oligohydramnios and a non-significantly higher rate of hydramnios. No other significant differences were seen between the groups for anesthesia use, first and second stage duration, presence of meconium in amniotic fluid, cord problems, and birth weight. Inclusion criteria Low risk pregnancy Singleton gestation Vertex presentation Term delivery (greater than 37 completed		monitor patterns were checked and the findings dcumented hourly. The same obstetrician collected the data after carefully evaluating both the monitor files and the flow charts. Tracings were interpreted using the guidelines of the National Institute of Child Health and Human Development Research Planning Workshop. The cumulative depth of decelerations or bradycardia was classified by a nadir of less than 100 but at least 70 beats per minute, and decelerations with a nadir less than 70 beats per minute. Information was collected about labor duration,	bpm pH < 7.2 OR 5.1 (95% CI 1.4 to 21.4) p = 0.008 Base deficit of ≥ 12 OR 3.5 (95% CI 0.8 to 15.8) p = 0.101 Variable decelerations < 70 bpm pH < 7.2 OR 16.3 (95% CI 3.8 to 80.5) p < 0.001 Base deficit of ≥ 12 OR 10.5 (95% CI 1.9 to 56.4) p = 0.006 Late decelerations pH < 7.2 OR 15.2 (95% CI 2.8 to 91.4) p < 0.001 Base deficit of ≥ 12 OR 17.3 (95% CI 2.9 to 101.9) p = 0.002 Bradicardia ≥ 70 bpm pH < 7.2 OR 2.3 (95% CI 0.3 to 17.1)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	weeks gestation) Exclusion criteria Uninterpretable tracings Immediate caesarean because of maternal or fetal indications, such as clinical evidence of cephalopelvic disproportion or placental insufficiency Previous caesarean section Pre-existing heart or lung disease Fetuses with known growth restriction or malformations		performance of an episiotomy, mode of delivery (spontaneous, vacuum, or caesarean), neonatal sex, birth weight, presence of cord problems (nuchal cord or true knot of the cord), Apgar scores, and acid-base status (in particular, metabolic acidosis). The umbilical cord was clamped immediately after delivery. Arterial blood was drawn into a 2-ml plastic syringe that was flushed with heparin, and then transferred to the pH machine located in the delivery ward. The pH was considered abnormal when it was lower than 7.2. Base deficit of 12 mmol/l or	p = 0.390 Base deficit of ≥ 12 OR 3.8 (95% CI 0.3 to 44.2) p = 0.282 Bradycardia < 70 bpm pH < 7.2 OR 26.6 (95% CI 5.2 to 150.3) p < 0.001 Base deficit of ≥ 12 OR 5.2 (95% CI 0.8 to 31.9) p = 0.007 Bradycardia < 70 bpm pH < 7.2 OR 2.2 (95% CI 0.3 to 17.1) p = 0.728 Base deficit of ≥ 12 OR 5.1 (95% CI 0.6 to 46.1) p =0.098 Pathologic FHR patterns during 2nd stage of labour (compared with normal tracing) associated with fetal acidosis (pH < 7.2 and base deficit of ≥ 12) n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			greater was considered the threshold of fetal metabolic acidosis at delivery. Newborn morbidity included admission to the intensive care unit or delayed discharge from the hospital because of fetal indications. The local ethics institutional review board approved the study. Analysis Comparison of group means was performed with the SPSS version 8.0 statistical package (SPSS Inc., Chicago, IL). Chi-square or Fisher's exact test was used for comparison of proportions. Student's t-test was applied for comparison of	28 Late decelerations OR 3.9 (95% CI 1.1 to 13.1) p = 0.029 Abnormal tracing during the 1st stage OR 3.4 (95% CI 1.3 to 8.7) p = 0.011 Bradycardia < 70 bpm OR 3.0 (95% CI 1.02 to 8.6) p = 0.045	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			means. P < 0.05 was considered statistically significant. Multiple logistic regression models were used to investigate the independent contributions of obstetric factors to abnormal FHR patterns during the second stage of labor and to investigate the contributions of those patterns to selected fetal outcomes. Odds ratios (ORs) and their 95% confidence intervals (CIs) were calculated from the regression coefficients.		
Full citation Spencer,J.A., Badawi,N., Burton,P., Keogh,J., Pemberton,P., Stanley,F., The intrapartum CTG prior to	Sample size Cases n = 55 Controls n = 39 Characteristics	Interventions Fetal heart rate patterns	Details All cases of neonatal encephalopathy developing during the first seven days of life in term infants	Results Comparison of first and last sections of CTG between cases of neonatal encephalopathy and controls. Individual	Limitations Low intra-observer agreement No exclusionn criteria or women's characteristics

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
neonatal encephalopathy at term: a case-control study, British Journal of Obstetrics and Gynaecology, 104, 25-28, 1997 Ref Id 197160 Country/ies where the study was carried out Australia Study type Case control Aim of the study To compare cardiotocograph (CTG) records during labour in cases of neonatal encephalopathy and matched controls. Study dates Eight months during 1992 Source of funding British council and The	Not specified Inclusion criteria One or more of the following features present during the first week of life: - Seizures - Absent or altered responsiveness - Abnormal muscular tone, feeding difficulties of central origin - Difficulty with central control of respiration Exclusion criteria Not specified		were identified from five hospitals (two teaching and three peripheral) in Perth, Western Australia. One control per case was subsequently selected by matching for hospital of delivery, time and day of the week, sex, and maternal insurance status. All cases and controls had a neurological examination within the first seven days of birth. Clinical data were obtained from the obstetric case notes and a maternal questionnaire. The selected CTG traces were interpreted without knowledge of the outcome. A note was made of baseline rate, amplitude and frequency of the	parameters and Krebs' score derived from 30 min sections. FIGO classification derived from 60 min sections. First CTG section Cases n = 38 Controls n = 35 Late decelerations Cases Yes n = 2 No n = 36 Controls Yes n = 0 No n = 35 FHR acceleration Cases Yes n = 16 No n = 22 Controls Yes n = 8 No n = 27 FHR variability Cases ≤ 5bpm n = 4	reported Other information FIGO FHR pattern Abnormal (pathological) Baseline FHR: < 100, > 170 Variability (amplitude bpm): < 5 for 40 min Deceleration: severe variable, severe repeated early, prolonged, late or sinusoidal Suspicious Baseline FHR: 100 – 110, 150 - 170 Variability (amplitude bpm): 5 – 10 for 40 min > 25 Deceleration/30 min: variable Normal Baseline FHR: 120 - 150 Variability (amplitude bpm): 6 - 25 Deceleration/30 min: none

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Royal Society and The Royal College of Obstetrician and Gynaecologists (Ethicon travel grant)			variability, presence of accelerations, and presence and type of decelerations. Krebs' intrapartum CTG score 9 for the first and last 30 min of the trace was calculated, as defined. The total score for each section of CTG was considered abnormal (score 0-3), suspicious (score 4-6) or normal (score 7-10) and these classifications were reduced to two groupings for analyses. The FIGO classification 3 was also determined for the first and last hour of each CTG. Half of the traces were reviewed on a second occasion, at least 10 days later. Intra-observer reproducibility was evaluated using	> 5 bpm n = 34 Controls ≤ 5bpm n = 2 > 5 bpm n = 33 Krebs' score Cases 0-3 n = 2 4-10 n = 36 Controls 0-3 n = 1 4-10 n = 34 FIGO Classification Cases Abnormal n =19 Normal n = 19 Control Abnormal n = 9 Normal n = 26 First CTG section Cases n = 38 Controls n = 35 Late decelerations Cases Yes n = 17	FHR scoring for internal FHR monitoring; for each of the criteria 0 to 2 points may be given so that a score of 0 to 10 may be obtained Abnormal: score 0 – 3 Suspicious: score 4 – 6 Normal: score 7 – 10 Score 0 Baseline FHR: < 100, > 180 Variability (amplitude bpm): < 3 Variability (frequency bpm): < 3 Acceleration/30 min: 0 Deceleration/30 min: late, severe variable, atypical variable = 0 score Score 1 Baseline FHR: 100 - 119, 161 -180 Variability (amplitude bpm): 3 - 5 > 25 Variability (frequency

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Cohen's Kappa. Analysis Associations between case-control status and binary explanatory variables were assessed using the x2 test for association, or Fisher's exact test if the expected cell count was 5 or less.	No n = 19 Controls Yes n = 8 No n = 23 FHR acceleration Cases Yes n = 26 No n = 10 Controls Yes n = 15 No n = 16 FHR variability Cases ≤ 5bpm n = 14 > 5 bpm n = 22 Controls ≤ 5bpm n = 4 > 5 bpm n = 27 Krebs' score Cases 0-3 n = 19 4-10 n = 17 Controls	bpm): 3 - 6 Acceleration/30 min: 1 -4 Deceleration/30 min: moderate variable Score 2 Baseline FHR: 120 - 160 Variability (amplitude bpm): 6 - 25 Variability (frequency bpm): > 6 Acceleration/30 min: > 4 Deceleration/30 min: none, early

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				0-3 n = 10 4-10 n = 21 IGO Classification Cases Abnormal n =32 Normal n = 4 Control Abnormal n = 16 Normal n = 15 Intra-observer reproducibility using Cohen’s Kappa for the 1st and last sections of CTG traces (Krebs' score) First section: 0.58 (95% CI 0.30 to 0.87) Last section 0.40 (95% CI 0.16 to 0.62) Intra-observer reproducibility using Cohen’s Kappa for the 1st and last sections of CTG traces (FIGO classification) First section: 0.47 (95% CI 0.24 to 0.70) Last section 0.33 (95% CI	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				0.12 to 0.55)	
Full citation Spencer,J.A., Johnson,P., Fetal heart rate variability changes and fetal behavioural cycles during labour, British Journal of Obstetrics and Gynaecology, 93, 314-321, 1986 Ref Id 174553 Country/ies where the study was carried out UK Study type Case control study Aim of the study To evaluate the cycle of low and high fetal heart rate (FHR) and fetal behavioural cycles Study dates March 1983 to July 1983	Sample size n = 301 consecutive fetal heart rate (FHR) recording Characteristics Prostagladine/oxytocin Cycle present n = 163 (93%) No cycle present n = 110 (88%) pethidine/epidural Cycle present n = 159 (90%) No cycle present n = 117 (94%) Inclusion criteria Term birth Exclusion criteria Not specified	Interventions FHR variability	Details During the study period all 1st stage cardiotocograph (CTG) recordings with ≥ 6 hour duration were analysed for cycles of low and high FHR variability episodes. Each episode was visually identified by the change in long term variability of ≥ 5 beats per minute maintained for ≥ 5 minutes duration. A complete cycle required both low and high FHR variability episodes with changes before and after. The actual variability during the quiet episode (episodes of low FHR variability) of cycles was recorded as > 5	Results Mode of birth in presence and on presence of FHR variability cycles Instrumental vaginal birth Cycle present n = 159 (90%) No cycle present n = 117 (94%) Caesarean section Cycle present n = 70 (40%) No cycle present n = 51 (41%)	Limitations No demographic data reported. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Grant from DHSS and the MRC			or < 5 beats/min, and the predominant variability of CTG without cycle was also recorded as > 5 or < 5 beats/min. A minimum of two cycles required before a CTG was regarded as showing evidence of fetal behavioural state changes. Analysis: The CTG analysis was performed independently by two observers without knowledge of detail s of labour outcomes. All information were coded and SPSS were used for data analysis. Statistical comparison made using Student's t-test and chi square.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Williams,K.P., Galerneau,F., Intrapartum fetal heart rate patterns in the prediction of neonatal acidemia, American Journal of Obstetrics and Gynecology, 188, 820-823, 2003 Ref Id 174581 Country/ies where the study was carried out Canada Study type Cohort Aim of the study To correlate changes in the intrapartum electronic fetal heart rate patterns with the development of significant neonatal acidemia. Study dates January 1997 to January	Sample size n = 488 fetuses Characteristics Not specified Inclusion criteria Term pregnancy (> 37 weeks) Birth of neonates within 30 minutes of the bradycardia Continous electronic fetal monitoring for 2 hours before the delivery Umbilical cord artery and cord blood gases done at birth Exclusion criteria Fetal anomality Multiple gestation	Interventions Fetal heart rate patterns	Details Study population consisted of n = 488 women who had continuous electronic fetal monitoring during labor for the last 2 hours. Umbilical artery cord gas analysis performed at birth. One investigator blinded to the cord gas outcome reviewed all 488 tracings using the National Institute of Child Health and Human Development guidelines for fetal heart rate monitoring. The women were placed in six groups, depending on the absence or presence of normal variability (amplitude > 5 beats) during the last hour of monitoring combined with the absence of	Results Women with normal variability and accelerations, even in the presence of late decelerations or variable decelerations, maintained an umbilical artery pH 7.0 or greater in more than 97% of cases. In the presence of minimal/absent variability (amplitude < 5) for at least an hour, the incidence of significant acidemia (pH < 7.0) ranged from (12%-31%): Outcome variable corelated with different intrapartum electronic fetal monitoring parameters Group 1 (normal variability) n = 42 Umbilical artery pH (mean ± SD) 7.24 ± 0.07 Base deficit (mean ± SD) 3.62 ± 3.16 Incidence of pH < 7.0: 0% (p < 0.05 vs. group 1, 2, 3) Incidence of pH < 7.1: 9.5% Incidence of base deficit <	Limitations Other information Fetal Heart rate traces were assessed based on the National Institute of Child Health and Human Development guidelines for FHR monitoring Neonatal acidosis defined as a pH of less than 7.0 at birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
2000 Source of funding Not specified			decelerations or the presence of variable or late decelerations. The relationship between changes in variability and the outcome variables of pH and base deficit in the six groups was assessed with analysis of variance and Chi Square test. Significance was set at the P < 0.05 level.	16: 0% Incidence of base deficit < 12: 2.4% Group 2 (normal variability and late decelerations) n = 173 Umbilical artery pH (mean ± SD) 7.18 ± 0.07 Base deficit (mean ± SD) -6.17 ± 3.14 Incidence of pH < 7.0: 1.7% Incidence of pH < 7.1: 13.3% Incidence of base deficit < 16: 0% Incidence of base deficit < 12: 4.6% Group 3 (normal variability and and variable decelerations) n = 219 Umbilical artery pH (mean ± SD) 7.18 ± 0.08 Base deficit (mean ± SD) -6.24 ± 3.6 Incidence of pH < 7.0: 23% Incidence of pH < 7.1: 9.1% Incidence of base deficit < 16: 0.91% Incidence of base deficit <	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				12: 5.5% Group 4 (decreased variability) n = 13 Umbilical artery pH (mean ± SD) 7.07 ± 0.2 Base deficit (mean ± SD) -9.8 ± 7.7 (p < 0.05 vs. group 4 and 5) Incidence of pH < 7.0: 31% (p < 0.05 vs. group 1, 2, 3 and 6) Incidence of pH < 7.1: 38.5% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 16: 23.1% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 12: 38.5% (p < 0.05 group 1, 2, 3 and 6) Group 5 (decreased variability and late deceleration) n = 25 Umbilical artery pH (mean ± SD) 7.01 ± 0.14 Base deficit (mean ± SD) -9.58 ± 6.14 (p < 0.05 vs. group 4 and 5)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Incidence of pH < 7.0: 24% (p < 0.05 vs. group 1, 2, 3 and 6) Incidence of pH < 7.1: 44% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 16: 24% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 12: 32% (p < 0.05 group 1, 2, 3 and 6) Group 6 (decreased variability and varable decelerations) n = 16 Umbilical artery pH (mean ± SD) 7.19 ± 0.14 (p < 0.05 vs. group 2, 3, 4 and 5) Base deficit (mean ± SD) 3.37 ± 5.07 Incidence of pH < 7.0: 12.5% Incidence of pH < 7.1: 18.8% Incidence of base deficit < 16: 12.5% Incidence of base deficit < 12: 12.5% Umbilical artery blood gas	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				value in the absence of accelerations Group 4 n = 8 Umbilical artery pH (mean ± SD) 6.97 ± 0.17 Base deficit (mean ± SD) -13.06 ± 7.07 Incidence of pH < 7.0: 62.5% Incidence of pH < 7.1: 62.5% Incidence of base deficit < 16: 37.5% Incidence of base deficit < 12: 62.5% Group 5 n = 19 Umbilical artery pH (mean ± SD) 7.01 ± 0.13 Base deficit (mean ± SD) -13.15 ± 6.64 Incidence of pH < 7.0: 31.6% Incidence of pH < 7.1: 52.6% Incidence of based deficit < 16: 26.3% Incidence of based deficit < 12: 42.1%	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Group 6 n = 8 Umbilical artery pH (mean ± SD) 7.08 ± 0.2 Base deficit (mean ± SD) -9.95 ± 6.25 Incidence of pH < 7.0: 25% Incidence of pH < 7.1: 37.5% Incidence of base deficit < 16: 25% Incidence of base deficit < 12: 25%	
Full citation Williams,K.P., Galerneau,F., Fetal heart rate parameters predictive of neonatal outcome in the presence of a prolonged deceleration, Obstetrics and Gynecology, 100, 951-954, 2002 Ref Id 174549 Country/ies where the study was carried out Canada Study type	Sample size n = 186 women Characteristics Not specified Inclusion criteria Term pregnancy (> 37 weeks) An identified prolonged deceleration/bradycardia for > 2 minutes with fall < 100 bpm Birth of neonates within	Interventions Fetal heart rate tracing	Details Study's population consisted of n = 186 women with term gestations who had continuous electronic fetal monitoring for at least 2 hours before delivery, with an identified bradycardia during that period. Each woman had umbilical artery cord analysis done and delivery within 30 minutes of that bradycardia. The last	Results Outcome variable correlated with different intrapartum electronic fetal monitoring parameters Group 1 (normal variability and recovery) n = 128 Umbilical artery pH (mean ± SD) 7.17 ± 0.09 Base deficit (mean ± SD) -6.54 ± 3.9 Incidence of pH < 7.0: 2% (p < 0.05 vs. group 2 and 3) Incidence of pH < 7.1: 22% Incidence of pH < 7.0: 1% Incidence of pH < 7.0: 5% P < 0.001	Limitations Other information Fetal heart rate traces were assessed based on the National Institute of Child Health and Human Development guidelines for FHR monitoring Neonatal acidosis defined as a pH of less than 7.0 at birth Prolonged deceleration/bradycardia: > 2 minutes with a fall to <

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Cohort Aim of the study To correlate the presence of baseline variability and the duration of a prolonged deceleration/bradycardia in intrapartum fetal heart rate (FHR) tracings with the development of neonatal acidemia Study dates January 1997 to January 2000 Source of funding Not specified	30 minutes of the bradycardia Continous electronic fetal monitoring (EFM) for 2 hours before the delivery Umbilical cord artery and cord blood gases done at birth Exclusion criteria Not specified		hour of all electronic monitoring tracings was reviewed by one investigator blinded to the cord gas outcome reviewed using the National Institute of Child Health and Human Development guidelines for FHR monitoring. The presence or absence of variability before the bradycardia and recovery or no recovery of the bradycardia were assessed and women were categorised into four groups. Group 1 (n = 128 women) with normal variability and recovery before 10 minutes , group 2 (n = 40 women) with normal variability and no recovery within 10 minutes, group 3 (n = 9 women) with	 Group 2 (normal variability and no recovery) n = 40 Umbilical artery pH (mean ± SD) 7.13 ± 0.15 Base deficit (mean ± SD) -7.15 ± 5.1 Incidence of pH < 7.0: 18% Incidence of pH < 7.1: 33% Incidence of pH < 7.0: 8% Incidence of pH < 7.0: 13% P < 0.001 Group 3 (decreased variability and recovery) n = 9 Umbilical artery pH (mean ± SD) 7.11 ± 0.11 Base deficit (mean ± SD) -10.32 ± 3.68 Incidence of pH < 7.0: 44% Incidence of pH < 7.1: 56% Incidence of pH < 7.0: 11.1% Incidence of pH < 7.0: 22% P < 0.001 Group 4 (decreased variability and no recovery) n = 9 Umbilical artery pH (mean ±	100 bpm

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			decreased variability and recovery within 10 minutes, and group 4 (n = 9 women) with decreased variability and no recovery within 10 minutes. Two cutoffs were used to define abnormal pH; a pH < 7.0 and a pH < 7.1. Two cutoffs were also used for base deficit, a base deficit > -16 and a base deficit > -12. Analysis Analysis of variance and the chi2 test were used to asses the relationship between the various groups. A multiple logistic regression model was developed with the parameters of amplitude and recovery used to	SD) 6.83 ± 0.16 (p < 0.05 vs. group 1,2,3) Base deficit (mean ± SD) -20.17. ± 6.0 (p < 0.05 vs. group 1,2,3) Incidence of pH < 7.0: 78% (p < 0.05 vs. group 1 and 2) Incidence of pH < 7.1: 89% (p < 0.05 vs. group 1) Incidence of pH < 7.0: 78% (p < 0.05 vs. group 1 and 2) Incidence of pH < 7.0: 89% (p < 0.05 vs. group 1 and 2) P < 0.001	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			predict pH at birth.		
Full citation Williams,K.P., Galerneau,F., Comparison of intrapartum fetal heart rate tracings in patients with neonatal seizures vs. no seizures: what are the differences?, Journal of Perinatal Medicine, 32, 422-425, 2004 Ref Id 121348 Country/ies where the study was carried out USA Study type Case control Aim of the study To examine which intrapartum fetal heart rate parameters in the presence of severe neonatal acidosis (pH < 7.0) appropriately	Sample size Seizure n = 25 No seizure (controls) n = 25 Characteristics There were no significant differences observed between the seizure and no seizure group in maternal age (32 ± 5 vs 34 ± 3), gravidity (2 ± 1 vs 2 ± 2), gestational age (39 ± 2 vs 38 ± 3) and neonatal birth weight. Inclusion criteria Singleton pregnancy Term ≥ 37 weeks Presence of neonatal convulsions with 24 - 48 hours of birth secondary to hypoxic	Interventions Fetal heart rate parameters	Details The neonatal and antenatal records of the women who fit the inclusion criteria were reviewed. The cases with confirmed diagnoses of HIE (based on the clinical criteria and nureo-imaging) and cord pH < 0.7 were chosen for the study. The intrapartum fetal heart rate tracings of neonates who developed neonatal seizures secondary to HIE were compared with matched neonates with similar pH (pH < 0.7) and gestational age (> 37) who did not develop seizures. All women had at least 2 hours of intrapartum fetal	Results Incidence of fetal heart rate parameters (seizure n = 25, no seizure n = 25) Bradycardia Seizure n = 14 (56%) No seizure n = 21 (84%) Odds ratio 0.24 (0.06 to 0.92) p = 0.062 Variable deceleration Seizure n = 9 (36%) No seizure = 15 (50%) Odds ratio 0.38 (0.12 to 1.18) p = 0.156 Late decelerations Seizure n = 8 (32%) No seizure n = 13 (52%) Odds ratio 0.43 (0.14 to 1.37) p = 0.256 Minimal/absent variability Seizure n = 16 (64%) No seizure n = 9 (36%)	Limitations Exclusion criteria not specified No definitions for all FHR features and abnormal FHR given Other information The tracing was reviewed in two 1 hour segments according to NICHD classification Minimal baseline variability: amplitude variation of ≤ 5 bpm Absent baseline variability: no amplitude variation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
predicts the development of neonatal seizures in the context of hypoxic ischemic encephalopathy (HIE). Study dates January 1997 to January 2000 Source of funding Not specified	ischemic encephalopathy Exclusion criteria Not specified		heart rate patterns available for review. The fetal heart rate parameters (prolonged deceleration, variable and late decelerations, variability, accelerations, fetal heart rate baseline and duration of the fetal heart rate abnormality) were reviewed. Analysis Comparison between the groups was done using chi-square and Fisher's exact test for nominal data, and Student's t-test for continuous data.	Odds ratio 3.16 (1 to 10.03) p = 0.080 Accelerations Seizure n = 6 (24%) No seizure = 12 (36%) Odds ratio 0.34 (0.10 to 1.15) p = 0.140 Duration of abnormal FHR(min) Seizure 72 ± 12 No seizure 36 ± 18 p < 0.001 Baseline FHR (beats/min) Seizure 143 ± 11 No seizure 146 ± 16 p = 0.444	

1.1.11 Does the use of fetal scalp stimulation as an adjunct to electronic fetal monitoring improve the predictive value of monitoring and clinical outcomes when compared to: a) EFM alone, b) EFM plus ECG

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Full citation Anyaegbunam,A.M., Ditchik,A., Stoessel,R., Mikhail,M.S., Vibroacoustic stimulation of the fetus entering the second stage of labor, Obstetrics and Gynecology, 83, 963-966, 1994 Ref Id 202123 Country/ies where the study was carried out USA Aim of the study To evaluate the fetal heart rate response to vibroacoustic stimulation of fetuses entering the second stage of labour as a predictor of neonatal outcome Study type Randomised controlled study	Sample size N = 632 Vibroacoustic stimulation (VAS) = 316 Sham stimulation = 316 Characteristics Maternal age (years) - mean ± SD VAS = 26 ± 4 Sham = 24 ± 3 Nulliparous VAS = 40.5% Sham = 44.6% Gestational age at delivery (weeks) - mean ± SD VAS = 39 ±1 Sham = 38 ± 2 Birthweight (g) - mean ± SD VAS = 3430 ± 438 Sham = 3363 ± 381	Tests 5 seconds of fetal vibroacoustic stimulation	Methods Consecutive volunteers who met the study criteria were included. Women were assigned to the study or control group based on a pre-generated list of random numbers - allocation was to VAS if the next number was odd, and to sham stimulation if the number was even. A 5c electronic larynx (AT&T, Special Needs Center, Parsippany, NJ) was placed above the symphysis on the mother's abdomen. The larynx was activated for 5 seconds, 30 seconds after a uterine contraction, and the fetal heart rate (FHR) trace was marked and the response recorded. In the sham stimulation group the artifiical larynx was not activated but the FHR trace was marked in a similar fashion.	Results Prevalence of acidosis (umbilical) pH < 7.20 18/316 (6%) a. For umbilical cord pH <7.20 All values calculated by NCC from data in Table 3 Sensitivity: 22.2% (3.02 to 41.43) Specificity: 77.18% (72.42 to 81.95) PPV: 5.56% (0 to 10.85) NPV: 94.26% (91.34 to 97.18) LR+: 0.97 (0.40 to 2.37) LR-: 1.01 (0.78 to 1.30) b. For Apgar score < 7 at 5 minutes All values calculated by NCC from data in Table 3 Sensitivity: 30% (1.60 to 58.40) Specificity: 77.45% (72.77 to 82.13) PPV: 4.17% (0 to 8.78) NPV: 97.13% (95.04 to 99.23) LR+: 1.33 (0.50 to 3.51) LR-: 0.90 (0.60 to 1.36) Cord pH	Limitations Only outcome data reported for those receiving the active intervention (VAS) - case series Allocation concealment unclear Period of FHR observation for qualifying acceleration following stimulus not reported Indirectness: All participants had reassuring FHR traces; unclear whether any women were considered high risk Other information Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics)

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>Study dates
July 1991 - July 1992

Source of funding
Not reported</td>
<td>Low arterial pH (<7.20)
VAS = 5.7%
Sham = 4.7%

Inclusion Criteria
Gestational age ≥37 weeks, singleton fetus, reassuring heart rate patterns, cephalic presentation, absence of heavy meconium and fully dilated cervix

Exclusion Criteria
Not reported</td>
<td></td>
<td>FHR traces were interpreted by an investigator blinded to group allocation. An acceleration was defined as an increase over baseline of at least 15 bpm for at least 15 seconds. Those receiving VAS were stratified into 3 groups: acceleration, initial acceleration followed by immediate deceleration, and no response.

Samples of umbilical artery and vein blood were obtained at birth and tested for pH, carbon dioxide pressure, oxygen pressure and base defecit</td>
<td>
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>4</td><td>68</td></tr>
<tr><td>Predictive Test -ve</td><td>14</td><td>230</td></tr>
</table>
Apgar score
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>3</td><td>69</td></tr>
<tr><td>Predictive Test -ve</td><td>7</td><td>237</td></tr>
</table>
</td>
<td>For 2x2 table acceleration and acceleration followed by deceleration were considered a negative stimulation test result</td>
</tr>
<tr>
<td>Full citation
Arulkumaran,S., Ingemarsson,I., Ratnam,S.S., Fetal heart rate response to scalp stimulation as a</td>
<td>Sample size
N = 50

Characteristics
Suspicious trace = 32/50 (64%)</td>
<td>Tests
Fetal scalp stimulation for 15 seconds carried out with Allis' tissue forceps</td>
<td>Methods
Fetal heart rate was monitored with a scalp electrode and the trace interpreted by two senior members of staff.</td>
<td>Results
Prevalence of acidosis 4% (2/50)

Predictive accuracy of no acceleration following fetal scalp</td>
<td>Limitations
Study sample represents population: unclear whether consecutive women were included, length</td>
</tr>
</table>

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>test of fetal well-being in labour, Asia-Oceania Journal of Obstetrics and Gynaecology, 13, 131-135, 1987
Ref Id
201763
Country/ies where the study was carried out
Singapore
Aim of the study
To evaluate the response of the fetus to painful pinch stimulation of the scalp and its relation to fetal acid base balance when a suspicious or ominous fetal heart rate was encountered

Study type
Case-series
Study dates
Not reported

Source of funding
Not reported</td>
<td>Ominous trace = 18/50 (36%)

Inclusion Criteria
Women in the first stage of labour with cephalic presentation

Exclusion Criteria
Not reported</td>
<td>(closed to first ratchet)</td>
<td>Suspicious trace defined as: no accelerations and reduced baseline variability (5-10 bpm) or abnormal baseline rate or flat baseline (< 5 bpm) or variable decelerations without ominous features. Ominous trace defined as: flat baseline and abnormal baseline rate or repeated late decelerations or reperated variable decelerations with ominous feautres (duration > 60 seconds, beat loss > 60 beats, slow recovery, rebound tachycardia, late deceleration component). Fetal heart rate changes were so classified if it persisted after corrective measures of alteration of position of the mother, hydration, oxygen inhalation and omission of oxytocin infusion.</td>
<td>stimulation (Allis clamp)
a. For FBS pH < 7.20
All values calculated by NCC from data in Table 1
Sensitivity: 100% (100 to 100)
Specificity: 83.33% (72.79 to 93.88)
PPV: 20% (0 to 44.79)
NPV: 100% (100 to 100)
LR+: 6 (3.19 to 11.30)
LR-: 0 (NC)

b. For caesarean section
All values calculated by NCC from data in Table 2
Sensitivity: 60% (29.64 to 90.36)
Specificity: 90% (80.70 to 99.30)
PPV: 60% (29.64 to 90.36)
NPV: 90% (80.70 to 99.30)
LR+: 6 (2.08 to 17.29)
LR-: 0.44 (0.21 to 0.96)

FBS pH
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>2</td><td>8</td></tr>
</table>
</td>
<td>of study period not reported
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: period of fetal heart rate observation for qualifying acceleration following stimulus not reported
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: time between stimulation, fetal blood sample and delivery not reported
Statistical analysis is appropriate for study design: yes
Indirectness: unclear whether women were considered high risk</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			Scalp stimulation was carried out for 15 seconds when the fetal heart rate recording was at the baseline rate. The presence or absence of immediate fetal heart tate acceleration was noted. Acceleration was defined as at least 15 beats above the baseline for at least 15 seconds duration. Within 20 min of the test stimulation fetal blood sampling was performed with the mother in in the left lateral position. Management was according to FBS results and continued CTG trace.	Predictive Test -ve: 0 / 40 Caesarean section Reference Test +ve / Reference Test -ve Predictive Test +ve: 6 / 4 Predictive Test -ve: 4 / 36	Other information Authors define an acceleration as a positive stimulation test but do not report any accuracy statistics calculated using this definition. NCC calculated predictive values using no acceleration as definition of positive stimulation test, in line with other included studies. Two babies who had negative tests and acidotic scalp pH values had cord arterial pH values below 7.20 at birth but none had low Apgar score (< 7) at 5 minutes.
Full citation Bartelsmeyer,J.A., Sadovsky,Y., Fleming,B., Petrie,R.H., Utilization of fetal heart	Sample size N = 104 Characteristics Gestational age	Tests 5 seconds of continuous fetal vibroacoustic stimulation (VAS)	Methods Women having FBS were studied over a 24 month period. Immediately prior to FBS fetal VAS was	Results Prevalence of acidosis 14/104 (13%) Predictive value of no acceleration	Limitations Study sample represents population: unclear whether consecutive women

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
rate acceleration following vibroacoustic stimulation in labor to predict fetal acidemia and base deficit levels, Journal of Maternal-Fetal Medicine, 4, 120-125, 1995 Ref Id 202115 Country/ies where the study was carried out USA Aim of the study To evaluate if vibroacoustic stimulation can predict fetal scalp blood base defecit levels in addition to pH levels. Study type Case-series Study dates 24-month period (study dates not reported) Source of funding Not reported	(weeks) - mean ± SD, N 15bpm x 15 sec acceleration = 38.8 ± 1.7, 52 10bpm x 10 sec acceleration = 39.2 ± 2.3, 23 No acceleration = 37.7 ± 3.1, 29 Birth weight (g) - mean ± SD 15bpm x 15 sec acceleration = 3343 ± 482, 52 10bpm x 10 sec acceleration = 3339 ± 507, 23 No acceleration = 2855 ± 872, 29 Inclusion Criteria Women having fetal scalp blood sampling (FBS) Exclusion Criteria Not reported		performed using a model 5C electronic artificial larynx (AT&T Consumer Products, USA) which produces a mixed frequency sound of 81 Hz and 81 db measured at 1 m in air. A single stimulus was applied continuously for 5 seconds to the maternal abdomen one-third of the distance from the symphysis pubis to the umbilicus. Accelerations of the fetal heart rate (FHR) occurring within 20 seconds of VAS were recorded as a positive response. The amplitude and duration of acceleratory response was recorded and FHR trcaes interpreted by either of two investigators. FHR responses were classified in to three groups: FHR response of at least 15 bpm for 15	following VAS a. For fetal blood sample pH < 7.20 All values calculated by NCC from data in Table 4 (corresponds to sensitivity reported in text of paper) Sensitivity: 79% (57.08 to 100) Specificity: 52.22% (41.9 to 62.54) PPV: 20.37% (9.63 to 31.11) NPV: 94% (87.42 to 100) LR+: 1.64 (1.12 to 2.33) LR-: 0.41 (0.15 to 1.14) b. For Apgar score < 7 at 5 min All values calculated by NCC from data in Table 2 Sensitivity: 83.33% (53.51 to 100) Specificity: 52.04% (42.15 to 61.93) PPV: 9.62% (1.6 to 17.63) NPV: 98.08% (94.34 to 100) LR+: 1.74 (1.15 to 2.62) LR-: 0.32 (0.05 to 1.93) FBS pH <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr></table>	were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome Outcome of interest is sufficiently measured in participants: yes Important potential cofounders are accounted for: time between VAS and delivery not reported Statistical analysis is appropriate for study: yes Indirectness of population: based on gestational age mean and SD for 'no acceleration' population not all fetuses were delivered at term; unclear whether any women were considered high

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			seconds, FHR response of at least 10 bpm for 10 seconds but less than 15 bpm for 15 seconds and no response. FHR was recorded by an internal scalp electrode. FBS was performed immediately following VAS.	<table><tr><td>Predictive Test +ve</td><td>11</td><td>43</td></tr><tr><td>Predictive Test -ve</td><td>3</td><td>47</td></tr></table> Apgar score <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>5</td><td>47</td></tr><tr><td>Predictive Test -ve</td><td>1</td><td>51</td></tr></table>	risk Other information Authors' definition of positive stimulation test: no acceleration For 2x2 table no response and FHR response of at least 10 bpm for 10 seconds but less than 15 bpm for 15 seconds were considered a positive stimulation test result
Full citation Chauhan,S.P., Hendrix,N.W., Devoe,L.D., Scardo,J.A., Fetal acoustic stimulation in early labor and pathological fetal acidemia: a preliminary report, Journal of	Sample size N = 271 Characteristics Maternal age (years) - mean ± SD 24.4 ± 6.0 Nulliparous	Tests 3-seconds of vibroacoustic stimulation (VAS)	Methods 3-second fetal VAS was performed by placing the stimulator unit (Corometrics model 146, Wallingford, CT) over the symphysis. If no acceleration of fetal heart rate (FHR) occurred within 1 min of	Results Prevalence of acidosis a. pH < 7.10 8/271 (3.3%) b. pH < 7.00 4/271 (1.6%) Predictive value of no acceleration	Limitations Study sample represents population: not consecutive (women only included when one of the study authors was available) Loss to follow-up is unrelated to key

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Maternal-Fetal Medicine, 8, 208-212, 1999 Ref Id 201734 Country/ies where the study was carried out USA Aim of the study To determine if a non-reactive response to fetal acoustic stimulation in early labour can predict a significantly higher risk of umbilical arterial pH < 7.10 or < 7.00 Study type Case-series Study dates 6-month period (dates not reported) Source of funding Not reported	104/271 (82%) Mean gestational age (weeks) - mean ± SD 39.1 ± 1.5 Mean birth weight (g) - mean ± SD 3328 ± 486 Inclusion Criteria 1] Singleton gestation 2] In early active labour (cervical dilation of 5 cm or less) 3] no contraindication to continue labour 4] vertex presentation 5] no narcotics 6] umbilical arterial blood gas anaylsis within 30 min of delivery 7] ≥ 37 weeks' gestational age		stimulation, additional pulses were applied at 1-min intervals with a maximum of 3 pulses. If 10 min after the third stimuli there was no acceleration (acceleration defined as an increase of 15 bpm lasting for at least 15 seconds) of FHR then the response was considered non-reactive. Immediately after birth a segment of umbilical cord was doubly clamped and umbilical arterial and venous blood samples were collected. Blood gas analyses were performed within 30 min of delivery. Caesarean delivery for fetal distress was undertaken if fetal bradycardia, late decelerations, or moderate to severe variable decelerations occurred and were unresponsive to	following VAS a. For umbilical pH < 7.10 Values as reported in Table 2; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 44% (11.98 to 76.91) Specificity: 91% (87.79 to 94.65) PPV: 15% (1.41 to 28.21) NPV: 97.95 (96.17 to 99.73) LR+: 5.06 (2.21 to 11.59) LR-: 0.61 (0.34 to 1.09) b. For umbilical pH < 7.00 Values as reported in Table 2; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 50% (1 to 99) Specificity: 91% (87.14 to 94.13) PPV: 7% (0 to 17.29) NPV: 99.18 (98.05 to 100) LR+: 5.34 (1.87 to 15.24) LR-: 0.55 (0.21 to 1.47) c. For cesearean section Values as reported in Table 2; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 37% (3.95 to 71.05) Specificity: 92% (87.39 to 94.35) PPV: 11% (0 to 22.97)	characteristics: no loss to follow up Prognostic factor is adequately measured in participants: 10-minute window for reaction to 3rd stimulus, compared with 1-min window for reaction to 1st and 2nd stimuli Outcome of interest is sufficiently measured in participants: results reported for pH < 7.10 and < 7.00 (standard definition is < 7.20) Important potential confounders are accounted for: yes Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk Other information

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td></td>
<td>Exclusion Criteria
Not reported</td>
<td></td>
<td>conservative management such as changes in maternal position, hydration, supplemental oxygenation, transcervical amnioinfusion and use of tocolytics for intrauterine resuscitation. Scalp stimulation was performed prior to proceeding with urgent caesarean delivery for abnormal FHR. Scalp pH was not obtained due to nonavailability of the machine.

Results of VAS were not used in the management of the woman's labour.</td>
<td>NPV: 97% (96.17 to 99.73)
LR+: 4.11 (1.55 to 10.87)
LR-: 0.69 (0.40 to 1.18)

Umbilical cord pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>4</td><td>23</td></tr>
<tr><td>Predictive Test -ve</td><td>5</td><td>239</td></tr>
</table>
Umbilical cord pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>2</td><td>25</td></tr>
<tr><td>Predictive Test -ve</td><td>2</td><td>242</td></tr>
</table>
</td>
<td>Authors' definition of positive stimulation test: no acceleration

Number of stimulations applied
One stimulation = 214/271 (78.9%)
Two stimulations = 19/271 (7%)
Three stimulations = 38/271 (14%)
Of the 38 fetuses who received three stimulations, only 11 had an acceleration with 10 min of last VAS application (definition of response)

Interval between first VAS to delivery
Full study population = 7.9 ± 6.9 hours
Caesarean section for distress = 7.3 ± 4.3 hours vs. No caesarean section = 7.9 ± 6.9 hours</td>
</tr>
</table>

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td>Caesarean section<table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>3</td><td>24</td></tr><tr><td>Predictive Test -ve</td><td>5</td><td>239</td></tr></table></td><td>Umbilical arterial pH < 7.10 = 7.2 ± 6.0 hours vs. umbilical arterial pH ≥ 7.10 = 7.9 ± 6.6 hours
Umbilical arterial pH < 7.00 = 9.5 ± 8.0 hours vs. umbilical arterial pH ≥ 7.00 = 8.0 ± 6.9 hours</td></tr>
<tr><td>Full citation
Clark,S.L., Gimovsky,M.L., Miller,F.C., Fetal heart rate response to scalp blood sampling, American Journal of Obstetrics and Gynecology, 144, 706-708, 1982
Ref Id
201761
Country/ies where the study was carried out
USA
Aim of the study
To ascertain the correlation between</td><td>Sample size
N = 200

Characteristics
Not reported

Inclusion Criteria
Not reported

Exclusion Criteria
Not reported</td><td>Tests
Endoscope placement and fetal scalp blood sampling (scalp puncture served as fetal scalp stimulation)</td><td>Methods
The labour records of women who delivered at Los Angeles County/University of Southern California Women's Hospital during a 2-year period were reviewed. Intrapartum fetal heart rate tracings of 200 women who had undergone fetal scalp blood sampling were chosen sequentially.
Fetal heart rate tracings were reviewed blindly, without knowledge of the pH values obtained at the time of sampling. They</td><td>Results
Prevalence of FBS pH < 7.21 19/200 (10%)

Predictive value of no acceleration following fetal scalp puncture for FBS pH < 7.21
All values calculated by NCC using data in Table I
Sensitivity: 100% (100 to 100)
Specificity: 93.37% (89.75 to 96.99)
PPV: 61.29% (44.14 to 78.44)
NPV: 100% (100 to 100)
LR+: 15.08 (8.73 to 26.06)
LR-: 0 (NC)

FBS pH</td><td>Limitations
Study sample represents population: unclear whether consecutive women were included
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: period of fetal heart rate observation for qualifying acceleration following stimulus not reported
Outcome of interest is</td></tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
fetal acid-base status and the ability of the fetus to manifest a reassuring fetal heart rate pattern in response to tactile stimulation provided by fetal blood sampling Study type Case-series Study dates A 2-year period (dates not reported) Source of funding Not reported			were judged to be either reactive (demonstrating fetal heart rate acceleration of 15 bpm lasting 15 seconds) or non-reactive in response to endscope placement and scalp puncture.	<table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>19</td><td>12</td></tr><tr><td>Predictive Test -ve</td><td>0</td><td>169</td></tr></table>	sufficiently measured in participants: yes Important potential confounders are accounted for: time between stimulation, fetal blood sampling and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: gestational age not reported - at least one woman was in pre-term labour (32 to 33 weeks' gestation); unclear whether any women were considered high risk Other information Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics)

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					All FBS was performed during the first stage of labour. Mean (range) scalp pH Acceleration in response to stimulation = 7.32 (7.21 to 7.42) No acceleration in response to stimulation = 7.16 (6.95 to 7.31)
Full citation Clark,S.L., Gimovsky,M.L., Miller,F.C., The scalp stimulation test: a clinical alternative to fetal scalp blood sampling, American Journal of Obstetrics and Gynecology, 148, 274-277, 1984 Ref Id 202086 Country/ies where the study was carried out	Sample size N = 100 Characteristics Gestational age Preterm (33 to 35 weeks) = 4/100 (4%) Term (37 to 41 weeks) = 76/100 (76%) Post-term (≥ 42 weeks) = 20/100 (20%)	Tests 15 seconds of gentle digital pressure on the scalp through the dilated cervix, followed by transvaginal application on fetal scalp of Allis clamp closed to first ratchet and left in place for 15 seconds	Methods 100 fetuses with heart tracings indicating possible acidosis were prospectively enrolled by the clinical resident on the labour and delivery floor after review of the woman's clinical course and fetal heart rate (FHR) pattern. FHR response to each stimulation (15 seconds of gentle digital pressure	Results Prevalence of acidosis pH < 7.20 19/64 (30%) Predictive accuracy of no acceleration following fetal scalp stimulation (FSS) (Allis clamp) for FBS pH < 7.20 [only in those fetuses who had not responded to initial digital FSS] All values calculated by NCC from data presented in Fig 2 Sensitivity: 100% (100 to 100) Specificity: 33.33% (19.56 to 47.11)	Limitations Study sample represents population: unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: period of FHR observation for qualifying acceleration

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>USA
Aim of the study
To compare the correlation between heart rate accelerations in response to non-invasive tactile stimulation of the fetal scalp and subsequent pH obtained at scalp blood sampling

Study type
Case-series
Study dates
Not reported

Source of funding
Not reported</td>
<td>Inclusion Criteria
Fetuses with heart rate tracings indicating possible acidosis mandating scalp blood sampling

Exclusion Criteria
Not reported</td>
<td></td>
<td>followed by 15 seconds application of Allis clamp) was observed, followed by scalp blood sampling in the usual manner.

Each tracing was reviewed by one of the authors without knowledge of the fetal scalp pH and was judged to be reactive or non-reactive to each stimulus as well as to the stimulus of the scalp puncture itself.

Reactive response was defined as an acceleration of fetal heart rate of 15 bpm lasting at least 15 seconds</td>
<td>PPV: 38.78% (25.13 to 52.42)
NPV: 100% (100 to 100)
LR+: 1.5 (1.22 to 1.84)
LR-: 0 (NC)

FBS pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>19</td><td>30</td></tr>
<tr><td>Predictive Test -ve</td><td>0</td><td>15</td></tr>
</table>
</td>
<td>following stimulus not reported
Outcome of interest is sufficiently measured in participants: results not adequately reported digital stimulation
Important potential confounders are accounted for: time between stimulation, FBS and delivery not reported
Statistical analysis is appropriate for study design: yes - although data not sufficiently reported for digital scalp stimulation

Indirectness of population: 76% of fetuses were delivered at term; fetuses had failed to respond to digital stimulation; unclear whether any women were considered high risk</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					Other information Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics). 2x2 table could not be calculated for digitial fetal scalp stimulation. 2x2 table could be calculated for predictive accuracy of response to Allis clamp stimulation for the 64 fetuses who did not respond with an acceleration to digital stimulation. Data not reported for response to stimulation of scalp puncture. Data reported in Fig 2 (used to caclulate 2x2

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					table) specifiy percentage of fetuses with pH < 7.20 and percentage of fetuses with pH > 7.20. Unclear in which group fetuses with a pH of 7.20 were included. All women were in the first stage of labour.
Full citation Edersheim,T.G., Hutson,J.M., Druzin,M.L., Kogut,E.A., Fetal heart rate response to vibratory acoustic stimulation predicts fetal pH in labor, American Journal of Obstetrics and Gynecology, 157, 1557-1560, 1987 Ref Id 201764 Country/ies where the study was carried out	Sample size N = 188 responses N = 127 women Characteristics Not reported Inclusion Criteria ≥ 34 weeks' gestation, active labour with ruptured membranes, and evidence of abnormal fetal heart rate tracings	Tests 3 seconds of fetal vibroacoustic stimulation (VAS) followed by the inicision of fetal scalp blood sampling (FBS) serving as fetal scalp stimulation.	Methods FBS was performed where fetal heart rate (FHR) tracings were suspicious or equivocal. FBS was also performed with meconium plus FHR abnormality such as decreased beat-to-beat variability or fetal tachycardia. FHR was monitored continuously by Corometrics 112 fetal heart rate monitor. 60 seconds before FBS a	Results Prevalence of acidosis pH < 7.20 6/188 (3%) [acidotic samples, not fetuses] 1. Predictive accuracy of an acceleration a. Following vibroacoustic stimulation for FBS pH > 7.20 As reported in Table II and text of paper; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 63.7% (56.75 to 70.72) Specificity: 100% (100 to 100) PPV: 100% (100 to 100) NPV: 8.33% (1.95 to 14.72) LR+: NC	Limitations Study sample represents population: unclear how many women were in preterm labour, unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
USA Aim of the study To examine the relationship between vibratory acoustic stimulation, direct fetal scalp stimulation, and fetal scalp blood pH Study type Case-series Study dates March 1985 - March 1986 Source of funding Not reported	Exclusion Criteria Not reported		single 3-second VAS was applied over the fetal vertex with the Western Electric Model 5c electronic artificial larynx. FHR was observed for 60 seconds and FBS was performed by standard puncture technique and analysed on a Corometrics 220 pH system. FHR response to both VAS and fetal scalp stimulation was recorded and correlated with pH value obtained. An acceleration was defined as an increase in FHR above the baseline of 15bpm sustained for 15 seconds occurring within 60 seconds after either stimulation.	LR-: 0.36 (0.30 to 0.44) b. Following fetal scalp stimulation for FBS pH > 7.20 As reported in Table II and text of paper; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 43.4% (36.21 to 50.61) Specificity: 100% (100 to 100) PPV: 100 % (100 to 100) NPV: 5.5% (1.22 to 9.79) LR+: NC LR-: 0.57 (0.50 to 0.64) 2. Predictive accuracy of no acceleration a. Following vibroacoustic stimulation for FBS pH < 7.20 All values calculated by NCC using data presented in Table II Sensitivity:100% (100 to 100) Specificity: 63.74% (56.75 to 70.72) PPV: 8.33% (1.95 to 14.72) NPV: 100% (100 to 100) LR+: 2.76 (2.27 to 3.24) LR-: 0 (NC) b. Following fetal scalp stimulation for FBS pH < 7.20	blinded to outcome; Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk Other information Responses to both VAS and fetal scalp stimulation were recorded in 188 instances in 127 women Authors' definition of positive stimulation test: acceleration Authors' definition of positive fetal scalp

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				All values calculated by NCC using data presented in Table II Sensitivity: 100% (100 to 100) Specificity: 43.41% (36.21 to 50.61) PPV: 5.5% (1.22 to 9.79) NPV: 100% (100 to 100) LR+: 1.77 (1.56 to 2.01) LR-: 0 (NC) FBS pH Reference Test +ve / Reference Test -ve Predictive Test +ve: 116 / 0 Predictive Test -ve: 66 / 6 FBS pH Reference Test +ve / Reference Test -ve Predictive Test: 79 / 0	test: no acidosis pH > 7.20 First set of predictive accuracy results in evidence table are as reported in the study Second set of predictive accuracy results were calculated by NCC with a recalculated 2x2 table using a definition of positive stimulation test being no acceleration and definition of positive fetal scalp test of acidosis pH < 7.20, in line with other studies included in this review.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

+ve

Predictive Test -ve	103	6

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	6	66
Predictive Test -ve	0	116

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	6	103
Predictive Test -	0	79

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				ve	
Full citation Elimian,A., Figueroa,R., Tejani,N., Intrapartum assessment of fetal well-being: a comparison of scalp stimulation with scalp blood pH sampling, Obstetrics and Gynecology, 89, 373-376, 1997 Ref Id 201856 Country/ies where the study was carried out USA Aim of the study To determine if and to what extent the need for scalp pH sampling is decreased by the scalp stimulation test and whether redefinition of reactivity and presence of fetal heart rate (FHR) variability preceding	Sample size N = 108 Characteristics Mean gestational age 39.2 ± 1.7 weeks Mean birthweight 3240 ± 579 g Mean maternal age 24.2 ± 5.9 years Nulliparous 73/108 (68%) Indications for FBS* Moderate to severe variable decelerations = 84/108 (78%) Late decelerations = 12/108 (11%) Baseline tachycardia = 5/108 (5%) Baseline bradycardia = 3/108 (3%)	Tests 15 seconds of gentle digital fetal scalp stimulation	Methods 108 consecutive women were enterted prospectively in to the study. The decision to perform fetal scalp blood sampling (FBS) was made by the attending senior resident in the labour and delivery suite after review of the woman's clinical course and FHR trace. 15 seconds of digital fetal scalp stimulation was performed through the dilated cervix, followed 1 to 2 minutes later by FBS in the usual manner. Each FHR trace was marked at the time of both stimulations and judged to be reactive or non-reactive in response to both digital stimulation and scalp puncture. Reactive response	Results Prevalence of acidosis pH < 7.20 15/108 (14%) Predictive value of no acceleration following digital fetal scalp stimulation (FSS) (first FSS intervention) for fetal blood sample pH < 7.20 All values calculated by NCC from data in Table 1 (corresponds to sensitivity, specificity, PPV reported in text of paper) Sensitivity: 100% (100 to 100) Specificity: 54.84% (44.72 to 64.95) PPV: 26.32% (14.88 to 37.75) NPV: 100% (100 to 100) LR+: 2.21 (1.77 to 2.77) LR-: 0 (NC) Predictive value of no acceleration following scalp puncture (second FSS intervention) for fetal blood sample pH < 7.20 Calculated by NCC from data in Table 1 (corresponds to sensitivity, specificity, PPV reported in text of paper)	Limitations Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome; period of FHR observation for qualifying acceleration following stimulus not reported Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between stimulation, FBS and delivery not reported Statistical analysis is appropriate for study

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>scalp stimulation further decreased the need for fetal scalp blood sampling

Study type
Case-series
Study dates
January - September 1995

Source of funding
Not reported</td>
<td>Decreased variability = 4/108 (4%)

*percentage calculated by NCC-WCH, do not add up to 100% due to rounding up

Inclusion Criteria
FHR patterns, recorded by fetal scalp electrode, suggestive of possible acidosis

Exclusion Criteria
1] HIV positive or positive for hepatitis B surface antigen
2] Herpes virus lesions
3] Women in whom scalp was inaccessible for sampling</td>
<td></td>
<td>defined as an acceleration of 15 bpm lasting at least 15 seconds. FHR reaction was then correlated with scalp blood pH values (using 220 pH system, Corometrics Medical Systems, Wallingford, CT, USA). Fetal acidosis defind as scalp pH < 7.20</td>
<td>Sensitivity: 100% (100 to 100)
Specificity: 53.76% (43.63 to 63.9)
PPV: 25.86% (14.59 to 27.13)
NPV: 100% (100 to 100)
LR+: 2.16 (1.73 to 2.69)
LR-: 0 (NC)

FBS pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>15</td><td>42</td></tr>
<tr><td>Predictive Test -ve</td><td>0</td><td>51</td></tr>
</table>
FBS pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>15</td><td>43</td></tr>
<tr><td>Predictive Test -</td><td>0</td><td>50</td></tr>
</table>
</td>
<td>design: yes

Indirectness: 5% of women were in pre-term labour (34-36 weeks); unclear whether any women were considered high risk

Other information
Authors' definition of positive stimulation test: no acceleration.

5/108 (4.6%) had a gestational age of 34-36 weeks.

Where there was more than one FBS only the last sample was used for analysis.

Variability of FHR was performed before scalp stimulation and confirmed by two of the authors blinded to scalp pH results - it is</td>
</tr>
</table>

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td><table><tr><td>ve</td><td></td><td></td></tr></table></td><td>unclear whether FHR response (reactive or non-reactive) to stimulation was also assessed blindly.</td></tr>
<tr><td>Full citation
Ingemarsson,I., Arulkumaran,S., Reactive fetal heart rate response to vibroacoustic stimulation in fetuses with low scalp blood pH, British Journal of Obstetrics and Gynaecology, 96, 562-565, 1989
Ref Id
202006
Country/ies where the study was carried out
Unclear
Aim of the study
To describe fetal heart rate responses to vibroacoustic stimulation of the fetus in labour</td><td>Sample size
N = 33

Characteristics
Not reported

Inclusion Criteria
Women undergoing fetal blood sampling because of suspicious or ominous fetal heart rate (FHR) traces in the first stage of labour

Exclusion Criteria
Not reported</td><td>Tests
5 seconds of fetal vibroacoustic stimulation (VAS)</td><td>Methods
Women between 35 and 42 gestational weeks received fetal blood sampling (FBS).
Before FBS a model 5C electronic artifical larynx (Western Electric, Bell Telephone) was applied to the maternal abdomen in the region of the fetal head for 5 seconds. A response was defined as reactive if the FHR showed an acceleration of 15 bpm for 15 seconds immediately after the sound stimulation.
FBS was taken by one of the authors within 20 minutes of sound stimulation with the woman in the left lateral</td><td>Results
Prevalence of acidosis pH <7.20
4/51 (8%)

Predictive accuracy of no acceleration following VAS
a. For FBS pH <7.20
All values calculated by NCC using data presented in Table 1 and 2
Sensitivity: 50% (1 to 99)
Specificity: 68.97% (52.13 to 85.80)
PPV: 18.18% (0 to 40.97)
NPV: 90.91% (78.90 to 100)
LR+: 1.61 (0.53 to 4.94)
LR-: 0.73 (0.26 to 1.99)

FBS pH<table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictiv</td><td>2</td><td>9</td></tr></table></td><td>Limitations
Study sample represents population: unclear, characteristics not reported; unclear whether consecutive women were included
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: time between stimulation, FBS and delivery not</td></tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Study type Case-series Study dates Not reported Source of funding Not reported			position. Cord artery blood was taken at caesarean section in 15 women when FBS was not possible due to high head and inadequate dilatation of the cervix. Acidosis was defined as pH < 7.20 Suspicious or omnious FHR traces showed late decelerations (intermittently or repeatedly), pronounced variable decelerations (depth > 60 bpm or lasting for > 60 seconds or both), tachycardia with late or variable decelerations, or reduced variability (< 5 bpm lasting for > 60 min) indicative of possible fetal acidosis	<table><tr><td>e Test +ve</td><td></td><td></td></tr><tr><td>Predictive Test -ve</td><td>2</td><td>20</td></tr></table>	reported Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk Other information Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics). 51 women were recruited in to the study but data for both stimulation test plus FBS test only reported for 33 women. Individual data are reported for 11 fetuses with no FHR response

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					to VAS and and no FHR response to FBS (the scalp puncture acting as the stimulus). These data were used to caclulate predictive accuracy statistics for VAS (FBS pH < 7.20). Results were the same for FBS and so predictive accuracy statistics for FBS (FBS pH < 7.20) were not calculated.
Full citation Irion,O., Stuckelberger,P., Moutquin,J.M., Morabia,A., Extermann,P., Beguin,F., Is intrapartum vibratory acoustic stimulation a valid alternative to fetal scalp pH determination?, British Journal of Obstetrics and Gynaecology, 103, 642-647, 1996	Sample size N = 421 samples N = 253 women Characteristics Maternal age (years) - mean ± SD 28.3 ± 4.4 Gestational age (weeks) - mean ± SD 39.1 ± 1.6 Operative delivery	Tests 5 seconds of fetal vibroacoustic stimulation (VAS)	Methods All fetal scalp blood samplings (FBS) for abnormal intrapartum fetal heart rate (FHR) tracings at > 30 pregnancy weeks were consecutively included in the study. FHR abnormalities were the presence of at least one of the following: late decelrations, decreased	Results Prevalence of acidosis 31/421 (7.4%) 1. Predictive accuracy of an acceleration following VAS a. For FBS pH > 7.20 As reported in Table 3 of paper Sensitivity: 52% (47 to 57) Specificity: 77% (63 to 92) PPV: 97% (94 to 99) NPV: 11% (7 to 16) LR+: 2.29 (1.19 to 4.43) LR-: 0.62 (0.50 to 0.77)	Limitations Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Ref Id 201885 Country/ies where the study was carried out Switzerland Aim of the study To determine the validity of fetal heart rate accelerations, either spontaneous or induced by vibratory acoustic stimulation, as an indicator of fetal wellbeing according to subsequent scalp pH values Study type Case-series Study dates Over a 15 month period (dates not reported) Source of funding Not reported	for fetal distress 106/253 (42%) Forceps or vacuum extractor = 75/253 (30%) Caesarean section = 30/253 (12%) [one operative delivery not accounted for in text of study] Inclusion Criteria Abnormal intrapartum fetal heart rate tracings at > 30 weeks' pregnancy Exclusion Criteria No cases were excluded		baseline variability (beat-to-beat variability < 5 bpm for 20 min), severe variable decelerations, moderate or severe bradycardia (< 100 bpm for 3 min), tachycardia (baseline rate > 160 bpm). Every time FBS was deemed necessary, VAS was performed by applying a model 5C electronic artificial larynx (Western Electric, New York) to the maternal abdominal wall above the fetal vertex for 5 sec. FHR tracing was observed for at least 60 sec after VAS. FBS was performed by scalp puncture for pH determination within 5 min. Reactivity was defined as FHR acceleration of at least 15 bpm above the baseline level, lasting for at least 15 sec. Tracings	b. For FBS pH > 7.25 As reported in Table 3 of paper Sensitivity: 56% (51 to 62) Specificity: 65% (57 to 74) PPV: 78% (73 to 84) NPV: 40% (33 to 47) LR+: 1.63 (1.26 to 2.11) LR-: 0.67 (056 to 0.80) 2. Predictive accuracy of no acceleration following VAS a. For FBS pH < 7.20 All values calculated by NCC using data presented in Table 2 Sensitivity: 77.42% (62.70 to 92.14) Specificity: 51.54% (46.58 to 56.50) PPV: 11.27% (7.02 to 15.51) NPV: 96.63% (94.18 to 99.09) LR+: 1.60 (1.29 to 1.98) LR-: 0.44 (0.23 to 0.85) b. For FBS pH < 7.25 All values calculated by NCC using data presented in Table 2 Sensitivity: 65.38% (57.21 to 73.56) Specificity: 56.01% (50.31 to	confounders are accounted for: time between FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: unclear how many women were in preterm labour, unclear whether any women were considered high risk Other information Responses to both VAS and fetal scalp stimulation were recorded in 421 instances in 253 consecutive women Authors' definition of positive stimulation test: acceleration Authors' definition of positive fetal scalp test: no acidosis pH > 7.20

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td>were blindly assessed by one author for the presence of VAS-induced reactivity prior to FBS.</td><td>61.72)
PPV: 39.91% (33.33 to 46.48)
NPV: 78.37% (72.77 to 83.96)
LR+: 1.49 (1.24 to 1.78)
LR-: 0.62 (0.48 to 0.80)

FBS pH
<table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>201</td><td>7</td></tr><tr><td>Predictive Test -ve</td><td>189</td><td>24</td></tr></table>
FBS pH
<table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>163</td><td>45</td></tr></table></td><td>First set of predictive accuracy results in evidence table are as reported in the study Second set of predictive accuracy results were calculated by NCC with a recalculated 2x2 table using a definition of positive stimulation test being no acceleration and definition of positive fetal scalp test of acidosis pH < 7.20, in line with other studies included in this review.</td></tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Predictive Test -ve: 128, 85 FBS pH (Reference Test +ve / Reference Test -ve) Predictive Test +ve: 24, 189 Predictive Test -ve: 7, 201 FBS pH (Reference Test +ve / Reference Test -ve) Predictive Test +ve: 85, 128 Predictive Test -ve: 45, 163	
Full citation	Sample size	Tests	Methods	Results	Limitations

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>Lazebnik,N., Neuman,M.R., Lysikiewicz,A., Dierker,L.R., Mann,L.I., Response of fetal heart rate to scalp stimulation related to fetal acid-base status, American Journal of Perinatology, 9, 228-232, 1992
Ref Id
202013
Country/ies where the study was carried out
USA
Aim of the study
To determine whether fetal scalp stimulation during active labour results in a fetal heart response, and whether the magnitude and direction of any change is related to fetal acid-base status

Study type
Case-series
Study dates</td>
<td>N = 104

Characteristics
Not reported

Inclusion Criteria
Not reported

Exclusion Criteria
Not reported</td>
<td>The incision of fetal scalp blood sampling (FBS) served as fetal scalp stimulation</td>
<td>Term fetuses during labour were studied by scalp pH. All fetuses were monitored by an internal scalp electrode and intrauterine pressure catheter. The timing of stimulation was marked on fetal heart tracings.

Recordings of fetal heart rate (FHR) were digitised by tracing the curves on a digitising tablet (Houston Instruments DT-114). Data were then run through a computer program that sampled it every 0.5 seconds. The FHR was recorded, digitised and sampled for 15 to 25 minutes before and after FBS. The 5 minutes immediately preceding FBS were omitted from the analysis. FHR was averaged for 5 minutes before the beginning of preparations for the FBS procedure and over 1 minute</td>
<td>Prevalence of acidosis pH <7.20
15/104 (14%)

Predictive value of mean change in heart rate < 15bpm following fetal scalp stimulation for fetal blood sample pH < 7.20
As reported in Table 4 of paper; NCC calculated confidence intervals, LR+ and LR-
Sensitivity: 73% (50.95 to 95.71)
Specificity: 17% (9.08 to 24.63)
PPV: 13% (5.81 to 20.08)
NPV: 79% (60.62 to 97.28)
LR+: 0.88 (0.64 to 1.21)
LR-: 1.58 (0.61 to 4.12)

FBS pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>11</td><td>74</td></tr>
<tr><td>Predictive Test -ve</td><td>4</td><td>15</td></tr>
</table>
</td>
<td>Study sample represents population: unclear whether consecutive women were included
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: yes
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: time between FBS and delivery was recorded but not reported
Statistical analysis is appropriate for study design: yes

Indirectness of outcome: standard definition of acceleration not used; net difference in heart rate of more than 15</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Not reported Source of funding Not reported			immediately following FBS to obtain pre- and post-stimulation mean heart rates. The effect of fetal scalp stimulation was examined by setting the time of scalp incision at zero and determining the FHR at 0.5 second intervals before and after the scalp incision from the digitised heart rate recordings. Subjects were divided in to three groups according FBS pH and mean and standard error of the heart rate for each group was determined for each 0.5 second sample point. These values were then plotted as a function of time for each group.		bpm was applied; population and inclusion and exclusion criteria not sufficiently reported to assess indirectness of population Other information Authors' definition of positive stimulation test: mean increase in FHR <15 bpm. Some fetuses underwent more than one scalp blood sampling; only the first sampling was used to avoid the effect of habituation. All fetuses with FBS pH < 7.20 were tested at delivery for acidosis by cord blood gas analysis.
Full citation Lin,C.C., Vassallo,B.,	Sample size N = 113	Tests 3 seconds of	Methods 3-seconds of VAS using	Results Prevalence of acidosis	Limitations Study sample

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Mittendorf,R., Is intrapartum vibroacoustic stimulation an effective predictor of fetal acidosis?, Journal of Perinatal Medicine, 29, 506-512, 2001 Ref Id 201886 Country/ies where the study was carried out USA Aim of the study The hypothesis is that intrapartum vibroacoustic stimulation is an effective predictor of fetal acidosis during labour Study type Case-series Study dates 1 July 1995 - 30 April 1997 Source of funding	Characteristics Stage of labour First stage = 53 Second stage = 60 Gestational age Term (≥ 37 weeks) = 94 Pre-term (≥ 34, < 37 weeks) = 13 Very pre-term (< 34 weeks) = 6 Inclusion Criteria Singleton gestations in active phase of first or second stage of labour and exhibiting abnormal fetal heart rate (FHR) patterns (moderate to severe variable decelerations or late decelerations, with or without baseline tachycardia or significantly decreased baseline	fetal vibroacoustic stimulation (VAS)	an artificial larynx (model 5E, AT&T, Van Nuys, CA, USA) was applied to the maternal abdomen directly over the fetal head. For women in the second stage of labour VAS was applied to the suprapubic area, or if the fetal head was at plus two station or lower, directly to the fetal head on parietal or occiput area with a sterile latex glove covered VAS applicator. FHR response was monitored; a positive response was defined as 15bpm acceleration above baseline for a duration ≥ 15 seconds. No response or a deceleration after VAS suggested an acidotic fetus. A biphasic repsonse, defined as an acceleration followed by a deceleration was considered equivocal.	31/113 (27%) Predictive value of no acceleration following VAS a. For fetal blood sample pH < 7.20 Values as reported in Table II; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 39% (21.56 to 55.86) Specificity: 93% (87.05 to 98.32) PPV: 67% (44.89 to 88.44) NPV: 80% (71.96 to 88.04) LR+: 5.29 (2.18 to 12.86) LR-: 0.66 (0.50 to 0.88) b. For Apgar score < 7 at 5 minutes Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 100% (100 to 100) Specificity: 86% (79.95 to 92.78) PPV: 17% (0 to 33.88) NPV: 100% (100 to 100) LR+: 7.33 (4.58 to 11.74) LR-: 0 (NC) c. For NICU admission Values as reported in Table V;	represents population: unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcom; period of FHR observation for qualifying acceleration following stimulus was not reported Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between FBS and delivery for women in first stage of labour unclear Statistical analysis is appropriate for study design: yes

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Not reported	variability). Women with known medical or obstetric complications, such as diabetes, hypertension, preeclampsia or fetal growth restriction were included. Exclusion Criteria Multiple gestation, congenital fetal malformations, gestational age < 28 weeks and administration of narcotic analgesia to the mother within the last 3 hours		Scalp blood was obtained immediately following VAS testing during the first stage of labour. During the second stage of labour, one or several VAS testings were performed, so that the time intervals between the last VAS testing and the delivery of the fetus were within 15 minutes. Umbilical blood sample was obtained at delivery for fetal blood pH and blood gas analysis in every case by a Corometric 220 pH System (Wallingford, CT). The decision to perform fetal scalp blood sampling or caeserean section was made by the attending physician or senior resident assessing the FHR tracing and reviewing the clinical course.	NCC calculated LR+, LR- and all confidence intervals Sensitivity: 55% (33.20 to 76.80) Specificity: 92% (87.11 to 97.84) PPV: 61% (38.59 to 83.63) NPV: 91% (84.64 to 96.42) LR+: 7.31 (3.23 to 16.51) LR-: 0.49 (0.30 to 0.79) d. For neonatal morbidity Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 71% (37.96 to 105) Specificity: 88% (81.49 to 93.98) PPV: 28% (7.09 to 48.47) NPV: 98% (95.01 to 101) LR+: 5.82 (2.91 to 11.63) LR-: 0.33 (0.10 to 1.05) FBS pH <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>12</td><td>6</td></tr><tr><td>Predictive Test -</td><td>19</td><td>76</td></tr></table>	Indirectness of population: 17% of women were in pre-term labour; high risk women were included (numbers not reported) Other information While authors state a positive stimulation test was FHR acceleration, statistics reported are for no acceleration predicting acidosis (< 7.20). Authors' definition of positive stimulation test: no acceleration. When more than one fetal blood pH value was obtained, only the last one was used for analysis.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

ve | | |

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	3	15
Predictive Test -ve	0	95

NICU admission

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	11	7
Predictive Test -ve	9	86

Neonatal morbidity

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				<table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>5</td><td>13</td></tr><tr><td>Predictive Test -ve</td><td>2</td><td>93</td></tr></table>	
Full citation Polzin,G.B., Blakemore,K.J., Petrie,R.H., Amon,E., Fetal vibro-acoustic stimulation: magnitude and duration of fetal heart rate accelerations as a marker of fetal health, Obstetrics and Gynecology, 72, 621-626, 1988 Ref Id 201800 Country/ies where the study was carried out USA Aim of the study To evaluate whether	Sample size N = 100 Characteristics Gestational age (weeks) - mean ± SD, N 15 bpm x 15 sec acceleration = 39.4 ± 1.9, 57 10 bpm x 10 sec acceleration = 39.1 ± 2.5, 20 No acceleration = 38.3 ± 3.1, 23 Birth weight (g) - mean ±SD, N 15 bpm x 15 sec	Tests 5 seconds of continuous fetal vibroacoustic stimulation (VAS)	Methods Over a period of 20 months, when one of the study authors was available, 100 women were studied using the standard indications for fetal scalp blood sampling (FBS; late, moderate or severe variable fetal heart rate (FHR) decelerations, fetal tachycardia or bradycardia, or poor FHR variability longer than 30 minutes). Immediately before FBS, VAS was performed using a Model 5C electronic artificial larynx (AT&T	Results Prevalence of acidosis < 7.20 10/100 (10%) Predictive value of no acceleration following VAS a. For fetal blood sample pH < 7.20 All values calculated by NCC from data presented in Table 4 (see Other information) Sensitivity: 90% (71.41 to 100) Specificity: 84.44% (76.96 to 91.93) PPV: 39.13% (19.88 to 59.08) NPV: 98.70 % (96.17 to 100) LR+: 5.79 (3.43 to 9.77) LR-: 0.11 (0.02 to 0.76)	Limitations Study sample represents population: not consecutive (women only included when one of the study authors was available) Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome Outcome of interest is sufficiently measured in participants: yes

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
there are significant differences in the intrapartum fetal acid-base status according to the magnitude and duration of fetal heart rate accelerations in response to fetal vibroacoustic stimulation. The predictive value of these responses in the detection of the acidotic versus non-acidotic fetus during labour was also examined. Study type Case-series Study dates Over a 20 month period (dates not reported) Source of funding Not reported	acceleration = 3289 ± 527, 57 10 bpm x 10 sec acceleration = 3043 ± 588, 20 No acceleration = 2703 ± 909, 23 Inclusion Criteria Active phase of labour, singleton gestation, vertex presentation Exclusion Criteria Not reported		Consumer Products, USA), which produced a mixed-frequency sound of 81 Hz and 81 db at 1 m in air. A single stimulus was applied continuously for 5 seconds to the maternal abdomen one-third of the distance from the symphysis pubis to the umbilicus. FHR accelerations, if they occurred, began within 20 seconds of the stimulus. FHR responses were classified in to three groups: FHR acceleration of ≥ 15 bpm lasting ≥ 15 seconds, 10-15 bpm lasting 10-15 seconds, or no acceleration. FBS was performed immediately after VAS, usually in the left lateral position. Mean pH values were derived from logarithmic tables.	b. For fetal blood sample pH < 7.25 All values calculated by NCC from data presented in Table 4 (see Other information) Sensitivity: 45.45% (24.65 to 66.26) Specificity: 83.33% (75.06 to 91.60) PPV: 43.48% (23.22 to 63.74) NPV: 84.41% (76.31 to 92.52) LR+: 2.73 (1.39 to 5.36) LR-: 0.65 (0.44 to 0.97) c. For Apgar score < 7 at 5 minutes All values calculated by NCC from data presented in Table 2 Sensitivity: 50% (9.99 to 90.01) Specificity: 57.45% (47.45 to 67.44) PPV: 6.98% (1 to 14.59) NPV: 94.74% (88.94 to 100) LR+: 1.18 (0.51 to 2.71) LR-: 0.87 (0.38 to 1.97) FBS pH <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr></table>	Important potential confounders are accounted for: time between FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: based on gestational age mean and SD for 'no acceleration' population not all fetuses were delivered at term; unclear whether any women were considered high risk Other information Authors' definition of positive stimulation test: no acceleration. Predictive accuracy statistics presented in Table 3 of study report do not account for the full study population -

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

Predictive Test +ve	9	14
Predictive Test -ve	1	76

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	10	13
Predictive Test -ve	12	65

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	3	40

data for 10bpm x 10sec population not included with the no acceleration population. Therefore, data extracted for full study population from Table 4 and all statistics calculated by NCC.

For the 2x2 table no acceleration and FHR acceleration ≥ 10 bpm and 10 sec but < 15 bpm and 15 sec were considered a positive stimulation test result.

In nearly all cases FHR was recorded by internal scalp electrode.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Predictive Test -ve: 3 / 54	
Full citation Sarno,A.P., Ahn,M.O., Phelan,J.P., Paul,R.H., Fetal acoustic stimulation in the early intrapartum period as a predictor of subsequent fetal condition, American Journal of Obstetrics and Gynecology, 162, 762-767, 1990 Ref Id 201730 Country/ies where the study was carried out USA Aim of the study To evaluate the usefulness of fetal acoustic stimulation in the early intrapartum period as a predictor of subsequent fetal condition	Sample size N = 201 Characteristics Maternal age (years) - mean ± SD 25.9 ± 5.5 Nulliparous 74/201 (37%) Gestational age (weeks) - mean ± SD 40.1 ± 2.2 Duration of ruptured membranes (hours) - mean ± SD 14.2 ± 17.0 Duration of labour (hours) - mean ± SD 17.4 ± 8.5 Inclusion Criteria	Tests 3 seconds of fetal vibroacoustic stimulation (VAS)	Methods Consecutive women who met inclusion criteria were included over the study period, during periods of availability of the first author. Following admission electronic fetal monitoring was instituted. A 40-min baseline fetal heart rate (FHR) monitor tracing was obtained, then VAS was performed using a fetal acoustic stimulator (Corometrics model 146, Wallingford, CT, USA), sound level 82 dB at 1 m in air. The acoustic stimulator was placed on the maternal abdomen over the fetal vertex and a 3-second pulse of stimulation applied. If no acceleration of FHR was noted within 1 min an	Results Predictive value of no acceleration following VAS a. For Apgar score < 7 at 1 minute Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 24.1% (8.56 to 39.71) Specificity: 95.9% (92.98 to 98.88) PPV: 50% (23.81 to 76.19) NPV: 88.2% (83.62 to 92.85) LR+: 5.93 (2.25 to 15.66) LR-: 0.79 (0.64 to 0.97) b. For Apgar score < 7 at 5 minutes Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 33.3% (0 to 71.05) Specificity: 93.8% (90.47 to 97.22) PPV: 14.3% (0 to 32.62) NPV: 97.9% (95.79 to 99.93) LR+: 5.42 (1.54 to 19.05) LR-: 0.71 (0.40 to 1.25)	Limitations Study sample represents population: included women who were considered high risk Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential cofounders are accounted for: time between VAS and delivery not reported Statistical analysis is appropriate for study: yes Indirectness of population: 118/201 (59%) had one or

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>Study type
Case-series
Study dates
1 August 1987 - 1 November 1987

Source of funding
Not reported</td>
<td>Gestational age ≥ 37 weeks, singleton fetus, vertex presentation, latent phase of labour (cervical dilatation ≤ 4 cm)

Exclusion Criteria
Not reported</td>
<td></td>
<td>additional pulse was administered to a maximum of three pulses, each 1 minute apart.

A reactive response was defined as one or more accelerations of the FHR 15 bpm from baseline, persisting for 15 seconds. A non-reactive response was defined as failure to elicit a qualifying acceleration after any of three separate stimuli and for 10 minutes after the last stimulus.

Care was taken not to perform acoustic stimulation during or immediately after a uterine contraction to avoid periods of transient fetal hypoxia and for standardisation of the technique.

The result of stimulation was blinded from the</td>
<td>c. For caesarean delivery for fetal distress
Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals
Sensitivity: 31.2% (8.54 to 53.96)
Specificity: 95.1% (92.04 to 98.24)
PPV: 35.7% (10.61 to 60.81)
NPV: 94.1% (90.75 to 97.49)
LR+: 6.42 (2.44 to 16.89)
LR-: 0.72 (0.52 to 1.01)

Apgar score
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>7</td><td>7</td></tr>
<tr><td>Predictive Test -ve</td><td>22</td><td>165</td></tr>
</table>
Apgar score
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
</table>
</td>
<td>more complications of pregnancy [complications not reported]

Other information
Authors' definition of positive stimulation test: no acceleration.</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			physcians who managed the woman's labour. All FHR tracings were read by a single examiner without knowledge of the prior fetal acoustic stimulation results. Outcome was assessed by incidences of meconium staining, fetal distress requiring caesarean delivery, Apgar scores < 7 at 1 and 5 minutes, subsequent abnormal FHR patterns and perinatal mortality.	<table><tr><td>Predictive Test +ve</td><td>2</td><td>12</td></tr><tr><td>Predictive Test -ve</td><td>4</td><td>183</td></tr></table> Caesarean section <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>5</td><td>9</td></tr><tr><td>Predictive Test -ve</td><td>11</td><td>176</td></tr></table>	
Full citation Smith,C.V., Nguyen,H.N., Phelan,J.P., Paul,R.H., Intrapartum assessment of fetal well-being: a comparison of fetal acoustic stimulation with acid-base	Sample size N = 64 Characteristics FHR abnormality indicating need for fetal blood sampling Intermittent late decelerations = 20/64 (31%)	Tests ≤ 3 seconds of fetal vibroacoustic stimulation (VAS)	Methods Immediately before fetal blood sampling (FBS) with the woman in the dorsal lithotomy position, transabdominal acoustic stimulation of the fetus was accomplished by a Model 5C electronic artificial larynx (Western	Results Prevalence of acidosis pH < 7.25 18/64 (28%) Predictive value of no acceleration following VAS for fetal blood sample pH < 7.25 All values calculated by NCC from data in Table II Sensitivity: 100% (100 to 100)	Limitations Study sample represents population: unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>determinations, American Journal of Obstetrics and Gynecology, 155, 726-728, 1986
Ref Id
201855
Country/ies where the study was carried out
USA
Aim of the study
To compare acoustically evoked accelerations of the fetal heart rate (FHR) with fetal acid-base status

Study type
Prospective cohort study
Study dates
Not reported

Source of funding
Not reported</td>
<td>Severe variable decelerations = 14/64 (22%)
Absent variability = 12/64 (19%)
Tachycardia = 11/64 (17%)
Repetitive late decelerations = 7/64 (11%)

Inclusion Criteria
Women with FHR tracings sufficiently abnormal to merit either fetal blood sampling (FBS) or immediate caesarean delivery for fetal distress

Exclusion Criteria
Not reported</td>
<td></td>
<td>Electric). The artificial larynx produces a vibratory acoustic stimulus of approximately 80 Hz and 82 dB, measured at 1 m in air. The stimulus was applied overlying the fetal vertex for ≤ 3 seconds. The response was termed reactive if an immediate acceleration of 15 bpm and 15 seconds was evident. If a qualifying acceleration was not present, the stimulus was repeated at 1-minute intervals for a maximum of three times. Fetal scalp sampling was then accomplished by existing protocol.

In 15 cases where scalp sampling was not possible immediate cesearean delivery was performed. In all cases the fetus was delivered within 15 minutes of the stimulus. The arithmetic</td>
<td>Specificity: 65.22% (51.45 to 78.98)
PPV: 52.94% (36.16 to 69.72)
NPV: 100% (100 to 100)
LR+: 2.88 (1.94 to 4.27)
LR-: 0 (NC)

FBS pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>18</td><td>16</td></tr>
<tr><td>Predictive Test -ve</td><td>0</td><td>30</td></tr>
</table>
</td>
<td>Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome
Outcome of interest is sufficiently measured in participants: yes
Important potential cofounders are accounted for: length of stimulation not standardised (≤ 3 seconds); time between VAS and deliveries that were not caesarean births not reported
Statistical analysis is appropriate for study: yes
Indirectness: unclear whether any women were considered high risk</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			mean of the umbilical arterial and venous pH determinations was calculated.		Other information Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics). Five fetuses that failed to respond to VAS did respond to the stimulus of FBS scalp puncture (data for scalp puncture not sufficiently reported to construct 2x2 table).
Full citation Spencer,J.A., Predictive value of a fetal heart rate acceleration at the time of fetal blood sampling in labour, Journal of Perinatal Medicine, 19, 207-215, 1991 Ref Id	Sample size N = 138 Characteristics Gestation ≥ 37 weeks 133/138 (96%) Nulliparous	Tests The incision of fetal scalp blood sampling served as fetal scalp stimulation	Methods Data were collected from all cases that required intrapartum fetal scalp blood sampling (FBS) due to concerns regarding the CTG during 1 year at the John Radcliffe Maternity Hospital, Oxford.	Results Prevalence of acidosis < 7.20 6/138 (4%) 1. Predictive value of an acceleration following fetal scalp stimulation a. For fetal blood sample pH ≥ 7.20 As reported in Table V; NCC	Limitations Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
196967 Country/ies where the study was carried out UK Aim of the study To present the results of a 1-year audit of all cases requiring fetal scalp blood sampling during labour at a major teaching hospital, with particular emphasis on the relationship between the fetal heart rate reaction at the time of fetal scalp blood sampling and the fetal scalp pH Study type Case-series Study dates Not reported Source of funding Not reported	110/138 (80%) Mode of delivery Normal vaginal delivery = 38/138 (27%) Operative vaginal delivery = 60/138 (43%) Caesarean section = 40/138 (30%) Inclusion Criteria Not reported Exclusion Criteria Not reported		Fetal heart rate (FHR) records were derived from the fetal electrocardiogram using a spiral electrode and an HP 8040 fetal monitor (Hewlett Packard, Uxbridge, UK). FHR reaction to FBS was noted to be either an acceleration (transient rise above baseline of more than 15 bpm for longer than 15 seconds), no response or a deceleration (transient fall below baseline of more than 15 bpm for longer than 15 seconds). Fetal scalp blood was collected into heparinised capillary tubes for immediate blood gas analysis using an ABL 3 (Radiometer, Copenhagen). Fetal pH was related to the FHR before the FBS and to the FHR reaction at the time.	calculated LR+, LR- and all confidence intervals Sensitivity: 52.3% (43.75 to 60.79) Specificity: 100% (100 to 100) PPV: 100% (100 to 100) NPV: 8.7% (2.05 to 15.34) LR+: NC LR-: 0.48 (0.40 to 0.57) b. For fetal blood sample pH ≥ 7.25 All values calculated by NCC from data in Table IV Sensitivity: 53.57% (44.33 to 62.81) Specificity: 65.38% (47.10 to 83.67) PPV: 86.96% (79.01 to 94.90) NPV: 24.64% (14.47 to 34.81) LR+: 1.55 ((0.89 to 2.70) LR-: 0.71 (0.50 to 1.00) 2. Predictive value of no acceleration following fetal scalp stimulation a. For fetal blood sample pH < 7.20 All values calculated by NCC from data in Table IV Sensitivity: 100% (100 to 100) Specificity: 52.27% (43.75 to	in participants: unclear whether assessor blinded to outcome; period of FHR observation for qualifying acceleration following stimulus was not reported Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between stimulation, FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: 96% delivered at term; unclear whether any women were considered high risk Other information Authors' definition of positive stimulation

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				60.79) PPV: 8.70% (2.05 to 15.34) NPV: 100% (100 to 100) LR+: 2.10 (1.75 to 2.50) LR-: 0 (NC) b. For fetal blood sample pH < 7.25 All values calculated by NCC from data in Table IV Sensitivity: 65.38% (47.10 to 83.67) Specificity: 53.57% (44.33 to 62.81) PPV: 24.64% (14.47 to 34.81) NPV: 86.96% (79.01 to 94.90) LR+: 1.41 (1.00 to 1.98) LR-: 0.87 (0.79 to 0.95) c. For Apgar score < 7 at 1 minute All values calculated by NCC from data in Table III Sensitivity: 54.00% (40.19 to 67.81) Specificity: 52.27% (41.84 to 62.71) PPV: 39.13% (27.61 to 50.65) NPV: 66.67% (55.54 to 77.79) LR+: 1.13 (0.81 to 1.58) LR-: 0.88 (0.61 to 1.26) d. For Apgar score < 7 at 5 minutes	test: acceleration (≥ 15 bpm above baseline for ≥ 15 seconds) Authors' definition of positive FBS pH; a. no acidosis ≥7.20; b. no acidosis ≥ 7.25 First set of predictive accuracy results in evidence table are as reported in the study. Second set of predictive accuracy results were calculated by NCC with a recalculated 2x2 table using a definition of positive stimulation test being no acceleration and definition of positive fetal scalp test of a. acidosis pH < 7.20 and b. acidosis pH < 7.25 in line with other studies included in this review. Data for Apgar score < 7 at 1 and 5 minutes was calculated from Apgar

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Calculated by NCC from data in Table III Sensitivity: 100% (100 to 100) Specificity: 50.36% (41.99 to 58.74) PPV: 1.45% (0 to 4.27%) NPV: 100% (100 to 100) LR+: 2.01 (1.70 to 2.38) LR-: 0 (NC) FBS pH Reference Test +ve / Reference Test -ve Predictive Test +ve: 69 / 0 Predictive Test -ve: 63 / 6 FBS pH Reference Test +ve / Reference Test -ve Predictive Test: 60 / 9	≥ 7 at 1 and 5 minutes reported in Table III, to be in line with other studies included in this review. Approximately 50% of labours were monitored by CTG because of perceived risk factors or the use of epidural analgesia. Only the first FBS on any single patient was included in the analysis.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

+ve		
Predictive Test -ve	52	17

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	6	63
Predictive Test -ve	0	69

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	17	52
Predictive Test -	9	60

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				ve	

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	27	42
Predictive Test -ve	23	46

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	1	68
Predictive Test -ve	0	69

Full citation	Sample size	Tests	Methods	Results	Limitations
Tannirandorn,Y., Wacharaprechanont,T.,	N = 140	3-seconds of fetal vibroacoustic	After admission to the delivery room, blood	Predictive value of no acceleration following VAS for poor perinatal	Study sample represents population:

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>Phaosavasdi,S., Fetal acoustic stimulation for rapid intrapartum assessment of fetal well-being, Journal of the Medical Association of Thailand, 76, 606-612, 1993
Ref Id
201731
Country/ies where the study was carried out
Thailand
Aim of the study
To evaluate the usefulness of fetal acoustic stimulation in the early intrapartum period as a rapid screening test to predict subsequent fetal condition

Study type
Prospective cohort study
Study dates
Not reported</td>
<td>Characteristics
Nulliparous 88/140 (63%)

Gestational age (weeks) - mean (range)
39.5 (37 - 43)

Antenatal risk factors
Post-term (≥ 42 weeks) = 14/140 (10%)
Poor weight gain = 11/140 (7.8%)
Pre-eclampsia = 9/140 (6.4%)
No antenatal care = 5/140 (3.6%)
Oligohydraminos = 1/140 (0.7%)
Others (poor obstetric history, intrauterine growth restriction, diabetes etc.) = 5/140 (3.6%)

Inclusion Criteria
Gestational age ≥ 37 weeks, cephalic</td>
<td>stimulation (VAS)</td>
<td>pressure was monitored at 10-min intervals and a tocodynamometer and Doppler FHR transducer (Sonic Aid FM 3, Oxford, UK) were applied to the abdomen and adjusted for best signal.

Fetal heart rate (FHR) and uterine contractions were recorded for 15 to 20 min. Acoustic stimulation was then performed using a fetal acoustic stimulator (Corometrics 146, CT, USA; sound level 82 dB at 1 m in air) placed on the maternal abdomen over the fetal head and a 3-sec pulse of sound stimulation was applied. If no acceleration of the FHR was noted within 30 sec an additional pulse was administered to a maximum of 3 pulses, 30 seconds apart. Care was taken not to perform acoustic stimulation</td>
<td>outcome
Values as reported in Table 4; NCC caclulcated LR+, LR- and all confidence intervals
Sensitivity: 71.4% (37.96 to 100)
Specificity: 99.2% (97.78 to 100)
PPV: 83.3% (53.51 to 100)
NPV: 98.5% (96.45 to 100)
LR+: 95 (12.75 to 707.63)
LR-: 0.29 (0.09 to 0.93)

Poor perinatal outcome
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>5</td><td>1</td></tr>
<tr><td>Predictive Test -ve</td><td>2</td><td>132</td></tr>
</table>
</td>
<td>unclear whether consecutive women were included
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: yes
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: 15-minute window for reaction to 3rd stimulus, compared with 30-sec window for reaction to 1st and 2nd stimuli; time between VAS and delivery not reported
Statistical analysis is appropriate for study design: yes
Indirectness of population: 32% of women had one or more antenatal</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Source of funding Not reported	presentation, latent phase of labour (cervical dilatation ≤ 3 cm), intact membranes Exclusion Criteria Women with spurious labour who had not been delivered within 24 hours of admission and those with twin pregnancies or known fetal abnormalities were excluded from analysis		during or immediately after uterine contractions to avoid periods of transient fetal hypoxia and for standardisation of the technique. A reactive response to VAS was defined as one or more accelerations of FHR ≥ 15 bpm from the baseline persisting for 15 seconds. A non-reactive response was defined as a failure to elicit a qualifying acceleration after any of three separate stimuli and for 15 min after the last stimulus. All VAS results were interpreted by a single examiner without knowledge of the perinatal outcome. Obstetricians managing the woman's labour were not informed of the results of VAS. Perinatal outcome was considered poor when		complication (10% had a gestational age ≥ 42 weeks) Indirectness of outcome: composite of poor perinatal outcome Other information Authors' definition of positive stimulation test: no acceleration

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			there was perinatal death, a 5-min Apgar score < 7, fetal distress requiring caesarean section, thick meconium stained amniotic fluid or admission to the neonatal intenstive care unit.		
Full citation Trochez,R.D., Sibanda,T., Sharma,R., Draycott,T., Fetal monitoring in labor: are accelerations good enough?, Journal of Maternal-Fetal and Neonatal Medicine, 18, 349-352, 2005 Ref Id 201769 Country/ies where the study was carried out UK Aim of the study To investgate whether accelerations evoked by fetal scalp stimulation from routine vaginal examination	Sample size N = 54 Characteristics Mode of delivery Spontaneous vertex = 17/54 (31%) Instrumental = 22/54 (41%) Emergency caesarean section = 15/54 (28%) Inclusion Criteria Term (> 37 weeks gestation) singleton fetuses where FBS was obtained in labour	Tests Fetal scalp stimulation during vaginal examination (method and duration of stimulation not reported)	Methods 69 fetuses were identified during the study period but information retrieval was only possible in 54 (78%), in whom 70 scalp blood sample procedures were performed. The CTG traces for all of these fetuses were reviewed by an investigator blind to the outcome. A portion of the trace starting from the point of the vaginal examination, as indicated by routine markings made on the CTG by the attending midwife, was reviewed for	Results Prevalence of acidosis ≤ 7.20 5/70 (7%) Predictive value of no acceleration fetal scalp stimulation a. For fetal blood sample pH ≤ 7.20 As reported in Table I and Table II of paper Sensitivity: 40% (7.26 to 82.96) Specificity: 69.23% (56.4 to 79.76) PPV: 9.09% (2.52 to 27.81) NPV: 93.75% (83.16 to 97.85) LR+: 1.3 (0.27 to 6.24) LR-: 0.87 (0.44 to 1.70) b. For cord pH ≤ 7.20 Calculated by NCC from data in Table III Sensitivity: 40% (-2.94 to 82.94)	Limitations Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: period of FHR observation for qualifying acceleration following stimulus not reported Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between stimulation,

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>prior to fetal blood sampling (FBS) predicted the absence of fetal acidosis at the time of the FBS

Study type
Case-series
Study dates
November 2002 - November 2003

Source of funding
Not reported</td>
<td>Exclusion Criteria
Not reported</td>
<td></td>
<td>accelerations. Accelerations were defined as an increase in fetal heart rate above the baseline of at least 15bpm for at least 15 seconds.

The position of the presenting part was determined and recorded in all cases ensuring scalp stimulation.</td>
<td>Specificity: 75.86% (60.29 to 91.44)
PPV: 22.22% (-4.94 to 49.38)
NPV: 88% (75.26 to 100)
LR+: 1.66 (0.47 to 5.80)
LR-: 0.79 (0.38 to 1.67)

c. For Apgar score < 7 at 5 minutes
Calculated by NCC from data in Table III
Sensitivity: 50% (1 to 99)
Specificity: 69.57% (56.27 to 82.86)
PPV: 12.5% (-3.71 to 28.71)
NPV: 94.12% (86.21 to 102.03)
LR+: 1.64 (0.56 to 4.80)
LR-: 0.72 (0.26 to 1.95)

FBS pH
<table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>2</td><td>20</td></tr></table></td>
<td>FBS and delivery reported only for acidotic babies, not whole study population
Statistical analysis is appropriate for study design: yes

Indirectness: unclear whether any women were considered high risk

Other information
Authors' definition of positive stimulation test: no acceleration

43/54 (80%) had one scalp sampling, 6/54 (11%) had two and 5/54 (9%) had 3, giving a total of 70 FBS procedures.

48/54 (89%) of women were in the first stage of labour with</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Predictive Test -ve: 3 / 45 Cord pH Predictive Test +ve: 2 / 7 Predictive Test -ve: 3 / 22 Apgar score Predictive Test +ve: 2 / 14 Predictive Test -ve: 2 / 32	dilatation ranging from 5 to 9cm; 6/54 (11%) were at full dilatation. The five acidotic fetuses were all delivered within 30 minutes of scalp blood sampling; 4 by caesarean section and one by instrumental delivery. Cord pH data were not available for 16 fetuses; 7/16 had a positive FSS test result (no CTG acceleration), 9/16 had a negative FSS results (CTG acceleration)
Full citation	Sample size	Tests	Methods	Results	Limitations

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Umstad,M., Bailey,C., Permezel,M., Intrapartum fetal stimulation testing, Australian and New Zealand Journal of Obstetrics and Gynaecology, 32, 222-224, 1992 Ref Id 201865 Country/ies where the study was carried out UK Aim of the study To evaluate the usefulness of intrapartum fetal stimulation tests in routine clinical practice Study type Case-series Study dates 6-month period (dates not reported) Source of funding The Royal Women's	N = 60 Characteristics All fetuses were at least 36 weeks' gestation Inclusion Criteria Fetal heart rate (FHR) tracing significantly abnormal such that fetal scalp blood sampling (FBS) was indicated Exclusion Criteria Not reported	3 seconds of fetal vibroacoustic stimulation (VAS) followed by the incision of FBS serving as fetal scalp stimulation	Several minutes prior to FBS, a 3-second VAS was applied over the fetal head via a Corometrics Fetal Acoustic Stimulator (model 146), which generates a sound level of 82 db at 1 m in air. FBS was performed in the usual manner in either lithotomy (with appropriate tilt) or left lateral positions. A Corometrics Model 220 pH Analyzer was used to assess pH of both fetal capillary and umbilical artery blood samples. FHR traces were reported by one of the study authors who was blinded to the results of FBS, Apgar scores, mode of delivery and umbilical artery cord pH values. A reactive FHR response was defined as an acceleration ≥ 15bpm for ≥ 15 seconds occuring	Prevalence of acidosis < 7.20 8/60 (13%) Prevalence of acidosis < 7.25 23/60 (38%) Predictive value of no FHR acceleration following VAS a. For fetal blood sample pH < 7.20 As reported in Table 4; NCC calculated LR+, LR- and all confidence intervals Sensitivity:100% (100 to 100) Specificity: 59.6% (46.28 to 72.95) PPV: 27.6% (11.32 to 43.85) NPV: 100% (100 to 100) LR+: 2.48 (1.78 to 3.45) LR-: 0 (NC) b. For fetal blood sample pH < 7.25 As reported in Table 3; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 100% (100 to 100) Specificity: 83.8% (71.91 to 95.66) PPV: 79.3% (64.57 to 94.05) NPV: 100% (100 to 100) LR+: 6.17 (2.96 to 12.83)	Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: yes - assessor blinded to outcome Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk Other information Authors' definition of positive stimulation

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Hospital/3AW Clinical Research Foundation			within 60 seconds of the stimulus. Fetal scalp stimulation responses were assessed by determining the reaction to fetal scalp puncture with the guarded scalpel blade during FBS.	LR-: 0 (NC) Predictive value of no FHR acceleration following fetal scalp stimulation (scalp puncture) c. For fetal blood sample pH < 7.20 As reported in Table 6 NCC calculated LR+, LR- and all confidence intervals Sensitivity: 62.5% (28.95 to 96.05) Specificity: 67.3% (54.56 to 80.06) PPV: 22.7% (5.22 to 40.24) NPV: 92.1% (83.53 to 101) LR+: 1.91 (0.98 to 3.71) LR-: 0.56 (0.22 to 1.39) d. For fetal blood sample pH < 7.25 As reported in Table 5 NCC calculated LR+, LR- and all confidence intervals Sensitivity: 82.6% (67.12 to 98.10) Specificity: 91.9% (83.10 to 100) PPV: 86.4% (72.02 to 100) NPV: 89.5% (79.72 to 99.23) LR+: 10.19 (3.39 to 30.63) LR-: 0.19 (0.08 to 0.46) FBS pH	test: no acceleration. Results of fetal stimulation tests were not used in the obstetric management of the women.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	8	21
Predictive Test -ve	0	31

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	23	6
Predictive Test -ve	0	31

FBS pH

	Reference Test +ve	Reference Test -ve

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Predictive Test +ve: 5 / 17 Predictive Test -ve: 3 / 35 FBS pH Reference Test +ve / Reference Test -ve Predictive Test +ve: 19 / 3 Predictive Test -ve: 4 / 34	

1.1.12 Does the use of fetal blood sampling as an adjunct to electronic fetal monitoring (EFM) improve outcomes, when compared to a) EFM alone; b) EFM plus ECG (including ST analysis)?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation	Sample size	Interventions	Details	Results	Limitations
Alfirevic,Z., Devane,D.,	Total number of studies	Intervention:	Electronic searches	Thirteen studies are	Attrition bias

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Gyte,G.M., Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. [55 refs]Updated, Cochrane Database of Systematic Reviews, 5, CD006066-, 2013 Ref Id 65685 Country/ies where the study was carried out Various Study type Systematic review of RCTs Aim of the study To evaluate the effectiveness and safety of continuous cardiotocography (CTG) when used as a method to monitor fetal wellbeing during labour Study dates Assessed as up-to-date ..... Included studies: Athens 1993	included n = 13 Number of study reported outcomes for CTG plus fetal blood sampling (FBS) intervention n = 8 Characteristics Athens 1993 RCT. Randomisation by tossing a coin on admission. Mothers and obstetricians not blinded; neonatologists collecting data on neonatal outcomes were blinded Population: n = 1428 Inclusion: mixed-risk, women with a singleton pregnancy at ≥ weeks' gestation admitted in spontaneous labour or for induction of labour. Exclusion: Women with known fetal congenital or chromosomal abnormalities. Intervention: Continuous CTG without FBS n = 746 Comparison: Intermittent	continuous CTG during labour Control: No fetal heart monitoring Intermittent auscultation of fetal heart rate with a Pinard or Doppler Intermittent CTG	The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by contacting the Trials Search Coordinator. CENTRAL, MEDLINE, EMBASE were searched, and hand searching of journals and conference proceedings was done. Dissertation abstracts and National Research Register was searched for accessing gray literature. No language restrictions were applied. Selection of studies Two review authors independently assessed all potential studies for inclusion. There was no disagreement regarding the eligibility for inclusion that needed to be resolved through consultation with a third person. Data extraction and management A form was designed to extract data, and two	identified and included in this systematic review but only eight (8) studies had CTG plus FBS as an intervention. Therefore outcomes related to those studies are reported here: Continuous CTG and FBS versus IA Neonatal seizures No. studies: 5 n = 15004 Continuous CTG and FBS n = 7542 IA n = 7462 RR 0.49 (95% CI 0.29 to 0.84) Cerebral palsy No. studies: 2 n = 13252 Continuous CTG and FBS n = 6609 IA n = 6643 RR 1.74 (95% CI 0.97 to 3.11) Caesarean section No. studies: 7 n = 16001 Continuous CTG and FBS n = 8027	reported by the author for the included studies Athens 1993 Attrition bias: (A) less than 3% of participants excluded. Allocation concealment: no Copenhagen 1985 Attrition bias: (B) 3% to 9.9% of participants excluded (1061 women agreed to participate; 92 excluded). Allocation concealment: unclear Dallas 1986 Attrition bias: information not available. Allocation concealment: no

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study period: October 1990 to June 1991. Copenhagen 1985 Study period: January 1981 to January 1982 (date women expected to deliver) Dallas 1986 Study period: information not available Denver 1976 Study period: information not available Denver 1979 Study period: July 1975 to July 1977 Dublin 1985 Study period: March 1981-April 1983 Lund 1994 Study period: October 1989 May 1991 Melbourne 1976 Study period: March 1974 -	auscultation (IA) n = 682 CTG: external unless trace poor when internal CTG used Copenhagen 1985 RCT. Randomisation by random sampling. Method of randomisation unclear. Population n = 969 women, high- and low-risk women, only diabetics excluded. 3 twins in CTG group and 6 twins in IA group Intervention: Continuous CTG in conjunction with FBS (CTG: external or internal) n = 482 Comparison: IA n = 487 Dallas 1986 Quasi RCT. Randomisation by alternate months; selective monitoring (policy of using monitoring only in high-risk pregnancies) versus		authors extracted them. It was analysed in RevMan. Where information was unclear, the reviewers attempted to contact the original authors. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Selection bias (allocation concealment) - Attrition bias - Blinding: lack of blinding was not considered to undermine the validity of the study - Incomplete outcome data - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, weighted mean difference and their 95%	IA n = 7974 RR 1.34 (1.14 to 1.58) Instrumental vaginal birth No. studies: 6 n = 15755 Continuous CTG and FBS n = 7905 IA n = 7850 RR 1.27 (1.16 to 1.39) Cord blood acidosis No. studies: 1 n = 1075 Continuous CTG and FBS n = 540 IA n = 535 RR 0.45 (0.16 to 1.29) Any pharmacological analgesia No. studies: 2 n = 828 Continuous CTG and FBS n = 482 IA n = 367 RR 0.99 (0.90 to 1.07)	Denver 1976 Attrition bias: (A) less than 3% of participants excluded. Allocation concealment: unclear Denver 1979 Attrition bias: (A) less than 3% of participants excluded. Allocation concealment: unclear Dublin 1985 Attrition bias: (A) less than 3% of participants excluded. FBS was performed when the duration of labour exceeded 8 hours. This occurred in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
April 1975 Melbourne 1981 Study period: information not given New Delhi 2006 No good information on study methodology Pakistan 1989 Study period: 1988-1989 Seattle 1987 Study period: Nov 1981 - Feb 1985 Sheffield 1978 Study period: July 1976 - June 1977 Source of funding Not specified	universal monitoring (use of a monitor for every pregnancy in which the fetus was considered viable i.e. irrespective of risk status). Population: n = 34,995 women. Data were extracted for 14,618 women with low-risk pregnancies; 7288 in universal monitoring group where all women monitored by CTG, and 7330 in selective monitoring where low-risk women monitored by IA. Intervention: Continuous CTG (CTG: no information on external or internal) n = 7288 Comparison: IA n = 7330 Denver 1976 RCT. Randomised by sealed envelope. Population n = 483. High-risk women; those with meconium stained fluid, needing oxytocin or		CI were used. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis, with the denominator being set as the number randomised minus any participants whose outcomes were known to be missing. For the purpose of the sensitivity analysis 'high quality' was defined as a trial having allocation concealment classified as 'adequate'. Analysis If high levels of heterogeneity (> 50%) were identified, pre-specified sensitivity analysis was done according to the quality of the trials. A random effects model was used as an overall summary where appropriate.		77/6474 (1.2%) of women in the CTG arm and 139/6486 (2.1%) of women in the IA arm. Lund 1994 Attrition bias: (A) less than 3% of participants excluded. Allocation concealment: unclear Melbourne 1976 Attrition bias: information not available. One obstetrician withdrew his participants from the trial. It is not clear if this was pre- or post-randomisation nor is it clear how may participants were withdrawn. Allocation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	abnormal fetal heart tones during labour were eligible to participate. Intervention: Continuous CTG without FBS versus (CTG: internal) n = 242 Comparison: IA n = 241 Denver 1979 RCT. Randomisation by random numbers in sealed envelopes. Population: n = 690 high risk women participating with 5 sets of twins. Intervention 1: Continuous CTG with FBS (CTG: external until internal feasible) n = 229 Intervention 2: Continuous CTG without FBS (CTG: external until internal feasible) n = 230 Comparison: IA n = 231 Dublin 1985 RCT. Randomisation by opaque, sealed envelopes. Population: n = 12,964		Fixed-effect meta-analysis was used in the absence of substantial heterogeneity between the trials. Random effects meta-analyses were used where heterogeneity was present or suspected.		concealment: yes Melbourne 1981 Attrition bias: (B) 3% to 9.9% of participants excluded. Allocation concealment: no New Delhi 2006 No good information on study methodology. Pakistan 1989 Attrition bias: (A) less than 3% of participants excluded. Allocation concealment: no Data extracted from unpublished trial lodged with Cochrane centre. Seattle 1987 Attrition bias: (D)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Mixed risked women at > 28 weeks' gestation, in labour. Total of 12,964 women participated. Intervention: Continuous CTG in conjunction with FBS versus (CTG: internal) n = 6474 Comparison: IA n = 6490 Attrition bias: (A) less than 3% of participants excluded. Study period: March 1981-April 1983 Lund 1994 RCT. Randomisation by shuffled opaque envelopes. Population: n = 4044 women with low to moderate risk factors during labour. Intervention: Continuous CTG with FBS versus (CTG: no information on external or internal) n = 2029 Comparison: Intermittent CTG with FBS (CTG: no information on external				more than 20% of participants excluded. Allocation concealment: unclear Sheffield 1978 Attrition bias: (A) less than 3% of participants excluded. Allocation concealment: unclear Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	or internal) n = 2015 Melbourne 1976 RCT. Randomised by cards in sealed numbered envelopes. Population: n = 350 high-risk mothers. Intervention: Continuous CTG with FBS (CTG: external) n = 175 Comparison: Intermittent auscultation n = 175 Melbourne 1981 RCT. Randomisation by cards; envelopes unsealed; biased randomisation in one of the participating hospitals; 62 low parity women excluded post-hoc in order to correct for inequality in randomisation. Population: n = 989 low-risk women. Intervention: Continuous CTG without FBS (CTG: external until membranes				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	ruptured then internal) n = 445 Comparison: Intermittent auscultation n = 482 New Delhi 2006 RCT; no details on how this was undertaken. Population: n = 100 women who had had one previous low-transverse caesarean section. For this pregnancy, singleton and cephalic. Intervention: Continuous CTG n = 50 Comparison: IA n = 50 Pakistan 1989 RCT. Randomisation by woman selecting a sealed, unnumbered envelope. Population: n = 200 High-risk women (all participants had meconium stained liquor). Intervention: Continuous CTG with FBS (external)				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	n = 100 Comparison: IA n = 100 Attrition bias: (A) less than 3% of participants excluded. Study period: 1988-1989 Seattle 1987 RCT. Randomisation by numbered, sealed envelopes. Population: n = 386 high-risk women. Preterm labour (28-32 weeks' gestation), estimated fetal weight 700-1750 g. Intervention: Continuous CTG with FBS (CTG: external until rupture of membranes then internal) n = 188 Comparison: IA n = 188 Sheffield 1978 RCT. Randomisation by sealed envelopes; details not described. Population: n = 504 women with mixed-risk.				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Intervention: Continuous CTG without FBS versus (CTG: internal) n = 253 Comparison: IA n = 251 Inclusion criteria Randomised and quasi randomised studies comparing continuous cardiotocography (CTG) with or without fetal blood sampling (FBS) with a) no fetal monitoring b) intermittent auscultation of the fetal heart rate using a pinarad stehoscope or hand held doppler or intermittent CTG. Studies using less robust methods of allocation (for example, alternation) were not included. Exclusion criteria Not reported				
Full citation	Sample size	Interventions	Details	Results	Limitations
Noren,H., Luttkus,A.K., Stupin,J.H., Blad,S.,	Cases n = 97 (Marked acidosis n = 53,	STAN analysis plus	From a European Union multicenter study on clinical	Time between onset of significant ST events (FHR	Data from a previously

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Arulkumaran,S., Erkkola,R., Luzietti,R., Visser,G.H., Yli,B., Rosen,K.G., Fetal scalp pH and ST analysis of the fetal ECG as an adjunct to cardiotocography to predict fetal acidosis in labor--a multi-center, case controlled study, Journal of Perinatal Medicine, 35, 408-414, 2007 Ref Id 121268 Country/ies where the study was carried out Norway Study type Retrospective cohort Aim of the study To assess the relationship between scalp pH (fetal blood sampling [FBS]) and ST analysis in situations of acidosis with special emphasis on the timing of cardiotocography (CTG), FBS and ST changes during labor Study dates	Moderate acidemia n = 44) Control n = 97 Characteristics There were statistically significant differences observed in two groups (cases and controls) on antenatal factors, primigravidae and cord pH. Significantly more operative deliveries observed in marked acidosis and moderate acidemia cases compared with controls. Admission to neonatal care unit was significantly higher in marked acidosis cases compared with the matching control. Inclusion criteria Pregnancy > 36 weeks, high risk pregnancy, women with suspicious or abnormal external CTG, induced or	electronic fetal monitoring (EFM) plus FBS	implementation of the STAN methodology, 911 cases were identified where a scalp-pH had been obtained. A total of n = 6999 cases were recorded during the study period in maternity units and 911 cases were identified where a FBS was performed. Each ward had a research midwife responsible for education and data collection. The decision for need of FBS was left to the clinician in charge and time and pH reading was recorded. In 53 cases, marked cord artery acidosis was found (cord artery pH < 7.06) and 44 cases showed moderate acidemia at birth (pH 7.06-7.09). Comparisons were made with 97 control cases (pH ≥ 7.20). Intervention: Clinical management was guided by CTG interpretation supported by computerised ST waveform assessment	plus ST indication to intervene) and birth FHR+ST events recorded within 16 min of delivery (cord artery pH ≥ 7.20) n = 17/28(61%) STAN indications recorded >16 min (cord artery pH ≥ 7.20) n = 13/69 (19%) OR 6.66 (2.53 to 17.55) P < 0.001 Distribution of FBS and ST guideline indication to intervene (marked acidosis) Women with abnormal FBS Marked acidosis n = 24/53 (45%) Control n = 4/53 (7.5%) Number of samples with scalp pH > 7.19 Marked acidosis n = 43 Control n = 53 Number of samples with scalp pH 7.15 - 7.19 Marked acidosis n = 6	published study used. Not clear how the observers assessed the data. Results reported poorly and inconsistently Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
October 2000 to June 2002 Source of funding Not reported	oxytocin augmented labour or meconium stained liquor Exclusion criteria Not specified		(ST log) and or FBS according to the study protocol. The ST log automatically notified the staff if any ST events occurred and intervention was required in case of combined CTG and ST changes. Intervention was also indicated by occurrence of preterminal CTG (complete loss of variability and reactivity). No intervention was recommended if CTG was normal, irrespective of the ST. During the 1st stage of labour identification and alleviation of the cause of hypoxia was the intervention. If that was not possible operative delivery was recommended. In the 2nd stage of labour, if the ST changes appeared, immediate delivery was recommended. In the event of abnormal CTG and normal ST during the second stage of labour, a maximum of 90 min was recommended	Control n = 1 Number of samples with scalp pH < 7.15 Marked acidosis n s 21 Control n = 3 Number of adequately monitored Marked acidosis n = 46/53 (86.8%) Control n = 42/53 (79.2%) ST indication Marked acidosis n = 41/53 (77.4%) Control n = 20/53 (37.7%) No ST indication (adequately monitored) Marked acidosis n = 5/46 (11%) Control n = 22/42 (52.4%) Distribution of FBS and ST guideline indication to intervene (moderate acidemia) Women with abnormal FBS Moderate acidemia n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			before delivery. FBS was optional during the 1st and 2nd stage of labour. In the cases that there was no indications to intervene, the recording continued until delivery. Analysis: The results were evaluated with Medical statistical software. Student's t test or Mann-Whitney test were used for testing continuous variables. Fisher's exact test was used for discrete variables.	24/53 (45%) Control n = 4/53 (7.5%) Number of samples with scalp pH > 7.19 Moderate acidemia n = 57 Control n = 61 Number of samples with scalp pH 7.15 - 7.19 Moderate acidemia n = 10 Control n = 0 Number of samples with scalp pH < 7.15 Moderate acidemia n = 13 Control n = 0 Number of adequately monitored Moderate acidemia n = 40/44 (91%) Control n = 32/44 (72.7%) ST indication Moderate acidemia n = 24/44 (54.5%) Control n = 10/44 (22.7%) No ST indication	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(adequately monitored) Moderate acidemia n = 16/40 (40%) Control n = 22/32 (68.8%) Cases with abnormal CTG and their relation to FBS and ST Abnormal CTG patterns Normal ST n = 60/121 (49.6%) Abnormal ST n = 61/121 (50.4%) Cases with an abnormal CTG and cord artery pH < 7.10 n = 84/121 (69%): Abnormal ST n = 70/84 (83%) Abnormal FBS (< 7.20) Normal ST n = 7*/60 (11.7%) Abnormal ST n = 29/61 (47.5%) Normal FBS Normal ST n = 50/60 (83.3%) Abnormal ST n = 12†/61	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(19.7%) No FBS inconection with abnormal CTG Normal ST n = 3‡/60 (5%) Abnormal ST n = 20/61 (32.8%) *All had FBS taken at the 2nd stage of labour and n = 6 had respiratory acidosis with normal neonatal period, n = 1 had cord pH >= 7.20 †n = 5/12 developed acidosis subsequently and n = 7 had a normal cord acid base ‡All developed acidosis FBS and ST indication of abnormality in cases with CTG changes noted at the start of ST recording Total ST findings with normal FBS Normal ST n = 43/44 (97.7%) Abnormal ST n = 1/44 (2.3%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Total ST findings with abnormal FBS Normal ST n = 3/17 (17.6%) Abnormal ST n = 14/17 (82.4%) ST findings with normal FBS (marked acidosis) Normal ST n = 14*/14 (100%) Abnormal ST n = 0/14 (0%) Total ST findings with abnormal FBS (marked acidosis) Normal ST n = 2/7 (28.6%) Abnormal ST n = 5/7 (71.4%) ST findings with normal FBS (marked acidemia) Normal ST n = 29†/30 (96.7%) Abnormal ST n = 1/30 (3.3%) ST findings with abnormal FBS (marked acidemia) Normal ST n =1/10 (10%) Abnormal ST n = 9/10	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(90%) Special care baby unit was associated with low Apgar scores (< 7 at 5 min) Marked acidosis: 15/26 (58%) Moderate acidosis: 4/14 (26%) The corresponding rate for control group was 1 of 12 (8%) * n =11/14 subsequently developed ST changes and those that did not, ST changes were inadequately recorded † n = 2 developed subsequent ST changes	
Full citation Stein,W., Hellmeyer,L., Misselwitz,B., Schmidt,S., Impact of fetal blood sampling on vaginal delivery and neonatal outcome in deliveries complicated by pathologic fetal heart rate: a population based cohort	Sample size n = 49,560 deliveries, 26% underwent FBS Characteristics No significant differences observed between the two groups in neonatal	Interventions EFM plus FBS	Details Data collection Data about mother, pregnancy, and birth were collected from the perinatal birth register of Hense, using an evaluated 76 item questionnaire. From 1990 to 2000, the perineal birth	Results Spontaneous birth (no presence of additional risk factor) EFM + FBS n = 2191 (82%) EFM alone n = 7678 (76.7%) OR 1.41 (95% CI 1.27 to 1.58)	Limitations Choice of treatment unrelated to confounders (selection bias): unclear Groups comparable at

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study, Journal of Perinatal Medicine, 34, 479-483, 2006 Ref Id 121315 Country/ies where the study was carried out Germany Study type Population based cohort study Aim of the study To compare the impact of electronic fetal monitoring (EFM) alone vs. EFM with additional fetal blood sampling (FBS) in vaginal deliveries complicated by pathologic fetal heart rate (FHR). Study dates All deliveries in Hesse between 1990 and 2000 Source of funding Not reported	sex, birth weight < 2.5 kg, birth weight > 4 kg and maternal risk in pregnancy. Gestational age > 40 Weeks, maternal age > 35 years, and additional risk factors at birth was significantly associated with FBS. Inclusion criteria Pathologic fetal heart rate Singleton pregnancy Vaginal birth Cephalic presentation Exclusion criteria Not reported		register of Hense recorded data of 589,609 births > 35 weeks. Of these, 49,450 births fulfilled the inclusion criteria. Analysis Bivariate analyses between the usage of FBS and the characteristics of the newborn, mother and birth were performed on only those records with no missing values for any maternal covariates. To assess the effect of FBS in the deliveries with pathological FHR on the mode of birth and neonatal outcomes, univariate regression analysis was performed and odds ratios (OR) and their corresponding 95% confidence intervals (95% CI) were calculated.	Spontaneous birth (in presence of additional risk factor) EFM + FBS n = 5912 (57.8%) EFM alone n = 13974 (52.4%) OR 1.24 (95% CI 1.19 to 1.30) Vaginal assisted birth (no presence of additional risk factor) EFM + FBS n = 472 (16.8%) EFM alone n = 2336 (23.3%) OR not reported Vaginal assisted birth (in presence of additional risk factor) EFM + FBS n = 4318 (42.2%) EFM alone n = 12679 (47.6%) OR not reported Neonatal outcomes	baseline: unclear Groups received same/similar care (apart from intervention): unclear Blinding of those assessing outcomes: no Missing data/loss to follow-up: unclear Precise definition of outcomes: yes Valid and reliable method of outcome assessment: unclear Intention-to-treat analysis performed: no Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Severe fetal acidosis (umbilical artery pH < 7.0) EFM + FBS n = 64 (0.5%) EFM alone n = 307 (0.91%) OR 0.55 (95% CI 0.42 to 0.72) Apgar score < 5 after 7 min EFM + FBS n = 78 (0.61%) EFM alone n = 314 (0.86%) OR 0.71 (95% CI 0.55 to 0.90) Admission to neonatal unit EFM + FBS n = 1025 (8.0%) EFM alone n = 3220 (8.8%) OR 0.90 (95% CI 0.83 to 0.96) Reanimation EFM + FBS n = 652 (5.1%) EFM alone n = 3220 (8.8%) OR 0.80 (95% CI 0.73 to 0.88)	
Full citation Becker,J.H., Westerhuis,M.E., Sterrenburg,K., van den Akker,E.S., van,Beek E.,	Sample size At least one FBS performed for n = 301 women. n = 224	Interventions FBS in conjunction with electronic	Details Data were used from women monitored in the STAN arm of a previously published	Results FBS in deliveries monitored by ST-analysis of the fetal ECG related to the trial	Limitations Large number of women in whom at least one FBS

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Bolte,A.C., van Dessel,T.J., Drogtrop,A.P., van Geijn,H.P., Graziosi,G.C., van Lith,J.M., Mol,B.W., Moons,K.G., Nijhuis,J.G., Oei,S.G., Oosterbaan,H.P., Porath,M.M., Rijnders,R.J., Schuitemaker,N.W., Wijnberger,L.D., Willekes,C., Visser,G.H., Kwee,A., Fetal blood sampling in addition to intrapartum ST-analysis of the fetal electrocardiogram: evaluation of the recommendations in the Dutch STAN[REGISTERED] trial, BJOG: An International Journal of Obstetrics and Gynaecology, 118, 1239-1246, 2011 Ref Id 156994 Country/ies where the study was carried out Netherlands Study type Prospective cohort study Aim of the study To evaluate the	complete ST recordings were available for assessment Characteristics Not specified Inclusion criteria Women in labour with a high risk singleton pregnancy in cephalic position at term Exclusion criteria Not specified	fetal monitoring (EFM) and ST wave analysis	multi centre randomised controlled trial; participants had been randomly assigned to monitoring by cardiotocography (CTG) combined with ST-analysis of the fetal electrocardiogram (ECG) (index group) or CTG without ST-analysis (control group). This study was on the women randomised to the index group in whom FBS was undertaken. In women in the index group, a scalp electrode was applied to the fetal head and connected to a STAN S21 or S31 fetal heart monitor (Neoventa Medical, Gothenburg, Sweden). Clinical management was guided by the STAN clinical guidelines. In the study protocol FBS was recommended in three situations: (1) start of STAN registration with an intermediary or abnormal CTG trace	protocol Number of FBS According to trial protocol n = 171 Not according to trial protocol n = 126 pH > 7.25 According to trial protocol n = 112/171 (65.5%) Not according to trial protocol n = 96/126 (76.2%) pH 7.20 - 7.25 According to trial protocol n = 33/171 (19.3%) Not according to trial protocol n = 15/126 (12%) pH < 7.20 According to trial protocol n = 17/171 (10%) Not according to trial protocol n = 10/126 (7.9%) Missing pH According to trial protocol n = 9/171 (5.3%) Not according to trial protocol n = 5/126 (4%)	performed were excluded for the analysis for various reason (not specified) Data from a previously published trial were used Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
recommendations for additional fetal blood sampling (FBS) when using ST-analysis of the fetal electrocardiogram. Study dates January 2006 until July 2008 Source of funding Funded by a grant from ZonMW, the Dutch Organisation for Health Research and Development			(2) abnormal CTG trace for more than 60 minutes without ST-events (3) poor ECG signal quality in the presence of an intermediary or abnormal CTG trace. Poor signal quality was defined as absence of ST-information for more than 4 minutes or less than one average ECG-complex per minute within a period of 10 minutes. If FBS showed a pH < 7.20, an immediate delivery was advised. If the pH was between 7.20 and 7.25 the advice was to repeat FBS after 30 minutes. If the pH was > 7.25, the fetal condition was considered well enough to continue labour. Presence of STAN abnormalities (defined in the protocol) was also an indication for immediate delivery. Data analysis All STAN recordings of	FBS in deliveries monitored by ST-analysis of the fetal ECG related to reasons according to the trial protocol Number of FBS Total n = 171 Abnormal CTG (cardiotocography) at start n = 18 Intermediary CTG at start n = 9 Abnormal CTG > 60 min without ST events n = 111 Poor ECG signal quality n = 33 pH > 7.25 Total n = 112 Abnormal CTG at start n = 9 Intermediary CTG at start n = 9 Abnormal CTG > 60 min without ST events n = 69 Poor ECG signal quality n = 25 pH 7.20 - 7.25 Total n = 33 Abnormal CTG at start n = 5	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			women in the index group in which at least one FBS was performed, was assessed by two observers. They examined whether or not additional FBS was performed according to the trial protocol. When there was a disagreement, the opinion of a third observer was decisive. The observers were only provided with information on the timing of FBS, without knowledge of its result, other clinical parameters obtained during labour, or the neonatal outcome. For each FBS the following items had to be scored: (1) classification of the CTG as normal, intermediary, abnormal or (pre)terminal within a 60-minute period before performance of FBS (2) duration of an intermediary, abnormal or (pre)terminal CTG in minutes (3) interpretation of any ST-events; and	Intermediary CTG at start n = 0 Abnormal CTG > 60 min without ST events n = 24 Poor ECG signal quality n = 4 pH < 7.20 Total n = 17 Abnormal CTG at start n = 2 Intermediary CTG at start n = 0 Abnormal CTG > 60 min without ST events n = 12 Poor ECG signal quality n = 3 Missing pH Total n = 9 Abnormal CTG at start n = 2 Intermediary CTG at start n = 0 Abnormal CTG > 60 min without ST events n = 6 Poor ECG signal quality n = 1 Relation of presence or absence of significant ST-events and preterminal CTG	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			(4) judgement of whether FBS was performed according to the randomised controlled trial protocol. Observers evaluated whether the FBS was performed according to the trial protocol, and assessed the relation between pH result measured by FBS and the reason to perform FBS was described. In the cases of protocol violation (FBS not performed according to the trial protocol) the relation between pH results of FBS and ST-waveform interpretation regarding fetal indications to intervene, was evaluated. Fetal acidosis was defined as an FBS pH < 7.20. Women were classified as being treated 'not according to trial protocol' if at least one of the FBS was not performed according to the trial protocol. Metabolic acidosis for neonates was	with results of FBS not taken according to protocol Indication to intervene (at least on significant ST events) Total n = 34 pH < 7.20 n = 8 (23.5%) pH 7.20 - 7.25 n = 5 (14.7 %) pH > 7.25 n = 19 (60%) Missing value n = 2 (5.9 %) No indication to intervene (total n = 92) pH < 7.20 n = 2 (2.2%) pH 7.20 - 7.25 n = 10 (11%) pH > 7.25 n = 77 (83.7%) Missing value n = 3 (3.2%) Preterminal CTG (total n = 1) pH < 7.20 n = 1 (100%) pH 7.20 - 7.25 n = 0 pH > 7.25 n = 0 Missing value n = 0 Neonatal outcomes FBS was taken according to the trial protocol Neonates with metabolic acidosis at birth	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			defined as an umbilical cord artery pH < 7.05 and base deficit > 12 mmol/l.	n = 3 One out of these three women had abnormal CTG for 36 minutes + poor ECG quality before FBS with pH 7.9. In other n = 2 women FBS performed because of abnormal CTG > 60 min and result of FBS was normal but CTG abnormalities persisted. For one women the time between FBS and birth was only 20 minutes, in the other one it was 9 hours with an abnormal CTG for the last 115 minutes (FBS pH 7.32, umbilical cord artery pH 6.93). FBS was performed not according to the trial protocol Neonates with metabolic acidosis at birth n = 3 In all three women earlier intervention was recommended based on significant ST-events. In one of these women multiple	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				FBS were performed because of an abnormal CTG-pattern (pH 7.38, 7.33, 7.31, 7.28 and 7.28). The final two FBS were both preceded by a significant ST-event. Abnormalities on CTG persisted hereafter and ST-analysis showed one more significant ST-event 76 minutes after the last FBS, during the second stage of labour. Time between that last FBS and birth was 114 minutes, after a failed vacuum extraction, caesarean section performed baby born with cord pH 6.95 and died because of severe asphyxia and encephalopathy.	

1.1.13 What is the time from the decision to perform a fetal blood sample to having the blood result?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Annappa,R., Campbell,D.J., Simpson,N.A., Fetal blood sampling in labour and the decision to delivery interval, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 141, 10-12, 2008 Ref Id 92285 Country/ies where the study was carried out England Study type Prospective case series of consecutive attempts at fetal blood sampling (FBS) Aim of the study To determine the time interval from the decision to the result for fetal blood sampling (FBS) and the time from an abnormal pH to the birth of the baby Study dates	N = 107 (This was the number of attempts to do FBS, involving 72 women) Characteristics BMI (n/total (%)) ≤ 25: 44/72 (61.1) > 25: 28/72 (38.9) Cervical dilatation in cm (n/total (%)) ≤ 5: 27/72 (37.5) > 5: 45/72 (62.5) Operator grade (n/total (%)) SHO/SSHO: 41/72 (56.9) SPR/Senior Registrar: 31/72 (43.1) Inclusion criteria Consecutive attempts at FBS	Fetal blood sampling	Consecutive attempts at FBS over the study period were reported. Operators performed the procedure with women in either lithotomy or left lateral position. Fetal capillary blood samples were collected in a heparinised glass tube and analysed using a Bayer Rapid Lab 840 blood gas analyser. All details were recorded in a document designed for this audit. If a sample was taken but judged to be inadequate, another sample was taken. 107 attempts yielded 177 samples due to the need for repeat samples. The time interval was taken from the decision to perform FBS to the result of a successfully attained sample. Non-parametric tests were used for the analysis. The time from the decision to the result was compared for each factor using Mann-Whitney tests. Regressions analysis was undertaken to investigate the	Time from decision to the result of the FBS a. Median/minutes (IQR): 17 (11 - 22) b. Time taken > 30 minutes (n/total (%)): 5/107 (4.7) [Note: the median time for preparation was 8 minutes (IQR 7 - 15), and the median time to perform the procedure was 10 minutes (IQR 9 - 16)] Factors affecting the time interval between decision to result of FBS/minutes (median (IQR)) a. BMI ≤ 25: 13 (11 - 17) > 25: 17 (14 - 22) (p < 0.001) b. Cervical dilatation ≤ 5: 22 (16 - 25) > 5: 15 (10 - 17) (p < 0.0001)	Inclusion or exclusion criteria and characteristics of the study population are not reported in detail; therefore, it is not possible to establish whether women had low risk pregnancies. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
April 1st 2006 to August 1st 2006 Source of funding None reported	Exclusion criteria None reported		factor, while controlling for other factors.	c. Operator grade SHO/SSHO: 17 (17 - 22) SPR/Senior Registrar: 13 (10 - 17) ($p < 0.001$) These were all independent predictors in the regression model, when including all factors. No valid comparisons for position or epidural could be done, because 95% of women had epidural and 95% of women had FBS taken in the left lateral position. Number of samples needed (n) One: 46 Two: 52 Three: 9 Failed to obtain sample: 2 (Note: 23/177 (13%) of samples were inadequate for analysis)	

1.1.14 What is the predictive value of the following measures, for maternal and neonatal outcomes: fetal blood pH analysis, fetal blood lactate analysis, fetal acid-base status, and fetal-base deficit?

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Full citation Bakr,A.F., Al-Abd,M., Karkour,T., Fetal pulse oximetry and neonatal outcome: a study in a developing country, Journal of Perinatology, 25, 759-762, 2005 Ref Id 121095 Country/ies where the study was carried out Egypt Study type Prospective cohort study Aim of the study To compare the diagnostic value of fetal pulse oximetry with that of fetal scalp blood gas for an abnormal neonatal outcome in cases with abnormal fetal heart rate tracings Study dates June 2001 to May 2002 Source of funding	Sample size N = 150 Characteristics None reported Inclusion Criteria Abnormal fetal heart rate tracing (criteria not reported) Complete screening panel (fetal pulse oximetry, fetal scalp blood gas and umbilical cord blood gas) Exclusion Criteria None reported	Tests Fetal scalp pH analysis	Methods Informed consent was given by all participants before enrolment. Routine care was given to all patients. Women were monitored with a fetal oxygen saturation monitor and an average value of 30 minutes reading was calculated. A fetal scalp blood gas was taken. An umbilical cord gas sample was obtained shortly following birth, prior for the baby being moved from the delivery area. Abnormal neonatal outcome was	Results Predictive value of pH ≤ 7.20 (95% CI) a. For umbilical artery pH ≤ 7.15 Sensitivity: 72% (58 to 82) Specificity: 53% (42 to 63) PPV: 57% (48 to 65)* [NCC: 51% (40 to 61)] NPV: 43% (35 to 51)* [NCC: 74% (63 to 85)] LR+: 1.54 (1.17 to 2.02)† LR-: 0.53 (0.34 to 0.83)† b. For abnormal neonatal outcome Sensitivity: 82% (65 to 91) Specificity: 52% (42 to 61) PPV: 57% (48 to 64)* [NCC: 36% (26 to 47)] NPV: 43% (35 to 51)* [NCC: 89% (82 to 97)] LR+: 1.69 (1.33 to 2.16)† LR-: 0.36 (0.18 to 0.71)† * values reported here are as reported in the study; however, the PPV and NPV values do not match	Limitations Study sample represents population: unclear - no characteristics of the study population are reported Loss to follow-up is unrelated to key characteristics: no loss to follow-up Prognostic factors is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: no details about mode of birth or when they intervened are reported

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>None, institutional resources</td>
<td></td>
<td></td>
<td>defined as having any of the following:
- Apgar score ≤ 7 at 5 minutes
- Secondary respiratory distress
- Transfer to NICU
- Neonatal arterial blood pH ≤ 7.15
- Neonatal death

The diagnostic value of fetal blood sampling (FBS) and fetal pulse oximetry were compared for their ability to predict umbilical cord blood pH ≤ 7.15 and abnormal neonatal outcome. Sensitivity, specificity and predictive values were calculated. (Note: this review deals only with FBS; therefore, data for fetal pulse</td>
<td>the 2x2 data reported in the study. NCC calculations are reported in square brackets following study data.
† calculated by the NCC-WCH technical team, as likelihood ratios were not reported in the study

pH <= 7.2 for UA pH <= 7.15
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>43</td><td>42</td></tr>
<tr><td>Predictive Test -ve</td><td>17</td><td>48</td></tr>
</table>
pH <= 7.2 for abnormal neonatal outcome
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>31</td><td>54</td></tr>
<tr><td>Predictive Test -ve</td><td>7</td><td>58</td></tr>
</table>
</td>
<td>Statistical analysis is appropriate for study design: yes

For PPV and NPV, calculations reported in the study are not consistent with the 2x2 data that are reported.

Indirectness of population: not reported whether women were low risk in pregnancy. Also, it is likely that some women had an interval of longer than 1 hour between FBS and birth; however, the mean and SD suggest that the vast majority will have been an under an hour which is why the study was included

Other information
The mean time lag</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			oximetry are not reported)		between the fetal blood gas analysis and birth was 36.7 ± 15.3 minutes.
Full citation East,Christine E., Leader,Leo R., Sheehan,Penelope, Henshall,Naomi E., Colditz,Paul B., Intrapartum fetal scalp lactate sampling for fetal assessment in the presence of a non-reassuring fetal heart rate trace, Cochrane Database of Systematic Reviews, -, 2011 Ref Id 151307 Country/ies where the study was carried out Sweden Study type Systematic review Aim of the study To evaluate the effectiveness and risks of fetal scalp lactate sampling in the assessment of fetal well-being during labour, compared with no testing or alternative testing Study dates	Sample size N = 2 trials N = 3348 mother and baby pairs Characteristics Westgren 1998 N = 341 Inclusion criteria: abnormal fetal heart rate during labour and fetal blood sample (FBS) deemed necessary by the attending physician Interventions: - pH analysis was performed in the delivery ward (35 microlitres using ABL 510) - lactate analysis was performed at bedside	Tests pH analysis Lactate analysis	Methods Searching and identification of studies The Trials Search Co-ordinator was contacted to search the Cochrane Pregnancy and Childbirth Group's Trials Register (November 2009). At least 2 review authors independently assessed all potential studies for inclusion. Data extraction and management A form was designed to extract data. Two review authors did data	Results ALL SAMPLES Mode of birth (n/total) a. Spontaneous vaginal birth Lactate: 709/1667 pH: 709/1652 RR 0.91 (95% CI 0.67 to 1.24) Heterogeneity: I2 = 64% [therefore, random effects model was used] Test for overall effect: Z = 0.62 (p = 0.54) [2 studies: Westgren 1998; Wiberg-Itzel 2008] b. Assisted vaginal birth Lactate: 415/1667 pH: 455/1652 RR 0.90 (95% CI 0.81 to 1.01) Heterogeneity: I2 = 0.0% Test for overall effect: Z = 1.73 (p = 0.084)	Limitations This systematic review does not have any limitations. Indirectness: it is unclear whether these women had low risk pregnancies; for most outcomes, time interval between FBS and birth is not reported. The following represent the review authors assessment of the risk of bias of the included studies: Westgren 1998 Adequate sequence generation: unclear, method not reported

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Review content was assessed as up-to-date in February 2010 Source of funding Department of Obstetrics and Gynaecology and Pregnancy Research Centre, Department of Perinatal Medicine, University of Melbourne, Royal Women's Hospital, Australia School of Women's and Children's Health, University of New South Wales, Royal Hospital for Women, Randwick, Australia Perinatal Research Centre, University of Queensland, Royal Brisbane & Women's Hospital, Australia	(5 microlitres using Lactate card) Cut-off action values: pH < 7.20; lactate 2.9 - 3.09 mmol/l was deemed suspicious, and > 3.08 mmol/l was deemed abnormal. No standard advice was given regarding action, so that clinician would consider whole clinical picture, not just one value Wiberg-Itzel 2008 N = 3007 randomised; N = 2992 analysed Inclusion criteria: singleton pregnancy, cephalic presentation at 34 or more weeks, clinical indication for fetal scalp blood analysis during labour Post-randomisation exclusion: multiple		extraction and data was entered into RevMan and checked for accuracy. If any data was unclear, an attempt was made to contact the study authors to provide details. Two review authors assessed risk of bias using criteria outlined in the Cochrane Handbook: - The method used to generate the allocation sequence - Allocation concealment - Blinding - Incomplete outcome data, including attrition and exclusions - Selective reporting bias	[2 studies: Westgren 1998; Wiberg-Itzel 2008] c. Caesarean section Lactate: 472/1667 pH: 432/1652 RR 1.09 (95% CI 0.97 to 1.22) Heterogeneity: I2 = 0.0% Test for overall effect: Z = 1.50 (p = 0.13) [2 studies: Westgren 1998; Wiberg-Itzel 2008] d. Operative delivery for non-reassuring fetal status Lactate: 580/1496 pH: 571/1496 RR 1.02 (95% CI 0.93 to 1.11) Heterogeneity: NA Test for overall effect: Z = 0.34 (p = 0.74) [1 study: Wiberg-Itzel 2008] Neonatal death* Lactate: 0/1496 pH: 3/1496	Adequate allocation concealment: yes Blinding: No blinding of participants; blinding of clinicians not feasible; no blinding of outcome assessors reported Incomplete outcome data: excludes women with protocol violations (n = 1 from lactate group, n = 13 from pH group Selective reporting: unclear Other bias: unclear Wiberg-Itzel 2008 Adequate sequence generation: yes Adequate allocation concealment: yes Blinding: No blinding

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	pregnancy, gestational age < 34 weeks Interventions: - pH analysis was done using different blood gas analysers - Lactate was measured with the Lactate Pro Cut-off action values: - pH: normal > 7.25, pre-acidaemia 7.21 - 7.25, acidaemia < 7.21 - Lactate: normal < 4.2 mmol/l, pre-acidaemia 4.2 - 4.8 mmol/l, acidaemia > 4.8 mmol/l Following pre-acidaemia, the recommendation was for further sampling 20 - 30 minutes later if no other indications for intervention. Following acidaemia, management		- Other sources of bias Data analysis Fixed-inverse variance meta-analysis was used for combining data, where the authors judged the trials' populations and methods to be sufficiently similar. Where there was suspected clinical or methodological heterogeneity between studies, sufficient to suggest that treatment effects could differ, the authors planned to use random effects meta-analysis. Where substantial heterogeneity was identified in a fixed effects meta-analysis, the analysis was	RR 0.14 (95% CI 0.01 to 2.76) Heterogeneity: NA Test for overall effect: Z = 1.29 (p = 0.20) [1 trial: Wiberg-Itzel 2008] * Based on data reported in the full text of the trial, the causes of death were lung hypoplasia due to diaphragmatic hernia (n = 2) and congenital cardiac fibrosis (n = 1). Neonatal encephalopathy (n/total)† Lactate: 6/1496 pH: 6/1496 RR 1.00 (95% CI 0.32 to 3.09) Heterogeneity: NA Test for overall effect: Z = 0.0 (p = 1.0) [1 trial: Wiberg-Itzel 2008] † Based on data reported in the full text of the trial, this was hypoxic ischaemic encephalopathy. In the lactate group, 5 cases were mild and one was moderate. In the pH group, 4 cases were mild and 2 were moderate.	of participants; blinding of clinicians not feasible; no blinding of outcome assessors reported Incomplete outcome data: There were post-randomisation exclusions for 8 of lactate group (twins n = 7, < 34 weeks n = 5) and 7 of the pH group (twins n = 3, < 34 weeks n = 4). All other data reported by intention to treat, but FBS was not undertaken in all women due to: - sampling or analysis failure (lactate: 18, pH: 155) - rapid delivery, need for expedited delivery, reassuring CTG, withdrew consent, no reason given (lactate: 81, pH: 106)

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	decisions were made by the attending clinicians Inclusion Criteria Published and unpublished randomised and quasi-randomised trials comparing fetal scalp lactate testing with no testing or alternative additional tests (e.g. pH, fetal pulse oximetry) to evaluate fetal status in the presence of a non-reassuring cardiotocograph (CTG) during labour Exclusion Criteria None reported		repeated using random effects. There were planned sub-group analyses by stage of labour, gestation, and concurrent use of alternative tests; however, there were not sufficient data to do this.	Admission to NICU (n/total) Lactate: 167/1496 pH: 164/1496 RR 1.02 (95% CI 0.83 to 1.25) Heterogeneity: NA Test for overall effect: Z = 0.17 (p = 0.86) [1 trial: Wiberg-Itzel 2008] Apgar score < 7 at 5 minutes (n/total) Lactate: 50/1667 pH: 44/1652 RR 1.13 (95% CI 0.76 to 1.68) Heterogeneity: I2 = 0.0% Test for overall effect: Z = 0.59 (p = 0.56) [2 trials: Westgren 1998; Wiberg-Itzel 2008] Metabolic acidaemia (umbilical artery pH < 7.05 + base deficit > 12 mmol/l) Lactate: 44/1360 pH: 47/1315	There was incomplete umbilical cord blood gas analysis for the following outcomes: - metabolic acidaemia: lactate group 9%, pH group 12% - pH: lactate group 8%, pH group 12% Selective reporting: unclear Other bias: unclear Other information Success rate of fetal blood sampling (n/total (%)) Lactate: 1478/1496 (97.8%) pH: 1341/1496 (89.6%) [1 trial: Wiberg-Itzel 2008]

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				RR 0.91 (95% CI 0.60 to 1.36) Heterogeneity: NA Test for overall effect: Z = 0.48 (p = 0.63) [1 trial: Wiberg-Itzel 2008] Cord blood gas values at birth a. Umbilical artery pH < 6.98 (n/total) Lactate: 4/171 pH: 8/156 RR 0.46 (95% CI 0.14 to 1.49) Heterogeneity: NA Test for overall effect: Z = 1.30 (p = 0.19) [1 trial: Westgren 1998] b. Umbilical artery pH < 7.00 (n/total) Lactate: 21/1376 pH: 24/1322 RR 0.84 (95% CI 0.47 to 1.50) Heterogeneity: NA Test for overall effect: Z = 0.59 (p = 0.56) [1 trial: Wiberg-Itzel 2008] c. Umbilical artery pH < 7.10 (n/total)	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Lactate: 121/1376 pH: 131/1322 RR 0.89 (95% CI 0.70 to 1.12) Heterogeneity: NA Test for overall effect: Z = 0.99 (p = 0.32) [1 trial: Wiberg-Itzel 2008] d. Umbilical artery lactate > 4.68 mmol/l (n/total)‡ Lactate: 20/171 pH: 29/156 RR 0.63 (95% CI 0.37 to 1.07) Heterogeneity: NA Test for overall effect: Z = 1.72 (p = 0.085) [1 study: Westgren 1998] e. Umbilical artery base deficit (mean ± SD) Lactate: 8 ± 3.8 [n = 171] pH: 8.7 ± 4.6 [n = 156] MD - 0.70 (95% CI - 1.62 to 0.22) Heterogeneity: NA Test for overall effect: Z = 1.49 (p = 0.14)	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				[1 study: Westgren 1998] f. Umbilical artery base deficit > 19.2‡ Lactate: 1/171 pH: 3/156 RR 0.30 (0.03 to 2.89) Heterogeneity: NA Test for overall effect: Z = 1.04 (p = 0.30) [1 study: Westgren 1998] ‡ According to the original trial paper, the thresholds used by Westgren were chosen according to the 1st or 99th centile of normal values, which are reported in another study SUB-GROUP ANALYSIS OF FBS TAKEN WITHIN 60 MINUTES OF DELIVERY Operative delivery for non-reassuring fetal status Lactate: 380/684 pH: 257/508	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				RR 1.10 (95% CI 0.98 to 1.22) Heterogeneity: NA Test for overall effect: Z = 1.68 (p = 0.092) [1 study: Wiberg-Itzel et al., 2008) Apgar score < 7 at 5 minutes Lactate: 28/684 pH: 21/508 RR 0.99 (95% CI 0.57 to 1.72) Heterogeneity: NA Test for overall effect: Z = 0.03 (p = 0.97) [1 study: Wiberg-Itzel et al., 2008) Metabolic acidaemia (umbilical artery pH < 7.05 + base deficit > 12 mmol/l) (n/total) Lactate: 25/684 pH: 20/508 RR 0.93 (95% CI 0.52 to 1.65) Heterogeneity: NA Test for overall effect: Z = 0.25 (p = 0.80) [1 study: Wiberg-Itzel et al., 2008)	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Umbilical artery pH < 7.00 (n/total) Lactate: 10/684 pH: 11/508 RR 0.68 (95% CI 0.29 to 1.58) Heterogeneity: NA Test for overall effect: Z = 0.59 (p = 0.56) [1 study: Wiberg-Itzel et al., 2008)	
Full citation Hon,E.H., Khazin,A.F., Paul,R.H., Biochemical studies of the fetus. II. Fetal pH and apgar scores, Obstetrics and Gynecology,Obstet.Gynecol., 33, 237-255, 1969 Ref Id 159922 Country/ies where the study was carried out USA Study type Case-series Aim of the study Not reported Study dates	Sample size N = 194 patients Characteristics No details given Inclusion Criteria None reported Exclusion Criteria None reported	Tests pH analysis	Methods Patients were monitored using electrocardiogram (ECG), fetal heart rate (FHR) patterns, monitoring of uterine contractions and blood pressure monitoring. Biochemical measures included maternal, fetal and neonatal pH, pO2, pCO2, base deficit, lactate, pyruvates and haemoglobin.	Results Correlation between 1 minute Apgar scores and fetal blood pH at different intervals before birth All samples Apgar 7-10 - Time interval (mean ± SD): 80.35 ± 114.50 - Apgar (mean ± SD): 8.56 ± 0.64 - pH (mean ± SD): 7.28 ± 0.058 - r: 0.0812 - number of samples: 851 - p-value: < 0.05 Apgar 1-6 - Time interval (mean ± SD): 144.65 ± 171.49 - Apgar (mean ± SD): 3.63 ± 2.03	Limitations No 2x2 data are available for samples taken within an hour of birth. Study sample represents population: unclear, as very few details are given Loss to follow-up is unrelated to key characteristics: unclear Prognostic factors are adequately measured in

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Not reported Source of funding Supported in part by grants from the National Institute of Child Health and Human Development			1392 fetal scalp samples were obtained in total, of which 1117 samples were included in the study (194 patients). At the start of the study, pH was determined twice, once in early labour and once during late labour. However, during the later parts of the study, more frequent sampling was done, and reached as high as 28 per person. Apgar score was assessed as follows: - 7 - 10 was considered high - 6 or less was considered low	- pH (mean ± SD): 7.26 ± 0.082 - r: 0.3395 - number of samples: 257 - p-value: < 0.005 Within 60 minutes Apgar 7-10 - Time interval (mean ± SD): 14.70 ± 13.64 - Apgar (mean ± SD): 8.56 ± 0.64 - pH (mean ± SD): 7.27 ± 0.059 - r: -0.0004 - number of samples: 530 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 19.22 ± 15.23 - Apgar (mean ± SD): 3.13 ± 2.04 - pH (mean ± SD): 7.23 ± 0.093 - r: 0.4402 - number of samples: 106 - p-value: < 0.005 Within 45 minutes Apgar 7-10 - Time interval (mean ± SD): 12.49 ± 10.49 - Apgar (mean ± SD): 8.54 ± 0.65 - pH (mean ± SD): 7.27 ± 0.060 - r: 0.0037	participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: mode of birth is not reported Statistical analysis is appropriate for study design: yes Other information This study population appears to be the same as Khazin et al., but different data are reported

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			A pH of 7.20 was used as the pH threshold.	- number of samples: 500 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 15.51 ± 10.31 - Apgar (mean ± SD): 3.20 ± 2.00 - pH (mean ± SD): 7.23 ± 0.089 - r: 0.4248 - number of samples: 96 - p-value: < 0.005 Within 30 minutes Apgar 7-10 - Time interval (mean ± SD): 10.05 ± 7.15 - Apgar (mean ± SD): 8.57 ± 0.64 - pH (mean ± SD): 7.27 ± 0.060 - r: 0.0203 - number of samples: 456 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 13.50 ± 8.50 - Apgar (mean ± SD): 3.23 ± 2.06 - pH (mean ± SD): 7.22 ± 0.089 - r: 0.4608 - number of samples: 87 - p-value: < 0.005	

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				Within 15 minutes Apgar 7-10 - Time interval (mean ± SD): 7.28 ± 4.18 - Apgar (mean ± SD): 8.61 ± 0.64 - pH (mean ± SD): 7.27 ± 0.064 - r: 0.0111 - number of samples: 371 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 7.64 ± 4.25 - Apgar (mean ± SD): 3.53 ± 2.17 - pH (mean ± SD): 7.21 ± 0.104 - r: 0.5490 - number of samples: 53 - p-value: < 0.005 Within 5 minutes Apgar 7-10 - Time interval (mean ± SD): 2.87 ± 1.35 - Apgar (mean ± SD): 8.58 ± 0.68 - pH (mean ± SD): 7.25 ± 0.073 - r: 0.0154 - number of samples: 142 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 2.71 ±	

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				1.32 - Apgar (mean ± SD): 3.47 ± 2.07 - pH (mean ± SD): 7.23 ± 0.083 - r: 0.7376 - number of samples: 17 - p-value: < 0.005 Correlation between 5 minute Apgar scores and fetal blood pH at different intervals before birth All samples Apgar 7-10 - Time interval (mean ± SD): 89.85 ± 118.90 - Apgar (mean ± SD): 8.99 ± 0.74 - pH (mean ± SD): 7.28 ± 0.060 - r: 0.04343 - number of samples: 1029 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 164.83 ± 240.04 - Apgar (mean ± SD): 4.20 ± 1.57 - pH (mean ± SD): 7.23 ± 0.097 - r: 0.3485 - number of samples: 79 - p-value: <0.005 Within 60 minutes:	

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				Apgar 7-10 - Time interval (mean ± SD): 15.52 ± 14.31 - Apgar (mean ± SD): 9.11 ± 0.69 - pH (mean ± SD): 7.27 ± 0.061 - r: 0.0607 - number of samples: 595 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 14.48 ± 8.69 - Apgar (mean ± SD): 4.00 ± 1.82 - pH (mean ± SD): 7/18 ± 0.098 - r: 0.3880 - number of samples: 41 - p-value: <0.01 Within 45 minutes: Apgar 7-10 - Time interval (mean ± SD): 12.87 ± 10.63 - Apgar (mean ± SD): 9.12 ± 0.68 - pH (mean ± SD): 7.27 ± 0.06 - r: 0.0019 - number of samples: 555 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 14.48 ± 8.69	

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				- Apgar (mean ± SD): 4.00 ± 1.82 - pH (mean ± SD): 7/18 ± 0.098 - r: 0.3880 - number of samples: 41 - p-value: <0.01 Within 30 minutes: Apgar 7-10 - Time interval (mean ± SD): 10.33 ± 7.35 - Apgar (mean ± SD): 9.15 ± 0.67 - pH (mean ± SD): 7.27 ± 0.06 - r: 0.0044 - number of samples: 503 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 14.06 ± 8.38 - Apgar (mean ± SD): 3.95 ± 1.81 - pH (mean ± SD): 7.18 ±0.096 - r: 0.3591 - number of samples: 40 - p-value: < 0.05 Within 15 minutes: Apgar 7-10 - Time interval (mean ± SD): 7.27 ± 4.17 - Apgar (mean ± SD): 9.22 ± 0.63 - pH (mean ± SD): 7.27 ± 0.063	

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				- r: -0.0120 - number of samples: 400 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 8.31 ± 4.44 - Apgar (mean ± SD): 4.21 ± 1.84 - pH (mean ± SD): 7.16 ± 0.114 - r: 0.4261 - number of samples: 24 - p-value: < 0.05 Within 5 minutes: Apgar 7-10 - Time interval (mean ± SD): 2.83 ± 1.34 - Apgar (mean ± SD): 9.18 ± 0.65 - pH (mean ± SD): 7/25 ± 0.071 - r: -0.0534 - number of samples: 151 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 3.31 ± 1.44 - Apgar (mean ± SD): 4.25 ± 1.58 - pH (mean ± SD): 7.18 ± 0.080 - r: 0.6171 - number of samples: 8 - p-value: < 0.05	

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Full citation Kerenyi,T.D., Falk,S., Mettel,R.D., Walker,B., Acid-base balance and oxygen saturation of fetal scalp blood during normal and abnormal labors, Obstetrics and Gynecology, 36, 398-404, 1970 Ref Id 169762 Country/ies where the study was carried out USA Study type Case-series Aim of the study Not stated Study dates Not reported Source of funding None reported	Sample size N = 33 (However, only 23 were taken within 1 hour of delivery and hence constitute the population of interest) Characteristics Of the study population who had a fetal blood sample (FBS) taken within an hour of birth: 8 had normal labours and gave birth to babies with an Apgar score of 6 or better, following a blood sample taken within 1 hour of birth (range 10 minutes to 55 minutes). Dilatation was rim in one woman, 6-9 in 5 women and full in 2 women.	Tests pH analysis within 60 minutes of birth	Methods Fetal blood sampling was done with the patient in the lithotomy position, after the membranes had either been ruptured artificially or had spontaneously ruptured. An endoscope was put through the os and pressed against the head. The scalp was cleaned and at the time of a contraction was sprayed with ethyl chloride to produce hyperaemia. A silicone preparation was applied to enhance blood beading. A puncture was made with a 2mm blade and blood was collected in a	Results The following predictive value measures were calculated by the technical team, based on data reported in tables 1 - 3 of the paper. The calculations only include fetal scalp samples that were taken within 1 hour of birth (n = 23). There is missing data for 2 arterial samples. Predictive value of pH < 7.10 (95% CI) a. For Apgar score < 7 at 1 minute Sensitivity: 25.00% (0.50 to 49.50) Specificity: 100 (NC) PPV: 100 (NC) NPV: 55.00% (33.20 to 76.80) LR+: infinite LR-: 0.75 (0.54 to 1.04) b. For Apgar score < 7 at 5 minutes Sensitivity: 66.67% (13.32 to 100) Specificity: 95.00% (85.45 to 100) PPV: 66.67% (13.32 to 100) NPV: 95.00% (85.45 to 100) LR+: 13.33 (1.68 to 105.79) LR-: 0.35 (0.07 to 1.74) c. For umbilical artery pH < 7.10 Sensitivity: 33.33% (0 to 86.68)	Limitations Study sample represents population: Many of the women were not low risk; inclusion and exclusion criteria are not reported Loss to follow-up is unrelated to key characteristics: No loss to follow-up Prognostic factors are adequately measured in participants: There are missing data for between 4 and 5 (17 - 22%) out of the 23 women for base deficit values. Outcome of interest is sufficiently measured in participants: There are missing data for 2/23 arterial pH measurements Important potential

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	7 had complicated labours and gave birth to babies with an Apgar score of 6 or better after an FBS within an hour of birth (range 1 minute - 40 minutes): Case 5: abnormal fetal heart rate (FHR), pitocin drip, secondary uterine inertia, - Full dilatation Case 15: Toxemia - Full dilatation Case 22: Relative cephalopelvic disproportion, eclamptic - Full dilatation Case 23: premature (2300 g), fetal tachycardia - Full dilatation Case 27: meconium staining - Full dilatation Case Elm 4: toxemia, relative chronic		heparinised tube after suction was applied by mouth. The sample was immediately analysed. Samples were taken periodically during labour. If any value was abnormal, the analysis was immediately repeated and the result compared to the maternal blood. As the series went on, maternal acid-base status was found to be a useful tool in determining whether acidosis started in the mother or the baby. At delivery, blood samples from the cord were collected before clamping. The clinical status	Specificity: 94.44% (83.86 to 100) PPV: 50.00% (0 to 100) NPV: 89.47% (75.67 to 100) LR+: 6.00 (0.50 to 72.21) LR-: 0.71 (0.31 to 1.58) Predictive value of pH ≤ 7.20 (95% CI) a. For Apgar score < 7 at 1 minute Sensitivity: 58.33% (30.44 to 86.23) Specificity: 72.73% (46.41 to 99.05) PPV: 70.00% (41.60 to 98.40) NPV: 61.54% (35.09 to 87.99) LR+: 2.14 (0.73 to 6.28) LR-: 0.57 (0.27 to 1.23) b. For Apgar score < 7 at 5 minutes Sensitivity: 66.67% (13.32 to 100) Specificity: 60.00% (38.53 to 81.47) PPV: 20.00% (0 to 44.79) NPV: 92.31% (77.82 to 100) LR+: 1.67 (0.64 to 4.37) LR-: 0.56 (0.11 to 2.86) c. For umbilical artery pH < 7.1 Sensitivity: 100% (NC) Specificity: 66.67% (44.89 to 88.44) PPV: 33.33% (2.5 to 64.13) NPV: 100% (NC) LR+: 3.00 (1.56 to 5.77)	confounders are accounted for: Mode of birth is not reported Statistical analysis is appropriate for study design: Yes Other information Further information about cases of low Apgar score at 5 minutes Case 14: - Meconium staining, fetal tachycardia - Tested at 19 minutes before birth - Apgar of 2 at 1 minute and 5 at 5 minutes Case 18: - Fetal distress, irregular and slow FHR - Tested at 25 minutes before birth - Baby was stillborn Case 30:

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	pulmonary diseaese (CPD), premature rupture of membranes (RoM), tachycardia, rim and full dilatation - Full dilatation Case 26: Class D diabetes - Full dilatation 8 had complicated labours and gave birth to depressed babies within an hour of FBS (range 16 minutes to 40 minutes): Case 3: relative CPD, pitocin drip - 7 cm dilatation Case 12: CPD - Full dilatation Case 14: meconium staining, fetal tachycardia - 5-6 cm dilatation Case 18: fetal distress, irregular and slow FHR [still born] - Full dilatation Case 19: CPD, fetal		of the baby was evaluated at 1 minute and 5 minutes. All patients delivered under local or regional anaesthesia, where possible. Patients received varying amounts of meperidine and scopolamine for analgesia.	LR-: 0.00 (NC) Predictive value of pH ≤ 7.25 (95% CI) a. For Apgar score < 7 at 1 minute Sensitivity: 75.00% (50.50 to 99.50) Specificity: 9.09% (0 to 26.08) PPV: 47.37% (24.92 to 69.82) NPV: 25.00% (0 to 67.44) LR+: 0.83 (0.57 to 1.20) LR-: 2.75 (0.33 to 22.69) b. For Apgar score < 7 at 5 minutes Sensitivity: 66.67% (13.32 to 100) Specificity: 15.00% (0 to 30.65) PPV: 10.53% (0 to 24.33) NPV: 75.00% (32.56 to 100) LR+: 0.78 (0.35 to 1.78) LR-: 2.22 (0.33 to 15.01) c. For umbilical artery pH < 7.1 Sensitivity: 100% (NC) Specificity: 22.22% (3.02 to 41.43) PPV: 17.65% (0 to 35.77) NPV: 100% (NC) LR+: 1.29 (1.00 to 1.65) LR-: 0 (NC) Predictive value of base deficit > 10 mEq/l (95% CI) a. For Apgar score < 7 at 1 minute	- Cephalopelvic disproportion, irregular FHR, caesarean section - Tested at 40 minutes before birth - Apgar of 4 at 1 minute and 6 at 5 minutes Further information about cases of low arterial pH (< 7.10) at birth Case 12: - Cephalopelvic disproportion - Tested at 16 minutes before birth and had pH of 7.12 - Artery pH of 7.06 Case 18: - Fetal distress, irregular and slow FHR - Tested at 25 minutes before birth and had pH of 6.64 - Baby was stillborn

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	distress, FHR 60, cord around shoulder - Full dilatation Case 24: prolonged RoM, amniotis, fetal sepsis - Full dilatation Case Elm 3: toxemia, type II dips, CPD - Full dilatation Case 30: CPD, irregular FHR, caesarean - 7 cm dilatation Inclusion Criteria None reported Exclusion Criteria None reported			Sensitivity: 25.00% (0 to 55.01) Specificity: 90.91% (73.92 to 100) PPV: 66.67% (13.32 to 100) NPV: 62.50% (38.78 to 86.22) LR+: 2.75 (0.30 to 25.35) LR-: 0.83 (0.53 to 1.28) b. For Apgar score < 7 at 5 minutes Sensitivity: 0 (NC) Specificity: 83.33% (66.12 to 100) PPV: 0 (NC) NPV: 93.75% (81.89 to 100) LR+: 0 (NC) LR-: 1.20 (0.98 to 1.48) c. For umbilical artery pH < 7.10 Sensitivity: 0 (NC) Specificity: 81.25% (62.12 to 100) PPV: 0 (NC) NPV: 86.67% (69.46 to 100) LR+: 0 (NC) LR-: 1.23 (0.97 to 1.56) Predictive value of base deficit > 12 mEq/l (95% CI) a. For Apgar score < 7 at 1 minute Sensitivity: 25.00% (0 to 55.01) Specificity: 100% (NC) PPV: 100 (NC) NPV: 64.71% (41.99 to 87.42) LR+: infinite	and had arterial pH of 6.81 Case Elm 3: - Toxemia, type II dips, cephalopelvic disproportion - Tested at 25 minutes before birth and had pH of 7.15 - Artery pH of 7.08

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				LR-: 0.75 (0.51 to 1.12) b. For Apgar score < 7 at 5 minutes Sensitivity: 0 (NC) Specificity: 88.89% (74.37 to 100) PPV: 0 (NC) NPV: 94.12 (82.93 to 100) LR+: 0 (NC) LR-: 1.13 (0.96 to 1.32) c. For umbilical artery pH < 7.10 Sensitivity: 0 (NC) Specificity: 87.50% (71.29 to 100) PPV: 0 (NC) NPV: 87.50% (71.29 to 100) LR+: 0 (NC) LR-: 1.14 (0.95 to 1.38) Predictive value of base deficit > 12.5 mEq/l (95% CI) a. For Apgar score < 7 at 1 minute Sensitivity: 12.50% (0 to 35.42) Specificity: 100 (NC) PPV: 100 (NC) NPV: 61.11% (38.59 to 83.63) LR+: infinite LR-: 0.88 (0.67 to 1.14) b. For Apgar score < 7 at 5 minutes Sensitivity: 0 (NC) Specificity: 94.44% (83.86 to 100)	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				PPV: 0 (NC) NPV: 94.44% (83.86 to 100) LR+: 0 (NC) LR-: 1.06 (0.95 to 1.18) c. For umbilical artery pH < 7.10 Sensitivity: 0 (NC) Specificity: 93.75% (81.89 to 100) PPV: 0 (NC) NPV: 88.24% (72.92 to 100) LR+: 0 (NC) LR-: 1.07 (0.94 to 1.21) FBS pH < 7.1 for Apgar < 7 at 1 minute <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>3</td><td>0</td></tr><tr><td>Predictive Test -ve</td><td>9</td><td>11</td></tr></table> FBS pH < 7.1 for arterial pH < 7.10 <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>1</td><td>1</td></tr></table>	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

Predictive Test -ve	2	17

FBS pH <= 7.20 for arterial pH < 7.1

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	3	6
Predictive Test -ve	0	12

FBS pH <= 7.20 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	7	3
Predictive Test -ve	5	8

FBS pH <= 7.20 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

Predictive Test +ve	2	8
Predictive Test -ve	1	12

FBS pH <= 7.25 for arterial pH < 7.1

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	3	14
Predictive Test -ve	0	4

FBS pH <= 7.25 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	9	10
Predictive Test -ve	3	1

FBS <= 7.25 for Apgar < 7 at 5 minutes

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	2	17
Predictive Test -ve	1	3

FBS base deficit > 10 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	2	1
Predictive Test -ve	6	10

FBS base deficit > 10 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	3
Predictive Test -ve	1	15

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

FBS base deficit > 10 for arterial pH < 7.10

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	3
Predictive Test -ve	2	13

FBS base deficit > 12 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	2	0
Predictive Test -ve	6	11

FBS base deficit > 12 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	2

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

Predictive Test -ve	1	16

FBS base deficit > 12 for arterial pH < 7.10

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	2
Predictive Test -ve	2	14

FBS base deficit > 12.5 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	1	0
Predictive Test -ve	7	11

FBS base deficit > 12.5 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				<table><tr><td>Predictive Test +ve</td><td>0</td><td>1</td></tr><tr><td>Predictive Test -ve</td><td>1</td><td>17</td></tr></table> FBS base deficit > 12.5 for arterial pH < 7.10 <table><tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr><tr><td>Predictive Test +ve</td><td>0</td><td>1</td></tr><tr><td>Predictive Test -ve</td><td>2</td><td>15</td></tr></table>	
Full citation Khazin,A.F., Hon,E.H., Quilligan,E.J., Biochemical studies of the fetus. 3. Fetal base and Apgar scores, Obstetrics and Gynecology, 34, 592-609, 1969 Ref Id 170426 Country/ies where the study was carried out USA Study type Case-series	Sample size N = 194 Characteristics 80 patients had complications of pregnancy such as toxemia, Rh sensitisation, diabetes, premature rupture of membranes, clinically diagnosed fetal distress or post-dates	Tests pH analysis	Methods Fetal blood samples were collected according to Saling's technique, but glass capillary tubes were used instead of plastic. Patients were monitored using electrocardiogram (ECG), fetal heart rate (FHR)	Results The following calculations were performed by the technical team, based on 2x2 data reported in the text for 130 babies who had samples taken within 30 minutes of birth: Predictive accuracy (95% CI) of a fetal base deficit of > 12.5 mEq/l for: a. 1-minute Apgar score < 7 Sensitivity: 31.82% (12.35 to 51.28) Specificity: 92.59% (87.65 to 97.53) PPV: 46.67% (21.42 to 71.91)	Limitations Study sample represents population: 80/194 women had complications in labour; very few other details about the population are reported Loss to follow-up is unrelated to key characteristics: no loss to follow-up

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Aim of the study Not reported Study dates Not reported Source of funding Supported in part by research grants from the National Institute of Child Health and Human Development, USPHS, and a grant from the Health Sciences Computing Facility	(proportions of each are not reported) Inclusion Criteria Not reported Exclusion Criteria Not reported		patterns, monitoring of uterine contractions and blood pressure monitoring. Biochemical measures included maternal, fetal and neonatal pH, pO2, pCO2, base deficit, lactate, pyruvates and haemoglobin. Umbilical artery and vein blood was obtained before the first breath of the infant, from a doubly clamped segment of the umbilical cord. A radiometer microelectrode was done to determine pH. Fetal scalp blood samples were obtained during different stages of labour, and between 1 and	NPV: 86.96% (80.80 to 93.11) LR+: 4.30 (1.74 to 10.62) LR-: 0.74 (0.55 to 0.98) b. 5-minute Apgar score < 7 Sensitivity: 42.86% (6.20 to 79.52) Specificity: 90.24% (85.00 to 95.49) PPV: 20.00% (0 to 40.24) NPV: 96.52% (93.17 to 99.87) LR+: 4.39 (1.60 to 12.06) LR-: 0.63 (0.33 to 1.21) Correlation between 1 minute Apgar score and fetal base-deficit at different intervals before birth All samples - Apgar 7 - 10 Time interval (mean ± SD): 86.06 ± 111.55 Apgar (mean ± SD): 8.53 ± 0.63 Base deficit / mEq/l (mean ± SD): 7.91 ± 2.80 number of samples: 472 r: -0.1459 p-value: < 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 194.54 ± 225.81 Apgar (mean ± SD): 3.29 ± 2.08 Base deficit / mEq/l (mean ± SD):	Prognostic factors are adequately measured in participants: very few details about what happened to the babies during labour Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: mode of birth is not reported Statistical analysis is appropriate for study design: yes Other information Further information about the false negatives (i.e. base deficit ≤ 12.5 mEq/l but with a low Apgar score at 1 minute, table 5 in paper) 1. - 2 samples taken, at

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			35 samples were taken per patient. Fetal base determinations were done on 602 samples taken from 140 patients (1 - 17 per patient). Apgar score at 1 and 5 minutes were taken. 1 - 6 was considered low, and 7 - 10 was considered high. This was first done for all samples, and then restricted to samples taken within the last 30 minutes of labour. To determine the impact of time interval between fetal base determination and birth on predictive values, correlation coefficients were taken for all	8.26 ± 3.39 number of samples: 130 r: +0.0387 p-value: > 0.05 60 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 15.75 ± 15.05 Apgar (mean ± SD): 8.48 ± 0.67 Base deficit / mEq/l (mean ± SD): 8.27 ± 2.95 number of samples: 277 r: -0.2002 p-value: <0.005 - Apgar 1 - 6 Time interval (mean ± SD): 19.70 ± 12.05 Apgar (mean ± SD): 3.16 ± 2.03 Base deficit / mEq/l (mean ± SD): 9.75 ± 3.85 number of samples: 45 r: -0.2056 p-value: > 0.05 45 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 12.80 ± 11.04 Apgar (mean ± SD): 8.47 ± 0.67	20 minutes and 16 minutes prior to birth - BD 11.1 - 11.3 - Late decelereations (+++), hyperactivity (+++) - Apgar scores: 2, 5 2. - 5 samples taken, at between 320 and 18 minutes prior to birth - BD 8.8 - 10.3 - Variable decelerations (++), Caput (+++) - Forceps applied with traction for 7 minutes - Apgar scores: 4, 7 3. - 3 samples taken, at between 12 and 9 minutes prior to birth - BD 9.4 - 12.4 - Variable decelerations (+) - Shoulder dystocia, midforceps

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			samples, then restricted to those in the last 60, 45, 30, 15 and 5 minutes preceding birth.	Base deficit / mEq/l (mean ± SD): 8.32 ± 2.99 number of samples: 257 r: -0.1817 p-value: <0.005 - Apgar 1 - 6 Time interval (mean ± SD): 18.38 ± 10.59 Apgar (mean ± SD): 3.26 ± 2.03 Base deficit / mEq/l (mean ± SD): 9.72 ± 3.68 number of samples: 43 r: -0.2167 p-value: > 0.05 30 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 9.94 ± 7.50 Apgar (mean ± SD): 8.52 ± 0.66 Base deficit / mEq/l (mean ± SD): 8.39 ± 2.98 number of samples: 230 r: -0.1825 p-value: < 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 14.59 ± 7.43 Apgar (mean ± SD): 3.31 ± 2.15	- Apgar scores: 6, 9 4. - 2 samples taken at between 24 and 22 minutes prior to birth - BD 7.2 - Variable decelerations (++) - Twin A, variable decelerations with delivery - Apgar scores: 5, 9 [Note: there was one further case, but the sample was taken outside the time of interest; therefore details have not been reported here]

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Base deficit / mEq/l (mean ± SD): 10.43 ± 3.31 number of samples: 35 r: -0.2664 p-value: > 0.05 15 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 6.84 ± 4.06 Apgar (mean ± SD): 8.58 ± 0.66 Base deficit / mEq/l (mean ± SD): 8.28 ± 2.98 number of samples: 185 r: -0.1812 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 8.58 ± 4.36 Apgar (mean ± SD): 3.44 ± 2.55 Base deficit / mEq/l (mean ± SD): 10.57 ± 3.36 number of samples: 18 r: -0.3553 p-value: > 0.05 5 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 3.01 ± 1.37	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Apgar (mean ± SD): 8.61 ± 0.68 Base deficit / mEq/l (mean ± SD): 8.49 ± 2.46 number of samples: 81 r: -0.0590 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 1.75 ± 0.50 Apgar (mean ± SD): 2.50 ± 2.38 Base deficit / mEq/l (mean ± SD): 10.68 ± 1.08 number of samples: 4 r: -0.9259 p-value: Correlation between 5 minute Apgar score and fetal base-deficit at different intervals before birth All samples - Apgar 7 - 10 Time interval (mean ± SD): 94.26 ± 114.80 Apgar (mean ± SD): 9.01 ± 0.70 Base deficit / mEq/l (mean ± SD): 7.97 ± 2.92 number of samples: 559 r: -0.0918 p-value: < 0.05	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				- Apgar 1 - 6 Time interval (mean ± SD): 307.45 ± 326.20 Apgar (mean ± SD): 4.65 ± 1.25 Base deficit / mEq/l (mean ± SD): 8.11 ± 3.27 number of samples: 43 r: -0.3210 p-value: < 0.05 60 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 16.31 ± 14.94 Apgar (mean ± SD): 9.08 ± 0.68 Base deficit / mEq/l (mean ± SD): 8.35 ± 3.06 number of samples: 309 r: -0.0960 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 16.31 ± 7.99 Apgar (mean ± SD): 4.62 ± 1.76 Base deficit / mEq/l (mean ± SD): 11.47 ± 3.18 number of samples: 13 r: -0.8362 p-value: < 0.005	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				45 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 13.48 ± 11.25 Apgar (mean ± SD): 9.08 ± 0.68 Base deficit / mEq/l (mean ± SD): 8.38 ± 3.06 number of samples: 287 r: -0.0663 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 16.31 ± 7.99 Apgar (mean ± SD): 4.62 ± 1.76 Base deficit / mEq/l (mean ± SD): 11.47 ± 3.18 number of samples: 13 r: -0.8362 p-value: < 0.005 30 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 10.34 ± 7.61 Apgar (mean ± SD): 9.11 ± 0.64 Base deficit / mEq/l (mean ± SD): 8.51 ± 3.03 number of samples: 253 r: -0.1383 p-value: < 0.05	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				- Apgar 1 - 6 Time interval (mean ± SD): 15.13 ± 7.05 Apgar (mean ± SD): 4.50 ± 1.78 Base deficit / mEq/l (mean ± SD): 11.84 ± 3.02 number of samples: 12 r: -0.8359 p-value: < 0.005 15 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 6.91 ± 4.07 Apgar (mean ± SD): 9.21 ± 0.58 Base deficit / mEq/l (mean ± SD): 8.36 ± 2.98 number of samples: 197 r: -0.1454 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 9.75 ± 4.45 Apgar (mean ± SD): 4.33 ± 2.58 Base deficit / mEq/l (mean ± SD): 12.42 ± 4.12 number of samples: 6 r: -0.9366 p-value: < 0.005	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				5 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 2.96 ± 1.37 Apgar (mean ± SD): 9.21 ± 0.62 Base deficit / mEq/l (mean ± SD): 8.55 ± 2.44 number of samples: 84 r: -0.1517 p-value: 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 2.00 (NA) Apgar (mean ± SD): 6 (NA) Base deficit / mEq/l (mean ± SD): 11.80 (NA) number of samples: 1 r: NA p-value: NA FBS base deficit > 12.5 for Apgar < 7 at 1 minute |	Reference Test +ve	Reference Test -ve
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Predictive Test +ve	7	8
Predictive	15	100		

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Test -ve</td><td></td><td></td></tr>
</table>

FBS base deficit > 12.5 for Apgar < 7 at 5 minutes
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>3</td><td>12</td></tr>
<tr><td>Predictive Test -ve</td><td>4</td><td>111</td></tr>
</table>
</td><td></td></tr>
<tr><td>Full citation
Kubli,F.W., Influence of labor on fetal acid-base balance, Clinical Obstetrics and Gynecology, 11, 168-191, 1968
Ref Id
169765
Country/ies where the study was carried out
USA
Study type
Case-series
Aim of the study
Not reported

Study dates
1966 - 1967</td><td>Sample size
N = 77

Characteristics
none reported

Inclusion Criteria
Not reported

Exclusion Criteria
Not reported</td><td>Tests
pH within 30 minutes of birth</td><td>Methods
Very few details are reported, as this is a further analysis of another study by Hon (referenced as not published). 77 patients were selected in whom the last sample was done 30 minutes before birth. However, the authors report including 5 further patients with an abnormal pH value with or without</td><td>Results
The following measures were calculated based on 2x2 data reported in table 2a of the paper.

Predictive value of pH < 7.20 for an Apgar < 7 (reported as ≤ 6) at 1 minute
Sensitivity: 57.14% (31.22 to 83.07)
Specificity: 84.13% (75.10 to 93.15)
PPV: 44.44% (21.49 to 67.40)
NPV: 89.83% (82.12 to 97.54)
LR+: 3.60 (1.74 to 7.45)
LR-: 0.51 (0.28 to 0.94)

Correlation of fetal scalp measurements with umbilical cord measurements (r value)*</td><td>Limitations
Study sample represents population: Unclear, exclusion and inclusion criteria are not reported and there are no characteristics reported
Loss to follow-up is unrelated to key characteristics: Unclear
Prognostic factors are adequately measured in participants: Yes</td></tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Source of funding Supported in part by Public Health Service Research Grant from the National Heart Institute and a Grant from DFG (Deutsche Forschungsgemeinschaft)			depression. For all patients, continuous fetal heart rate monitoring was done and amniotic fluid pressure was recorded.	a. pH: 0.76 b. Base excess: 0.90 Note: this relates to 31 samples from uncomplicated, spontaneous births where the FBS was done within 5 minutes of birth * There is some discrepancy between data reported in the text and in the figures; data from the text have been reported here FBS pH < 7.20 for Apgar < 7 at 1 minute Reference Test +ve / Reference Test -ve Predictive Test +ve: 8 / 10 Predictive Test -ve: 6 / 53	Outcome of interest is sufficiently measured in participants: Yes Important potential confounders are accounted for: No, there are very few details and mode of birth is not reported Statistical analysis is appropriate for study design: Unclear They restricted sample to those within 30 minutes, but then added a further 5 patients as they didn't have sufficient data. In general, this study is very badly reported. Other information Additional details about babies with low scalp pH but born vigorous ('false positives') Note: The detail

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					provided about the 'false positives' does not use the same threshold for high Apgar as the rest of the data reported; therefore, not all of the false positives have extra data reported for them. Out of the 7 babies with abnormal pH but an Apgar of at least 8: - 2 had unknown causes - In one, there was transient uterine hypertonus due to oxytocin over-dosage, which was associated with marked and prolonged late decelerations. - In the remaining 4 cases, the presence of severe or moderate cord compression was

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					suggested.
Full citation Wiberg-Itzel,E., Lipponer,C., Norman,M., Herbst,A., Prebensen,D., Hansson,A., Bryngelsson,A.L., Christoffersson,M., Sennstrom,M., Wennerholm,U.B., Nordstrom,L., Determination of pH or lactate in fetal scalp blood in management of intrapartum fetal distress: randomised controlled multicentre trial, BMJ, 336, 1284-1287, 2008 Ref Id 116763 Country/ies where the study was carried out Sweden Study type Randomised controlled study Aim of the study To examine the effectiveness of pH analysis of fetal scalp blood compared with lactate analysis in identifying hypoxia in labour to prevent acidaemia at birth Study dates December 2002 to December 2005	Sample size N = 3007 randomised Characteristics Maternal age/years (mean (range)) pH: 33.0 (19 - 49) Lactate: 32.5 (19 - 48) Parity (n (%)) - Nulliparous pH: 1179 (78.8) Lactate: 1155 (77.2) - Multiparous pH: 317 (21.2) Lactate: 341 (22.8) Gestational age/weeks+days (mean (range)) pH: 40+2 (34+0 - 44+2) Lactate: 40+3 (34+0 - 43+6) Fetal weight a.	Tests pH analysis Lactate analysis [data are reported for within 60 minutes of birth]	Methods Antenatal clinics gave information about the study to women who were late in pregnancy, and requested consent either then or when the woman was admitted in labour. If consent was not obtained, or the woman was distressed, she was cared for according to the protocols of the department she was in. 3007 women were randomised, and then 15 were excluded as per exclusion criteria. An internet based system was used for randomisation and data entry. Randomisation was	Results The following data was reported in the trial, and this was used to calculate the diagnostic accuracy data below. Incidence of metabolic acidaemia (n/total (%)) a. Split by pH status > 7.25: 7/281 (2.5) 7.25 - 7.21: 3/92 (3.3) < 7.21: 10/135 (7.4) b. Split by lactate status < 4.2: 6/344 (1.7) 4.2 - 4.8: 0/73 (0) > 4.8: 19/267 (7.1) Incidence of pH < 7.00 at birth (n/total (%)) a. Split by pH status > 7.25: 4/281 (1.4) 7.25 - 7.21: 2/92 (2.2) < 7.21: 5/135 (3.7) b. Split by lactate status < 4.2: 0/344 (0) 4.2 - 4.8: 0/73 (0) > 4.8: 10/267 (3.7)	Limitations Study sample represents population: unclear whether these women were definitely low risk during their pregnancy Loss to follow-up is unrelated to key characteristics: Not applicable because there was no loss to follow-up. However, there are some missing data: samples for cord pH measurement were missing in 174 in pH arm and 120 in lactate arm; however, it is unclear whether these came from the subset of the study population with measurements done within 60 minutes of

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Source of funding Signhild Engqvists Stiftelse, Almanna BB's Minnesfond, the regional city council research and development foundations, the health and medical committee of the region Vastra Gotaland, and Medexa, Lomma, Sweden	Mean/grams (range) pH: 3575 (1590 - 5680) Lactate: 3566 (1860 - 6110) b. Proportion with fetal weight < 2500 (n/total) pH: 39/1496 Lactate: 36/1496 Use of STAN monitor (n (%)) pH: 393 (26.2) Lactate: 392 (26.2) Inclusion Criteria Singleton pregnancy Cephalic presentation Gestational age ≥ 34 weeks Non-reassuring fetal heart rate trace that the clinician in charge considered to be an indication for FBS		stratified by department, and also by the use of electrocardiogram (ECG) as an adjunct to cardiotocography (CTG). At the point that the clinician decided to sample fetal scalp blood, the woman was randomised to either pH or lactate analysis. If sampling or analysis failed, management was based on other clinical information. Any crossover was regarded as a protocol violation. Scalp blood was sampled one to nine times for each fetus. In the pH group, successful sampling or analysis was	Incidence of Apgar < 7 at 5 minutes (n/total (%)) a. Split by pH status > 7.25: 9/281 (3.2) 7.25 - 7.21: 2/92 (2.2) < 7.21: 10/135 (7.4) b. Split by lactate status < 4.2: 4/344 (1.2) 4.2 - 4.8: 1/73 (1.4) > 4.8: 23/267 (8.6) The following diagnostic accuracy measures were calculated by the technical team, based on the above data. They refer to fetuses in whom fetal scalp blood was collected within 60 minutes of birth. Predictive accuracy of scalp pH < 7.21 a. For metabolic acidaemia Sensitivity: 50.00% (28.09 to 71.91) Specificity: 74.39% (70.51 to 78.26) PPV: 7.41% (2.99 to 11.83) NPV: 97.32% (95.68 to 98.96) LR+: 1.95 (1.23 to 3.10) LR-: 0.67 (0.43 to 1.05) b. For umbilical artery pH < 7.00	birth. Prognostic factors is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: not really applicable - women were randomised to receive lactate or pH Statistical analysis is appropriate for study design: yes Other information This study is also included in the Cochrane review (East et al., 2010) which has been included in this review. However, further data are available from the full text of the trial.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	Exclusion Criteria Multiple pregnancy Gestational age < 34 weeks		performed in 1008 fetuses, with a total of 1628 analyses of pH. In the lactate group, successful sampling was done in 1355 fetuses, with a total of 2301 analyses. End points were metabolic acidaemia in cord blood (defined as a pH < 7.05 and base deficit > 12 mmol/l) and pH < 7.00. Base deficit was calculated with the algorithm used by Radiometer blood gas analysers. Lactate was measured using a microvolume test strip device (Lactate Pro). Various pH analysers were used, but regular	Sensitivity: 45.45% (16.03 to 74.88) Specificity: 73.84% (69.98 to 77.71) PPV: 3.70% (0.52 to 6.89) NPV: 98.39% (97.11 to 99.67) LR+: 1.74 (0.89 to 3.38) LR-: 0.74 (0.43 to 1.27) c. For Apgar < 7 at 5 minutes Sensitivity: 47.62% (26.26 to 68.98) Specificity: 74.33% (70.45 to 78.21) PPV: 7.41% (2.99 to 11.83) NPV: 97.05% (95.33 to 98.77) LR+: 1.86 (1.16 to 2.98) LR-: 0.70 (0.47 to 1.06) Diagnostic accuracy of scalp pH ≤ 7.25 a. For metabolic acidaemia Sensitivity: 65.00% (44.10 to 85.90) Specificity: 56.15% (51.74 to 60.55) PPV: 5.73% (2.70 to 8.75) NPV: 97.51% (95.69 to 99.33) LR+: 1.48 (1.06 to 2.08) LR-: 0.62 (0.34 to 1.14) b. For umbilical artery pH < 7.00 Sensitivity: 63.64% (35.21 to 92.06) Specificity: 55.73% (51.37 to 60.10) PPV: 3.08% (0.83 to 5.33) NPV: 98.58% (97.19 to 99.96) LR+: 1.44 (0.91 to 2.27)	Data that have been reported in the Cochrane review will not be reported here. There were 155 protocol violations in the pH group (146 failed FBS and 9 failed analysis) and 18 in the lactate group (all failed sampling). However, data for these women would not be incorporated in this data, as they could not be classified by pH or lactate value. No fetal scalp blood was collected in 106 women in the pH arm and 81 in the lactate arm. In most cases a reason was not provided, however, some were as a result of rapid delivery, expedited

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			quality checks were performed. Guidelines for interpreting blood gas were: - pH > 7.25 or lactate < 4.2 mmol/l: normal - pH 7.21 - 7.25 or lactate 4.2 - 4.8 mmol/l: pre-acidaemia - pH < 7.21 or lactate > 4.8 mmol/l: acidaemia The guidelines for pre-acidaemia were to repeat the sample in 20-30 minutes if there was no other indication for intervention. For fetuses with acidaemia, the decision about delivery was left to the clinician. A sample size	LR-: 0.65 (0.30 to 1.43) c. For Apgar < 7 at 5 minutes Sensitivity: 57.14% (35.98 to 78.31) Specificity: 55.85% (51.44 to 60.26) PPV: 5.29% (2.38 to 8.2) NPV: 96.80% (94.74 to 98.86) LR+: 1.29 (0.88 to 1.90) LR-: 0.77 (0.47 to 1.27) Diagnostic accuracy of scalp lactate > 4.8 mmol/l a. For metabolic acidaemia Sensitivity: 76.00% (59.26 to 92.74) Specificity: 62.37% (58.67 to 66.07) PPV: 7.12% (4.03 to 10.2) NPV: 98.56% (97.42 to 99.70) LR+: 2.02 (1.59 to 2.57) LR-: 0.38 (0.19 to 0.78) b. For umbilical artery pH < 7.00 Sensitivity: 100% (100 to 100) Specificity: 61.87% (58.20 to 65.54) PPV: 3.75% (1.47 to 6.02) NPV: 100% (100 to 100) LR+: 2.62 (2.38 to 2.89) LR-: 0.00 (not calculable [NC]) c. For Apgar < 7 at 5 minutes Sensitivity: 82.14% (67.96 to 96.33) Specificity: 62.80% (59.11 to 66.50)	delivery, reassuring CTG or the withdrawal of consent.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			calculation calculated that a total of 2872 participants would be needed to detect a 100% increase in metabolic acidaemia with lactate, compared to a prevalence of 1.6% in the pH arm, with 80% power. To show a 50% reduction, 2907 cases in each arm would be needed. For the endpoint of pH < 7.00, 1141 cases in each arm were needed to detect a 50% decrease or increase. Interim analyses were done after 1400 and 2400 randomised cases. Following the second analysis,	PPV: 8.61% (5.25 to 11.98) NPV: 98.80% (97.76 to 99.85) LR+: 2.21 (1.81 to 2.70) LR-: 0.28 (0.13 to 0.63) Diagnostic accuracy of scalp lactate ≥ 4.2 mmol/l a. For metabolic acidaemia Sensitivity: 76.00% (59.26 to 92.74) Specificity: 51.29% (47.47 to 55.11) PPV: 5.59% (3.15 to 8.03) NPV: 98.26% (96.87 to 99.64) LR+: 1.56 (1.24 to 1.97) LR-: 0.47 (0.23 to 0.94) b. For umbilical artery pH < 7.00 Sensitivity: 100% (100 to 100) Specificity: 51.04% (47.26 to 54.81) PPV: 2.94% (1.15 to 4.74) NPV: 100% (100 to 100) LR+: 2.04 (1.89 to 2.21) LR-: 0.00 (NC) c. For Apgar < 7 at 5 minutes Sensitivity: 85.71% (72.75 to 98.68) Specificity: 51.83% (48.01 to 55.65) PPV: 7.06% (4.34 to 9.78) NPV: 98.84% (97.70 to 99.97) LR+: 1.78 (1.50 to 2.11) LR-: 0.28 (0.11 to 0.69)	

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td>the independent steering committee recommended stopping the trial after 3000 cases.

Data was analysed on an intention-to-treat basis. Chi-squared and relative risks were used to compared pH and lactate groups. p < 0.05 was considered significant.</td><td>Operative delivery due to fetal distress in women in whom fetal scalp blood was taken within 60 minutes of delivery (n/total (%))
a. In women randomised to pH analysis
pH > 7.25: 81/281 (28.8)
pH 7.21 - 7.25: 58/92 (63.0)
pH < 7.21: 118/135 (87.4)

b. In women randomised to lactate analysis
Lactate < 4.2: 79/334 (23.0)
Lactate 4.2 - 4.8: 50/73 (68.5)
Lactate > 4.8: 251/267 (94.0)

FBS < 7.21 for metabolic acidaemia
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>10</td><td>125</td></tr>
<tr><td>Predictive Test -ve</td><td>10</td><td>363</td></tr>
</table>
FBS < 7.21 for UA pH < 7.00
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
</table></td><td></td></tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

Predictive Test +ve	5	130
Predictive Test -ve	6	367

FBS < 7.21 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	10	125
Predictive Test -ve	11	362

FBS <= 7.25 for metabolic acidaemia

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	13	214
Predictive Test -ve	7	274

FBS <= 7.25 for pH < 7.00

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	7	220
Predictive Test -ve	4	277

FBS <= 7.25 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	12	215
Predictive Test -ve	9	272

Lactate > 4.8 for metabolic acidaemia

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	19	248
Predictive Test -ve	6	411

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Lactate > 4.8 for UA pH < 7.00 Reference Test +ve / Reference Test -ve Predictive Test +ve: 10 / 257 Predictive Test -ve: 0 / 417 Lactate > 4.8 for Apgar < 7 at 5 minutes Reference Test +ve / Reference Test -ve Predictive Test +ve: 23 / 244 Predictive Test -ve: 5 / 412 Lactate >= 4.2 for metabolic acidaemia Reference Test +ve / Reference Test -ve Predictive Test +ve: 19 / 321 Predictive: 6 / 338	

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Test -ve</td><td></td><td></td></tr>
</table>

Lactate >= 4.2 for UA pH < 7.00
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>10</td><td>330</td></tr>
<tr><td>Predictive Test -ve</td><td>0</td><td>344</td></tr>
</table>

Lactate >= 4.2 for Apgar < 7 at 5 minutes
<table>
<tr><td></td><td>Reference Test +ve</td><td>Reference Test -ve</td></tr>
<tr><td>Predictive Test +ve</td><td>24</td><td>316</td></tr>
<tr><td>Predictive Test -ve</td><td>4</td><td>340</td></tr>
</table>
</td><td></td></tr>
<tr><td>Full citation
Young,D.C., Gray,J.H., Luther,E.R., Peddle,L.J., Fetal scalp blood pH sampling: its value in an active obstetric unit, American Journal of Obstetrics and Gynecology,Am.J.Obstet.Gynecol., 136, 276-281, 1980</td><td>Sample size
N = 232 women

(Note: the last scalp sample was taken less than 1 hour before birth in 95 women, and they</td><td>Tests
Fetal scalp pH</td><td>Methods
232 women had a total of 335 pH determinations done (mean 1.5 per patient, range 1 to 5). 98% of sampling was due</td><td>Results
The following diagnostic accuracy measures have been calculated by the technical team, based on 2x2 data that was reported in the study. The data only relate to babies born within 1 hour of the fetal pH measurement. 136 babies who had</td><td>Limitations
Study sample represents population: there was a high proportion of women who would not be considered low risk</td></tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Ref Id 159915 Country/ies where the study was carried out Canada Study type Case-series Aim of the study To determine: - indications for fetal blood pH sampling - the incidence of fetal acidosis with each indication - incidence of neonatal depression related to fetal acidosis - complications of fetal blood sampling (FBS) - number of caesarean sections avoided - number of asphyxiated infants born less than 1 hour after fetal blood sampling Study dates January 1st 1978 to September 30th 1978 Source of funding	constitute the true population of interest) Characteristics Time between last FBS and birth (n (%)) < 1 hour: 95 (40.9) 1 - 2 hours: 67 (28.9) > 2 hours: 70 (30.2) Obstetric characteristics (n (%)) Pre-eclampsia toxaemia: 37 (16) Premature rupture of membranes: 23 (10) intrauterine growth restriction (IUGR): 19 (8) Prematurity: 9 (4) Post-maturity: 32 (14) Meconium-stained fluid: 77 (33) Oxytocin induced labour: 103 (44) Oral prostaglandin: 16 (7) Nulliparous: 162 (70) Epidural: 175 (75) Parenteral narcotic < 6 hours: 53 (23)		to changes in fetal heart rate. 95% of the samples in the study were done with the patients in a modified Sims' position. A Monoject Sterile Disposable Fetal Blood Sampling Kit was used for sample collection, and results were available within 10 minutes of sampling. The fetal heart trace in the hour before FBS were analysed and classified using ACOG Technical Bulletin 32, and in addition as follows: - Mild decelerations: less than 30 bpm in depth - Moderate decelerations: 30 -	a pH ≥ 7.25 and were born over an hour after the measurement were not included for these calculations: Diagnostic accuracy for neonatal depression (95% CI) a. pH < 7.20 Sensitivity: 37.50% (3.95 to 71.05) Specificity: 96.59% (92.80 to 100) PPV: 50.00% (9.99 to 90.01) NPV: 94.44% (89.71 to 99.18) LR+: 11.00 (2.64 to 45.84) LR-: 0.65 (0.38 to 1.11) b. pH < 7.25 Sensitivity: 50.00% (15.35 to 84.65) Specificity: 81.82% (73.76 to 89.88) PPV: 20.00% (2.47 to 37.53) NPV: 94.74% (89.72 to 99.76) LR+: 2.75 (1.21 to 6.26) LR-: 0.61 (0.30 to 1.23) The GDG report that neonatal depression was more frequent in babies with severe fetal acidosis. However, it was not more frequent in babies with mild acidosis when compared to normal scalp pH. They state that this may reflect the use of intrauterine resuscitation (oxygen by mask, repositioning, discontinuation	Loss to follow-up is unrelated to key characteristics: there was no loss to follow up Prognostic factor is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: there were differences in the proportion of babies born by CS, and this is not reported for the sub-group of babies with normal pH but who were born within an hour Statistical analysis is appropriate for study design: yes Indirectness of population: yes, a

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Life Insurance Association of Canada	Indication for fetal blood sampling (n (%)) Baseline: - Tachycardia: 14 (6) - Bradycardia: 15 (6) Decreased variability: 24 (10) Variable decelerations: - Mild: 22 (10) - Moderate: 84 (36) - Severe: 38 (16) Late decelerations: - Mild: 19 (8) - Moderate: 5 (2) Early decelerations: 7 (3) Other indications: 4 (2) Inclusion Criteria All patients having fetal scalp blood pH sampling (98% were		60 bpm in depth - Severe decelerations: greater than 60 bpm in depth - Persistent decelerations: longer than 30 minutes and with more than 50% of contractions - Variable decelerations that did not return to baseline were considered indicative of late recovery The FHR tracings were reviewed by members of the Perinatal Medicine Division without knowledge of pH values, to try and estimate whom they would have performed a caesarean on without knowledge	of oxytocin, etc.). The following data relate to the entire study population: Proportion of women having caesarean section (n/total (%)) pH < 7.20: 6/6 (100) - all 6 born within 1 hour of pH measurement pH 7.20 - 7.24: 7/14 (50) - all 14 born within 1 hour of pH measurement pH ≥ 7.25: 40/212 (19) - 76 born within 1 hour, 66 born within 1-2 hours, 70 born over 2 hours later Note: the overall CS rate was 23%, of which 25% were performed for fetal distress. Complications of fetal blood sampling (n (%) Bleeding: - Haematoma: 6 (2.6) - Abrasions: 3 (1.3) - Ecchymosis: 1 (0.4)	high proportion of women were not low risk Other information Further information regarding babies with severe fetal acidosis (pH < 7.20) in labour True positives (depressed at birth) Baby 1 - had severe pre-eclamptic toxaemia - fetal pH of 7.12 - 32 minutes before birth - Apgar of 1 at 1 minute and 3 at 5 minutes - FHR tracing decelerations: persistent, mild, late - cord pH 7.21/7.11 Baby 2 - had meconium and died at about 4 hours - fetal pH of 6.74

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td></td>
<td>due to fetal heart rate changes)

Exclusion Criteria
None reported</td>
<td></td>
<td>of pH values. For this, only patients with less than full dilatation of the cervix and who subsequently delivered vaginally were included.

Fetal acidosis was classified as:
- Mild: pH 7.20 - 7.24
- Severe: < 7.20

Neonatal depression was defined as one of:
- 1 minute Apgar less than 7 and the need for positive pressure resuscitation
- 5 minute Apgar less than 7</td>
<td>- Anaemia of unknown etiology: 1 (0.4)

Infection:
- Abscess: 1 (0.4)
- Cellulitis: 1 (0.4)
- Erythema: 1 (0.4)
- Herpes: 1 (0.4)

Total: 15 (6.5)

FBS pH < 7.20 for neonatal depression
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>3</td><td>3</td></tr>
<tr><td>Predictive Test -ve</td><td>5</td><td>85</td></tr>
</table>
FBS pH < 7.25 for neonatal depression
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>4</td><td>16</td></tr>
</table>
</td>
<td>- 37 minutes before birth
- Apgar of 0 at 1 minute and 1 at 5 minutes
- FHR tracing decelerations: persistent, moderate, late
- cord pH 6.79/6.60

Baby 3
- post-mature, hypertension, prior stillbirth
- fetal pH of 6.94
- 41 minutes before birth
- Apgar of 1 at 1 minute and 4 at 5 minutes
- FHR tracing decelerations: occasional severe, variable, late recovery, decreasing variability
- cord pH 7.14/7.09

False positives (normal Apgar</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Predictive Test -ve 4 72	scores) Baby 4 - chronic active hepatitis - fetal pH of 7.19 - 58 minutes before birth - Apgar of 9 at 1 minute and 10 at 5 minutes - FHR tracing decelerations: persistent, moderate, variable late recovery - cord pH Baby 5 - true knot in cord - fetal pH of 7.19 - 45 minutes before birth - Apgar of 9 at 1 minute and 10 at 5 minutes - FHR tracing decelerations: persistent mild late - cord pH 7.26/7.20 Baby 6

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					- 32 weeks, pre-eclamptic toxaemia, abruptio placentae - fetal pH of 7.16 - 38 minutes before birth - Apgar of 7 at 1 minute and 8 at 5 minutes - FHR tracing decelerations: persistent mild late - cord pH 7.19/7.17 Further information regarding babies whose pH was ≥ 7.25 but were born depressed (false negatives) Baby 1 - meconium, analgesic at 3 hours - fetal pH of 7.36 - 54 minutes before birth (vaginal birth) - Apgar of 4 at 1 minute and 6 at 5 minutes - FHR tracing

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					decelerations: moderate variable late recovery - cord pH 7.27/7.11 Baby 2 - meconium aspiration - fetal pH of 7.34 - 50 minutes before birth (vaginal birth) - Apgar of 4 at 1 minute and 8 at 5 minutes - FHR tracing decelerations: moderate variable - cord pH 7.14/7.10 Baby 3 - IUGR - fetal pH of 7.25 - 38 minutes before birth (vaginal birth) - Apgar of 4 at 1 minute and 6 at 5 minutes - FHR tracing decelerations: moderate variable late recovery

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					- cord pH 7.25/7.02 Baby 4 - meconium - fetal pH of 7.37 - 45 minutes before birth (vaginal birth) - Apgar of 6 at 1 minute and 9 at 5 minutes - FHR tracing decelerations: mild early - cord pH 7.37/7.34

1.1.15 What is the effectiveness of cardiotocography using telemetry compared with conventional cardiotocography?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Calvert,J.P., Newcombe,R.G., Hibbard,B.M., An assessment of radiotelemetry in the monitoring of labour, British Journal of	Sample size N = 200 Characteristics Proportion of nulliparous women (n/total (%)) Telemetry: 56/100	Interventions Telemetry (n = 100) Conventional cardiotocography (n = 100)	Details Recruitment and randomisation Women meeting the inclusion criteria were included if they were in spontaneous labour. "Randomisation" was done based on whether their pre-existing hospital number had a final digit that was odd or even.	Results Note: The authors did a subgroup analysis in the telemetry group by whether women elected to be out of bed for any period of labour (n = 45) or chose to remain in bed (n = 55). With the	Limitations Appropriate randomisation: No, hospital number was used Allocation concealment: No Groups comparable at baseline: The authors

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Obstetrics and Gynaecology, 89, 285-291, 1982 Ref Id 164973 Country/ies where the study was carried out Wales Study type Quasi-randomised trial (based on hospital number) Aim of the study To investigate the extent to which women would utilise the opportunity to get out of bed, to "investigate the disputed claims of the upright position" and to evaluate women's subjective assessment of labour with different types of monitoring	(56) Conventional: 50/100 (50) The authors report that there were no statistically significant differences in age, height, mid-pregnancy weight, social class and smoking. There were also no differences in mean gestational age, cervical dilatation, station of head, estimated duration of labour prior to admission, birth weight, admission at night, and proportion with husbands or near relatives with them. The actual data for these characteristics are not reported		Care protocol A forewater amniotomy was done if needed and all women had a fetal scalp electrode applied. An open ended fluid filled intrauterine catheter was inserted where possible, and if it could not be inserted, an abdominal transducer was used to record contractions. - Telemetry group A Hewlett-Packard 8030A fetal monitor was used in conjunction with the HP 80210A obstetrical telemetry system. The monitor was placed outside the first-stage room. During the second stage, the monitor was moved into the delivery room. Women were told that they could get out of bed to walk, sit in an easy chair, or use the day room where they could watch TV. - Conventional CTG group Women were monitored using the Hewlett-Packard 8030A fetal monitor and were nursed in bed throughout labour. They were nursed in the lateral position, or with a lateral tilt, to avoid caval compression. For all women, progress in labour was	exception of anxiety scores, where a pooled value was reported, overall reported telemetry values were calculated by technical team, summing groups A (ambulatory) and B (remaining in bed) reported in the study tables. Pooled SD was calculated using formula [((n1-1)*SD12 (n2-1)*SD22) / (n1 n2 - 2)]1/2 Degree of mobility a. Choosing to get out of bed (n/total (%)) Telemetry: 45/100 (45) Conventional CTG: NA b. Time spent out of bed/minutes (mean) Telemetry: 104 (range 3 - 260) Conventional CTG: NA [Nb: Out of those who left their beds initially, 34 (75%) women elected to	report that there were no statistically significant differences in reported demographic characteristics at baseline (see above), although do not report actual data Groups received same care (apart from intervention): Yes Blinding of participants: Not possible Blinding of staff providing care: Not possible Blinding of outcome assessors: No details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Although it is reported how anxiety and similar measures are

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Not reported Source of funding None reported	though. Inclusion criteria Singleton fetus At least 37 weeks gestation Vertex presentation No contraindication to vaginal delivery Confirmed spontaneous labour with uterine contractions occurring at least every 10 minutes and a cervix dilated at least 2.5 cm Exclusion criteria Previous stillbirth or neonatal death Previous caesarean section		monitored by vaginal exams every 2 hours. Analgesia was administered according to what the patient and midwife thought was appropriate. Management of the second and third stages of labour, the investigation and/or treatment of fetal heart anomalies, and protraction disorders or cessation of dilatation was the same in both arms of the study. Where possible, uterine activity was measured in Alexandria units for the 30 minutes before pain relief was given. Basal uterine tone was not assessed. The authors report that the cardiotocograph (CTG) traces from the two units were not distinguishable. Data collection and analysis Women were asked to complete a questionnaire on their pain, anxiety, comfort and restriction of mobility in first stage of labour, and degree of induced anxiety or reassurance as a result of the monitor. This was done within 24 hours of birth, as was based on linear analogue scales. Multiparous women who had prior experience of conventional monitoring were asked to compare their impression of the two	stay in bed by the time they were 7 cm dilated. No women left their bed solely to use the toilet] Mode of birth (n/total (%)) a. 'Normal' birth Telemetry: 77/100 (77) - Ambulatory: 34/45 (76) - Bed: 43/55 (78) Conventional CTG: 78/100 (78) b. Low forceps for delay Telemetry: 10/100 (10) - Ambulatory: 7/45 (16) - Bed: 3/55 (5) Conventional CTG: 8/100 (8) c. Rotational forceps Telemetry: 3/100 (3) - Ambulatory: 0/45 (0) - Bed: 3/55 (5) Conventional CTG: 2/100 (2) d. Forceps for fetal distress Telemetry: 4/100 (4)	reported, no details are given about how the clinical outcomes were recorded Intention-to-treat analysis performed: Yes Indirectness: Some higher risk women (e.g. those with previous CS) are excluded; however, the study population was not specifically limited to low risk women Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			systems. Statistical analysis was done using Student's t-test or chi-squared where appropriate, with $p < 0.05$ taken as statistically significant. Outcomes - Mode of birth: unclear how these data were collected - Pain relief: proportion of women using no pain relief, entonox only, pethidine, elective epidural, and 'emergency' epidural are reported [unclear how these data were collected] - Length of labour: length of 1st and 2nd stages are reported [unclear how these data were collected] - Women's experience: women were asked the following questions which are relevant to the GDG's designated outcomes: 1. How anxious did you feel? 2. How comfortable did you feel? 3. How restricted did you feel? 4. How much did the monitoring system give you reassurance? 5. How much did the monitoring system	- Ambulatory: 2/45 (4) - Bed: 2/55 (4) Conventional CTG: 3/100 (3) e. Forceps for hypertension Telemetry: 1/100 (1) - Ambulatory: 0/45 (0) - Bed: 1/55 (2) Conventional CTG: 2/100 (2) f. Caesarean section for delay Telemetry: 4/100 (4) - Ambulatory: 1/45 (2) - Bed: 3/55 (5) Conventional CTG: 5/100 (5) g. Caesarean section for fetal distress Telemetry: 1/100 (1) - Ambulatory: 1/45 (2) - Bed: 0/55 (0) Conventional CTG: 2/100 (2) Use of pain relief (n/total (%))	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			make you feel anxious? Those who had previous experience of conventional bedside monitoring (n = 57) were also asked about their current experience compared to previous experience.	a. None Telemetry: 2/100 (2) - Ambulatory: 1/45 (2) - Bed: 1/55 (2) Conventional CTG: 2/100 (2) b. Entonox only Telemetry: 18/100 (18) - Ambulatory: 3/45 (9)* - Bed: 15/55 (27) Conventional CTG: 13/100 (13) * This is as reported in the study; however, the technical team calculate that the % should be 6.7% based on quoted numerator and denominator c. Pethidine Telemetry: 73/100 (73) - Ambulatory: 38/45 (84) - Bed: 35/55 (64) Conventional CTG: 73/100 (73) d. Elective epidural Telemetry: 6/100 (6)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Ambulatory: 2/45 (4) - Bed: 4/55 (7) Conventional CTG: 12/100 (12) e. 'Emergency' epidural Telemetry: 10/100 (10) - Ambulatory: 3/45 (7) - Bed: 7/55 (13) Conventional CTG: 10/100 (10) Length of labour (mean ± SD) a. First stage, reported as hours.minutes Telemetry: NR† - Ambulatory: 7.51 ± 3.29 [equates to 7.85 ± 3.48 in decimals‡] - Bed: 6.55 ± 3.39 [equates to 6.92 ± 3.65 in decimals‡] Conventional CTG: 7.50 ± 4.41 [equates to 7.83 ± 4.68 in decimals‡] † Pooled mean and SD (in decimals) calculated by technical team: 7.34 ± 3.57	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				‡ calculated by technical team b. Second stage/minutes (reported for spontaneous births only) Telemetry: 30.2 ± 25‡ - Ambulatory: 38 ± 31 [n = 34] - Bed: 24 ± 19 [n = 43] Conventional CTG: 26 ± 19 [n = 78] ‡ calculated by technical team Women's views and experiences a. Anxiety score/100 (mean ± SD) Telemetry: 54 ± 32 [n = 100] - Ambulatory: 49 ± 33 [n = 45] - Bed: 58 ± 30 [n = 55] Conventional CTG: 45 ± 29 [n = 100] b. Comfort/100 (mean ± SD) Overall: 47 ± 29	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				The authors report no significant difference between groups c. Restriction score/100 (mean (SD NR)) Telemetry: 28.8§ - Ambulatory: 20 - Bed: 36 Conventional CTG: 31 [Note: the authors report that those who ambulated were significantly less restricted than either of the other groups. § overall telemetry mean was pooled by the technical team] d. Reassurance from monitoring/100 (mean) Telemetry: 74 Conventional CTG: 71 e. Anxiety from monitoring/100 (mean ± SD) Overall: 17 ± 24 The authors report no	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				significant difference between groups Comparison with previous internal monitoring (n/total (%)) a. Proportion of women finding this form of monitoring preferable Telemetry: 15/28 (53.6%) Conventional CTG: 3/29 (10.3%) b. Level of restriction (due to monitoring) compared with last labour Telemetry: - More restricted: 4/28 (14.3%) - Less restricted: 15/28 (53.6%) - Same: 9/28 (32.1%) Conventional CTG: - More restricted: 2/29 (6.9%) - Less restricted: 4/29 (13.8%) - Same: 23/29 (79.3%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				c. Level of anxiety (due to monitoring) compared to last labour Telemetry: - More restricted: 3/28 (10.7%) - Less restricted: 15/28 (53.6%) - Same: 10/28 (35.7%) Conventional CTG: - More restricted: 1/29 (3.4%) - Less restricted: 6/29 (20.7%) - Same: 22/29 (75.9%)	
Full citation Flynn,A.M., Kelly,J., Hollins,G., Lynch,P.F., Ambulation in labour, British Medical Journal, 2, 591-593, 1978 Ref Id 156248 Country/ies where the study was carried out England	Sample size N = 68 Characteristics Age/years (mean [range]) Ambulant: 23.3 (16 - 38) Recumbent: 22.0 (16 - 32) Height/cm (mean [range]) Ambulant: 159.8	Interventions Ambulation with telemetry (n = 34) Recumbency with conventional electronic fetal monitoring (EFM) (n = 34)	Details Recruitment and randomisation Patients who expressed an interest in ambulation during the antenatal period were randomly assigned to ambulation or recumbency when admitted in labour. [Note: those who remained in bed were told there were no more telemetry machines available] Care protocol After allocation, the electrode was applied to the presenting part and an intrauterine pressure catheter was inserted when the cervix was at least 2	Results Time spent ambulant/hours (mean [range]) Ambulant: 2.2 (0.8 - 8.3) Recumbent: NR Length of first stage of labour/hours (mean [SD not reported]) Ambulant: 4.1 Recumbent: 6.7 ($p < 0.01$) Mode of birth (n/total)	Limitations Appropriate randomisation: No details given Allocation concealment: No details given Groups comparable at baseline: There was a significant difference in station at entry (higher in ambulant group) Groups received same care (apart from

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Randomised controlled trial Aim of the study Not reported Study dates Not reported Source of funding Not reported	(146 - 173) Recumbent: 160.5 (146 - 171) Gestation/weeks (mean [range]) Ambulant: 40.8 (37.0 - 42) Recumbent: 40.4 (36.5 - 42) Cervix dilatation/cm (mean) Ambulant: 3.4 Recumbent: 3.6 (NS) Station of presenting part/cm from ischial spines Ambulant: -2.1 Recumbent: -1.7 ($p < 0.05$) Inclusion criteria Not reported Exclusion criteria Not reported		cm dilated. If waters hadn't broken spontaneously, an amniotomy was done. Dilatation and the station of the presenting part were assessed at the beginning of monitoring and then every 2-3 hours after that during later. Analgesia was given when the midwife felt that the woman was becoming distressed with pain, and augmentation (with oxytocin or prostaglandin) was indicated when there was a delay in labour. Ambulant group Women walked around for as long as they wanted, and were monitored using telemetry. A standard telemetry unit was adapted so it could read intrauterine pressure simultaneously. The woman was able to go to the TV room, help herself to a drink, go to the toilet, and "help with chores". If an IV was necessary for any reason, women went back to the bed. Recumbent group Women were nursed in the lateral position with conventional bedside fetal heart rate monitoring and intrauterine pressure monitoring.	a. "Normal" Ambulant: 31/34 Recumbent: 22/34 b. Assisted breech Ambulant: 1/34 Recumbent: 1/34 c. Forceps (for delay in second stage) Ambulant: 2/34 Recumbent: 10/34 d. Caesarean section (for fetal distress and failure to progress) Ambulant: 0/34 Recumbent: 1/34 [chi-squared test for entire mode of birth: $p < 0.01$] Need for pain relief (n/total) a. Pethidine with or without promazine Ambulant: 14/34 Recumbent: 26/34 b. Epidural	intervention): Yes Blinding of participants: Not possible Blinding of staff providing care: Not possible Blinding of outcome assessors: No details given Missing data/loss to follow-up: No Precise definition of outcomes:Yes Valid and reliable method of outcome assessment: Unclear - no details are given about how data were collected Intention-to-treat analysis performed: No details given either way Indirectness: - range of gestations in recumbent arm went down to 36.5; therefore, an unknown proportion of women

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			All women were cared for in bed during the second and third stages. Data collection and analysis No details are given about how relevant outcome data were collected. Outcomes reported - Mode of birth - Need for pain relief - Time spent ambulant - Length of first stage of labour	Ambulant: 0/34 Recumbent: 5/34 c. Pethidine with or without promazine plus epidural Ambulant: 0/34 Recumbent: 3/34 d. No analgesia Ambulant: 20/34 Recumbent: 0/34 (chi-squared test for all pain relief: $p < 0.001$) Dose of pain relief/mg (mean [range]) a. Pethidine Ambulant: 103 (50 - 150) Recumbent: 153 (100 - 300) b. Promazine Ambulant: 25 (all same dose) [n = 6] Recumbent: 28 (25 - 50) [n = 27] c. Epidural (bupivacaine) Ambulant: N/A	gave birth prior to 37 weeks. However, given the mean gestation in each group, this is unlikely to be a large proportion - 1/34 women in each arm (3%) had babies in breech presentation - study does not specifically state that the population was restricted to low risk women - very few details are given - this trial evaluates ambulating compared with recumbency as its primary goal; therefore, it is possible that women allocated to 'ambulation' behave differently to those allocated to just 'telemetry' Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Recumbent: 108.06 (37.5 - 200)	
Full citation Frenea,S., Chirossel,C., Rodriguez,R., Baguet,J.P., Racinet,C., Payen,J.F., The Effects of Prolonged Ambulation on Labor with Epidural Analgesia, Anesthesia and Analgesia, 98, 224-229, 2004 Ref Id 164987 Country/ies where the study was carried out France Study type Randomised controlled trial Aim of the study To investigate	Sample size N = 61 [Note: 62 were randomised but 1 was excluded for having incomplete data] Characteristics Age/years (mean ± SD) Ambulatory: 28.3 ± 4.3 Recumbent: 29.7 ± 4.1 Weight/kg (mean ± SD) Ambulatory: 65.9 ± 16.5 Recumbent: 64.1 ± 11.2 Height/cm (mean ± SD) Ambulatory: 166 ± 5	Interventions Ambulation monitored with telemetry (n = 30) Recumbency monitored with conventional continuous electronic fetal monitoring (n = 31)	Details Recruitment and randomisation Following their first dose of epidural, women were randomly allocated using sealed, numbered envelopes. Care protocol Fetal heart rate was continuously monitored and 500-1000 ml of Ringer's lactate was given in an IV infusion prior to the epidural. For the epidural, a test dose of 3 ml of 2% lidocaine with 1:200,000 epinephrine was given. Then, a first analgesic dose of 15ml of 0.08% bupivacaine with 1:200,000 epinephrine and 1 microgram/ml of sufentanil was injected in 2 boluses 5 minutes apart. Pain was assessed using a visual analogue scale (VAS) of 100 mm, and adequate analgesia was defined as < 30 mm. Randomisation occurred after this first dose. Ambulatory Women were asked to walk at least 15 minutes per hour, or 25% of the first stage of labour. Ambulation was	Results Degree of mobility a. Number of women who walked Ambulatory: 25/30* Recumbent: NR b. Time spent walking in those who walked (mean ± SD) Ambulatory: 64 ± 34 [n = 25] Recumbent: NR * 5 women did not walk: 2 required a CS before walking and 3 had postural hypotension despite treatment with IV ephedrine and a fluid bolus. The authors report that the use of oxytocin and bupivacaine in these women was comparable with those who walked. Duration of labour/minutes (mean ± SD)	Limitations Appropriate randomisation: Method of sequence generation is not reported Allocation concealment: Probably - envelopes were sealed although it is not specifically stated if they were opaque Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: Not possible Blinding of staff providing care: Not possible Blinding of outcome assessors: No details given Missing data/loss to follow-up: 1 woman

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
duration of labour and pain scores by comparing ambulence and recumbency in women with uncomplicated term pregnancies receiving epidural analgesia Study dates February 1998 to March 1999 Source of funding Not reported	Recumbent: 164 ± 7 Gestation/weeks (mean ± SD) Ambulatory: 40.1 ± 1.0 Recumbent: 40.1 ± 1.3 Nulliparity (n/total) Ambulatory: 18/30 Recumbent: 18/31 Elective induction of labour (n/total) Ambulatory: 6/30 Recumbent: 13/31 Cervical dilatation at insert of epidural (mean ± SD) Ambulatory: 3.6 ± 1.0 Recumbent: 3.6 ± 0.8 [Note: there were no significant differences between the two		allowed 15-20 minutes after the initial injection, as long as there was no postural hypotension, motor block in lower limbs, proprioception impairment or fetal heart decelerations. The woman's companion or the midwife accompanied the woman the entire time that she was walking. Telemetry was used to continuously monitor them during ambulation. Women returned to bed when they had an epidural top-up or experienced sensory changes/weakness. Walking stopped at full dilatation. Recumbent group Women were confined to bed in dorsal or lateral recumbency. The monitoring of the group was similar, just without telemetry. In both groups, intermittent top-up of 15ml of the solution was given whenever the woman had pain again. If the pain (VAS > 30) persisted for 15 minutes after the top-up then an additional 5ml of 0.25% bupivacaine was given. The maximum dose of sufentanil did not exceed 30 micrograms. Analgesia was managed by the anaesthesiologist.	a. Epidural to birth Ambulatory: 304 ± 137 Recumbent: 289 ± 164 (p = 0.70) b. Epidural to complete cervical dilatation Ambulatory: 239 ± 125 [n = 25] Recumbent: 199 ± 111 [n = 28] (p = 0.23) c. "Expulsion" phase Ambulatory: 56 ± 42 [n = 25] Recumbent: 62 ± 59 [n = 28] (p = 0.65) Cervical dilatation rate in cm/hour (mean ± SD) Ambulatory: 1.9 ± 1.1 [n = 25] Recumbent: 2.5 ± 1.7 [n = 28] (p = 0.17) Need for pain relief a. Amount of bupivacaine in mg/hour (mean ± SD)	initially randomised to the recumbency group was excluded due to incomplete data; 5/30 (17%) of women in the ambulatory arm and 3/31 (10%) of women in the recumbent arm had missing data for epidural-CCD interval and expulsion phase and cervical dilatation rate Precise definition of outcomes: yes Valid and reliable method of outcome assessment: unclear how most outcome data were collected (except for women's views and satisfaction, which were reported as being assessed with an interview) Intention-to-treat analysis performed: Yes Indirectness:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	groups in for any of these characteristics] Inclusion criteria ASA physical status I or II parturients requesting epidural Singleton pregnancy from 37-42 weeks gestation Fixed, cephalic, uncomplicated presentation 3-5 cm cervical dilatation at the time of epidural insertion Normal fetal heart rate pattern Exclusion criteria Unfixed cephalic presentation		Labour was otherwise managed by midwives. Augmentation was used if labour was considered ineffective, and amniotomy was also done if the membranes were intact. Oxytocin infusion was interrupted during ambulation. Data collection and analysis The sample size calculation generated a target of 26 patients in each group in order to detect a 30% reduction in the length of the first stage of labour; however, it was decided to enrol at least 60. Data were analysed using chi-squared for frequency data and Student's t-test for discrete data. $p < 0.05$ was considered statistically significant. Outcomes - duration of labour: time from epidural to birth, from epidural to complete dilatation and length of the expulsion phase are reported - mode of birth - umbilical artery pH: mean is reported	Ambulatory: 6.4 ± 2.2 Recumbent: 8.4 ± 3.6 (p = 0.01) b. Number of top ups (mean ± SD) Ambulatory: 3.0 ± 1.2 Recumbent: 3.4 ± 1.7 (p = 0.36) c. Interval between top ups in minutes (mean ± SD) Ambulatory: 135 ± 44 Recumbent: 116 ± 39 (p = 0.07) Mode of birth (n/total) a. Spontaneous Ambulatory: 19/30 Recumbent: 23/31 b. Forceps Ambulatory: 6/30 Recumbent: 4/31 c. Caesarean section Ambulatory: 5/30 Recumbent: 4/31 (p = 0.65 for whole of	- primarily a study of ambulation vs. recumbency (but reported that women had telemetry when ambulating); therefore, women may have acted differently being randomised to ambulation than if they had simply been randomised to telemetry. Other information Note: all of these women were having an epidural

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Cervical dilatation more than 5 cm Contraindication to epidural Systolic arterial blood pressure < 100 mm Hg before epidural insertion Twin pregnancy History of caesarean section Any known complication of pregnancy including breech		- pain relief: number of top-ups, amount of bupivacaine and interval between top-ups are reported - mobility: mean walking time - women's views: proportion of women who were extremely satisfied; proportion of women who would choose to walk again in a future labour. These were assessed with an interview the day after birth	mode of birth) Umbilical artery pH (mean ± SD) Ambulatory: 7.27 ± 0.06 Recumbent: 7.24 ± 0.09 (p = 0.16) Women's views (n/total) a. Extremely satisfied They report that 19 vs. 22 women were "extremely satisfied", but not which way round these figures are. p = 0.56 though, so the difference is not significant. b. Would choose to walk again in a future labour 28/30 ambulatory patients would choose to walk again in a future labour	
Full citation Haukkamaa,M., Purhonen,M., Teramo,K., The monitoring of labor by telemetry,	Sample size N = 60 Characteristics Parity (n/total (%))	Interventions Telemetry (n = 31) Conventional cardiotocography	Details Recruitment and randomisation Women were matched for age (± 5 years), parity (parity I or II) and duration of pregnancy (± 1 week). Following matching, the telemetric	Results Duration of labour (mean ± SD) a. Length of first stage of labour/hours	Limitations Appropriate randomisation: Method not reported Allocation concealment: No -

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Journal of Perinatal Medicine, 10, 17-22, 1982 Ref Id 159849 Country/ies where the study was carried out Finland Study type Clinical trial, consisting of matched pairs with randomisation within pairs Aim of the study To determine the duration of labour and need for analgesia in women monitored with telemetry To study the safety of telemetry in the upright position after rupture of membranes	Telemetry: - I: 13/31 (41.9) - II: 18/31 (58.1) Conventional CTG: - I: 12/29 (41.4) - II: 17/29 (58.6) 20/31 (65%) of the telemetry group and 19/29 (66%) of the conventional CTG group received oxytocin in the 'opening phase'. Inclusion criteria Healthy women with an "uneventful" pregnancy Birth between 38 and 42 weeks Exclusion criteria No details given	(CTG) (n = 29)	method was assigned at random to one of the two women. The other women were monitored with conventional CTG. The authors report that matched control women were not found within 2 days for 2 of the telemetric women; however, it is not clear why this should be the case given that they previously reported that women were assigned after matching. Care protocol 10/31 (32%) women in the telemetry group and 7/29 (24%) in the conventional CTG group had amniotomy. The fetal heart rate was monitored in both groups using a scalp electrode, and the uterine contractions were measured using an external tocodynamometer. Internal monitoring was done following either spontaneous or artificial rupture of membranes when the cervix was 2-4 cm dilated. Patients assigned to telemetry were encouraged to sit or walk during the 'opening phase'. Nitrous oxide-oxygen, pethidine, and epidural were used for analgesia when needed. Data collection and analysis	Telemetry: 7.5 ± 4.5* - parity I: 10.2 ± 5.4 (n = 13) - parity II: 5.6 ± 3.8 (n = 18) Conventional CTG: 7.6 ± 4.3* - parity I: 8.9 ± 4.6 (n = 12) - parity II: 6.6 ± 4.1 (n = 17) b. Time taken for dilatation of the cervix to get from 3 ± 1 cm to 10 cm/minutes Telemetry: 285.4 ± 130.1* - parity I: 369 ± 158 (n = 13) - parity II: 225 ± 106 (n = 18) Conventional CTG: 264.7 ± 113.4* - parity I: 267 ± 103 (n = 12) - parity II: 263 ± 120 (n = 17)	they report that two telemetry patients could not be matched. The fact that they were assigned prior to matching would have the result that, if a match had been found, it would have not been concealed that they would be assigned to conventional CTG Groups comparable at baseline: Yes, they were matched on parity, age and gestational age Groups received same care (apart from intervention): Yes Blinding of participants: Not possible Blinding of staff providing care: Not possible Blinding of outcome assessors: No details given Missing data/loss to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Not reported Source of funding Not reported			Clinical events and use of analgesia were monitored during labour. Student's t-test and chi-square test were used to analyse data. Outcomes - Duration of labour: length of first stage, and time taken for dilatation to increase from 3 ± 1 cm to 10 cm are reported - Need for pain relief: use of pethidine, nitrous oxide and epidural are reported - Mode of birth - Degree of mobility: some qualitative information is given	* Pooled mean and SD calculated by technical team. Pooled SD calculated using formula [((n1-1)*SD12 + (n2-1)*SD22) / (n1 + n2 - 2)]1/2 Degree of mobility The authors report that 4 of the primiparas and two of the "secondparas" in the telemetry group refused to get out of bed. This was thought to be as a result of exhaustion due to pain. The time spent in the upright position ranged from 10-90% of the time. The also report that, although most women found it helpful to walk during the first part of labour, most preferred lying down in the second half of the 'opening phase'. Need for pain relief (n/total (%)) a. Pethidine	follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: Unclear - definition of 'uneventful pregnancy' is not given (inclusion/exclusion criteria are quite vague) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Telemetry: 16/31 (61.6)† - parity I: 11/13 (85) - parity II: 5/18 (28) Conventional CTG: 21/29 (72.4)† - parity I: 12/12 (100) - parity II: 9/17 (52.9) b. Nitrous oxide Telemetry: 20/31 (64.5)† - parity I: 9/13 (69) - parity II: 11/18 (61) Conventional CTG: 21/29 (72.4)† - parity I: 9/12 (75) - parity II: 12/17 (71) c. Epidural block Telemetry: 3/31 (9.7)† - parity I: 3/13 (23) - parity II: 0/18 (0) Conventional CTG: 5/29 (17.2)† - parity I: 3/12 (25) - parity II: 2/17 (12) † calculated by the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				technical team pooling the proportions for the different parities Mode of birth (n/total (%)) a. Vacuum extraction Telemetry: 4/31 (12.9) Conventional CTG: 2/29 (6.9) b. Forceps Telemetry: 0/31 (0) Conventional CTG: 1/29 (3.4) c. Caesarean section Telemetry: 0/31 (0) Conventional CTG: 2/29 (6.9) [Note: the indications were maternal or uterine exhaustion and inertia, except in two of the conventional CTG women where fetal asphyxia was suspected due to fetal heart rate (FHR) changes in the second stage]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				The authors also report that no fetal or maternal complications occurred, but no further details are given.	
Full citation Hodnett,E., Patient control during labor. Effects of two types of fetal monitors, JOGN Nursing, 11, 94-99, 1982 Ref Id 164998 Country/ies where the study was carried out Canada Study type Aim of the study To investigate the maintenance of control in labour Study dates	Sample size N = 30 Characteristics Not reported Inclusion criteria Married, low-risk, primigravidae Attended prenatal classes in which Lamaze techniques were taught Consented to participate in the study Underwent uncomplicated vaginal deliveries	Interventions Radiotelemetric fetal monitoring (n = 15) Standard electronic fetal monitoring (n = 15)	Details Recruitment and randomisation Obstetricians and prenatal educators identified women who met the inclusion criteria and explained the study to them. If they consented, then at the point of admission to the labour and delivery unit, she was randomised to either radiotelemetry or standard electronic fetal monitoring. Care protocol As soon as the labour room staff decided that monitoring should begin, the assigned monitoring was begun. - Conventional monitoring group The decision about internal vs. external monitoring was made by the physicians, based on their clinical judgement. - Radiotelemetry Only internal monitoring was possible.	Results Degree of mobility a. Time spent out of bed/minutes (mean [SD not reported]) Telemetry: 142.7 Standard: 8.7 $p < 0.0005$ b. Proportion of women not getting out of bed during labour Telemetry: 0/15 Standard: 9/15 [Note: the telemetry group spent between 30 and 300 minutes out of bed] Need for pain relief a. Receiving analgesia Telemetry: 0/15	Limitations Appropriate randomisation: Unclear - no details given Allocation concealment: Unclear - no details given Groups comparable at baseline: Unclear - no details given Groups received same care (apart from intervention): Yes Blinding of participants: Not possible Blinding of staff providing care: Not possible Blinding of outcome assessors: Unclear - no details given Missing data/loss to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not reported Source of funding Ontario Ministry of Health Canadian Nurses Foundation	Exclusion criteria Not reported		This required artificial rupture of membranes (ARM) if the membranes had not ruptured spontaneously. This was done only if and when there was no clinical contraindication. Data collection and analysis During labour each subject kept a written record of how much time they spent out of bed, between the beginning of monitoring and the transfer to the delivery room. The Labour Agentry Scale was completed within 48 hours of birth, and an interview was conducted by an investigator. Other information was obtained from medical records. Data were analysed using Student's t-test, Fisher's exact test or chi-square as appropriate. Statistical significance was set as $p < 0.05$. Note: the Labour Agentry Scale was a 28 item scale which had been developed by testing a previous 76 item scale on a sample of 100 women. Outcomes - Degree of mobility: time spent out of bed is reported, as well as proportion of women not getting out of bed	Standard: 0/15 b. Epidural Telemetry: 9/15* Standard: 15/15 * calculated by the technical team. The authors report that no women in the experimental group received analgesia and that instead epidural was provided; they then report that 6 members of that group had no anaesthesia. This calculation is corroborated by references later in the paper. Labour Agentry Scale Scores (mean) Telemetry: 148.07 - those without epidural: 162.1 [n = 6] - those with epidural: 138.67 [n = 9] Standard: 128.87	follow-up: No Precise definition of outcomes: No - it is unclear what the possible range of scores for the Labour Agentry Scale is Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: only married primigravidae were included and they had to have had an uncomplicated vaginal delivery - it is not clear how the population was selected because they recruited them prenatally Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Need for pain relief - Women's views and satisfaction	Views about labour (n/total) a. More pleasant than expected (i.e. less painful, more satisfying, and/or shorter) Telemetry: 8/15 Standard: 1/15 [Note: the authors report that the remaining 14 women from the control group gave one or more negative responses, e.g. more painful, longer, less satisfying] b. Maintained control Telemetry: 10/15 Standard: 4/15 $p < 0.05$ Attitudes about fetal monitoring 28/30 women though that the fetal monitor had an effect of their labour experience (1 from each arm said no effect).	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- fetal monitor had positive effect Telemetry: 14/15 Standard: 5/15 - fetal monitor had negative/mixed effect Telemetry: 0/15 Standard: 9/15 - fetal monitor had no effect Telemetry: 1/15 Standard: 1/15 Telemetry group: - positive responses centred around reassurance about the condition of the fetus and freedom from restraint - 10 out of the 14 had had conventional monitoring before and so could compare the two - their negative responses about the external monitor centred around discomfort from abdominal belts and the	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				external monitor interfering with movement Control group: - those giving positive responses felt that it reassured them about the baby's condition, and also gave positive responses with regards to assistance with beginning breathing techniques at the onset of contractions - 2 gave totally negative comments and 7 gave mixed responses. The negative comments were around the discomfort of the belt during contractions and the inability to move or attain a comfortable position during labour. 2 women said that the monitor made them anxious. [Note: there were further comments, but these were not to do with	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				monitoring and were not specific] Other details of outcomes reported They report that duration of labour was not significantly different between the 2 groups (mean 13.48 hours overall) and that there was no significant difference in the type of birth (spontaneous or forceps); however, actual data are not given.	
Full citation Karraz,M.A., Ambulatory epidural anesthesia and the duration of labor, International Journal of Gynaecology and Obstetrics, 80, 117-122, 2003 Ref Id 66535 Country/ies where the study was	Sample size N = 221 Characteristics Nulliparous (n (%)) Ambulatory: 97 (69.3) Non-ambulatory: 47 (63.5) Age/years (mean ± SD) Ambulatory: 27.4 ±	Interventions Ambulatory epidural with telemetry (n = 144) Non-ambulatory epidural with a fixed monitoring system (n = 77) [However, 3 from the ambulatory group and 2 from	Details Recruitment and randomisation Women meeting the inclusion criteria and who agreed to participate, based on 2:1 chance of being allocated to ambulation, were randomly assigned to either ambulatory or non-ambulatory groups. Care protocol Ambulatory group Women walked, sat in a chair or reclined in a semi-supine position. They were allowed to walk after fulfilling the following conditions:	Results Mode of birth (n/total (%)) a. Spontaneous vaginal birth Ambulatory: 117/141 (82.98) Non-ambulatory: 56/74 (75.67) [p = 0.45] b. Caesarean section Ambulatory: 13/141 (9.2) Non-ambulatory: 12/74 (16.2)	Limitations Appropriate randomisation: Method of randomisation not reported Allocation concealment: Unclear - no details given Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
carried out France Study type Randomised controlled trial Aim of the study To test the hypothesis that allowing women to walk with epidural analgesia has advantages with respect to mode of birth, use of local anaesthetic, oxytocin requirement and duration of labour Study dates February 1999 to April 2001 Source of funding Departments of Anaesthesiology and Obstetrics and Gynaecology at the	4.3 Non-ambulatory: 27.5 ± 4.6 Height/metres (mean ± SD) Ambulatory: 1.64 ± 6.3* Non-ambulatory: 1.63 ± 6.5* * this is as reported in the study - appears to be a units error in the reporting of standard deviation Weight before pregnancy/kg (mean ± SD) Ambulatory: 60.1 ± 8.4 Non-ambulatory: 62.7 ± 13.5 Weight at birth/kg (mean ± SD) Ambulatory: 74.7 ± 9.6 Non-ambulatory:	the non-ambulatory group were excluded as they had a birth less than 15 minutes after the epidural injection]	acceptable analgesia (VAS ≤ 30 mm), acceptable systolic blood pressure (≥ 100 mmHg), and ability to stand on one leg. Fetal heart rate was monitored during ambulation using a portable device, and if indicated, a portable syringe, because oxytocin injection was kept active during ambulation. Non-ambulatory group Women were not allowed to sit, walk or go to the bathroom. They only had permission to remain in the supine position, or to lie in a semi-supine or lateral position. Fetal heart rate was monitored using a fixed monitoring system. Both groups received intermittent epidural bolus injections of 0.1% ropivacaine with 0.6 micrograms/l sufentanil. Epidural analgesia blocks were initiated without a test dose. The first dose was determined according to the woman's height. Repeat injections were given when the women requested additional pain relief, without considering the VAS score. All repeat injections were a 10 ml dose. All injections were performed in the supine position. If acceptable pain relief was	[p = 0.15] c. Forceps Ambulatory: 11/141 (7.8) Non-ambulatory: 6/74 (8.1) Needing additional doses (5 ml after 20 minutes if VAS > 30) (n/total (%)) a. After first dose Ambulatory: 4/141 (2.8) Non-ambulatory: 6/74 (8.1) b. After repeat injections Ambulatory: 8/141 (3.9) Non-ambulatory: 13/74 (12.9) The authors also report that women were given between 1 and 6 re-injections and that there was no significant difference between the groups regarding number of re-injections Amount of local anaesthetic (in ml)	participants: Not possible Blinding of staff providing care: Not possible Blinding of outcome assessors: No details given Missing data/loss to follow-up: 5 women were excluded as they gave birth within 15 minutes of epidural Precise definition of outcomes: unclear at what point duration of labour was measured from Valid and reliable method of outcome assessment: Very few details given Intention-to-treat analysis performed: Yes Indirectness: - 39% of women in each arm had induction of labour - Study was of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Beauvais Central Hospital	75.6 ± 12.7 Cervical dilatation at epidural insertion/cm (mean ± SD) Ambulatory: 3.27 ± 1.3 Non-ambulatory: 3.37 ± 1.4 VAS before epidural insertion/mm (mean ± SD) Ambulatory: 77.1 ± 15.9 Non-ambulatory: 78.8 ± 14.2 Induced labour (n (%)) Ambulatory: 55 (39) Non-ambulatory: 29 (39.2) None of these characteristics were significantly different between the two groups		not achieved after the first dose, or 20 minutes after a repeat injection, then 5 ml additional dose was given. Ringers lactate was given as an IV infusion - 1000 ml before epidural insertion and 500 ml at each repeat injection. Data collection and analysis Data were compared using two-tailed t-tests and chi-squared tests. p ≤0.05 was considered significant. Outcomes - Mode of birth - Need for pain relief: number of women resorting to additional doses following initial or repeat injections; number of women requiring local anaesthetic (only reported for women with a normal vaginal birth) - Duration of labour: measured from the point of epidural insertion to birth	needed in women having a spontaneous vaginal birth (mean ± SD) Ambulatory: 27 ± 11 [n = 117] Non-ambulatory: 23 ± 11 [n = 56] [p = 0.09] Duration of labour/minutes (mean ± SD) Ambulatory: 173 ± 110 Non-ambulatory: 236 ± 131 [p = 0.001]	ambulation after epidural; therefore, it did not strictly match the comparison of interest and women may behave differently if assigned to ambulation with epidural than if assigned to telemetry Other information Note: all women were having an epidural

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria 36 to 42 weeks gestation Singleton pregnancy Cephalic presentation Uncomplicated pregnancy (presenting in spontaneous labour or scheduled for induced labour) Exclusion criteria Pre-eclampsia Previous caesarean section				
Full citation MacLennan,A.H., Crowther,C., Derham,R., Does the option to ambulate during spontaneous	Sample size N = 196 Characteristics Maternal age/years (mean ± SD)	Interventions Ambulation with fetal heart radiotelemetry (n = 96) Recumbency with	Details Recruitment and randomisation Women who met the inclusion criteria were randomised to either ambulation with telemetry or recumbency with conventional electronic fetal monitoring (EFM). Randomisation was done in	Results Mode of birth (n/total (%)) a. Spontaneous vaginal birth Telemetry: 64/96 (66.7) Conventional CTG:	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
labour confer any advantage or disadvantage?, Journal of Maternal-Fetal Investigation, 3, 43-48, 1994 Ref Id 165028 Country/ies where the study was carried out Australia Study type Randomised controlled trial Aim of the study To determine whether there is an advantage or disadvantage to having the option to ambulate in labour compared with labour in a recumbent position Study dates	Telemetry: 26.0 ± 1.1 Conventional CTG: 26.0 ± 5.0 Parity (n/total (%)) 0 Telemetry: 49/96 (51) Conventional CTG: 43/100 (43) 1-3 Telemetry: 47/96 (49) Conventional CTG: 57/100 (57) > 3 Telemetry: 0/96 (0) Conventional CTG: 0/100 (0) Gestational age (mean ± SD) Telemetry: 40.0 ± 1.1 Conventional CTG: 40.0 ± 1.7 Proportion of	conventional fixed electronic fetal heart rate monitoring (n = 100)	balanced variable blocks with stratification by parity (nulliparous vs. multiparous). Allocation was done by opening the next in a series of opaque, sealed envelopes. During the study period, 389 women declined to participate. The main reasons were not wishing to lose option of ambulating (46%), no intention of ambulating (11%), not wanting EFM (15%), not wanting membrane rupture (20%), or other/not known (8%). Care protocol Following trial entry, all women had artificial rupture of membranes (ARM) if they had not spontaneously ruptured and a fetal scalp electrode was applied. - Ambulation group Women had fetal heart rate monitoring using a Hewlett Packard radiotelemetric system connected to a monitor. They were encouraged to ambulate but were also given the option of sitting or lying down when they wanted. - Recumbent group Women were monitored using fixed fetal monitoring, with the scalp	72/100 (72) OR 0.78 (95% CI 0.42 to 1.43) [Note: Among women in telemetry group who chose to ambulate, 21/37 (57%) had spontaneous vaginal birth. Among women who could have ambulated but chose not to, 43/59 (73%) had a spontaneous vaginal birth. This is not a statistically significant difference.] b. Instrumental vaginal birth Telemetry: 26/96 (27.1) Conventional CTG: 21/100 (21.0) OR 1.39 (95% CI 0.72 to 2.68) c. Caesarean section Telemetry: 6/96 (6.3) Conventional CTG: 7/100	Groups received same care (apart from intervention): Yes Blinding of participants: Not possible Blinding of staff providing care: Not possible Blinding of outcome assessors: No details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: - Some higher risk women were excluded; however, the study does not specifically report restricting the population to low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not reported Source of funding Grants from the Queen Victoria Hospital Research Foundation, Hewlett Packard Ltd and Cadbury Schweppes Pty Ltd	women with artificial rupture of membranes (n/total (%)) Telemetry: 70/96 (73) Conventional CTG: 73/100 (73) Birth weight/kg (mean ± SD) Telemetry: 3.4 ± 0.5 Conventional CTG: 3.5 ± 0.4 Expected time to second stage/hours (mean) Telemetry: 3.8 [SD NR] Conventional CTG: 3.9 [SD NR] Note: there were no significant differences between the two arms with respect to demographic characteristics		electrode attached directly via leads to the monitor. Women generally chose a semi-recumbent position, with the head end of the bed at a 45 degree angle; however, they could also be on their side with lower elevation. The delivery suite had lengthy corridors available for walking, and two separate sitting rooms. Data collection and analysis Data were collected from case notes and from a rating that women gave after her labour. Statistical analysis was done in EpiInfo, using Student's t-test for continuous variables and chi-squared for other variables. Odds ratios and 95% confidence intervals are reported. Outcomes - Mode of birth: extracted from case notes - Length of labour: both length of labour and time from entry to birth are reported (data extracted from case notes) - Need for pain relief: proportion of	(7.0) OR 0.89 (95% CI 0.29 to 2.72) Measures of length of labour (mean ± SD) a. Length of labour Telemetry: 8.9 ± 5.2 Conventional CTG: 8.5 ± 4.4 (NS) b. Entry to birth interval Telemetry: 5.0 ± 3.9 Conventional CTG: 4.9 ± 3.5 (NS) [Note: Among women in telemetry group who chose to ambulate, mean entry to birth interval was 6.2 ± 4.1. Among women who could have ambulated but chose not to, mean interval was 4.2 ± 3.5.] Need for pain relief (n/total (%))	women - This trial evaluates ambulating vs. recumbency; therefore, the objective is slightly different from that of the review. It is possible that allocation to 'ambulation' might have increased women's likelihood of ambulating, when compared to women just allocated to telemetry in a different trial Other information No other relevant information.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria Confirmation of established spontaneous labour by the presence of regular contractions less than 10 minutes apart and cervical dilatation of 3 cm or more Cephalic presentation 3 or less cm above the ischial spines Singleton fetus 37-42 weeks gestation Ability to ambulate if given the opportunity Informed patient consent Exclusion criteria		women having epidural and narcotic analgesia are reported (extracted from case notes) - Degree of mobility: proportion of women choosing to ambulate for at least half an hour; mean time spent in upright, sitting, or recumbent position (extracted from case notes) - Satisfaction: assessed after labour using visual analogue score of 0-10 (ranging from "totally unacceptable" to "completely acceptable") rated by women - Perinatal death: extracted from case notes - Admission to level II or III nursery: extracted from case notes	a. Epidural analgesia Telemetry: 43/96 (44.8) Conventional CTG: 52/100 (52) OR 0.75 (95% CI 0.43 to 1.31) b. Narcotic analgesia Telemetry: 39/96 (40.6) Conventional CTG: 40/100 (40) OR 1.03 (95% CI 0.58 to 1.81) Degree of mobility a. Choosing to ambulate for at least half an hour (n/total (%)) Telemetry: 37/96 (39%) Conventional CTG: NR b. Time spent in upright position/hours (mean ± SD)* Telemetry: 1.5 ± 0.8 [n = 37] Conventional CTG: NR c. Time spent	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Intravenous therapy Hypertension (defined as > 90 mmHg diastolic blood pressure) Epidural or narcotic analgesia at or before entry to trial Evidence of possible fetal distress Previous prostaglandin pre-treatment Induced labour Physical inability to ambulate			sitting/hours (mean ± SD)* Telemetry: 0.3 ± 0.8 Conventional CTG: NR d. Time spent recumbent/hours (mean ± SD)* Telemetry: 4.5 ± 3.7 Conventional CTG: NR * For time spent upright, it is definitively stated that this is only reported for women choosing to ambulate. For time spent sitting or recumbent, it is not clear whether this is for all women or just the 37. Satisfaction/10 (mean ± SD) Telemetry - Those choosing to ambulate: 9.1 ± 1.5 [n = 37] - Those choosing to remain recumbent: 7.6 ± 2.8 [n = 59]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Conventional CTG: 7.7 ± 3.0 [nb: Pooled mean ± SD for telemetry arm (calculated by technical team): 8.2 ± 2.39†] † Pooled SD calculated using formula [((n1-1)*SD12 + (n2-1)*SD22) / (n1 + n2 - 2)]1/2 Admission to level II or level III nursery (n/total (%)) Telemetry: 6/96 (6.25) Conventional CTG: 4/100 (4) OR not reported Perinatal death (n/total (%)) Telemetry: 0/96 (0) Conventional CTG: 0/100 (0)	

1.1.16 What are women's views and experiences of fetal monitoring in labour?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Parisaei,M., Harrington,K.F., Erskine,K.J., Maternal satisfaction and acceptability of foetal electrocardiographic (STAN[REGISTERED]) monitoring system, Archives of Gynecology and Obstetrics, 283, 31-35, 2011 Ref Id 134248 Country/ies where the study was carried out UK Study type Prospective questionnaire-based study Aim of the study To assess the acceptability of the fetal electrocardiographic (STAN®) monitoring system by women at a London Hospital Study dates November 2003 to June 2005	Sample size Total n = 125 Characteristics Population consisted of women with high risk pregnancy (diabetes, pre-eclampsia, previous caesarean section) or intrapartum risk factors (meconium stained liquor, oxytocin augmentation). 78% of the population were believed to be low risk at their antenatal booking. Mean age (year): 28.8 (SD 6.3) Nulliparous: 75% Spoke English fluently: 83% Ethnicity African: 40% White: 30%	Interventions Fetal electrocardigraphic (STAN) monitoring	Details A specified questionnaire was designed to assess the women's acceptability for STAN. The study was conducted in a university hospital in East London with 4000 deliveries in a year. Women who had STAN monitoring were provided with information sheets about the study. Women were asked to fill in the questionnaire after their birth (the majority of women filled in the questionnaire on the day of birth). The information	Results 1) Did the midwife (s) looking after you in labour explain the reasons why your baby was monitored continuously in labour? Yes: 93% (CI 85% to 98%) 2) Did the doctor (s) looking after you in labour explain the reasons why your baby was monitored continuously in labour? Yes: 99% (CI 83% to 99.9%) 3) Did you understand how the STAN system monitors your baby's wellbeing in labour? Yes: 95% (CI 87% to 99%) 4) Did you think the STAN system is an acceptable additional way of monitoring your baby in	Limitations Unclear if the questionnaire was a validated tool or not Unclear how and who developed the questionnaire Questionnaire response rate was 61% (77/125) Unclear how and by whom data were analysed Unclear what explanation given to women about reasons why her baby was monitored continuously in labour 13.3% of study population had a language problem Unclear if women received unbiased information about STAN and how it assesses baby's well being

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not specified	Asian: 10% Other: 20% Intrapartum characteristics in cohort of women being monitored by STAN Induction of labour: 37% Meconuim stained liquor: 50% Epidural use: 80% Fetal blood sampling performed: 13% Syntocinon infusion utilised: 67% Spontaneous vaginal birth: 29% Emergency caesarean section (CS): 54% (215 of CS were for fetal distress according to STAN clinical protocol) Inclusion criteria Term pregnancy (> 37 weeks gestation)		sheet and the questionnaire were reviewed by a clinical psychologist. n = 125 women were monitored with STAN during the study period. The questionnaire consisted of 7 yes or no questions and a space was also provided for further comments. Analysis: Two-Folded and categorical data were summarised using percentages and hypothesis tests. Continuous data were summarised using mean for normally distributed data	labour? Yes: 95% (CI 87% to 99%) 5) Did you feel reassured by having the STAN system as well as the CTG monitor in labour? Yes: 96% (CI 89% to 99%) 6) Would you have the STAN system again in future labours if we needed further information about your baby's wellbeing in labour Yes: 93% (CI 85% to 98%) 7) Would you recommend the STAN system to your friends who are going to be mothers? Yes: 89% (CI 80% to 95%) the majority would only do if they were high risk and there was a need for continuous fetal monitoring.	Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Singleton pregnancy Exclusion criteria Multiple pregnancy Women with viral infection (HIV or Hepatitis B and C)		and median for non-normal data.		
Full citation Hindley,C., Hinsliff,S.W., Thomson,A.M., Pregnant women's views about choice of intrapartum monitoring of the fetal heart rate: a questionnaire survey, International Journal of Nursing Studies, 45, 224-231, 2008 Ref Id 136975 Country/ies where the study was carried out UK Study type Qualitative exploratory descriptive Aim of the study To investigate women's view on intrapartum fetal monitoring	Sample size Total n = 63 Characteristics Antepartum sample Total n = 63 Gestation when questionnaire completed 34-36 weeks 6 days n = 45 37-40 weeks n = 18 Age Under 20 n = 3 20-24 yr n = 14 25-29 yr n = 20 30-34 yr n = 20 35-39 yr n = 6 Ethnicity	Interventions Intrapartum electronic fetal monitoring (EFM)	Details A total of 63 pregnant women at low obstetric risk were approached to complete antepartum and postpartum questionnaires. The sample were recruited from two maternity hospitals (centre 1 n = 30; centre 2 n = 33). After gaining informed consent, women were asked to complete the first questionnaire	Results Women's preference of electronic fetal monitoring (EFM) antenatal survey (n = 63) Women did not prefer one specific option. Majority preferred a combination of intermittent and continuous EFM n = 35/63 (56%) Postnatal survey (n = 38) Number of women received EFM n = 23/38 (61%) Women's preference of mobility during labour antenatal survey	Limitations Participants recruited from two different hospitals, the influence of different setting should be considered when interpreting the data. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
techniques and informed choice. Study dates Not specified Source of funding NHS, Northern region Research and Development Directorate	White n = 49 Others n = 12 Missing n = 2 Jarman deprivation score Low deprivation (30 - 39.99) n = 14 Not deprived (below 30) n = 48 Missing n = 1 Educational qualifications No recorded qualification n = 2 Secondary education qualification n = 9 Further education qualification n = 38 Higher education n = 14 Parity Primigravida n = 31 Multigravida n = 32 Postpartum sample n = 38 Completion of questionnaire in		between 34 and 40 weeks of pregnancy. Sixty-three (n = 63) women completed antepartum questionnaires, 38 of these 63 women also completed postpartum questionnaires. Questionnaire A validated tool (from an informed choice across maternity care) was modified and used for women's preferences of fetal monitoring. The developed questionnaire was piloted with a small sample and modified according to the results. Themes chosen for the	Stay mobile or off the bed n = 46/63 (73%) Postnatal survey Women reported stayed in bed n = 16/38 (40%) Women's preference for decision making on fetal monitoring antenatal survey Women wanted the final decision after considering midwife's view: antepartum n = 35/63 (56%); intrapartum n = 28/63 (44%) Postnatal survey Women had conceded decision making to midwife in intrapartum period n = 14/38 (38%) Choice/control preference antenatal survey Felt choice of being in control is important n = 61/63 Felt midwives did not	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	weeks postpartum 0-2 weeks n = 24 3-4 weeks n = 8 > 5 weeks n = 5 Missing n = 1 Type of birth Normal Instrumental Emergency caesarean section Analgesia Epidural n = 8 Narcotic n = 12 Entonox n = 11 Other n = 3 None n = 4 Age Under 20 n = 1 20-24 yr n = 5 25-29 yr n = 10 30-34 yr n = 17 35-39 yr n = 5 Ethnicity White n = 30 Others n = 7 Missing n = 1		questionnaire were identified from a background literature review. The antepartum questionnaire contained 28 items and aimed to elicit information on women's knowledge and preferences of intrapartum fetal monitoring. The postpartum questionnaire had 21 items and asked for information about monitoring preferences for labour and actual monitoring outcomes. Data collection Women were approached at 34	facilitate a choice in intrapartum fetal method antenataly n = 59/63 (94%) Not received enough information and discussion to make a choice regarding fetal monitoring method n = 25/63 (40%) Importance of information antenatal survey Women were aware of different type of monitoring n = 59/63 (94%) Knew all type of monitoring except pinnard n = 46/63 (73%) Felt it is very important to have information on intrapartum fetal monitoring n = 54/63 (86%) Postnatal survey Felt it is very important to have information on intrapartum fetal	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Jarman deprivation score Low deprivation (30 - 39.99) n = 7 Not deprived (below 30) n = 30 Missing n = 1 Parity Primigravida n = 16 Multigravida n = 22 Inclusion criteria Women with no underlying medical condition (low risk pregnancy) Predicted a vaginal birth Exclusion criteria Not specified		weeks of their pregnancy at the antenatal clinic. The midwife was the first point of contact, referring suitable women to the researcher to discuss the study in detail. An information pack plus the questionnaire and a stamped envelope were given to women. Women who did not return their questionnaire were approached in their next antenatal visit and reminded about the study (only one reminder was permitted based on ethics committee's approval). Following	monitoring n = 15/38 (39%) Sources of information antenatal survey Felt midwife had not explicitly given any information on monitoring n = 41/63 (65%) Felt had the information from media n = 36/63 (57%) Women relied on past experience n = 29/63 (46%) Felt had informed choice or partially had informed choice n = 25/63 Postnatal survey Felt that they have been given informed choice n = 15/38 (39%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			women's birth of a healthy infant, they were sent the postpartum questionnaire and stamped addressed envelope, together with a letter of congratulations. Women were not followed up if they failed to respond. Data analysis The data were analysed using SPSS 10.1. The analysis of data was descriptive. Frequency count and cross-tabulations were used.		
Full citation Shields,D., Fetal and maternal monitoring: maternal reactions to fetal monitoring, American	Sample size Total n = 30 Characteristics	Interventions Internal electronic fetal monitoring	Details The time that women were monitored ranged	Results Scores Women in positive range: n = 22	Limitations Data and results poorly reported. Very old study, advances in technology

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Journal of Nursing, 78, 2110-2112, 1978 Ref Id 170538 Country/ies where the study was carried out Canada Study type Prospective observational study Aim of the study To examine women's experience and reaction to fetal monitoring Study dates Not specified Source of funding Not specified	Age: ranged 17 to 42 Married: n = 19, Single: n = 9, Separated: n = 2 White: n = 16 Black: n = 14 Primiparous: n = 18 Multiparous: n = 12 Reason women were monitored Failure to progress and oxytocin stimulation: n = 7 Induced labour: n = 18 Poor obstetrical history: n = 1 research on normal labour: n = 4 Mode of birth Spontaneous vaginal birth: n = 8 Forceps delivery: n = 13 Vacuum extraction: n = 2 Caesarean section: n = 7		from 1 hour to 12 hours (no more details about the monitoring machine provided). To assess the general attitudes of women regarding the fetal monitoring, the author developed a "mood and feeling inventory". The scale consisted of a list of adjectives that women marked according to their feelings in a scale ranging from 1 (not at all) to 6 (very much). The negative scale consisted of eight words; apprehensive, uneasy, tense, frightened, worried, upset,	Women in negative range: n = 8 Highly negative category: n = 2 Highly positive category: n = 3 One woman had a high negative score (-3.46). She expressed a high degree of negativity throughout the interview. She expressed that she received "too little information about the equipment", and did not like the idea of attaching it to the baby's head. She felt that, the monitoring was not a good indicator of what was happening; while she was in severe pain, she was told by the nurse that the equipment showed mild pain. She also expressed that "the head is the most important part and I was worried about brain damage because of the	should be considered when interpreting the data. A self-developed scale used with unclear validity. 18/30 women were multiparous. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Mean length of labour Multiparous: n = 6 hours and 26 min nuliparous: n = 12 hours and 9 min mean duration of monitoring: 5 hours and 16 min Inclusion criteria Women who had internal fetal monitoring during labour and delivered at term Exclusion criteria Not specified		nervous. The positive scale consisted of six words; relaxed, confident, peaceful, comfortable, optimistic, calm. Women were asked to mark the scale regarding their feeling during the fetal monitoring (as they remembered). Women were interviewed by the author within 48 hours of birth. Their positive or negative attitudes toward the monitoring experience were assessed. Interviews were carried out using a open-ended questionnaire.	clamp". One woman with the highest negative score (-3.75) said she "felt like a battery being charged with all those wires and connections". From three women who had a high positive score, one woman with a score of 4.17, said she "Knew exactly what was going on and therefore was not afraid". The women with a score of 4.45, was a "little frightened" but thought it was an "exciting idea" compared with other labours and felt that "monitoring seemed to make it shorter and more interesting". The woman with the highest positive score of 4.87 thought monitoring was "a fantastic, good idea". No differences were observed between these five women with the rest of the study's population.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Analysis A positive and a negative response for each woman was tabulated and a mean score was calculated. The negative score was subtracted from the positive score and the difference served as an indication of an overall positive or negative reaction. The maximum difference of 5 that could happen between the positive and negative scores of one woman were divided into high, medium, or low, positive or negative and women were placed by their scores in those	When a Chi square computation was performed between the inventory scores and the age, race, parity, marital status length labour and length of monitoring, no significant difference in the results were observed. Understanding the reason for monitoring (determined by comparing women's response to the reason for monitoring, to the reason given in women's chart): Good understanding: n = 27 Partially understood: n = 3 (n = 2/3 were women with high negative score) Information received Adequate: n = 27 (20 said that had full information and 7 said said they received as much as they requested)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			categories.	No adequate information received: n = 3 Nurse's presence All women expressed their desire about wanting nurses to stay with them all the time. n = 17 wanted nurses for supportive care. n = 6 expressed a desire for the nurses presence as a person that could intervene in some way if necessary. Worries about monitoring No worries: n =7 Some worries (not the same as those during pregnancy): n = 11 (4 expressed fears related to the electrodes) Some worries (as same as those during pregnancy): n = 12 (fearing that baby would be deformed in some way or die) Complain about	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				monitoring Getting comfortable: the most frequent complaint was with regard to difficulty in getting comfortable. Some women were annoyed about the fact that when the electrode fell off, an additional vaginal examination was needed to reapply the electrode. Complaints about vaginal examination mainly related to the privacy and too many people being present in the room. Noise of fetal heart beat: was considered discomforting by 2 women because of fears that it would stop (one expressed she "worried the whole time that the baby's heart would stop if the machine stopped"). Caregiveres n = 4 women expressed that the clinicians were	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				the cause of some discomfort for them. Two out of these four women considered the facial expression of the physician frightening. The other 2 women thought that some staff were unfamiliar with the machine and found this disquieting. One woman thought that the clinician had more interest in the machine than they did with her, she said "they all came with the machine and they all left with the machine"	
Full citation Hansen,P.K., Smith,S.F., Nim,J., Neldam,S., Osler,M., Maternal attitudes to fetal monitoring, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 20, 43-51, 1985 Ref Id 171177 Country/ies where the study was carried out Denmark	Sample size Total n = 655 Characteristics A: preferred auscultation (AUS-P), B: preferred electronic fetal monitoring (EFM-P), C: undecided (UD), P (A:B), p (a:b:c)	Interventions EFM vs. Auscultation	Details Parallel to a randomised clinical trial concerning alternative methods of intrapartum fetal surveillance (electronic fetal monitoring [EFM] and auscultation [AUS]) an	Results Women's preference: EFM (electronic fetal monitoring) n = 39.5% AUS (Ausculatation) n = 32.4% UD (undecided) n = 28% Sources of information Antenatal classes Total number: n = 326 AUS-P: 40%	Limitations Unclear if the outcome assessors were blinded to the study groups allocation 41% of study population were not available for the second interview. The reason was not specified Inclusion and exclusion

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Prospective observational study Aim of the study To examine women's view on of intrapartum fetal surveillance methods Study dates January to August 1981 Source of funding Not specified	Number Aus-p: n = 212 EFM-p: n = 259 UD: 184 Age (mean ± SD) Aus-p: 27.8 ± 4.7 EFM-p: 28.1 ± 5.1 UD: 26.3 ± 5.6 p (A:B) = ns p (A:B:C) < 0.001 Pathological obesity AUS-p: n = 0 EFM-p: n = 9 UD: n = 8 p (A:B) < 0.01 p (A:B:C) < 0.05 High risk pregnancy AUS-p: n = 46 EFM-p: n = 109 UD: n = 49 p (A:B) < 0.001 p (A:B:C) < 0.001 There were no statistically significant differences observed between the three		investigatory interview was carried out, in order to examine women's views on fetal monitoring. The first interview was conducted when women were at 36 weeks gestation. In the first semi-structured interview women were told about the study and consent was obtained. They were asked about their knowledge of fetal monitoring during labour and their source of information. They were also asked about their preference and asked to state the advantages and	EFM-P: 38% UD: 22% Books Total number: n = 130 AUS-P: 47% EFM-P: 35% UD: 22% Newspaper Total number: n = 100 AUS-P: 45% EFM-P: 40% UD: 15% Doctors Total number: n = 90 AUS-P: 59% EFM-P: 32% UD: 9% Parents (a monthly magazine from a patient's movement) Total number: n = 59 AUS-P: 66% EFM-P: 24% UD: 11% Radio and TV Total number: n = 56	criteria not specified Significantly more women in EFM-P group had high risk pregnancy No subgroup analysis performed based on parity (nuliparous and multiparous women) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	groups on pre-eclampsia, bleeding in pregnancy, twins, anaemia, pathological HPL, pathological estriol, Diabetes, previous sterility. Inclusion criteria Not specified Exclusion criteria Not specified		disadvantages of the two different methods. The interview lasted about 20 minutes. Out of 665 participants, 655 women were interviewed (ten refused to participate) and 385 women were again interviewed. Women were asked to state their preference for EFM or AUS and also state the advantages and disadvantages of the two methods. All women who had the predelivery interview, were interviewed again on the 2nd or 3rd day after delivery. The person that performed the	AUS-P: 36% EFM-P: 46% UD: 19% All with information of EFM Total number: n = 560 AUS-P: 35% EFM-P: 41% UD: 24% Not heard of EFM Total number: n = 95 AUS-P: 18% EFM-P: 32% UD: 51% Distribution of preference related to place of antenatal classes: The department Total number: n = 321 AUS-P: 31% EFM-P: 42% UD: 27% Women's liberation Total number: n = 64 AUS-P: 70% EFM-P: 20% UD: 9%	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			2nd interview was blinded to the women's preference stated at the first interview regarding fetal monitoring. Mothers were asked how their labour was monitored, what the advantages or disadvantages were of the method used and how they would want the fetal heart monitored in future deliveries. Analysis Analysis of variance was used in the statistical evaluation of age and parity. Elsewhere X2 statistics were	Public schools Total number: n = 35 AUS-P: 35% EFM-P: 37% UD: 27% Private institution Total number: n = 31 AUS-P: 26% EFM-P: 48% UD: 26% No birth preparing courses Total number: n = 213 AUS-P: 21% EFM-P: 42% UD: 36% Advantage and disadvantages of AUS mentioned postpartum by AUS-P (n = 85) and EFM-P (n = 94) groups who had their labour monitored by auscultation: No pain to the child AUS-P: 11% EFM-P: 3%	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			used.	p <0.05 No discomfort from sensors and belt AUS-P: 58% EFM-P: 30% p <0.05 Increased contact to personnel AUS-P: 25% EFM-P: 15% p <0.05 More natural childbirth AUS-P: 72% EFM-P: 45% p <0.05 Advantage and disadvantages of EFM mentioned postpartum by AUS-P (n = 36) and EFM-P (n = 66) groups who had their labour monitored by EFM: EFM promoting husband involvement AUS-P: 25% EFM-P: 45%	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				p < 0.05 More positively influenced by EFM signal/trace AUS-P: 31% EFM-P: 67% p < 0.01 Possibility of quick intervention AUS-P: 44% EFM-P: 62% p <0.05 Continuous precise surveillance AUS-P: 45% EFM-P: 70% p < 0.05 Enforced mobility AUS-P: 22% EFM-P: 20% p < 0.05 Technical milieu AUS-P: 25% EFM-P: 3% p <0.05 Disturbance from EFM	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				signals AUS-P: 20% EFM-P: 3% p < 0.05 Fear of the trauma to the child AUS-P: 5% EFM-P: 2% p < 0.05	
Full citation Mangesi,L., Hofmeyr,G.J., Woods,D.L., - Assessing the preference of women for different methods of monitoring the fetal heart in labour, - South African Journal of Obstetrics and Gynaecology, 15, 2009- Ref Id 187897 Country/ies where the study was carried out South Africa Study type Prospective cross sectional study Aim of the study To assess which method of fetal monitoring was preferred by	Sample size Total n = 100 women Characteristics Not specified Inclusion criteria Women in first stage of active labour Exclusion criteria Women in second stage of labour Twin pregnancy Preterm labour Evidence of fetal	Interventions Fetal stethoscope, cardiotocography (CTG), Doppler ultrasound monitor (FHRM)	Details Convenience sampling was used, participants who were in the active phase of the first stage of labour were recruited from a hospital (in the Eastern Cape province, South Africa) after the study was explained and verbal consent obtained (no further details were reported). A researcher spent approx. 30	Results First maternal preference: Fetal stethoscope: 13/97 FHRM: 72/97 CTG: 12/97 Second maternal preference: Fetal stethoscope: 58/97 FHRM: 17/97 CTG: 22/97 n = 2 women were unable to decide n = 1 loss of data The fetal stereoscope was disliked because of causing discomfort during the examination and CTG	Limitations No details of the women's characteristics reported Women provided with the study's information when they were in labour Consent obtained verbally Intervention applied in very short period of time Not clear when participants were asked about their preference Poor report with limited information provided Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
labouring women Study dates Not specified Source of funding Not specified	distress		minutes with each woman; 10 minutes were spent explaining the study and obtaining consent, 10 minutes were spent monitoring the fetal heart with the stereoscope and a Doppler (FHRM), and for the last 10 mins the fetal heart was monitored with a caridotocograph and if the tracing was unsatisfactory a doctor was notified. Participants were asked to indicate their first and second preferred method. Data Analysis	was disliked because it often confined women to the bed and the securing belt of the carditocograph restricted women's movements	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Data were recorded in a collecting sheet and then entered into Epi_Info 2002 computer software (no further detail provided).		

1.1.17 Does the use of fetal electrocardiogram (ECG) analysis with continuous electronic fetal monitoring (EFM) improve outcomes when compared with continuous EFM alone?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Neilson,James P., Fetal electrocardiogram (ECG) for fetal monitoring during labour, Cochrane Database of Systematic Reviews, -, 2013 Ref Id 151274 Country/ies where the study was carried out Various	Sample size Total n = 16295 Electrocardiogram (ECG) + cardiotocograph (CTG) n = 8179 CTG alone n = 8116 Characteristics Amer-Wahlin 2001 4966 women in labour at > 36 weeks with singleton	Interventions Intervention: CTG + ECG (ST or PR analysis) Control: CTG only	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by the Trials Search Coordinator. CENTRAL, MEDLINE, EMBASE, were searched, and hand searching of journals and conference proceedings was done. No language restrictions were applied.	Results 1 Caesarean section Total no. of studies: 6 total n = 16295 1.1 ST analysis: No. of studies: 5 n = 15338 ECG + CTG n = 876/7697 CTG alone n =	Limitations Westerhuis 2010 There was no blinding for women and clinicians, and a secondary analysis on 61 babies with adverse outcomes (metabolic acidosis in umbilical cord artery, PH < 7.00, sign of severe hypoxic ischaemic encephalopathy [HIE] and perinatal death) showed

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Systematic review of RCTs Aim of the study To compare the effects of analysis of fetal electrocardiogram waveforms during labour with alternative methods of fetal monitoring. Study dates Assessed as up-to-date on Feb. 2013 Source of funding The university of Liverpool, UK	pregnancies, cephalic presentation and perceived need for continuous fetal heart rate monitoring via a fetal scalp electrode - high-risk pregnancies, suspicious or abnormal cardiotocography, induced labour, oxytocin augmentation, meconium-stained amniotic fluid or epidural analgesia. The trial took place between 1998 and 2000 in 3 Swedish centres, Lund, Malmo, Gothenburg Intervention: CTG plus ST analysis of fetal ECG (2519 women) versus CTG alone (2477). The monitoring device was the STAN S21 (Neoventa Medical, Gothenburg) which incorporates an 'expert system' to provide advice to clinical staff. In this, it constitutes a technically more advanced system than used in the Westgate 1993 trial. Ojala 2006 1483 women randomised; 11		Weekly current awareness alert for a further of 44 journals was also considered. Selection of studies The author, Jim Neilson (JPN) assessed all potential identified studies for inclusion. Data extraction and management A form was designed to extract data, JPN extracted the data using the agreed form. It was analysed in RevMan. Where information was unclear, JPN contacted the original authors for further details. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Sequence generation	878/7641 RR 0.99 (95% CI 0.91 to 1.08) 1.2 PR analysis: No. of studies: 1 n = 957 ECG + CTG n = 79/482 CTG alone n = 98/475 RR 0.79 (95% CI 0.61 to 1.04) 2 Cord pH < 7.05 + base deficit >12 mmol/l No. of studies: 5 n = 14574 2.1 ST analysis: ECG + CTG n = 78/7318 CTG alone n = 113/7256 RR 0.78 (95% CI 0.44 to 1.37) 2.2 PR analysis: No. of studies: 0	the trial protocol was violated in 11 (42%) and 13 (19%) cases of study and control group respectively. Ojala 2006 n = 5 in CTG group and n = 78 in the ECG group had technical difficulties in achieving satisfactory monitoring. Amer-Wahlin 2001 A modified intention to treat analysis performed excluding non cephalic and preterm babies from the analysis. Strachan 2000 For unclear reason the result reported for 92.2% of study's population. Subgroup analysis of babies born with a low arterial PH showed no action for fetal distress had been taken in nearly

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	exclusions; clinical data available but blood gas data missing for 36. In labour at ≥ 36 weeks with singleton fetus, cephalic presentation, decision to perform amniotomy, no contraindication to scalp electrode. Sample size based on 50% reduction of umbilical artery pH < 7.10 Intervention: CTG plus ECG waveform analysis (STAN) (733 women) versus CTG (739 women). Fetal scalp sampling for pH estimation an option in either group. Recruitment in tertiary referral hospital in Finland 2003-4 Strachan 2000 957 women in labour with perceived need for continuous fetal heart rate monitoring (age > 35, maternal disease, adverse obstetric history, prematurity, suspected fetal growth restriction, antepartum haemorrhage, breech		- Allocation concealment - Blinding - Incomplete outcome data - Selective reporting bias - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, mean difference and standardised mean difference were used, depending on whether trials had measured outcomes on the same or different scales. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis as far as possible. The denominator being set as the number randomised minus any participants whose outcomes were	3 Neonatal encephalopathy No. of studies: 5 n = 15302 3.1 ST analysis: n = 15302 ECG + CTG n = 8/7678 CTG alone n = 15/7624 RR 0.54 (95% CI 0.24 to 1.25) 3.2 PR analysis: No. of studies: 0 4 Fetal blood sampling No. of studies: 5 n = 10628 4.1 ST analysis: No. of studies: 4 n = 9671 ECG + CTG n = 449/4870 CTG alone n =	75% of cases, suggesting study's protocol violation within the trial groups. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	presentation, multiple pregnancy, epidural analgesia, induction or augmentation of labour, abnormal cardiotocography, meconium, previous caesarean section). Results are only available for 957 women (92%) for reasons that are unclear. The trial took place in 5 centres: Nottingham and Dundee (UK), Hong Kong, Amsterdam (Netherlands) and Singapore Intervention: CTG plus fetal ECG (n = 482) versus CTG alone (n = 475). Vayssiere 2007 799 women in labor at 36 weeks or more, with a single fetus with cephalic presentation, and either abnormal cardiotocographic trace or thick meconium-stained amniotic fluid. Exclusions included maternal infections that contraindicated scalp electrode attachment (e.g. HIV), cardiac malformation, severely		known to be missing. Analysis Heterogeneity was regarded high if I2 > 30 and either T2 > 0 or there was a low P value (< 0.10) in the Chi2 test. A fixed-effect model was used for combining data where studies were assumed estimating the same underlying treatment effect. If substantial clinical or statistical hetrogenity detected, a random effects meta analysis was used. Fixed-effect meta-analysis was used where trials were comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where heterogeneity was present or suspected. If substantial heterogeneity	503/4801 RR 0.61 (95% CI 0.41 to 0.9) 4.2 PR analysis: No. of studies: 1 n = 957 ECG + CTG n = 81/482 CTG alone n = 88/475 RR 0.91 (95% CI 0.69 to 1.19) 5 Operative vaginal delivery 5.1 ST analysis No. of studies = 4 n = 9671 ECG + CTG n = 660/4870 CTG alone n = 731/4801 RR 0.89 (95% CI 0.81 to 0.98) 5.2 PR analysis No. of studies = 1 n = 957 ECG + CTG n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	abnormal cardiotocography at the time of recruitment was an option in both groups Intervention: CTG + fetal ECG (n = 399) versus CTG alone (n = 400). Scalp sampling for ph estimation Westerhuis 2010 5681 women in labour with a singleton fetus in vertex position, a gestational age 36 weeks or greater and a medical indication for electronic fetal monitoring. A medical indication is defined by either a high-risk pregnancy, induction or augmentation of labour, epidural anaesthesia, meconium-stained amniotic fluid or non-reassuring fetal heart rate Intervention group: CTG and ST-analysis. Control group: CTG. Westgate 1993		was detected, it was investigated using subgroup and sensitivity analysis.	116/482 CTG alone n = 122/475 RR 0.94 (95% CI 0.75 to 1.17) 6 Apgar score < 7 at 5 minutes No. of studies: 6 n = 1625 6.1 ST analysis: No. of studies: 5 n = 15302 ECG + CTG n = 103/7678 CTG alone n = 108/7624 RR 0.95 (95% CI 0.73 to 1.24) 6.2 PR analysis: No. of studies:1 n = 957 ECG + CTG n = 3/482 CTG alone n = 7/475 RR 0.42 (95% CI	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	2434 pregnant women, 1215 cardiotocography alone arm, 1219 ST waveform and CTG arm. (More than 34 weeks gestation with no gross fetal abnormality.) Intervention: CTG plus ST analysis (n =1219) versus CTG alone (n = 1215). Inclusion criteria Trials comparing analysis of any component of the fetal electrocardiographic (ECG) during labour with alternative fetal monitoring methods. Studies using less robust methods of allocation (for example, alternation) were not included. Exclusion criteria Not reported			0.11 to 1.62) 7 Neonatal intubation No. of studies: 2 n = 2393 7.1 ST analysis: No. of studies: 1 n = 1436 ECG + CTG n = 7/714 CTG alone n = 9/722RR 0.79 (95% CI 0.29 to 2.10) 7.2 PR analysis: No. of studies: 1 n = 957 ECG + CTG n = 6/482 CTG alone n = 8/475 RR 0.74 (95% CI 0.26 to 2.11) 8 Admission to neonatal care unit	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				No. of studies: 6 n = 16259 8.1 ST analysis: ECG + CTG n = 615/7678 CTG alone n = 685/7624 No. of studies: 5 n = 15302 RR 0.89 (95% CI 0.81 to 0.99) 8.2 PR analysis No. of studies: 1 n = 957 ECG + CTG n = 22/482 CTG alone n = 28/475 RR 0.77 (95% CI 0.45 to 1.33) 9 Perinatal death No. of studies: 6 n = 16295 9.1 ST analysis No. of studies: 5 n	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				= 15338 ECG + CTG n = 8/7697 CTG alone n = 5/7641 RR 1.49 (95% CI 0.53 to 4.18) 9.2 PR analysis No. of studies: 1 n = 957 ECG + CTG n = 1/482 CTG alone n = 0/475 RR 2.96 (95% CI 0.12 to 72.39)	
Full citation Amer-Wahlin,I., Kjellmer,I., Marsal,K., Olofsson,P., Rosen,K.G., Swedish randomized controlled trial of cardiotocography only versus cardiotocography plus ST analysis of fetal electrocardiogram revisited: analysis of data according to standard versus modified	Sample size n = 4966 labouring women at three Swedish labour wards Characteristics Not reported in the present paper (initial study included in Neilson 2011) Inclusion criteria	Interventions ITT analysis: the standard intention to treat analysis	Details Original trial conducted in 2001: 4966 women in labour at > 36 weeks with singleton pregnancies, cephalic presentation and perceived need for continuous fetal heart rate monitoring via a fetal scalp electrode - high-risk pregnancies, suspicious	Results Metabolic acidosis rates ITT (current analysis): CTG + ST: 17/2565 (0.66%) CTG only: 33/2484 (1.33%) RR 0.50 (95% CI 0.28 to 0.88)	Limitations Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
intention-to-treat principle, Acta Obstetricia et Gynecologica Scandinavica, 90, 990-996, 2011 Ref Id 157180 Country/ies where the study was carried out Sweden Study type Randomised trial Aim of the study To undertake a new analysis of data from the previously published Swedish randomised controlled trial on intrapartum fetal monitoring with cardiotocography (CTG-only) vs. CTG plus ST analysis of fetal electrocardiogram (CTG+ST), using current standards of intention-to-treat (ITT) analysis and to compare the results with those of the modified ITT (mITT) and per protocol	Eligible for the original study were women in active labour and singleton pregnancy ≥ 36 weeks, in cephalic presentation Exclusion criteria Not reported in the present paper (initial study included in Neilson 2011)		or abnormal cardiotocography, induced labour, oxytocin augmentation, meconium-stained amniotic fluid or epidural analgesia. The trial took place between 1998 and 2000 in 3 Swedish centres, Lund, Malmo, Gothenburg Intervention: CTG plus ST analysis of fetal ECG (2519 women) versus CTG alone (2477). The monitoring device was the STAN S21 (Neoventa Medical, Gothenburg) which incorporates an 'expert system' to provide advice to clinical staff. In this, it constitutes a technically more advanced system than used in the Westgate 1993 trial. Analysis: Modified intention to treat (mITT) was used.	p = 0.019 ITT (including imputed data): CTG + ST: 18/ 2565 (0.70%) CTG only: 35/2484 (1.41%) RR 0.50 (95% CI 0.28 to 0.88) p = 0.016 per protocol analysis: CTG + ST: 11/1926 (0.57%) CTG only: 27/1871 (1.44%) RR 0.40 (95% CI 0.20 to 0.80) p = 0.009 Original mITT: CTG + ST: 15/ 2159 (0.69%) CTG only: 31/2079(1.49%) RR 0.47 (95% CI	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
analyses Study dates Initial study was conducted in 2001 Source of funding No specific funding			mITT analysis: In that analysis the cases with severe malformation, preterm, breech delivery and those with invalid cord artery acid base data were excluded. A new mITT analysis was performed after 12 cases of misclassification (at primary clinical data collection) corrected. Present paper: New analysis of data performed according to the standard ITT principles included all women randomised and it followed the primary allocation to the study arms. ITT analysis: The standard intention to treat analysis was based on the initial allocation group; CTG only versus CTG+ST. The information was derived from the original data file generated by the STAN computers. The recording in	0.25 to 0.86) p = 0.015 mITT with correction for 10 previously misclassified cases and two misclassified case: CTG + ST: 12/2519** CTG only: 24/2447* RR 0.48 (95% CI 0.24 to 0.96) p = 0.038 *Acid based data available for n = 2079 **Acid based data available for n = 2159	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			n = 32 cases (n = 15 CTG only, n = 17 CTG+ST) were interrupted and automatic re-allocation was done by the recorder when the recording was resumed. In current analysis they stayed in their original allocation. Main outcomes measure: metabolic acidosis in umbilical artery at birth (pH < 7.05, base deficit in extracellular fluid > 12.0mmol/l) including samples of umbilical vein blood or neonatal blood if umbilical artery blood was missing.		

1.1.18 What is the effectiveness of different methods of intrauterine resuscitation for babies with and without meconium-stained liquor?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Abdel-Aleem,H., Amin,A.F., Shokry,M., Radwan,R.A., Therapeutic amnioinfusion for intrapartum fetal distress using a pediatric feeding tube, International Journal of Gynaecology and Obstetrics, , 94-98, 2005 Ref Id 118861 Country/ies where the study was carried out Egypt Study type Randomised controlled trial Aim of the study To evaluate the role of therapeutic amnioinfusion using a paediatric feeding tube in cases of intrapartum distress Study dates	N = 438 Characteristics The authors report that there were no statistically significant differences between the two groups in terms of age, parity, gestational age, incidence of mild pre-eclampsia, premature rupture of membranes and meconium stained amniotic fluid; however, the details of the two groups are not reported. Induction of labour (n (%)) Amnioinfusion: 20 (9.1) Control: 16 (7.3) Classification of fetal heart rate at admission (%) Non-reassuring Amnioinfusion: 52 Control: 53 Ominous Amnioinfusion: 48	Amnioinfusion (n = 219) Control (n = 219)	Recruitment and randomisation Women were assessed clinically for inclusion or exclusion. Fetal heart rate monitoring was done for everyone and those in whom it was determined to be non-reassuring or ominous (according to the Arias classification) were approached for participation as long as immediate delivery was not contemplated. The traces were assessed by two obstetricians, of whom one was independent of the trial. If women consented they were randomised to either amnioinfusion plus standard obstetric care, or just standard obstetric care. Randomisation was done using a computer-generated table of random numbers and	Caesarean section for fetal distress (n/total) Amnioinfusion: 105/219 Control: 149/219 RR 0.70 (95 % CI 0.60 to 0.83) Abnormal fetal heart rate pattern after amnioinfusion (n/total) Amnioinfusion: 105/219 Control: 149/219 RR 0.70 (95 % CI 0.60 to 0.83) Meconium below the vocal cords (n/total) Amnioinfusion: 5/219 Control: 14/219 RR 0.36 (95 % CI 0.13 to 0.97) Meconium aspiration syndrome (n/total) Amnioinfusion: 0/219 Control: 3/219 RR not reported	Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: not possible Blinding of staff providing care: not possible Blinding of outcome assessors: no details given Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: yes - 5 women did not receive amnioinfusion because the tube could not be passed through the cervix (due to uterine hypertonicity) but they

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
April 2003 to March 2004 Source of funding None reported	Control: 47 Cervical dilatation on admission/cm (mean ± SD) Amnioinfusion: 3.9 ± 1.1 Control: 3.8 ± 1.3 Inclusion criteria Single fetus Vertex presentation Gestational age greater than 37 weeks Cervical dilatation less than 5 cm Non-reassuring fetal heart rate trace indicating fetal distress Exclusion criteria Vaginal bleeding Fetal anomalies Uterine scars		allocation was through the use of sealed opaque envelopes. Care protocol Standard obstetric care The infusion of oxytocin was stopped, oxygen was administered and women were turned on to their left side to increase cardiac output. No amnioinfusion was done. Amnioinfusion Women received all of the above components of standard obstetric care, plus amnioinfusion. Transcervical amnioinfusion was carried out using a paediatric nasogastric feeding tube (number 8). 1 gram of amoxicillin was given intravenously as a prophylactic antibiotic, then the woman was placed in a	Need for neonatal intensive care unit (n/total) Amnioinfusion: 14/219 Control: 31/219 RR 0.45 (95 % CI 0.25 to 0.83) Neonatal death (n/total) Amnioinfusion: 0/219 Control: 1/219 RR not reported Uterine hypertonicity (n/total) Amnioinfusion: 16/219 Control: 14/219 RR 1.14 (95% CI 0.57 to 2.28)	were analysed in the amnioinfusion group Indirectness: - 9.1 % of the amnioinfusion group and 7.3% of the control group had induction of labour - study is not restricted to low risk women although some high risk groups were excluded - fetal blood sampling facilities were not available - it is not clear how many women in this study presented with meconium stained liquor Note: overall CS rate is not given, only reported for fetal distress Other information Amnioinfusion compared with no amnioinfusion for fetal distress [therapeutic]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Uterine anomalies Malpresentation Intrauterine growth retardation Maternal temperature higher than 38 degrees Grandmultiparity (> 5) Severe pre-eclampsia		dorsal position and genitalia were cleaned with antiseptic. If the membranes were found to be intact then they were ruptured prior to tube insertion in the posterior or posterior lateral quadrant of the pelvis. A bolus of 500 ml of sterile saline solution (at 37 degrees) was infused over 30 minutes, and this was followed by repeated slow infusions using a 20 ml syringe for a total of 1 litre. If the fetal heart rate (FHR) pattern had not become reassuring after the first 200 ml (this is as stated in the paper; however, appears to contradict the rest of the methods and therefore may be a typo), a caesarean section (CS) was performed. If the FHR		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			was corrected, the infusion was completed. After infusion of the first 500 ml, an IV was connected to another bottle of warmed saline solution which was infused continuously for 15 to 20 minutes by gravity. Then, the paediatric feeding tube was removed by gentle withdrawal. Women were monitored continuously until birth. Statistical analysis A sample size calculation was based on the caesarean section rate due to fetal distress (about 20%). It was calculated that with 80% power and a significance level of 5%, amnioinfusion would reduce the rate by 50%. This required a sample size of 438 women.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			t-tests, chi-squared tests and Fisher's exact test were used to analyse data. p < 0.05 was considered statistically significant. Analysis was done on an intention-to-treat basis. Outcomes reported - caesarean section for fetal distress - abnormal FHR after amnioinfusion - meconium below the vocal cords and meconium aspiration syndrome: assessed by a paediatrician - need for admission to NICU - neonatal death		
Full citation Afschar,P., Scholl,W., Bader,A., Bauer,M.,	Sample size N = 26 women were randomised	Interventions Atosiban (n = 13)	Details Recruitment and randomisation	Results Recovery to normal fetal heart rate (n/total)	Limitations Appropriate randomisation: unclear - it

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Winter,R., A prospective randomised trial of atosiban versus hexoprenaline for acute tocolysis and intrauterine resuscitation, BJOG: An International Journal of Obstetrics and Gynaecology, 111, 316-318, 2004 Ref Id 121082 Country/ies where the study was carried out Austria Study type Randomised controlled trial (pilot) Aim of the study To compare the efficacy and side effect profile of atosiban with hexoprenaline when used for intrauterine resuscitation of intrapartum fetal distress Study dates	[Note: 1431 women in labour were enrolled] Characteristics Age of mother/years (mean) Atosiban: 28.4 Hexoprenaline: 27.5 Gestational age/weeks (mean) Atosiban: 40.6 Hexoprenaline: 41.1 Spontaneous onset/minutes (mean) Atosiban: 11 Hexoprenaline: 13 Induction (n) a. With oxytocin Atosiban: 3 Hexoprenaline: 3 b. With prostaglandin Atosiban: 1 Hexoprenaline: 1	Hexoprenaline (n = 13)	1431 women with a singleton pregnancy at term in cephalic presentation were enrolled in the study; however, only those with fetal bradycardia were then randomised. Therefore, the sample size ended up being N = 26. Women were randomised using "treatment boxes" to atosiban or hexoprenaline. Care protocol Continuous fetal heart rate monitoring was done in the active phase of labour for all women. It was monitored for at least 30 minutes and the diagnosis of severe fetal bradycardia was made when there was a fetal heart rate of less than 80 beats per minutes for more than 3 minutes.	Atosiban: 12/13 Hexoprenaline: 13/13 [This appears to have taken a mean of 2 and 3 minutes respectively, but this is not clear from the way the data are reported] Umbilical artery pH (mean ± SD) Atosiban: 7.2 ± 0.08 Hexoprenaline: 7.2 ± 0.06 Forceps delivery (n/total) Atosiban: 0/13 Hexoprenaline: 1/13 [Note: it is also reported that 24 babies were delivered vaginally and that one baby was delivered by CS, but not which group the CS was in] Admission to NICU (n/total) Atosiban: 0/13 Hexoprenaline: 1/13 Perinatal death (n/total) Atosiban: 0/13 Hexoprenaline: 0/13	is only reported that "treatment boxes" were used Allocation concealment: unclear Groups comparable at baseline: unclear - no details given about the characteristics of the study groups Groups received same care (apart from intervention): yes Blinding of participants: no details given Blinding of staff providing care: no - boluses were given over different time periods Blinding of outcome assessors: no details given Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: There are conflicting reports on the admission to NICU - initially in the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
October 2000 to May 2001 Source of funding Atosiban was provided by Ferring Pharmaceuticals	Birth weight/grams (mean) Atosiban: 3322 Hexoprenaline: 3465 Inclusion criteria Singleton pregnancy at term Cephalic presentation At least 38 weeks gestation Presenting with a diagnosis of intrapartum fetal distress (severe fetal bradycardia) requiring intrauterine resuscitation Exclusion criteria Serious maternal disease (pre-eclampsia, maternal hypertension, HELLP syndrome, metabolic diseases) Fetal or placental abnormalities		- Atosiban group Women received 6.75 mg diluted in 4.9 ml of physiological saline administered over 1 minute - Hexoprenaline group Women received 5 micrograms diluted in 10 ml of physiological saline administered over 5 minutes Statistical analysis Data were analysed using Student's t-test or Fisher's exact test as appropriate. Outcomes reported - Recovery to normal fetal heart rate - Umbilical artery pH: mean values - Perinatal death - Need for admission to	Other details reported about labour Tocolysis (n/total) Atosiban: 12/13 Hexoprenaline: 13/13 Time to restart of contractions/minutes (mean ± SD) Atosiban: 8 ± 3 Hexoprenaline: 14 ± 4 Duration of fetal bradycardia/minutes (mean ± SD) Atosiban: 5.6 ± 2.1 Hexoprenaline: 6.5 ± 1.7 [p = 0.072]	text it says that none of the infants were transferred to NICU, but then it says that one infant was taken to NICU after the forceps delivery for observation and discharged after 5 days Intention-to-treat analysis performed: no details given No power calculation performed because it was a pilot study. Generally poorly reported. Indirectness: - 8/26 (31%) of women had induction with oxytocin or prostaglandin Other information Tocolysis for fetal distress: atosiban compared with hexoprenaline

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(intrauterine growth restriction (IUGR), fetal malformation)		NICU - Mode of birth		
Full citation Briozzo,L., Martinez,A., Nozar,M., Fiol,V., Pons,J., Alonso,J., Tocolysis and delayed delivery versus emergency delivery in cases of non-reassuring fetal status during labor, Journal of Obstetrics and Gynaecology Research, 33, 266-273, 2007 Ref Id 157015 Country/ies where the study was carried out Uruguay Study type Randomised controlled trial Aim of the study To determine whether fetal intrauterine resuscitation with beta-sympathomimetics is	Sample size N = 390 Characteristics Fetal heart rate pattern (n (%)) Late decelerations Fenoterol: 119 (61.6) Delivery: 118 (59.8) Bradycardia or tachycardia Fenoterol: 85 (44.0) Delivery: 84 (42.6) Absent: minimal variability Fenoterol: 22 (11.3) Delivery: 12 (6.0) Prolonged and variable decelerations Fenoterol: 17 (8.8) Delivery: 15 (7.6) Point of diagnosis Early first stage	Interventions Intrauterine resuscitation with fenoterol (n = 193) Emergency delivery (n = 197)	Details Recruitment and randomisation When women were admitted in labour, electronic fetal monitoring (EFM) was performed in women who presented with at least one of the following risk factors: - previous perinatal demise - maternal age > 40 - pathologies during pregnancy - alterations in fetal growth and development - dystocic labour - prolonged amenorrhoea (> 41 weeks) - premature rupture of membranes - metrorrhagia in the third trimester	Results Acidosis in the umbilical artery (n/total (%)) a. pH < 7.1 Fenoterol: 28/193 (14.5) Delivery: 42/197 (21.3) RR 1.47 (95% CI 0.95 to 2.27) b. Base excess < -12 Fenoterol: 33/193 (17.1) Delivery: 50/197 (25.4) RR 1.48 (95% CI 1 to 2.20) Admission to NICU (n/total (%)) Fenoterol: 16/193 (8.3) Delivery: 35/197 (17.8) RR 2.14 (95% CI 1.23 to 3.74) Mode of birth (n/total (%)) a. Caesarean section (CS) Fenoterol: 175/193 (90.7) Delivery: 159/197 (80.7)	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: not possible Blinding of staff providing care: not possible Blinding of outcome assessors: yes - neonatologists were blinded to the intervention Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
better for the baby than emergency delivery Study dates November 1st 2001 to June 1st 2004 Source of funding None reported	Fenoterol: 31 (16.0) Delivery: 38 (19.2) Late first stage Fenoterol: 81 (41.9) Delivery: 105 (53.2) Second stage Fenoterol: 41 (21.2) Delivery: 51 (25.8) Maternal age/years (mean ± SD) Fenoterol: 24.3 ± 7.08 Delivery: 23.4 ± 6.20 Gestational age/weeks (mean ± SD) Fenoterol: 38.9 ± 1.20 Delivery: 38.8 ± 1.60 Birth weight/grams (mean ± SD) Fenoterol: 3187 ± 479 Delivery: 3065 ± 500 Preterm (35-36 weeks on neonatal examination) (n (%)) Fenoterol: 14 (8.6) Delivery: 12 (7.4)		Pregnant women admitted in labour and who were found to have a non-reassuring fetal status (excluding reversible causes such as uterine hyperstimulation or maternal hypotension due to analgesia) were asked to participate. Non-reassuring fetal status was diagnosed according to the following definitions: 1. DIP II (late decelerations of the FHR) in at least 3 consecutive contractions 2. fetal bradycardia (< 110 bpm) or tachycardia (> 160 bpm) over 10 minutes, not improving with the mother's change of position 3. absent (undetectable) and minimal FHR variability (≤ 5 bpm), 10-minute	RR 1.63 (95% CI 1.10 to 2.42) b. Forceps Fenoterol: 9/193 (4.7) Delivery: 19/197 (9.6) RR not reported c. Spontaneous vaginal birth Fenoterol: 9/193 (4.7) Delivery: 19/197 (9.6) RR not reported [Note: there were 36 women in whom fetal intrauterine resuscitation was found to be ineffective. Of these, 7/36 babies required admission to NICU, 7/36 had pH < 7.1 and 7/36 had a base excess < -12. None of these were statistically significantly different to the emergency delivery arm] The authors report that the increase in CS in the intrauterine resuscitation	Indirectness: - 5.5% of women had no prenatal obstetric visits - study was not restricted to low risk women, although some high risk groups are excluded Other information Tocolysis for fetal distress: fenoterol compared with emergency delivery

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Premature rupture of membranes (n (%)) Fenoterol: 33 (17.1) Delivery: 37 (18.8) Prenatal obstetric visits (n (%)) Fenoterol: 155 (94.5) Delivery: 1544 (94.5) Intrauterine growth restriction (n (%)) Fenoterol: 28 (14.5) Delivery: 34 (17.3) Minor birth defects (n (%)) Fenoterol: 2 (1.2) Delivery: 2 (1.2) [Note: 2 polidactilias, 1 sindactilia, 1 clubfeet] Abruptio placentae [postpartum diagnosis] (n (%)) Fenoterol: 5 (2.5) Delivery: 5 (2.5) Anaemia [haemoglobin <		segments, when no drugs that may decrease heart-rate variability were administered and the situation was not improved with external cephalic stimulation 4. prolonged deceleration of FHR ≥ 15 bpm lasting at least 2 minutes, but less than 10 minutes from the onset to return to baseline, and variable decelerations of FHR below Randomisation was done using a computer program with randomly permuted blocks of 20. The sequence and allocation were in sealed envelopes which were opened in order. 572 women were evaluated for potential enrolment; however 182 were not randomised because	group when compared to the emergency delivery group was likely to be a result of the fact that when contractility is reduced, there is a reduced chance of spontaneous vaginal birth. They also note that intrauterine resuscitation provides the obstetric team with more time to perform a CS. Postpartum haemorrhage (n/total) Fenoterol: 0/193 (0) Delivery: 0/197 (0) Other information reported about labour Time between point of diagnosis of non-reassuring fetal status and birth/minutes (mean ± SD) Fenoterol: 34.54 ± 11.7 - effective resuscitation: 36.1 ± 11 - ineffective resuscitation: 26.6 ± 10.3 Delivery: 16.92 ± 7.63	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	11 mg/dl] (n (%)) Fenoterol: 3 (1.8) Delivery: 2 (1.2) Inclusion criteria Term, singleton pregnancy Cephalic presentation In labour with a cervix dilatation of more than 3 cm and a uterine contraction pattern of 3-5 in 10 minutes Non-reassuring fetal status diagnosed using standard electronic fetal heart rate (FHR) and uterine contraction monitoring Acceptance of participation by signing of written consent Exclusion criteria Maternal cardiopathy		they did not meet inclusion criteria, refused, or there was not time to obtain informed consent. Care protocol Intrauterine resuscitation group 0.5 mg of fenoterol bromhydrate was diluted in 500 ml of saline. It was administered intravenously at a rate of 0.1 mg per minute initially and then the rate was adjusted according to the response. The rate was adjusted in an effort to decrease uterine contractility while not increasing the woman's heart rate more than 30 beats per minute and while avoiding a decrease in blood pressure of more than 30 mmHg of systolic		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Hyperthyroidism Abruptio placentae or other placental "accidents" Hyperstimulation with oxytocin		pressure and/or more than 15 mmHg of diastolic pressure. Uterine contractions were recorded in the same strip as continuous EFM. 10 minutes after implementation of the fetal intrauterine resuscitation, the situation was evaluated to assess whether the FHR had improved, remained unchanged, or worsened. If the FHR had unchanged or had worsened, intrauterine resuscitation was considered ineffective and an emergency delivery (normally a CS but occasionally forceps) was done. If the FHR had improved, intrauterine resuscitation was		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			considered effective and utero-inhibition was maintained for 20 minutes under permanent surveillance. Then, a CS was done, or occasionally a forceps was more appropriate given the position of the fetal head. Emergency delivery group This group acted as the control group, as an emergency delivery was considered standard procedure upon diagnosis of a non-reassuring fetal status. The delivery was performed in the "shortest time possible" either by caesarean (usually) or forceps (if this was faster). In both groups, immediately after birth		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			the cord was double clamped and a sample of umbilical arterial blood was taken. Statistical analysis The sample size calculation was based on admission to NICU, which was assumed to be at a rate of 20% under usual management following the diagnosis of non-reassuring fetal status. With a power of 80% and an alpha-error of 0.05, 392 women in total were calculated to be needed to detect a decrease in the rate of NICU admission to 9.5%. Analysis was by intention-to-treat and involved all randomised women. Student's t-test and chi-squared were used as appropriate.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Outcomes reported - Acidosis in the umbilical artery: pH < 7.10 and/or base excess ≤ 12 - Admission to NICU: this was based on the presence of one or more of the following: alterations of the central nervous system [early seizures, hypotonia, and/or alterations of the sensorium], haemodynamic alterations [bradycardia, alterations of peripheral perfusion (cyanosis)], and respiratory issues such as respiratory distress and need of immediate resuscitation of the newborn [ventilation with positive pressure, external cardiac massage, administration of inotropic drugs]		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Mode of birth - Postpartum haemorrhage: reported as the number of women with bleeding as an adverse side-effect		
Full citation Burke,M.S., Porreco,R.P., Day,D., Watson,J.D., Haverkamp,A.D., Orleans,M., Luckey,D., Intrauterine resuscitation with tocolysis. An alternate month clinical trial, Journal of Perinatology, 9, 296-300, 1989 Ref Id 169108 Country/ies where the study was carried out USA Study type Clinical trial with alternate month allocation	Sample size N = 50 Characteristics There were no significant differences in any of the following characteristics (according to the authors) Maternal age/years (mean ± SD) Terbutaline: 24.1 ± 4.4 Control: 23.0 ± 5.0 Parity (mean ± SD) Terbutaline: 1.1 ± 1.2 Control: 0.9 ± 1.3 Gestational age/weeks (mean ± SD)	Interventions Terbutaline (n = 31) Control (n = 19)	Details Recruitment and allocation to study groups Informed consent was obtained from all women at the time of admission in labour, because any of them could potentially have fetal distress. 50 women were found to have fetal distress, established by any of the following criteria: 1. severe variable decelerations to 70 bpm or more and lasting for 60 seconds 2. persistent tachycardia with a fetal heart rate greater than	Results Umbilical cord gases (n/total (%)) a. venous pH < 7.25 Terbutaline: 9/31 (29) Control: 11/20 (55) b. venous CO2 > 55 Terbutaline: 3/29 (10) Control: 6/20 (30) c. venous O2 < 25 Terbutaline: 10/29 (35) Control: 9/20 (45) d. arterial pH < 7.25 Terbutaline: 21/28 (75) Control: 12/19 (63) e. arterial CO2 > 55 Terbutaline: 11/28 (39) Control: 9/19 (47)	Limitations Appropriate randomisation: this was not a randomised controlled trial - women were allocated to control or treatment groups in alternating months Allocation concealment: no Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: no details given Blinding of staff providing care: no details given Blinding of outcome assessors: no details given

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To evaluate the "usefulness" of intrauterine resuscitation with tocolysis Study dates September 1985 to May 1986 Source of funding None reported	Terbutaline: 39.1 ± 2.3 Control: 39.3 ± 3.2 Birth weight/grams (mean ± SD) Terbutaline: 2862 ± 633 Control: 2866 ± 740 Complications (n (%)) History of medical complications Terbutaline: 10 (32) Control: 6 (32) [Note: this was most frequently asthma, anaemia, IV drug use, hepatitis, and gestational diabetes] History of obstetrical complications Terbutaline: 13 (42) Control: 4 (21) [Note: this included history of premature labour, caesarean section (CS), pre-eclampsia, small for gestational age (SGA)		160 and showing a decreased beat to beat variability 3. persistent late decelerations 4. bradycardia of less than 90 bpm for more than 3 minutes 5. any fetal scalp pH sample of less than 7.20 regardless of fetal heart tracing, or less than 7.25 with an ominous tracing. When the decision had been made to do a CS, in the intervening time before delivery, women received either terbutaline or control therapy in alternate months. Care protocol All of the women were delivered by CS. The deliveries were attended by the paediatric house staff or neonatal nurse	[Note: arterial O2 is not reported] Neonatal death (n/total (%)) Terbutaline: 0/31 Control: 0/21 Blood loss over 1000 ml (n/total (%)) Terbutaline: 0/31 (0) Control: 6/19 (31.6) Other details reported It is also reported that the duration of labour was not significantly different between the two groups; however, no data are reported. In the patients that received terbutaline, the mean number of contractions dropped from 3.6 in 10 minutes before terbutaline to 0.31 in 10 minutes after (p = 0.02).	Missing data/loss to follow-up: there are missing data for the terbutaline group for all umbilical cord blood gas outcomes except for venous pH Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes, except blood loss was clinically estimated Intention-to-treat analysis performed: yes The denominators for some outcomes in the control group is reported to be 20 because there were multiple pregnancies. Unclear at what point terbutaline was given Indirectness: - very specific population, in terms of it being women who had a CS within 30 minutes of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	baby, stillborn baby and trisomy 18 baby] Current obstetrical complications Terbutaline: 19 (61) Control: 10 (53) [Note: this included placental abruption, > 42 weeks gestation, premature labour, SGA baby, oligohydramnios, pre-eclampsia, twins and drug abuse] Small for gestational age infant Terbutaline: 5 (16) Control: 3 (14) Heavy meconium staining Terbutaline: 12 (39) Control: 3 (14) Patterns of fetal distress observed Marked bradycardia after a previously reassuring trace was the most		clinicians who were responsible for neonatal resuscitation. Umbilical cord gases were obtained from most patients. Before the CS, women were managed according to the following protocols: - Control group This included standard procedures of maternal positioning, oxygen administration, intravenous fluids and stopping oxytocin. - Terbutaline group Women received all of the standard procedures, plus a 0.25 mg IV bolus of terbutaline over 1 minute. Statistical analysis Means were analysed using two-sided Student's t-test. Chi-squared test was used		tocolysis for fetal distress - not restricted to low risk, although women with diabetes or cardiac disease were excluded - there were two sets of twins in the control group - 39% of the study group and 14% of the control group had heavy meconium staining; however, it is not clear whether meconium staining occurred before or after recruitment into the study Other information Tocolysis for fetal distress: Terbutaline and standard care compared with standard care

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	common pattern. One baby had marked tachycardia over 180 beats per minute. A moderate bradycardia of 90-100 bpm was seen in 2 babies. A marked bradycardia of less than 90 bpm for more than 3 minutes was seen in 19 babies. Severe variable decelerations to less than 70 bpm for more than 60 seconds were seen in 8 babies. 16 had persistent late decelerations. 4 had combinations of mild to moderate variable decelerations with poor beat-to-beat variability or slow return to baseline. There was no signifcant difference in the two groups in the patterns. Inclusion criteria Women who had been delivered by caesarean section within 30 minutes of intrauterine		for proportions Outcomes reported - umbilical cord gases: arterial and venous pH and CO2 and venous O2 are reported - neonatal death - postpartum haemorrhage		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	resuscitation for fetal distress Exclusion criteria Insulin-dependent diabetes Cardiac disease Women who delivered vaginally (including instrumental vaginal delivery) [Note: this was in order that the urgency of fetal distress was more clearly defined and that the influence of a potentially difficult vaginal delivery was removed]				
Full citation Choudhary,D., Bano,I., Ali,S.M., Does amnioinfusion reduce caesarean section rate in meconium-stained amniotic fluid, Archives of Gynecology and Obstetrics, 282, 17-22, 2010	Sample size N = 292 Characteristics Maternal age/years (mean ± SD) Amnioinfusion: 23.97 ± 3.83 Control: 25.25 ± 4.70 [p = 0.210]	Interventions Amnioinfusion (n = 146) Control (n = 146)	Details Recruitment and randomisation The study was conducted in a teaching hospital in north India, which provided free obstetric services to underprivileged women. Women fulfilling the	Results Mode of birth (n/total (%)) a. "Normal" vaginal birth Amnioinfusion: 103/146 (70.54) Control: 46/146 (31.51) b. Forceps delivery Amnioinfusion: 0/146 (0) Control: 7/146 (4.79)	Limitations Appropriate randomisation: likely - they report that a list of randomly generated numbers was used, although it is not clear how the list was generated Allocation concealment:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 118893 Country/ies where the study was carried out India Study type Randomised controlled trial Aim of the study To evaluate the safety and efficacy of transcervical amnioinfusion during labour complicated by meconium stained amniotic fluid, in a setting with limited peripartum facilities, to lower the incidence of caesarean section Study dates Not reported Source of funding None reported	Proportion of primigravida women (%) Amnioinfusion: 43.8 Control: 43.5 [p = 1.00] Gestational age/weeks (mean ± SD) Amnioinfusion: 38.74 ± 1.13 Control: 38.80 ± 1.11 [p = 0.906] Booked antenatally (%) Amnioinfusion: 50 Control: 47.5 [p = 0.902] Induction of labour (n/total (%)) Amnioinfusion: 5/146 (3.4%) Control: 11/146 (7.5%) [p = 0.030] Cervical dilatation when meconium was detected/cm (mean ± SD) Amnioinfusion: 3.59 ±		inclusion criteria who gave informed consent were randomised to the amnioinfusion or control groups. Samples of amniotic fluid were taken after rupture of membranes and were evaluated clinically. Meconium was considered moderate if it was greenish, opaque and not watery and was considered thick if it had a 'pea-soup' quality with visually identifiable particulate matter. Care protocol Amnioinfusion group A nasogastric tube (no. 8) was inserted transcervically into the uterine cavity and passed above the baby's head. If the cervix was not dilated enough, the tube was inserted using a speculum. A bolus of 500 ml normal saline	c. Caesarean section Amnioinfusion: 43/146 (29.45) Control: 93/146 (63.39) - For fetal distress (n) Amnioinfusion: 26 Control: 83 - For arrest of labour (n) Amnioinfusion: 15 Control: 8 - For cephalopelvic disproportion (n) Amnioinfusion: 2 Control: 2 Perinatal death (n/total (%)) Amnioinfusion: 2/146 (1.4) Control: 16/146 (11.0) Meconium aspiration syndrome (n/total (%)) Amnioinfusion: 1/146 (0.68) Control: 23/146 (15.75) Other details about labour reported	likely - they report that sealed envelopes were used, although it is not clear if they were opaque Groups comparable at baseline: significant difference in proportion of women undergoing induction of labour in the two groups Groups received same care (apart from intervention): yes Blinding of participants: not possible Blinding of staff providing care: not possible Blinding of outcome assessors: neonatal outcome was assessed by a paediatrician who was blinded Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	1.42 Control: 3.81 ± 0.98 [p = 0.126] Birth weight/kg (mean ± SD) Amnioinfusion: 2.74 ± 0.38 Control: 2.65 ± 0.43 [p = 0.078] Inclusion criteria Women in labour at term (> 37 weeks) Singleton pregnancy Cephalic presentation Moderate or thick meconium Adequate pelvis Exclusion criteria Indications for immediate delivery such as cord prolapse		was infused over a period of 30 minutes, followed by 2 ml per minute under gravity. The infusion was continued until delivery occurred. Control group Women received standard labour management, without amnioinfusion. All women had the fetal heart rate monitored with auscultation every 15 minutes and uterine tone, intensity, frequency and duration of contractions were assessed by palpation every 30 minutes. The decision for a vaginal or operative delivery was taken if there were fetal heart rate abnormalities (bradycardia or irregularity for 10-20 minutes) or slow progress of labour.	Meconium detection to birth interval/minutes (mean ± SD) Amnioinfusion: 178.25 ± 101.81 Control: 129.25 ± 101.81 [p = 0.001] Incoordinate uterine activity (n/total) Amnioinfusion: 0/146 Control: 3/146 [p = 0.082]	The methods of statistical analysis reported are not relevant to the dichotomous outcomes which are reported. Indirectness: - Only 50% of the study group and 47.5% of the control group were booked antenatally - 3.4% of the study group and 7.5% of the control group had induction of labour (this is significantly different) - study is not restricted to low risk women, although some higher risk groups are excluded - women were monitored using auscultation; therefore, the authors classify the setting as one with "limited peripartum facilities" Other information Amnioinfusion compared with no amnioinfusion for

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Persistent fetal bradycardia Chorioamnionitis Antepartum haemorrhage Fetal malpresentation Fetal congenital anomaly Polyhydramnios Maternal cardiac or pulmonary disease Multiple gestation		All newborn babies had immediate oropharyngeal suctioning, as per standard protocol. Any babies not breathing vigorously had tracheal suctioning. Neonatal outcomes was assessed by a paediatrician blinded to group allocation. Statistical analysis The following is reported; however, it bears little resemblance to the outcomes reported, which do not appear to assess women at different time points: "Results were expressed as mean ± SD. Wilcoxon signed rank test were used to evaluate significant differences from baseline values within		meconium stained liquor

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			each group and Pearson correlation was used to assess the significance between the two groups at each time point. A p value of less than 0.05 was considered to be significant." Outcomes reported - Mode of birth - Perinatal death - Meconium aspiration syndrome (MAS): criteria included a typical chest radiograph and a clinical course consistent with MAS		
Full citation Hidaka,A., Komatani,M., Ikeda,H., Kitanaka,T., Okada,K., Sugawa,T., A comparative study of intrauterine fetal resuscitation by beta-stimulant and O2 inhalation, Asia-Oceania Journal of Obstetrics and	Sample size N = 101 Characteristics Nulliparous (n/total (%)) ß-stimulant: 38/57 (66.7) Oxygen: 35/44 (79.5)	Interventions ß-stimulant (n = 57) Oxygen (n = 44)	Details Care protocol ß-stimulant group Women who had type II dips more than 3 times were given a ß-stimulant (Isoxsuprine 5 mg 5% glucose 20 ml) over at least 30 seconds.	Results Success rate of recovery (n/total (%)) All women ß-stimulant: 54/57 (95) Oxygen: 8/44 (18) First stage ß-stimulant: 42/45 (93) Oxygen: 7/23 (30)	Limitations Choice of treatment unrelated to confounders (selection bias): unclear - the indication for intervention was specifically stated to be more than 3 type II dips in the ß-stimulant arm; however, in the oxygen

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Gynaecology, 13, 195-200, 1987 Ref Id 169283 Country/ies where the study was carried out Japan Study type Comparative observational study Aim of the study To evaluate ß-stimulant (Isoxsuprine 5 mg 5% glucose 20 ml) for resolving fetal distress and assess its effect on fetal heart rate and later fetal distress Study dates Not reported Source of funding None reported	Point at which type II dips were observed (n/total (%)) First stage of labour ß-stimulant: 45/57 (78.9) Oxygen: 23/44 (52.3) Second stage of labour ß-stimulant: 12/57 (21.1) Oxygen: 21/44 (47.7) Inclusion criteria Over 36 weeks gestational age Type II dips more than three times Exclusion criteria		Oxygen group (control) Women whose babies had signs of fetal distress (no criteria given) were treated with oxygen inhalation (6 litres/minute) by mask for about 10 minutes. If fetal heart rate recovery did not occur after 10 minutes of oxygen inhalation, ß-stimulant was given intravenously. The effect of the treatment on fetal heart rate and frequency of contractions was assessed for 30 minutes. Statistical analysis Chi-squared test was used to analyse data Outcomes reported - success rate: recovery from type II dips in the 30 minutes after	Second stage ß-stimulant: 12/12 (100 Oxygen: 1/21 (5) [Note: it is reported that out of the 54 women in the ß-stimulant group for which recovery was successful, 33 gave birth vaginally and 21 had a caesarean secion (CS). However, this detail is not reported for the oxygen group or the other 3 women in the ß-stimulant group] Further details reported about labour Frequency of uterine contractions in a 10 minute period (mean ± SD) Before onset of type II dips Vaginal birth: 3.5 ± 0.9 CS: 2.2 ± 1.5 Total: 3.0 ± 1.3 During type II dips Vaginal birth: 5.1 ± 1.0 CS: 3.2 ± 1.9 Total: 4.3 ± 1.7	arm it is just reported that women had indications of fetal distress (although it is later reported in the results section that women did have type II dips) Groups comparable at baseline: unclear - very few characteristics of the study population are reported; therefore, it is not possible to assess the comparability of the two groups Groups received same/similar care (apart from intervention): unclear - very few details about care given Blinding of those assessing outcomes: no details given Missing data/loss to follow-up: no Precise definition of outcomes: unclear how success was defined Valid and reliable method of outcome assessment: unclear how recovery

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			administration; split by whether the dips were observed in the first or second stages	After administration of Isoxsuprine Vaginal birth: 3.6 ± 0.9 CS: 2.1 ± 1.7 Total: 3.0 ± 1.5	was judged - may be a risk of bias Intention-to-treat analysis performed: yes Indirectness: - study population is not restricted to low risk women Other information ß-stimulant compared with oxygen for fetal distress
Full citation Hofmeyr,G.J., Xu,H., Amnioinfusion for meconium-stained liquor in labour. [68 refs][Update of Cochrane Database Syst Rev. 2009;(1):CD000014; PMID: 19160173], Cochrane Database of Systematic Reviews, CD000014-, 2010 Ref Id 121612 Country/ies where the	Sample size N = 13 trials N = 4143 women Characteristics * additional information which had to be accessed from the full text of the trials because it was not reported in the systematic review Cialone 1994 Inclusion criteria: labouring term and post-	Interventions Amnioinfusion (the infusion of physiological saline or lactated Ringers' solution into the amniotic cavity) compared with no, or sham, amnioinfusion	Details Identification of studies The Cochrane Pregnancy and Childbirth Group's Trials Register was searched in May 2009. This trials register contains trials identified from: - quarterly searches of the Cochrane Central Register of Controlled Trials - weekly searches of Medline	Results Maternal death or serious morbidity* Settings with standard peripartum surveillance Amnioinfusion: 15/986 Control: 15/989 RR 1.00 (95% CI 0.49 to 2.04) I2 = not applicable [Fixed effects; 1 trial: Fraser 2005] Settings with limited	Limitations Limitations of the systematic review Two studies were excluded from the review and the reason is stated as "inadequate information to confirm acceptable allocation concealment." However, multiple other studies have been included where there was no or unclear allocation concealment, as judged by the review authors.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study was carried out Various Study type Systematic review of randomised controlled trials Aim of the study To assess the effects of amnioinfusion for meconium-stained liquor in labour on maternal and perinatal morbidity and mortality Study dates The search was performed in May 2009; review content was assessed as up-to-date by the authors in November 2009 Source of funding University of the Witwatersrand, South Africa South African Medical	term women; uncomplicated antepartum course; singleton, vertex baby; gestation over 36 weeks; moderate to thick meconium assessed clinically Exclusion criteria: any obstetric risk factor other than meconium Sample size: N = 113 Intervention: amnioinfusion of room temperate normal saline (600 ml over 1 hour, followed by 150 ml per hour) Comparator: control group (no details given) Other details of care provided: Pad weight was measured hourly; if vaginal effluent was less than 100 ml per hour then an ultrasound examination was performed to exclude over-distension of the uterus * Country: USA		- hand searches of 30 journals and the proceedings of major conferences - weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts No language restrictions were applied. Data collection and analysis Trials were evaluated for methodological quality and appropriateness for inclusion without consideration of results. Two review authors independently assessed the studies for inclusion and any disagreements were resolved through discussion or consultation of a third person.	peripartum surveillance 0 trials for this outcome * unclear from Cochrane review how serious morbidity is defined [see 'other information'] Mode of birth a. Caesarean section for fetal distress Settings with standard peripartum surveillance Amnioinfusion: 151/1376 Control: 174/1389 RR 0.40 (95% CI 0.19 to 0.86) I2 = 71% [Random effects; 8 trials: Sadovsky 1989; Moodley 1998; Wenstrom 1989; Cialone 1994; Eriksen 1994; Macri 1992; Puertas 2001; Fraser 2005] - Settings with limited peripartum surveillance Amnioinfusion: 19/421	These two studies have been appraised for inclusion as individual papers because they were included in a previous version of this systematic review, which was included in the 2007 Intrapartum Care guideline. Risk of bias of included studies, as assessed by the authors of the systematic review, and indirectness as assessed by NCC-WCH technical team None of the obstetricians were blinded to the intervention. The authors of the systematic review also state that there were "several methodological shortcomings in all the studies except Fraser 2005". Cialone 1994 - unclear allocation concealment

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Research Council, South Africa	Eriksen 1994 Inclusion criteria: over 36 weeks gestation; active labour; thick meconium fluid Exclusion criteria: multiple gestation; malpresentation; fetal distress on admission; cervical dilatation of at least 7 cm; intra-amniotic infection Sample size: N = 95 Intervention: amnioinfusion with normal saline at room temperature (800 ml over 1 hour followed by 180 ml per hour) Comparator: control group (no details given) Other details of care provided: none given * Country: USA Fraser 2005 Inclusion criteria: women in labour with thick meconium stained amniotic fluid; single		A form was designed to extract the data and both review authors extracted it. Any discrepancies were resolved through discussion or consultation with a third person. Where any details were unclear, the review authors attempted to contact the original trial authors. Data were analysed using Review Manager. Risk of bias was assessed by the review authors according to the following criteria, which were judged to be adequate, inadequate or unclear: - Sequence generation - Allocation concealment - Blinding (for participants, personnel and outcome	Control: 38/434 RR 0.50 (95% CI 0.30 to 0.84) I2 = 0% [Random effects; 2 trials: Rathore 2002; Mahomed 1998] b. Caesarean section overall Settings with standard peripartum surveillance Amnioinfusion: 483/1682 Control: 516/1698 RR 0.78 (95% CI 0.60 to 1.02) I2 = 70% [Random effects; 11 trials: Sadovsky 1989; Moodley 1998; Wenstrom 1989; Spong 1994; Cialone 1994; Eriksen 1994; Macri 1992; Sood 2004; Puertas 2001; Hofmeyr 1998; Fraser 2005] Settings with limited peripartum surveillance	- discrepancy in birth weights not accounted for (no further details given) - 7 (13%) withdrawals from study group due to diabetes (n = 3) and request (n = 4); 1 withdrawal from control group on request - conflicting report of rate of meconium below cords in control group: 33/58 according to table, 34/58 according to text, 36/58 in previous report of same trial - Indirectness: none identified Eriksen 1994 - no report of neonatalogists being blinded - 15 (11%) women were excluded because of incomplete records (n = 9) or because they delivered before the intervention could be performed (n = 6) - there were more

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	fetus; cephalic presentation; gestational age at least 36 weeks; ruptured membranes; cervical dilatation of 2-7 cm; no indication for urgent delivery Exclusion criteria: suspected major fetal anomaly; chorioamnionitis; placenta praevia; vaginal bleeding; HIV or seropositive for Hepatitis B or C; active genital herpes; polyhydramnios; previous uterine incision other than low transverse; inability to comprehend the consent form Sample size: N = 1998 Intervention: amnioinfusion of saline via a transcervical sterile catheter (800 ml over 40 minutes, followed by 2 ml per minute to a maximum of 1500 ml). Infusion was discontinued if the baseline uterine pressure		assessors) - Incomplete outcome data - Selective reporting bias For the included studies, the level of attrition was noted. The impact of including studies with high levels of attrition were explored with sensitivity analyses. As far as possible, analyses were done on an intention to treat basis, attempting to include all women randomised to each group in the analysis. The I2 statistic was used to measure heterogeneity among the trials. If I2 was greater than 50%, pre-specified subgroup analyses were done. A random effects mode was used where there was substantial	Amnioinfusion: 51/417 Control: 73/428 RR 0.70 (95% CI 0.49 to 1.00) I2 = 18 [Random effects; 2 trials: Rathore 2002; Mahomed 1998] c. Instrumental vaginal delivery for fetal distress Settings with standard peripartum surveillance Amnioinfusion: 60/1136 Control: 56/1150 RR 1.09 (95% CI 0.76 to 1.55) I2 = 29% [Fixed effects; 3 trials: Cialone 1994; Puertas 2001; Fraser 2005] Settings with limited peripartum surveillance 0 trials for this outcome d. Instrumental vaginal	primiparous women in the study group compared to the control group (35/65 compared with 27/59) - mean value for umbilical artery pH is given as the whole group; however, the text reports that at least 1 baby with meconium aspiration syndrome had no cord blood result - Indirectness: study population was not restricted to low risk women (although women with multiple pregnancy and malpresentation were excluded) Fraser 2005 - no particular risk of bias (adequate randomisation, allocation concealment and outcome reporting) - 1.2% of women excluded due to loss to follow up or not meeting inclusion criteria - Indirectness: study was not particularly restricted

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	increased by 15 mmHg, the uterus failed to relax between contractions as assessed by palpation, or ultrasound examination showed polyhydramnios Comparator: no amnioinfusion Other details of care provided: all women had continuous electronic fetal monitoring (EFM) and suctioning of the baby's nasopharynx and oropharynx during and after delivery * Country: Multicentre trial - South Africa, Ireland, Guadeloupe, Switzerland, Canada, Argentina, Uruguay, USA, UK, Belgium, Brazil, Tunisia, Portugal Hofmeyr 1998 Inclusion criteria: women in labour; moderate or heavy meconium staining; gestation of at least 37 weeks;		statistical heterogeneity, or there was clinical and/or methodological heterogeneity between the studies. Subgroup analysis The following subgroup analyses were done: - Standard peripartum surveillance - Limited peripartum surveillance This was based on the fact that Mahomed 1998 and Rathore 2002 were conducted in settings with limited intrapartum surveillance and intervention and electronic fetal heart rate monitoring was not used. These were felt to differ from the other studies and therefore a subgroup analysis which was not pre-specified was performed. [Note:	delivery overall Settings with standard peripartum surveillance Amnioinfusion: 45/455 Control: 63/459 RR 0.73 (95% CI 0.51 to 1.04) I2 = 37% [Fixed effects; 6 trials: Moodley 1998; Spong 1994; Cialone 1994; Eriksen 1994; Puertas 2001; Hofmeyr 1998] Settings with limited peripartum surveillance Amnioinfusion: 18/420 Control: 25/433 RR 0.74 (95% CI 0.41 to 1.33) I2 = 73% [Fixed effects; 2 trials: Rathore 2002; Mahomed 1998] Overall Amnioinfusion: 63/875	to low risk women (although some groups of high risk women were excluded) Hofmeyr 1998 - unclear allocation concealment - Indirectness: study was not restricted to low risk women (although some groups of high risk women were excluded) Macri 1992 - unclear allocation concealment - Indirectness: study was not restricted to low risk women (although some groups of high risk women were excluded) Mahomed 1998 - unclear allocation concealment - 4 amnioinfusion allocations early in the study unaccounted for - Indirectness: no EFM available; not specifically

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	singleton, cephalic presentation Exclusion criteria: none reported Sample size: N = 352 Intervention: amnioinfusion of normal saline via an Intran or Nelaton intrauterine catheter (800 ml at 15 ml per minute and then maintenance of 3 ml per minute) Comparator: no amnioinfusion Other details of care provided: most women received EFM; 1 woman in the control group had amnioinfusion (but was analysed intention-to-treat) * Country: South Africa Macri 1992 Inclusion criteria: gestation of at least 37 weeks; thick meconium; 4-quadrant amniotic fluid index < 5 cm; normal fetal heart rate pattern;		overall results are not reported by the authors]	Control: 88/892 RR 0.73 (95% CI 0.54 to 0.99) I2 = 40% Meconium aspiration syndrome Settings with standard peripartum surveillance Amnioinfusion: 61/1672 Control: 84/1702 RR 0.52 (95% CI 0.26 to 1.06) I2 = 55% [Random effects; 11 trials: Sadovsky 1989; Moodley 1998; Wenstrom 1989; Spong 1994; Cialone 1994; Eriksen 1994; Macri 1992; Sood 2004; Puertas 2001; Hofmeyr 1998; Fraser 2005] Settings with limited peripartum surveillance Amnioinfusion: 10/423 Control: 43/429	restricted to low risk women (although some groups of high risk women were excluded) Moodley 1998 - unclear allocation concealment - no report of neonatalogists being blinded - Indirectness: none identified Puertas 2001 - method of sequence generation not reported - unclear allocation concealment - Indirectness: study was not restricted to low risk women (although some groups of high risk women were excluded) Rathore 2002 - no particular risk of bias (adequate sequence generation and allocation concealment) - no report of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	vertex presentation; estimated fetal weight of at least 2500 g; cervical dilatation of less than or equal to 5 cm; ruptured membranes Exclusion criteria: vaginal bleeding; chorioamnionitis; fetal anomalies; uterine anomalies; contraindication to labour Sample size: N = 170 Intervention: amnioinfusion with warmed saline (500 ml over 20-30 minutes followed by 250-500 ml as required to maintain a 4-quadrant amniotic fluid index above 10 cm) Comparator: control group (no details given) Other details of care provided: none given * Country: USA Mahomed 1998 Inclusion criteria: moderate or heavy meconium stained			RR 0.25 (95% CI 0.13 to 0.47) I2 = 0% [Random effects; 2 trials: Rathore 2002; Mahomed 1998] Meconium below vocal cords Settings with standard peripartum surveillance Amnioinfusion: 99/1634 Control: 258/1664 RR 0.31 (95% CI 0.18 to 0.53) I2 = 73% [Random effects; 10 trials: Sadovsky 1989; Wenstrom 1989; Spong 1994; Cialone 1994; Eriksen 1994; Macri 1992; Sood 2004; Puertas 2001; Hofmeyr 1998; Fraser 2005] Settings with limited peripartum surveillance Amnioinfusion: 10/100 Control: 24/100	neonatalogists being blinded - Indirectness: EFM was not available; study was not specifically restricted to low risk women (although some groups of high risk women were excluded) Sadovsky 1989 - unclear allocation concealment - study was not restricted to low risk women (although some groups of high risk women were excluded [note: women over 34 weeks gestation were included]) Sood 2004 - sequence generation and concealment of treatment allocation were judged inadequate (done with flip of a coin) - no report of neonatalogists being blinded - 3/99 (3%) women

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	amniotic fluid; singleton cephalic presentation in labour; gestation 37 weeks or more Exclusion criteria: indication for immediate delivery; chorioamnionitis; vaginal bleeding; fetal anomaly; maternal cardiac or pulmonary disease Sample size: N = 661 Intervention: amnioinfusion transcervically with a size 8 nasogastric tube with normal saline (500 ml infused over 30 minutes and then 500 ml at 2 ml per minute) Comparator: no amnioinfusion Other details of care provided: level of intrapartum surveillance limited by number of midwives; FHR auscultated every 30 minutes using Pinard stethoscope or hand-held doptone FHR detector;			RR 0.42 (95% CI 0.21 to 0.83) I2 = not applicable [Random effects; 1 trial: Rathore 2002] Heavy meconium staining Settings with standard peripartum surveillance Amnioinfusion: 1/65 Control: 55/73 RR 0.03 (95% CI 0.01 to 0.15) I2 = 30% [Fixed effects; 2 trials: Cialone 1994; Sadovsky 1989] Settings with limited peripartum surveillance 0 trials for this outcome Umbilical artery pH < 7.20 Settings with standard peripartum surveillance Amnioinfusion: 188/903 Control: 226/885	excluded where amnioinfusion was abandoned due to bleeding - study was not restricted to low risk women (although some groups of high risk women would have been excluded as a result of the inclusion criteria) Spong 1994 - inadequate concealment of treatment allocation (no further details given) - no report of neonatalogists being blinded - imbalance in group numbers (43 vs. 50) not accounted for - study was not restricted to low risk women (although some groups of high risk women were excluded) Wenstrom 1989 - unclear concealment of treatment allocation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	suctioning of the airways at delivery by midwives * Country: Zimbabwe Moodley 1998 Inclusion criteria: singleton, term, cephalic pregnancy in active labour; meconium-stained amniotic fluid grade 1-3; normal cardiotocograph (CTG) Exclusion criteria: medical or surgical conditions; chorioamnionitis; previous caesareans section Sample size: not reported Intervention: amnioinfusion with normal saline by gravity via a central venous manometer set and a nasogastric infant feeding tube (1 litre over 4 hours) Comparator: standard care Other details of care			RR 0.62 (95% CI 0.40 to 0.96) I2 = 73% [Random effects; 7 trials: Sadovsky 1989; Spong 1994; Cialone 1994; Macri 1992; Hofmeyr 1998; Puertas 2001; Fraser 2005] Settings with limited peripartum surveillance 0 trials for this outcome Variable decelerations Settings with standard peripartum surveillance Amnioinfusion: 328/1050 Control: 385/1051 RR 0.67 (95% CI 0.47 to 0.96) I2 = 80% [Random effects; 5 trials: Sadovsky 1989; Cialone 1994; Sood 2004; Puertas 2001; Fraser 2005] Settings with limited	- 5 (12%) women who did not receive amnioinfusion were excluded, of which 4 gave birth spontaneously after 30, 45, 60 and 180 minutes and 1 required an emergency CS. They have been included in the data for delivery outcomes. - study was not restricted to low risk women - only women with pyrexia were excluded Other information Amnioinfusion compared with no amnioinfusion for meconium stained liquor Further information extracted from the full text of Fraser et al., 2005: Perinatal death or serious perinatal morbidity was defined as the presence of at least one of the following: perinatal death, moderate or severe meconium aspiration

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	provided: continuous FHR monitoring was done * Country: South Africa Puertas 2001 Inclusion criteria: admitted for labour and delivery with moderately or thickly stained amniotic fluid; term pregnancy; no uterine scarring; spontaneous labour or induction of labour for meconium staining of the amniotic fluid; single fetus; vertex presentation; no fetal heart rate (FHR) changes suggesting fetal distress; no vaginal bleeding; no indication of vertically transmitted infectious disease Exclusion criteria: none reported Sample size: N = 206 Intervention: amnioinfusion with 0.9% saline via an infusion pump (600 ml per hour			peripartum surveillance 0 trials for this outcome Neonatal ventilation or neonatal intensive care unit admission Settings with standard peripartum surveillance Amnioinfusion: 10/230 Control: 25/242 RR 0.45 (95% CI 0.23 to 0.90) I2 = 0% [Fixed effects; 3 trials: Cialone 1994; Hofmeyr 1998; Sadovsky 1989] Settings with limited peripartum surveillance Amnioinfusion: 44/421 Control: 87/432 RR 0.52 (95% CI 0.37 to 0.73) I2 = 16% [Fixed effects; 2 trials: Rathore 2003; Mahomed 1998]	syndrome, hypotonia, assisted ventilation or intubation or more than 5 minutes duration, 5 minute Apgar score < 7, umbilical artery pH < 7.05, abnormal consciousness, need for tube feeding, convulsions, blood or lumbar culture positive for bacteria, major trauma including basal skull or long-bone fracture, spinal cord injury, or facial or brachial palsy. The breakdown of events was as follows (none were significantly different between the amnioinfusion and control groups): - Perinatal death: 10 - Meconium aspiration syndrome (MAS) according to clinical criteria: 74 - MAS on chest radiography: 32 - Hypotonia: 63

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	for 1 hour then 180 ml per hour until full cervical dilatation or basal uterine pressure increase to 20 mm Hg) Comparator: no amnioinfusion Other details of care provided: continuous FHR monitoring and intrauterine pressure monitoring was done * Country: Spain Rathore 2002 Inclusion criteria: at least 37 weeks gestation; singleton, cephalic presentation; moderate or thick meconium-stained fluid or meconium crit > 10% Exclusion criteria: chorioamnionitis; indication for immediate delivery; fetal congenital anomaly; antepartum haemorrhage; polyhydramnios; maternal cardiac or respiratory disease			Overall Amnioinfusion: 54/651 Control: 112/674 RR 0.51 (95% CI 0.38 to 0.68) I2 = 0% Neonatal encephalopathy Settings with standard peripartum surveillance Amnioinfusion: 0/30 Control: 2/30 RR 0.20 (95% CI 0.01 to 4.00) I2 not applicable [Fixed effects; 1 trial: Moodley 1998] Settings with limited peripartum surveillance Amnioinfusion: 1/320 Control: 14/329 RR 0.07 (95% CI 0.01 to 0.56) I2 not applicable	- Assisted ventilation or intubation > 5 minutes: 60 - 5 minute Apgar < 7: 55 - Arterial pH < 7.05: 45 - Abnormal consciousness: 31 - Need for tube feeding: 24 - Convulsion: 16 - Blood or lumbar culture positive for bacteria: 7 - Major fracture or palsy: 5 Maternal death or serious maternal morbidity was defined as the presence of any of the following: uterine rupture, amniotic fluid embolism, antepartum haemorrhage requiring urgent delivery, postpartum haemorrhage requiring transfusion, hysterectomy, admission to ICU, or disseminated intravascular coagulation The breakdown of events were as follows (none were significantly different

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Sample size: not reported Intervention: amnioinfusion with saline via FG 8 nasogastric tube (500 ml over 30 minutes and then 3 ml per minute; maximum dose 1 litre) Comparator: no amnioinfusion or uterine catheter Other details of care provided: no CTG was available * Country: India Sadovsky 1989 Inclusion criteria: singleton; more than a trace of meconium stained liquor; vertex presentation; > 34 weeks; anticipate delivery being over an hour away Exclusion criteria: malformations; chorioamnionitis; malpresentation; polyhydramnios; cord			[Fixed effects; 1 trial: Mahomed 1998] Overall Amnioinfusion: 1/350 Control: 16/359 RR 0.09 (95% CI 0.02 to 0.49) I2 = 0% Perinatal death or serious morbidity* Settings with standard peripartum surveillance Amnioinfusion: 112/986 Control: 99/989 RR 1.13 (95% CI 0.88 to 1.47) I2 = not applicable [Fixed effects; 1 trial: Fraser 2005] Settings with limited peripartum surveillance 0 trials for this outcome * unclear from Cochrane review how serious morbidity	between the amnioinfusion and control groups): - Uterine rupture: 3 - APH: 4 - Hysterectomy: 2 - Admission to ICU: 4 - Death: 1 - DIC: 4 - PPH: 22

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	prolapse; urgent delivery needed; maternal cardiac disease Sample size: N = 40 Intervention: amnioinfusion with saline (600 ml over 1 hour and then 180 ml per hour) Comparator: control group (no details given) Other details of care provided: none given * Country: USA Sood 2004 Inclusion criteria: in labour with thick staining of the amniotic fluid; singleton, vertex presentation; adequate pelvis; cervical dilatation > 5 cm; gestational age > 37 weeks Exclusion criteria: none reported Sample size: N = 199 Intervention: amnioinfusion with normal saline via a plastic suction catheter or amnioinfusion catheter			is defined [see 'other information'] Perinatal death Settings with standard peripartum surveillance Amnioinfusion: 5/1372 Control: 5/1390 RR 1.00 (95% CI 0.29 to 3.45) I2 = 0% [Fixed effects; 7 trials: Sadovsky 1989; Moodley 1998; Wenstrom 1989; Cialone 1994; Macri 1992; Hofmeyr 1998; Fraser 2005] Settings with limited peripartum surveillance Amnioinfusion: 5/424 Control: 14/435 RR 0.37 (95% CI 0.13 to 1.01) I2 = 0% [Fixed effects; 2 trials: Rathore 2002; Mahomed 1998]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	until returning fluid was clear (this was normally 1000 ml over 30-45 minutes) Comparator: no details given Other details of care provided: none; however, it is reported that FHR abnormalities were present before enrolment in 48/96 women in the amnioinfusion group and 60/100 in the control group * Country: India Spong 1994 Inclusion criteria: singleton; vertex presentation; 37 or more weeks; moderate to heavy meconium; no variable FHR decelerations Exclusion criteria: prenatally diagnosed fetal malformations; maternal temperature > 100.4 degrees Fahrenheit; evidence of			Overall Amnioinfusion: 10/1796 Control: 19/1825 RR 0.54 (95% CI 0.25 to 1.15) I2 = 0% Information extracted from full text of trials a. Number of fetal blood samples performed Fraser 2005: 33/986 (3.3%) of the amnioinfusion arm and 39/989 (3.9%) of the control arm had a fetal scalp blood-gas assessment (P = 0.48) Wenstrom 1989: every patient in the study had an FBS every 6 hours No further details are given in the included studies. b. Complications of women who underwent amnioinfusion (n (%)) Fraser 2005:	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	fetal distress Sample size: N = 93 Intervention: amnioinfusion with saline (600 ml bolus followed by 3 ml per minute) Comparator: standard care, which included amnioinfusion in 8/50 women for variable decelerations Other details of care provided: none given * Country: USA Wenstrom 1994 Inclusion criteria: thick meconium stained amniotic fluid Exclusion criteria: fetal distress; maternal pyrexia Sample size: N = 85 Intervention: amnioinfusion (1000 ml over 20-40 minutes, repeated 6-hourly). [Note: it is not specifically stated that this was with saline] Comparator: control			- Vaginal bleeding: 10/907 (1.1) - Uterine hypertonicity, polyhydramnios, or overdistension: 63/907 (6.9) In addition, 2 (0.2%) of the amnioinfusion group and 1 (0.1%) of the control group had a uterine rupture which was part of the composite outcome. 11 women (1.1%) in each arm had a postpartum haemorrhage (PPH). Macri 1992: - Reports no incidences of cord prolapse, uterine hypertonus or acute fetal distress during amnioinfusion in 85 women. Mahomed 1998: - Reports no complications of amnioinfusion in 325 women who received it Moodley 1998: - Reports no maternal complications related to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	group (no details given) Other details of care provided: none given * Country: USA Inclusion criteria Clinical trials comparing the effect of amnioinfusion for meconium stained liquor on clinically meaningful outcomes, with a control group Random allocation to treatment and control groups with adequate allocation concealment Violations of allocated management and exclusions after allocation not sufficient to materially affect outcomes Exclusion criteria None reported			amnioinfusion in the 30 women who received it Puertas 2001: - 17/103 had amnioinfusion stopped due to uterine hypertonia; however, none required intervention to reduce the pressure and in all women, uterine tone returned to normal spontaneously. Rathore 2002: - Incoordinate activity (strong painful contractions with absent/slow progression of cervix) occurred in 1/100 (1%) of women in amnioinfusion group and 2/100 (2%) in control group. Sadovksy 1989: - Reports no procedure related complications in the 40 women having amnioinfusion Sood 2004: - 3/99 women were excluded for having vaginal bleeding	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				during amnioinfusion - 6/96 women in the amnioinfusion gruop and 1/100 in the control group had uterine atony Wenstrom 1989: Report no adverse effects on mother linked to amnioinfusion (no further details)	
Full citation Kulier,R., Gulmezoglu,A.M., Hofmeyr,G.J., Van Gelderen,C.J., Betamimetics in fetal distress: randomised controlled trial, Journal of Perinatal Medicine, 25, 97-100, 1997 Ref Id 169373 Country/ies where the study was carried out South Africa Study type Randomised controlled trial	Sample size N = 37 Characteristics Passage of moderate or thick meconium before or after randomisation (n/total (%)) Hexoprenaline: 3/17 (17.6) Control: 12/19 (63.2) Age/years (mean (SE)) Hexoprenaline: 28.1 (1.55) Control: 26.3 (1.57) [p = 0.41] Gestational age/weeks	Interventions Hexoprenaline (n = 17) Control (n = 20)	Details Recruitment and randomisation Once the decision to perform a caesarean section (CS) (due to signs of fetal distress) had been taken by the attending doctor, women were approached and informed consent was obtained. Women were then randomised using numbered, sealed, opaque envelopes. Randomisation was done using computer generated random numbers in blocks of	Results Admission to NICU (n/total (%)) Hexoprenaline: 1/17 (5.9) Control: 0/20 (0) Cord blood gas values at birth (n/total (%)) a. Cord pH < 7.2 Hexoprenaline: 6/16 (37.5) Control: 10/17 (58.8) OR 0.42 (95% CI 0.08 to 2.10) b. Base excess < -10 Hexoprenaline: 3/16 (18.8) Control: 7/16 (43.8) OR 0.30 (95% CI 0.04 to	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: there was a significant difference in the proportion of babies passing meconium before or after randomisation (and it is not clear in how many it was present before randomisation compared to after) Groups received same care (apart from intervention): unclear - no details about the care received by the control

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To investigate whether hexoprenaline administered during labour for fetal distress improves neonatal outcome and has any adverse effects Study dates Not reported Source of funding None reported	(mean (SE)) Hexoprenaline: 38.5 (0.37) Control: 38.4 (0.44) [p = 0.76] Parity (mean (SE)) Hexoprenaline: 1.6 (0.30) Control: 1.3 (0.37) [p = 0.49] Cervix/cm (mean (SE)) Hexoprenaline: 5.8 (0.63) Control: 5.4 (0.56) [p = 0.64] Birth weight (mean (SE)) Hexoprenaline: 2899 (130.2) Control: 3106 (129.0) [p = 0.27] There was also no significant difference between the two groups in temperature and pulse rate at enrolment. Inclusion criteria Women with persistent fetal heart rate		ten. Care protocol - Hexoprenaline group 10 micrograms were administered as an IV bolus injection over 5 minutes. Pulse rate at randomisation and five minutes after the injection was recorded. - Control group No details given At randomisation the fetal heart rate trace was marked. They were later analysed by people blinded to patient details and group allocation and were classified as improved or unchanged. After the birth of the baby, the cord was clamped and an arterial blood sample was collected and analysed within 30 minutes.	1.82) Perinatal death (n/total (%)) a. Stillbirth Hexoprenaline: 0/17 (0) Control: 2/20 (10) [Note: one of the babies had hydrocephalus only identified at delivery; the other baby was stillborn to a mother who was referred for fetal distress from another clinic and was waiting for a CS] b. Neonatal death Hexoprenaline: 0/17 (0) Control: 0/20 (0) Fertal heart rate (FHR) tracing not improved (n/total (%)) Hexoprenaline: 5/13 (38.4) Control: 9/10 (90) OR 0.07 (95% CI 0 to 0.87) Need for resuscitation at birth (n/total (%)) Hexoprenaline: 1/16 (5.9)	group are reported Blinding of participants: no details given Blinding of staff providing care: no details given Blinding of outcome assessors: yes for those assessing the FHR trace Missing data/loss to follow-up: missing data for the rate of FHR trace improvement for 4/17 (24%) of study group and 10/20 (50%) of control group; missing data for cord pH for 1/17 (6%) in study group and 3/20 (15%) in control group; missing data for base excess for 1/17 (6%) in study group and 4/20 (20%) in control group Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: no particular details given but nothing to suggest otherwise

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	abnormalities consistent with fetal distress, in whom the decision to perform a caesarean had been taken Gestational age more than 35 weeks and in active labour Exclusion criteria Significant antepartum haemorrhage Cardiac disease Gross fetal abnormalities Receiving betamimetics for another indication (e.g. asthma)		Statistical analysis Chi-squared test and odds ratios were used to analyse categorical data. Fisher exact test was used where appropriate. Continuous data had its distribution checked and then was analysed using ANOVA. Outcomes reported - admission to NICU - cord blood gas values at birth: pH < 7.2 and base excess < -10 are reported - stillbirth - FHR tracing not improved	Control: 2/20 (10) OR 0.60 (95% CI 0.01 to 12.77) Blood loss/ml (mean (SE)) Hexoprenaline: 413 (36.4) Control: 498 (56.9) P = 0.24 Other details of labour reported Randomisation to delivery interval/minutes (mean (SE)) Hexoprenaline: 60 (6.2) Control: 54 (3.1) [p = 0.38]	Indirectness: - study was not restricted to low risk women, although some higher risk groups were excluded - data are not reported separately for women with and without meconium stained liquor - all of these women had the decision for a CS made; therefore, it is not possible to evaluate whether intrauterine resuscitation reduces the need to expedite delivery Other information Tocolysis for fetal distress: hexoprenaline compared with no treatment The mean randomisation to delivery interval was 60 minutes (SE 6.2) in the hexoprenaline group and 54 minutes (SE 3.1) in the control group (p = 0.31).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Magann,E.F., Cleveland,R.S., Dockery,J.R., Chauhan,S.P., Martin,J.N.,Jr., Morrison,J.C., Acute tocolysis for fetal distress: terbutaline versus magnesium sulphate, Australian and New Zealand Journal of Obstetrics and Gynaecology, 33, 362-364, 1993 Ref Id 169440 Country/ies where the study was carried out USA Study type Randomised controlled trial Aim of the study To determine whether terbutaline or magnesium sulphate (MgSO4) is more	Sample size N = 46 Characteristics Age/years (mean ± SD) Terbutaline: 26.4 ± 4.9 MgSO4: 25.9 ± 5.4 Gestational age at birth (mean ± SD) Terbutaline: 38.5 ± 2.2 MgSO4: 38.9 ± 1.7 Nulliparous women (n/total) Terbutaline: 7/23 MgSO4: 8/23 Inclusion criteria Women in whom there was fetal distress and the decision had been made to deliver by caesarean section Exclusion criteria Women with conditions that could potentially compromise	Interventions Terbutaline (n = 23) Magnesium sulphate (n = 23)	Details Recruitment and randomisation Continuous electronic fetal monuitoring (EFM) (with a scalp electrode) and uterine activity (measured with an internal pressure catheter) were used, and the decision to perform a caesarean section (CS) was based on a diagnosis of fetal distress: 1. diminished variability and variable decelerations of less than 60 beats per minute lasting longer than 60 seconds with a slow return to baseline 2. acute persistent bradycardia of less than 120 beats per minute for longer than 10 minutes 3. persistent late fetal heart rate decelerations with little or no variability	Results Resolution of signs of distress on trace (variable decelerations, bradycardia, and late decelerations) (n/total (%)) Terbutaline: 21/23 (91) MgSO4: 16/23 (70) Umbilical cord arterial pH < 7.20 Terbutaline: 2/23 (9) MgSO4: 7/23 (30) Other details reported Uterine activity/Montevideo units (mean ± SD) - Terbutaline Prior to tocolysis: 255.4 ± 108 After tocolysis: 115.81 ± 57.5 [p < 0.02] - MgSO4 Prior to tocolysis: 200.45 ± 36.9 After tocolysis: 228.6 ± 49.35	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: no Blinding of staff providing care: no Blinding of outcome assessors: yes - the investigators assessing the recovery of the trace were blinded Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: unclear, but no reason to suspect otherwise

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
effective in urgently decreasing uterine activity and fetal distress prior to caesarean section and to evaluate changes in fetal heart rate patterns Study dates Not reported Source of funding Supported in part by the Vicksburg Hospital Medical Foundation	haemodynamic stability (abruptio placentae, maternal haemorrhage or severe pre-eclampsia) Women who declined to participate		Discontinuation of oxytocin, fluid bolus, position change, oxygen or amnioinfusion were used in the patient without success and so the decision was made to perform a CS. Then, those women who consented were randomised using card selection from a sealed opaque envelope, where the assignment had been done using a random number table. Care protocol When the decision had been made to do a CS, women received one of the following: - a single dose of 0.25 mg of terbutaline by subcutaneous injection - a 4g IV bolus of magnesium sulphate Emergency caesarean	[p = 0.37] Decrease in uterine activity (n/total) Terbutaline: 23/23 (100) MgSO4: 16/23 (70) [Note: the response time for those with a decrease in uterine activity was 1.8 ± 0.74 minutes in the terbutaline group and 7.5 ± 2.1 minutes in the magnesium sulphate group]	Indirectness: - study is not restricted to low risk women and there are few higher risk groups excluded - the decision had already been taken to perform a CS Other information Tocolysis for fetal distress: terbutaline compared with magnesium sulphate [Note: It is specifically reported that other standard measures had already been tried without success]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			sections were started within 10-15 minutes of administration of the tocolytic in all patients. Statistical analysis Chi-squared test was used to analyse results Outcomes reported - resolution of fetal distress: determined by investigator (blinded) review of the trace and classified as unchanged or improved - umbilical cord arterial pH: cord blood was collected at time of CS and the proportion of babies with pH < 7.20 is reported		
Full citation Mercier,F.J., Dounas,M., Bouaziz,H., Lhuissier,C., Benhamou,D., Intravenous nitroglycerin to relieve intrapartum fetal distress related to uterine hyperactivity: a	Sample size N = 24 Characteristics Age/years (mean ± SD): 28.7 ± 0.7	Interventions Nitroglycerin 60 micrograms (n = 6) Nitroglycerin 90 micrograms (n = 18)	Details Care protocol and data collection During the study period, data were prospectively recorded for all women in labour in whom the attendant	Results Need for further doses (n/total (%)) 60 micrograms: 4/6 (66.7) 90 micrograms: 5/18 (27.8) (Note: the total dose ranged from 60 to 180 micrograms)	Limitations Choice of treatment unrelated to confounders (selection bias): unclear - decision was left up to attending physician Groups comparable at baseline: unclear - no

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
prospective observational study, Anesthesia and Analgesia, 84, 1117-1120, 1997 Ref Id 169467 Country/ies where the study was carried out France Study type Prospective comparative observational study Aim of the study To determine the success rate and safety of 60 and 90 microgram boluses of intravenous nitroglycerin for relieving fetal distress Study dates May 1995 to April 1996 Source of funding None reported	Weight/kg (mean ± SD): 68.5 ± 1.4 Parity (n/total (%)) - nulliparous: 21/24 (87.5) - multiparous: 3/24 (12.5) Type of fetal heart rate abnormality (n/total (%)) - severe and prolonged late deceleration (≤ 70 bpm for 4-10 minutes): 19/24 (79.2) - abnormal pattern (tachycardia, reduced baseline variability, or intermittent decelerations) followed by at least 4 consecutive severe late decelerations: 5/24 (20.8) [Note: no data comparing the two study groups are reported] Inclusion criteria Use of nitroglycerin IV to relieve fetal distress		anaesthesiologist used nitroglycerin IV to try and relieve fetal distress linked to uterine hyperactivity. Women were routinely monitored using continuous ultrasonographic fetal heart rate monitoring and external tocodynamometry. Acute active tocolysis was requested when there was an alarming fetal heart rate abnormality, which, if persistent, would have led to an emergency caesarean. The diagnosis of uterine hyperactivity was made based on over-frequent and/or sustained contractions, suggested by external tocodynamometric tracing and confirmed by abdominal palpation.	Efficacy of nitroglycerin (n/total (%)) 60 micrograms: 6/6 90 micrograms: 18/18 (Note: it is reported that efficacy was complete in 22 cases and partial in 2 cases, but not which groups these belonged to) It is reported that 7 women had a caesarean section; however, it is not reported what dose these women received and therefore, the data cannot be put into GRADE.	details given Groups received same/similar care (apart from intervention): yes Blinding of those assessing outcomes: no details given Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: efficacy was assessed by attending clinicians; therefore, unclear whether there may be a risk of bias Intention-to-treat analysis performed: yes Indirectness: - study is not restricted to low risk women and no high risk groups are reported as being excluded Other information Tocolysis for fetal distress: comparison of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	related to uterine hyperactivity Exclusion criteria		Nitroglycerin was prepared with a double dilution technique in saline and was injected within 2-5 minutes of the diagnosis of fetal distress, after oxygen administration, left lateral decubitus and stopping oxytocin had failed to resolve it. The dose of nitroglycerin was 60 or 90 micrograms and in the case of a partial or absent effect, a second dose was given within 2-3 minutes. The choice of dose was left to the discretion of the attending anaesthesiologist. Statistical analysis No details given in relation to the outcomes of interest Outcomes reported - efficacy of nitroglycerin: defined as		different doses of nitroglycerin [Note: It is specifically reported that other standard measures had already been tried without success]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			complete (fetal distress resolution within 4-5 minutes with normalisation of uterine activity), partial but sufficient (fetal distress resolution within 4-5 minutes but with residual mild uterine hyperactivity) or insufficient or absent		
Full citation Miyazaki,F.S., Nevarez,F., Saline amnioinfusion for relief of repetitive variable decelerations: a prospective randomized study, American Journal of Obstetrics and Gynecology, 153, 301-306, 1985 Ref Id 169476 Country/ies where the study was carried out USA Study type Randomised controlled trial	Sample size N = 96 Characteristics No details given Inclusion criteria In the first stage of labour At least 5 consecutive variable decelerations that did not respond to change in position and oxygen Exclusion criteria Ominous signs, such as flat baseline, late	Interventions Amnioinfusion (n = 49) Control (no amnioinfusion) (n = 47)	Details Recruitment and randomisation Women meeting the inclusion criteria who gave informed consent were randomised by drawing sealed envelopes which indicated the assignment. Care protocol A vaginal examination was done to exclude cord prolapse, and to establish dilatation and presentation. A scalp lead and intrauterine pressure catheter were	Results Complete relief of repetitive variable decelerations (n/total (%)) All women Amnioinfusion: 25/49 (51) Control: 2/47 (4.2) [p = 0.001] Multiparous women Amnioinfusion: 7/22 (31.8) Control: 2/26 (7.6) [p = 0.078] Nulliparous women Amnioinfusion: 18/27 (66.7) Control: 0/21 (0) [p = 0.001] Caesarean section for fetal	Limitations Appropriate randomisation: likely - not reported how sequence was generated but women were randomised by the drawing of envelopes Allocation concealment: likely - envelopes were sealed, although it is not reported if they were opaque Groups comparable at baseline: unclear - characteristics of the study population are not reported Groups received same care (apart from

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To investigate the effect of intrauterine saline amnioinfusion for the relief of repetitive variable decelerations in the first stage of labour Study dates July 1982 to March 1984 Source of funding None reported	decelerations, tachycardia to 180 beats per minute or more Thick meconium Some patients meeting the inclusion criteria were excluded for the following reasons: - differences in opinion among staff as to severity of decelerations requiring infusion, i.e. mild, moderate, or severe repetitive - 10% of the attending staff members refused to participate - some multiparous women were at the point of imminent birth - if the labour and delivery suite were very busy, women with mild or moderate repetitive variable decelerations were less likely to be included in the study		placed. It is reported by the authors that during the later part of the study, pre-infusion and post-infusion scanning was recommended; however, it was rarely done due to time limitations. - Amnioinfusion group Normal saline at room temperature was dripped in at a rate of 15-20 ml per minute until variable decelerations resolved, with an additional 250 ml given in excess. If the decelerations were not relieved by a single infusion of 800 ml, it was considered a failure (the average volume required for relief of variable decelerations was 250 ml [range 100 to 700 ml]). If variable decelerations returned after gross leakage of	distress (n/total (%)) All women Amnioinfusion: 9/49 (18.4) Control: 12/47 (25.5) [p = 0.547] Multiparous women Amnioinfusion: 5/22 (22.7) Control: 2/26 (7.7) [p = 0.289] Nulliparous women Amnioinfusion: 4/27 (14.8) Control: 10/21 (47.6) [p = 0.031] [Note: the authors report excluding one patient who had a CS for failure to progress, having had complete relief of decelerations. However, the quoted denominator is complete therefore it is not clear what group she was in] Complications of amnioinfusion The authors report that there was one case of cord prolapse in the	intervention): Amnioinfusion patients were kept in the left lateral position, whereas the control group were allowed to change position Blinding of participants: not possible Blinding of staff providing care: not possible Blinding of outcome assessors: no details given Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: no details given Many of the women excluded seem to have been excluded for reasons other than the a priori exclusion criteria, for example, because

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			fluid, then repeat infusions were done. Amnioinfusion patients were kept in the left lateral position. - Control group Very few details given apart from the fact that they were allowed to change position. Fetal heart rate tracings were reviewed by the authors and classified as either having complete relief, or no complete relief. Those with partial relief were included in the latter group. Statistical analysis Statistical analysis to compare proportions was done with chi-squared. Outcomes reported - caesarean section (CS) for fetal distress	amnioinfusion group.	some staff refused to participate or there was disagreement about the indications for amnioinfusion. Indirectness: - study was not restricted to low risk women and no higher risk groups were excluded Other information Amnioinfusion compared with no amnioinfusion for fetal distress [therapeutic] [Note: It is specifically reported that position change and oxygen had already been tried without success]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- complete relief of repetitive variable decelerations		
Full citation Patriarco,M.S., Viechnicki,B.M., Hutchinson,T.A., Klasko,S.K., Yeh,S.Y., A study on intrauterine fetal resuscitation with terbutaline, American Journal of Obstetrics and Gynecology, 157, 384-387, 1987 Ref Id 169545 Country/ies where the study was carried out USA Study type Randomised controlled trial Aim of the study To evaluate the use of terbutaline for the management of intrapartum fetal distress	Sample size N = 20 Characteristics Maternal age/years (mean (standard error [SE])) Terbutaline: 23.0 (1.3) Control: 26.0 (1.8) Gestational age/weeks (mean (SE)) Terbutaline: 39.7 (0.5) Control: 39.2 (1.8) Nulliparous (n/total (%)) Terbutaline: 5/11 (45.5) Control: 4/9 (44.4) Complications (n/total (%)) None Terbutaline: 3/11 (27.3) Control: 2/9 (22.2) Postdates	Interventions Terbutaline (n = 11) Control group (n = 9)	Details Recruitment and randomisation When women in labour showed signs of fetal distress (repetitive late decelerations or severe variable decelerations) with internal fetal heart rate monitoring, they were managed firstly with conventional procedures: oxygen administration, changing maternal position, putting her in the Trendelenburg position if needed, and stopping oxytocin infusion. If decelerations continued despite these measures, a fetal scalp blood sample was taken and if the pH was below 7.25 the woman was recruited for the	Results Change in fetal heart trace (n/total (%)) No further decelerations noted Terbutaline: 5/11 (45.5) Control: 0/9 (0) Continuing decelerations but at lower frequency and amplitude Terbutaline: 5/11 (45.5) Control: 0/9 (0) No improvement Terbutaline: 1/11 (9.1) Control: 9/9 (100) Fetal scalp pH (mean (standard error)) Terbutaline: 7.15 (SE 0.02) Control: 7.18 (SE 0.02) [not significant] Umbilical artery pH (mean (standard error))	Limitations Appropriate randomisation: unclear - simply states "randomly generated numbers" were used Allocation concealment: no details given Groups comparable at baseline: yes Groups received same care (apart from intervention): no particular details are given about how control group were managed, only that they received no medication Blinding of participants: no details given Blinding of staff providing care: no details given Blinding of outcome assessors: no details given Missing data/loss to follow-up: no

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates January 1984 to December 1985 Source of funding None reported	Terbutaline: 2/11 (18.2) Control: 2/9 (22.2) Intrauterine growth restriction (IUGR) Terbutaline: 2/11 (18.2) Control: 1/9 (11.1) Hypertension Terbutaline: 0/11 (0) Control: 1/9 (11.1) Meconium passage Terbutaline: 3/11 (27.3) Control: 2/9 (22.2) Prematurity Terbutaline: 0/11 (0) Control: 1/9 (11.1) Oligohydramnios Terbutaline: 1/11 (9.1) Control: 0/9 (0) Inclusion criteria Women with signs of fetal distress continuing despite the use of conventional methods (e.g. changing position) in whom a fetal scalp		study and randomised using "randomly generated numbers". Care protocol Following randomisation, while preparations for caesarean section were being done, women were given either: - 0.25 mg terbutaline sulphate injection subcutaneously - no medication Fetal heart rate monitoring continued in both groups until delivery. At the time of birth, blood samples were taken from the umbilical artery to measure pH. Immediately after birth, the babies were examined by a neonatologist or paediatrician. Statistical analysis	Terbutaline: 7.25 (SE 0.03) Control: 7.17 (SE 0.02) [p < 0.025] [Note: there was a significant difference between the mean scalp pH and mean arterial pH in the terbutaline group (p < 0.01) but the difference was not statistically significant (p-value not reported) in the control group] Perinatal death (n/total (%)) Terbutaline: 0/11 (0) Control: 0/9 (0) Caesarean section (n/total (%)) Terbutaline: 11/11 (100) Control: 9/9 (100) Other details reported about labour After terbutaline, 5 patients had completed cessation of uterine activity, whereas 6 showed diminished	Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: no particular details given; however, no reason to think it wasn't intention-to-treat Indirectness: - study is not restricted to low risk women and no high risk groups are reported as being excluded - 27% of the study group and 22% of the control group had meconium passage - it is not clear whether this was identified before or after randomisation - the decision had already been taken to perform a CS Other information Tocolysis for fetal distress: terbutaline

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	blood sample had a pH < 7.25 Exclusion criteria 7 women could not be included in the study because a fetal scalp blood sample was not taken before administration of terbutaline because immediate intervention was required		A t-test was used to compare pH values. p < 0.05 was considered significant. Outcomes reported - change in fetal heart rate trace - fetal scalp pH - umbilical artery pH - perinatal death - mode of birth	frequency of contractions. In the control group, no improvement was seen in uterine activity.	compared with no treatment [Note: It is specifically reported that other standard measures had already been tried without success]
Full citation Pullen,K.M., Riley,E.T., Waller,S.A., Taylor,L., Caughey,A.B., Druzin,M.L., El-Sayed,Y.Y., Randomized comparison of intravenous terbutaline vs nitroglycerin for acute intrapartum fetal resuscitation, American Journal of Obstetrics and Gynecology, 197, 414-416, 2007	Sample size N = 110 Characteristics Inclusion criteria 32 - 42 weeks gestation Singleton pregnancy Admitted in active labour or for induction of labour Non-reassuring fetal	Interventions Terbutaline (n = 57) Nitroglycerin (n = 53)	Details Recruitment and randomisation The criteria for a non-reassuring fetal heart tracing included: - prolonged deceleration (decrease in baseline fetal heart rate (FHR) to less than 100 bpm with a duration of more than 2 minutes) - severe variable deceleration (decrease	Results Overall success of intrauterine resuscitation (n/total (%)) Terbutaline: 41/57 (71.9) Nitroglycerin: 34/53 (64.2) Mode of birth (n/total (%)) a. Any operative delivery (CS, forceps or vacuum) for non-reassuring trace Terbutaline: 27/57 (47.4) Nitroglycerin: 25/53 (47.2) b. Caesarean section	Limitations Appropriate randomisation: unclear - method of randomisation not reported Allocation concealment: unclear - no details given Groups comparable at baseline: no details given Groups received same care (apart from intervention): yes Blinding of participants: yes Blinding of staff providing

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 169572 Country/ies where the study was carried out USA Study type Randomised controlled trial Aim of the study To compare the efficacy and safety of terbutaline and nitroglycerin for acute intrapartum fetal resuscitation Study dates October 2003 to June 2006 Source of funding None reported	heart rate tracing Exclusion criteria Women were excluded if the only indication was fetal tachycardia with reduced variability in the setting of chorioamnionitis.		in FHR to ≤ 70 bpm with a duration of at least 60 seconds but less than 2 minutes) - tachycardia with reduced variability (baseline FHR > 160 bpm) without evidence of chorioamnionitis, defined as fetal and/or maternal tachycardia with a maternal temperature of at least 38 degrees Women were excluded if the only indication was fetal tachycardia with reduced variability in the setting of chorioamnionitis. 956 women were enrolled, of which 110 (11.5%) were randomly assigned to receive terbutaline or nitroglycerin. Care protocol All women had	- Emergency CS within 1 hour for non-reassuring trace Terbutaline: 8/57 (14.0) Nitroglycerin: 12/53 (22.6) - Any CS for non-reassuring trace Terbutaline: 19/57 (33.3) Nitroglycerin: 17/53 (32.1) - Any CS Terbutaline: 30/57 (52.6) Nitroglycerin: 29/53 (54.7) c. Any instrumental vaginal delivery for non-reassuring trace* Terbutaline: 8/57 (14.0) Nitroglycerin: 8/53 (15.1) * Calculated by the technical team from the other data reported Postpartum haemorrhage (n/total) Terbutaline: 3/57 (5.3) Nitroglycerin: 2/53 (3.8) [Note: uterine atony	care: yes - the obstetrician was blinded Blinding of outcome assessors: unclear - however, if the obstetricians were the ones assessing outcomes then yes Missing data/loss to follow-up: the authors seem to have collected data on neonatal outcomes; however, they are not reported Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes, apart from PPH which was not defined and no details were given about how it was assessed Intention-to-treat analysis performed: no indication that intention to treat was not done Unclear why 956 women were enrolled but only 110 randomised

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			electronic fetal monitoring (EFM) and if there was evidence of an abnormal FHR, a cervical examination was done to evaluate presence of cord prolapse, dilatation and station. Then, the usual methods of fetal resuscitation were started, including position change, IV fluid hydration, oxygen by face mask and stopping any medications being used for augmentation and induction. Whether of not to try amnioinfusion was left to the judgement of the clinician. If these measures were not successful, women were given either: - terbutaline 250 micrograms IV - nitroglycerin 400 micrograms IV	occurred in 5 women in the terbutaline arm and 3 women in the NTG arm] Note: the authors also report in the text that no difference was seen in neonatal outcomes; however, no indication is given as to what these neonatal outcomes might be Other information reported about labour Contraction frequency in the 10 minutes after tocolytic administration (median in 10 minutes [25th - 75th percentile]) Terbutaline: 2.9 [1.7 - 3.3] Nitroglycerin: 4 [2.5 - 5] [p = 0.002]	Indirectness: - study was not restricted to low risk (and does not reporting excluding particular high risk groups) Other information Tocolysis for fetal distress: terbutaline compared with nitroglycerin [Note: It is specifically reported that other standard measures had already been tried without success] Need for additional tocolytics or doses (n (%)) Second agent at initial non-reassuring trace Terbutaline: 2 (3.5) Nitroglycerin: 2 (3.8) [p = 1.00] Subsequent tocolytic

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Maternal blood pressure and heart were recorded immediately before tocolysis and then at least every 15 minutes for an hour. If the trace did not improve, the decision about whether to repeat the dose or to proceed to an urgent delivery was left to the obstetrician. Statistical analysis Chi-squared, Fisher's exact and Mann Whitney tests were used as appropriate Outcomes reported - successful resuscitation: defined as complete resolution of the non-reassuring trace within 10 minutes, no recurrence of non-reassuring trace within 30 minutes of drug administration, and no operative delivery for		Terbutaline: 12 (21.1) Nitroglycerin: 9 (17.0) [p = 0.59]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			non-reassuring trace within 1 hour of drug administration. - mode of birth: rates of caesarean section (CS) and operative are reported - postpartum haemorrhage (PPH): not defined; method of assessing blood loss not reported		
Full citation Regi,A., Alexander,N., Jose,R., Lionel,J., Varghese,L., Peedicayil,A., Amnioinfusion for relief of recurrent severe and moderate variable decelerations in labor, The Journal of reproductive medicine, 54, 295-302, 2009 Ref Id 60772 Country/ies where the study was carried out	Sample size N = 148 Characteristics Cervical dilatation (n 9%)) ≤ 3 cm Amnioinfusion: 38 (52) Control: 35 (46.7) > 3 cm Amnioinfusion: 35 (48) Control: 40 (53.3)* * this is reported as 10 in	Interventions Amnioinfusion (n = 73) No amnioinfusion (control) (n = 75)	Details Recruitment and randomisation Women were recruited from those admitted in labour who met the inclusion criteria. Randomisation was done with a computerised random number table, with the allocation placed in sealed envelopes. Allocation was done by selecting the next, numbered, sealed opaque envelope.	Results Relief of variable decelerations (n/total (%)) Amnioinfusion: 58/73 (79.5) Control: 2/75 (2.7) [Note: the average time taken for relief of variable decelerations was 34.3 minutes (SD 21.3) in the amnioinfusion group; it is not reported for the control group. Recurrence of decelerations after initial relief was seen in 14 patients who were imminent to delivery because of the	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: Groups received same care (apart from intervention): yes Blinding of participants: not possible Blinding of staff providing care: not possible Blinding of outcome assessors: no details given

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
India Study type Randomised controlled trial Aim of the study To determine whether intrapartum amnioinfusion relieves recurrent moderate and severe variable decelerations in labouring women with clear or grade I meconium stained amniotic fluid and reduces caesarean section for fetal distress Study dates October 2003 to September 2004 Source of funding None stated	the paper, but with the correct % so it is likely to be a typo Colour of liquor (n (%)) Clear Amnioinfusion: 61 (83.6) Control: 65 (86.7) Grade I Amnioinfusion: 12 (16.4) Control: 10 (13.3) Antenatal risk factors (n (%)) Past dates Amnioinfusion: 13 (17.8) Control: 12 (16.0) Gestational hypertension Amnioinfusion: 14 (19.2) Control: 17 (22.7) Pre-eclampsia Amnioinfusion: 3 (4.1) Control: 2 (3.7) Oligohydramnios on scan Amnioinfusion: 7 (9.5) Control: 1 (1.3)		Care protocol Amnioinfusion group Amnioinfusion was done by placing a transcervical K-60 intrauterine single lumen catheter and then infusing 500 ml of warmed saline (37 degrees) as a bolus over 30 minutes, using the gravity drip method at the rate of 15-25 ml per minute. This was followed by a continuous infusion of the same saline at 3 ml per minute until delivery. Patients were monitored for any complications of amnioinfusion and the procedure was stopped if there was evidence of hypertonous or deteriorating fetal condition. Control group Received standard care	presence of nuchal cord] Caesarean section (n/total (%)) a. For non-reassuring fetal status - All women Amnioinfusion: 15/73 (20.54) Control: 24/75 (32) - Nulliparous women Amnioinfusion: 11/53 (20.7) Control: 21/52 (40.3) - Multiparous women Amnioinfusion: 4/20 (20) Control: 3/23 (12.5) b. For other indications (CPD, failed induction, failure to progress, arrest of descent) - All women Amnioinfusion: 13/73 (17.8) Control: 4/75 (5.3) - Nulliparous women Amnioinfusion: 12/53 (22.6*) Control: 4/52 (7.7*) - Multiparous women	Missing data/loss to follow-up: 61% of the study population have missing data for umbilical cord pH; admission to NICU is referred to in methods and results but never reported Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: 2 women were excluded after randomisation - in one woman, the K-60 catheter could not be introduced intracervically and in the other the woman gave birth before amnioinfusion could be started Trial was stopped early (after 150 women) and did not reach its sample size. Indirectness: - 63% of the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Gestational diabetes Amnioinfusion: 3 (4.1) Control: 3 (4.0) Overt diabetes Amnioinfusion: 0 (0) Control: 2 (2.7) Intrauterine growth restriction (IUGR) Amnioinfusion: 3 (4.1) Control: 5 (6.7) Others Amnioinfusion: 1 (1.4) Control: 4 (5.3) No risk factors Amnioinfusion: 29 (39.7*) Control: 29 (38.7) * reported as 9 in the table; however, this is clearly a typo Induction of labour (n (%)) Amnioinfusion: 46 (63) Control: 36 (48) Premature rupture of		(no further details given) Oxytocin for induction or augmentation was administered in both groups using standard indications. CS or operative vaginal delivery was done according to normal indications or when there was evidence of non-reassuring fetal status (i.e. due to occurrence of persistent severe variable or later decelerations). Statistical analysis A sample size calculation had estimated that 200 women in each group were needed to detect a reduction in the CS rate by half (from 20% to 10%) with a power of 80% and a 5% 2-tailed level of significance.	Amnioinfusion: 1/20 (5*) Control: 0/23 (0*) c. Total CS rate Amnioinfusion: 28/73 (38.4%) Control: 28/75 (37.3) * % are calculated by technical team, because the % reported in table VI of the study use the entire arm as the denominator, not the number of nulliparous/multiparous women Umbilical cord pH ≤ 7.2 (n/total (%)) All women Amnioinfusion: 20/23 (86.9) Control: 32/34 (94.1) Nulliparous women Amnioinfusion: 12/15 (80) Control: 20/20 (100) Multiparous women Amnioinfusion: 8/8 (100) Control: 12/14 (85.7)	amnioinfusion group and 48% of the control group had induction of labour - 60% of the amnioinfusion group and 61% of the control group had antenatal risk factors - some women have grade I meconium stained liquor; however, outcomes are not reported separately and it is a minority Other information Amnioinfusion compared with no amnioinfusion for fetal distress [therapeutic]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	membranes present (n (%)) Amnioinfusion: 23 (31.5) Control: 18 (24) Duration of premature rupture of membranes: interval between rupture and admission/hours (mean ± SD) Amnioinfusion: 6.96 ± 6.9 Control: 9.06 ± 10.9 [p = 0.443] Interval between rupture of membranes and delivery/hours (mean ± SD) Amnioinfusion: 11.14 ± 8.3 Control: 9.52 ± 8.6 [p = 0.247] There were also no significant differences in the proportion of women having artificial rupture of membranes or augmentation with oxytocin		Periodic analysis of results was planned, in order to discontinue the study if amnioinfusion was found to be beneficial. Results were analysed using the chi-squared test to compare categorical variables and Student's t-test to compare continuous variables. $p < 0.05$ was considered significant. Outcomes reported - CS rate: overall and for non-reassuring fetal status (i.e. fetal distress) - Relief of decelerations - Cord pH at birth: proportion with pH ≤ 7.2 - Any neonatal problems requiring admission to NICU: listed as an outcome		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	The authors also report that there were no differences between the two groups with regards to age, gestational age and parity. Most of the women in the study (105/148 [70.9%]) were nulliparous. Inclusion criteria Women in active labour in the first stage (cervical dilatation < 10 cm) Gestational age > 34 weeks Clear or grade I meconium staining of the amniotic fluid Presence of repetitive severe or moderate variable decelerations - Severe: decelerations to a depth of < 70 beats per minutes lasting for more than 60 seconds - Moderate: either more than 5 in number		but never reported		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	consecutively or those that followed > 50% of the contractions in a 20-minute period Exclusion criteria Variable decelerations with poor variability or delayed recovery Baseline bradycardia or tachycardia Repetitive late decelerations Grades II or III meconium stained amniotic fluid Previous caesarean section (CS) Presence of contraindication to vaginal delivery (e.g. fetal malpresentation or placenta praevia)				

1.1.19 What is the intra-rater and inter-rater reliability of scoring systems for meconium-stained liquor? What is the effectiveness of scoring/grading systems for improving neonatal and maternal outcomes when there is meconium stained liquor?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Morad,Y., Kaplan,B., Zangen,S., Rabinerson,D., Peleg,D., Merlob,P., Management of meconium-stained neonates, Journal of Obstetrics and Gynaecology, 18, 223-226, 1998 Ref Id 215207 Country/ies where the study was carried out Israel Study type Comparative observational study (Prospective data collection in scoring group, with retrospective controls) Aim of the study To assess the feasibility of a meconium scoring system for clinical use	Sample size N = 180 Characteristics Birth weight/grams (mean ± SD) Scoring: 3234 ± 416 Control: 3332 ± 400 [NS] Maternal age/years (mean ± SD) Scoring: 29.58 ± 5.09 Control: 27.73 ± 5.21 [P = 0.02] Gestational age/weeks (mean ± SD) Scoring: 39.88 ±	Interventions Meconium scoring (n = 80) Control (n = 100)	Details Scoring group The study group included babies meeting the inclusion criteria who were born either by caesarean section (CS) or vaginal birth. A neonatologist had to be present at each delivery through meconium stained liquor and for each CS. They then completed the following scoring system: 1. Was there fetal distress during prenatal monitoring? - No: 0 - Yes: 1 2. Was oropharyngeal suction performed before the first breath? - No: 1 - Yes: 0 3. What was the quality of the meconium? - Thin: 0 - Thick: 1 4. What was the clinical condition of the newborn	Results Mode of birth (n/total (%)) a. Spontaneous vaginal birth Scoring: 67/80 (83.7) Control: 89/100 (89) [P = 0.30] b. Caesarean section Scoring: 9/80 (11.3) Control: 6/100 (6) [P = 0.20] c. Vacuum delivery Scoring: 1/80 (1.3) Control: 4/100 (4) [P = 0.26] d. Forceps Scoring: 2/80 (2.5) Control: 1/100 (1) [P = 0.43] Intubation (n/total (%))	Limitations Choice of management unrelated to confounders (selection bias): yes Groups comparable at baseline: women in the scoring group were significantly older, had higher mean gravidity and higher mean parity Groups received same/similar care (apart from intervention): unclear - very few details reported Blinding of those assessing outcomes: not possible, as the comparison was done between different time points Missing data/loss to follow-up: mode of birth is missing for one woman in the study group Precise definition of outcomes: yes Valid and reliable method

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Scoring group: 1st June to 31st August 1993 Control group: May to September 1992 Source of funding Not reported	1.06 Control: 39.86 ± 1.20 [NS] Gravidity (mean ± SD) Scoring: 3.29 ± 2.32 Control: 1.84 ± 1.02 [P = 0.0001] Parity (mean ± SD) Scoring: 2.92 ± 2.25 Control: 2.24 ± 1.38 [P = 0.02] Smoker (n (%)) Scoring: 6 (7.5) Control: 8 (8) [NS] Male baby (n		(breathing, heart rate, skin colour) before intervention? - Normal: 0 - Cyanosis or absence of crying: 1 - Apnoea: 2 - Bradycardia (< 80 beats per minute): 2 Total: __ points A total score of 0-1 indicated the need for only gentle, short duration oropharyngeal suctioning. A total score of 2 or more indicated the institution of immediate intubation and suctioning of the upper and lower airways using a 3 - 3.5 mm endotracheal tube. Suction was continued during the tube removal. If the tracheal aspirate continued to contain meconium, the procedure was repeated until the airways were clear. The volume of fluid aspiration was measured, and fluid thickness (previously estimated by delivery room staff) was re-checked by the paediatrician to ensure accuracy.	Scoring: 18/80 (22.5) Control: 30/100 (30) [NS (p-value not reported)] Positive meconium suction (n/total (%)) Scoring: 8/80 (10) Control: 13/100 (13) [NS (p-value not reported)] Measures of meconium aspiration (n/total (%)) a. Meconium in aspirate Scoring: 13/80 (16) Control: 5/100 (5) [NS (p-value not reported)] b. Meconium aspiration syndrome Scoring: 4/80 (5) Control: 6/100 (6) [NS (p-value not reported)]	of outcome assessment: unclear - very few details given Intention-to-treat analysis performed: yes Method of analysis was not always appropriate - t-test was used for some variables which are not continuous. No power calculation is reported. The authors report in the abstract that intubations were significantly reduced; however, this is not supported by the data in the paper. Indirectness: Study was not restricted to low risk women Other information This study was included in the 2007 Intrapartum Care guideline

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(%)) Scoring: 33 (41.2) Control: 54 (54) [NS] Inclusion criteria Meconium-stained full term infants Exclusion criteria Not reported		The diagnosis of meconium aspiration syndrome was established based on clinical signs, characteristic chest X-rays, and oxygen dependency. Control group A comparison group was established by selecting a random group of infants born through meconium stained amniotic fluid in a set period during the previous year. For the control group, the procedure was to do laryngoscopy (100% of babies, compared to 0 in the study group) for direct visualisation of the neonatal glottis, and endotracheal suctioning when meconium staining of the vocal cords was observed. Note: the staff were the same for both groups Statistical analysis Student's t-test was used to analyse differences in mean continuous parameters (listed as	c. Meconium aspiration syndrome necessitating ventilation Scoring: 2/80 (2.5) Control: 2/100 (2) [NS (p-value not reported)] Mortality (n/total (%)) Scoring: 0/80 Control: 0/100 Note: Mortality is not directly reported, but the following makes it clear that no babies died: Scoring group: All babies except 1 were discharged in good condition within a week of hospitalisation, with no complications. 1 had a longer stay because of a pneumothorax and prolonged ventilation but was discharged in good condition Control group: All babies were discharged in good condition	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Apgar, gestational age, number of pregnancies, number of deliveries and estimation of meconium fluid thickness - however, some of these are not continuous and therefore, a t-test is not appropriate). Chi-squared and Fisher's exact test were used to compare categorical variables. p ≤ 0.05 was considered significant.		
Full citation Trimmer,K.J., Gilstrap,L.C.,III, "Meconiumcrit" and birth asphyxia, American Journal of Obstetrics and Gynecology, 165, 1010-1013, 1991 Ref Id 216203 Country/ies where the study was carried out USA Study type Observational study Aim of the study	Sample size N = 106 Characteristics No details given Inclusion criteria Term (defined as birth weight > 2500 grams) Meconium stained amniotic fluid Exclusion criteria Not reported	Interventions Measuring "meconiumcrit" Classifying meconium subjectively	Details The women had a 10 ml sample of amniotic fluid collected using an intrauterine pressure catheter (the first 10 ml was discarded). In addition to this initial sample, 57 women also had a second sample taken at the time of amniotomy to establish if the catheter would affect the sample quality or quantity. All samples were placed in glass tubes and centrifuged at 1000 revolutions per minute for 10 minutes. Meconiumcrit: Measured by dividing the solid volume by the total volume and then grading it	Results Degree of meconium as graded wth meconiumcrit compared with clinical estimate (n/total (%)) Thin Meconiumcrit: 61/106 (58) Clinical estimate: 58/106 (55) Moderate Meconiumcrit: 36/106 (34) Clinical estimate: 38/106 (36) Thick Meconiumcrit: 9/106 (8) Clinical estimate: 10/106	Limitations Study sample represents population: Study population is not restricted to low risk women and characteristics of the study population are not reported Loss to follow-up is unrelated to key characteristics: Not applicable - there was no loss to follow-up Prognostic factors are adequately measured in participants: Yes Outcome of interest is

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To evaluate the association of the consistency of meconium as measured by the 'meconiumcrit' and currently accepted markers of birth asphyxia, namely the 1- and 5-minute Apgar scores, umbilical artery cord blood pH and newborn seizures Study dates Not reported Source of funding Not reported			as thin (< 10%), moderate (10% - 30%) or thick (30%) based on that. The cut-offs had been selected arbitrarily before the start of the study. Grading subjectively: Classified as thin, moderate or thick by the attending physician The subjective grading was not known at the time of the centrifugation and meconiumcrit calculation. All newborns had umbilical cord blood gas analysis done - this was done on a double clamped section of cord, placed on ice and transported to the laboratory for analysis. The obstetrician also immediately suctioned the oropharynx with a bulb syringe after delivery of the fetal head. Paediatricians attended all deliveries complicated by meconium and vocal cords were visualised with a laryngoscope, followed by suctioning with a catheter. Meconium above or	(9) Spearman's p = 1.00 Pearson's r = 0.997 P = 0.047 Clinical outcomes reported split by meconiumcrit classification (non-comparative) Meconium aspiration - thin: 0/61 (0) - moderate: 0/36 (0) - thick: 2/9 (22) [Note: they were treated with aggressive airway management and subsequently did well] Neonatal seizures - thin: 0/61 (0) - moderate: 0/36 (0) - thick: 0/9 (0) Cord artery pH < 7.20 - thin: 8/61 (13) - moderate: 7/36 (19) - thick: 1/9 (11)	sufficiently measured in participants: Yes, although the neonatal outcomes are not reported for the comparison of the two models of classification Important potential confounders are accounted for: No confounders are reported Statistical analysis is appropriate for study design: Yes The way that the data are reported for the classifications does not make it clear where the cross-over in classification was - because it just reports the proportion classed as thin, thick etc., in each system, the cross-over could have been minimal and this would not be represented. It would have been more useful to report the proportion of those classified as thin in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			below the vocal cords was assessed in the delivery room. The subsequent diagnosis of meconium aspiration syndrome was based on characteristic X-ray findings and the clinical course in the nursery. Statistical analysis This was done using Fisher's exact test or chi-squared tests as appropriate.	[Note: all of these were between 7.00 and 7.20 because it is reported that no babies had a pH < 7.00] Neonatal death - thin: 0/61 (0) - moderate: 0/36 (0) - thick: 0/9 (0)	one system that were also classified as thin with the other system. Other information This study was included in the 2007 Intrapartum Care guideline
Full citation van Heijst,M.L., van,Roosmalen G., Keirse,M.J., Classifying meconium-stained liquor: is it feasible?, Birth, 22, 191-195, 1995 Ref Id 216202 Country/ies where the study was carried out Australia Study type Observational study Aim of the study	Sample size N = 16 samples, each judged 4 times by 20 midwives (therefore 1280 separate classifications) Characteristics No details given Inclusion criteria Meconium stained amniotic fluid	Interventions Classification of meconium staining	Details A consecutive series of 21 samples of meconium stained amniotic fluid were collected and stored at -18 degrees. Following thawing, they were classified independently by the study authors into thick, moderate and thin. Four from each category that had been classified unanimously were then selected, and four samples of clear liquor were added, to make 16 samples. These were all divided into two (therefore, there were 32 specimens) and coded.	Results Comparison between Standard Classification and Midwives' Assessment Clear meconium (as judged by the standard) - Midwife Clear [CORRECT]: 294/320 (91.9) - Midwife Thin: 23/320 (7.2) - Midwife Moderate: 3/320 (0.9) - Midwife Thick: 0/320 (0) Thin meconium (as judged by the standard)	Limitations No particular limitations were identified in this study. The following are simply considerations: - Midwives were blinded to duplicate samples and blinded to how they had classified the meconium before; therefore, this is unlikely to have affected the results. - All midwives had a lot of experience, and were attending a five day postgraduate course; therefore, the authors

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To establish whether it is possible to differentiate between different types of meconium Study dates Not reported Source of funding Not reported	Exclusion criteria Not reported		The 32 specimens were given to 20 midwives (on a postgraduate course) and they were asked to label the samples as clear, thin, moderate or thick. The samples were then collected, recoded, and resubmitted to the same midwives 4 hours later as a set of new cases. Between the two assessments, the midwives were given guidance on the usual definition of the categories: - Thick: dark green to black in colour with a thick or "tenacious" appearance, and/or any liquor that contained lumps of meconium - Moderate: any liquor falling in between thin and thick or with any doubt - Thin: pale green to yellow without lumps The following things were evaluated: 1. Ability of midwives to classify cases in the same category as the standard which was the authors' unanimous judgement (inter-individual agreement;	- Midwife Clear: 99/320 (30.9) - Midwife Thin [CORRECT]: 188/320 (58.8) - Midwife Moderate: 26/320 (8.1) - Midwife Thick: 7/320 (2.2) Moderate meconium (as judged by the standard) - Midwife Clear: 6/320 (1.9) - Midwife Thin: 150/320 (46.9) - Midwife Moderate [CORRECT]: 134/320 (41.9) - Midwife Thick: 30/320 (9.4) Thick meconium (as judged by the standard) - Midwife Clear: 10/320 (3.1) - Midwife Thin: 11/320 (3.4) - Midwife Moderate: 66/320 (20.6) - Midwife Thick	report that there may have been positive selection. - The midwives were given guidance between the two assessments; therefore, they performed the first assessment without guidance. Selection of clinically stable samples appropriate to the instrument and condition of interest: Yes Minimization of random error: Duplication of samples within sets helped to establish consistency and guidance about classification was given on second assessment Appropriate periods of time between measurements: Yes, and samples were re-coded Interpretation of frequently used reliability statistics: Yes, kappa statistic

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			accuracy) 2. Ability of midwives to classify duplicate cases consistently (intra-individual agreement; precision) A kappa statistic was calculated, which represents proportional agreement, corrected for agreements that occur by chance. The authors report (with reference to Altman) that the kappa statistic should be interpreted as follows: - 0: no agreement - < 0.20: poor agreement - 0.21-0.40: fair agreement - 0.41-0.60: moderate agreement - 0.61-0.80: good agreement - 0.81-1.00: very good agreement - 1.00: complete agreement	[CORRECT]: 233/320 (72.8) Inter-observer agreement (number of times midwives agreed with standard / 32) - First assessment (mean [range]) Exact agreement with standard: 20.5/32 [11 to 27] Kappa: 0.52 [0.13 to 0.79] - Second assessment (mean [range]) Exact agreeement: 21.8/32 [range 13 to 27] Kappa: 0.57 [0.21 to 0.79] Intra-observer agreement (number of times midwives agreed with themselves on the duplicate sample within a set / 32*) - First assessment (mean [range]) Exact agreement with herself: 23.7/32 [14 to 30] Kappa: 0.64 [0.24 to 0.91]	Generalisability of results: Unclear because the definition of moderate is quite vague and therefore it may not be easily applicable elsewhere Other information This study was included in the 2007 Intrapartum Care guideline

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Second assessment (mean [range]) Exact agreement with herself: 23.5 [18 to 30] Kappa: 0.63 [0.42 to 0.91] * this relates to 16 pairs of duplicates within a set of 32, but the value has been doubled to faciliate comparison with inter-observer agreement figures Each specific sample appeared 4 times in the test (duplicate within each set; 2 sets) and therefore, the authors also examined how many times a sample was coded identically on all 4 times by the midwife: - this occurred for 47.8% of the whole sample (153/320) - disregarding clear samples, the percentage was 35.8% (86/240)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- of the 12 non-clear samples each person saw, an average of 4.3 [range 0 to 7] were classified in the same category on each of the four occasions; and an average of 1.9 [range 0 to 6] differed on average by more than one category (i.e. thin to thick)	

1.1.20 When the need to intervene to expedite birth has been identified, what is the appropriate decision to delivery interval for a vaginal birth?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Eldridge,A., Johnson,N., How long does it take to perform an operative vaginal delivery?, Journal of Obstetrics and GynaecologyJ.Obstet.Gynaecol., 24, 230-232, 2004 Ref Id 240500 Country/ies where the study was carried out England	Sample size N = 49 Characteristics Mode of birth (n/total) Ventouse: 33/49 Rotational ventouse: 2/49 Lift-out forceps: 8/49 Rotational forceps: 2/49 Rotational ventouse	Interventions Decision to delivery interval (DDI)	Details Setting This study was conducted in the labour ward of a major maternity unit. At the point of the study the unit dealt with about 5000 women per year, with an additional 1500 low risk and uncomplicated births occurring in community settings or at home. The	Results * Calculated by NCC-WCH technical team Decision to delivery interval for different indications/minutes a. All births Median (range): 19.0 (6 - 85) Mean: 26.0 (95% CI 20 to 31)	Limitations Choice of treatment unrelated to confounders (selection bias): No details given on characteristics of study population Groups comparable at baseline: No details given on characteristics of study population Groups received

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Prospective observational study Aim of the study To evaluate how long it takes to achieve an operative vaginal delivery Study dates April 2002 (1 month) Source of funding None reported	followed by forceps: 2/49 Caesarean section for failed delivery: 2/49 Inclusion criteria All operative vaginal deliveries during the study period Exclusion criteria Not reported		authors report that resident career obstetricians staffed the labour ward, with daytime support from a consultant. They also report that "there are no staff shortages, midwives are experienced, there are no locums and the service does not use agency staff." Protocol for instrumental vaginal births Operative vaginal deliveries were performed by experienced obstetricians or by selected and accredited midwives. SHOs did not do operative vaginal deliveries. The indication for vaginal delivery was fetal distress (defined as an abnormal cardiotocograph [CTG]) in 29 cases, and 'other' in the remaining cases (the	b. Births for fetal distress only Median (range): 16.0 (6 - 61) Mean: 22 (95% CI 16 to 25) c. Births for other indications Median (range): 25 (8 - 85*) Mean: 33.75* Decision to delivery for different modes of birth/minutes (median) a. Forceps Median: 19.0 b. Ventouse Median: 18.0 The data on medians are reported in the text of the paper, but it is not clear whether these are actual mode of birth or planned mode of birth. It is also not clear where the rotational deliveries	same/similar care (apart from intervention): No details given Blinding of those assessing outcomes: No details given Missing data/loss to follow-up: 21% of the assisted vaginal births that occurred during the study period could not be included as their data collection sheets were spoilt Precise definition of outcomes: Yes, although no neonatal outcomes are reported Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Not applicable - the study just reports the decision to delivery interval for different modes of birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			majority were for failure to progress, with a minority for maternal exhaustion or meconium). Data collection Very few details are given, but there appear to have been data collection forms used, as the authors report that 62 assisted vaginal births occurred during the study period but 13 data collection forms were spolit or could not be used and therefore were discarded before analysis. Statistical analysis No details given Outcomes reported - Mode of birth: DDI is reported for each mode of birth	would fit, and where the ventouse followed by forceps would fit - given this, and the additional individual patient data available from the study, these medians are not included in the GRADE table. It is also reported that an episiotomy did not shorten median delivery intervals (19 minutes compared to 17 minutes) for the cases where no incision was required (n = 16). The following additional values for DDI could be calculated based on data reported in figure 1 in the study (note: rotational includes both rotational forceps and rotational ventouse, as it was not specified; categories are mutually exclusive)	Indirectness: Study population is not restricted to low risk women; the authors also report that "there are no staff shortages, midwives are experienced, there are no locums and the service does not use agency staff" and therefore the results may not be completely applicable to the situation in many units in England and Wales currently Other information This study was included in the 2007 guideline.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Forceps (n = 8): - Mean ± SD: 16.5 ± 8.30* - Range: 6 to 32* Ventouse (n = 33): - Mean ± SD: 22.7 ± 15.81* - Range: 8 to 84* Rotational (n = 4): - Mean ± SD: 54.8 ± 31.90* - Range: 17 to 85* Rotational ventouse followed by forceps (n = 2): - Mean ± SD: 50 ± 26.87* - Range: 31 to 69* Caesarean section (n = 2): - Mean ± SD: 55 ± 8.49* - Range: 49 to 61*	
Full citation Murphy,Deirdre J., Koh,Daisy K.M.,	Sample size N = 998	Interventions DDI	Details Setting	Results Decision to delivery for	Limitations Choice of treatment

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Cohort study of the decision to delivery interval and neonatal outcome for emergency operative vaginal delivery, American Journal of Obstetrics and GynecologyAm J Obstet Gynecol, 196, 145-145, 2007 Ref Id 241049 Country/ies where the study was carried out Scotland Study type Retrospective observational study Aim of the study To assess whether a target decision to delivery interval (DDI) is appropriate for emergency operative vaginal delivery and whether this would reduce adverse neonatal outcomes Study dates January 1998 to January 2003 Source of funding None reported	attempted operative vaginal deliveries (Note: there were an additional 23 babies with fetal distress in the second stage who went straight to an immediate caesarean section [CS]) Characteristics Location and success of attempted operative vaginal birth (n/total (%)) Labour room: 800/998 (80.2) - Successful: 798/800 (99.75) - Failed: 2/800 (0.25) Operating theatre: 198/998 (19.8) - Successful: 167/198 (84.3) - Failed: 31/198 (15.7) The 33 failed	categories (not mutually exclusive): 0 - 15 minutes > 15 minutes 0 - 30 minutes > 30 minutes	The hospital was a teaching hospital that dealt with around 3000 births per year and had obstetricians of a broad range of experience levels. The facility also received transfers from local midwifery units. The labour ward had protocols for instrumental vaginal delivery, but venue and instrument were down to the discretion of the attending obstetrician. Protocol for instrumental vaginal births The indications were classified according to standard criteria; however, only those for fetal distress were included in this study. The definition of fetal distress was based on abnormal features on a cardiotocograph (CTG) (persistent bradycardia,	each mode of birth/minutes a. Completed nonrotational forceps (n = 528) 0 - 15 minutes: 301 (57.0%) 0 - 30 minutes: 483 (91.5%) > 30 minutes: 45 (8.5%) Mean ± SD: 16.6 ± 10.6 Median (IQR): 15 (9 - 22) b. Completed nonrotational vacuums (n = 268) 0 - 15 minutes: 177 (66.0%) 0 - 30 minutes: 254 (94.8%) > 30 minutes: 14 (5.2%) Mean ± SD: 14.9 ± 11.7 Median (IQR): 13 (9 - 18) c. Completed rotational operative vaginal births	unrelated to confounders (selection bias): Having a first stage of labour longer than 12 hours, a second stage of labour > 2 hours, epidural, spinal anaesthesia, and general anaesthesia were all associated with the higher DDI groups (i.e. significantly lower odds of those things in 0-15 minutes and 0-30 minutes DDI groups when compared to > 15 and > 30 respectively). Perineal/pudendal infiltration was associated with the lower DDI groups (i.e. significantly higher odds in 0-15 minutes and 0-30 minutes DDI groups when compared to > 15 and > 30 respectively) Groups comparable at

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	operative vaginal births all had CS. Characteristics, split by DDI (n (%)) a. Nulliparous 0 - 15 minutes: 285 (51.2) > 15 minutes: 251 (56.9) OR 0.79 (95% CI 0.62 to 1.02) 0 - 30 minutes: 469 (53.4) > 30 minutes: 67 (55.8) OR 0.91 (95% CI 0.62 to 1.33) b. Induced labour 0 - 15 minutes: 188 (33.8) > 15 minutes: 156 (35.4) OR 0.93 (95% CI 0.72 to 1.21) 0 - 30 minutes: 300 (34.2)		late decelerations, complicated tachycardia, persistent poor variability) with or without meconium-stained liquor. Fetal blood sampling was available in the unit and was recommended in the case of CTG abnormalities unless delivery was imminent. Operative delivery was by forceps, vacuum or CS (either immediately or after a failed attempt at an instrumental vaginal birth). Rotational deliveries included Kiellands forceps, manual rotation followed by direct traction forceps, or rotational vacuum. Birth could be in a labour room or in an operating room with dedicated anaesthetic and theatre staff. Transfer to operating room was indicated for	(n = 169) 0 - 15 minutes: 66 (39.1%) 0 - 30 minutes: 124 (73.4%) > 30 minutes: 45 (26.6%) Mean ± SD: 22.8 ± 14.7 Median (IQR): 20 (12 - 31) d. CS after failed operative vaginal birth (n = 33) 0 - 15 minutes: 13 (39.4%) 0 - 30 minutes: 17 (51.5%) > 30 minutes: 16 (48.5%) Mean ± SD: 28.5 ± 18.3 Median (IQR): 29 (10 - 45) Mode of birth in each DDI category (n/total (%*)) a. DDI 0 - 15 minutes (n	baseline: See above - there were differences in the characteristics of the different DDI groups, which could have affected outcomes Groups received same/similar care (apart from intervention): Yes Blinding of those assessing outcomes: No details given; therefore unlikely Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Not applicable - this was a retrospective study associating different DDIs with different outcomes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	> 30 minutes: 44 (36.7) OR 0.90 (95% CI 0.60 to 1.33) c. Syntocinon augmentation 0 - 15 minutes: 141 (25.3) > 15 minutes: 124 (28.1) OR 0.87 (95% CI 0.65 to 1.15) 0 - 30 minutes: 227 (25.9) > 30 minutes: 38 (31.7) OR 0.75 (95% CI 0.50 to 1.14) d. First stage of labour > 12 hours 0 - 15 minutes: 108 (19.4) > 15 minutes: 111 (25.2) OR 0.71 (95% CI 0.52 to 0.96)		spinal/general anaesthesia, complex rotational instrumental deliveries, attempted operative vaginal births that were considered a trial with potential recourse to CS, and those where immediate CS was planned. Data collection All women meeting the inclusion criteria who had an operative birth in the second stage of labour were identified from the "MaterniTay" database. This was cross-referenced with labour ward records, operating theatre admission books, and the handwritten medical records where needed. The data were also cross-referenced with the Scottish morbidity record, which is completed for each woman and baby for	= 557) Completed operative vaginal birth: 544/557 (94.3) - Nonrotational forceps: 301 - Nonrotational vacuums: 177 - Rotational births: 66 Caesarean section after failed operative vaginal birth: 13/557 (2.3) [Note: Of the completed operative vaginal births, 525 were in the labour room and 19 were in the operating room] b. DDI 0 - 30 minutes (n = 878) Completed operative vaginal birth: 861/878 (98.1) - Nonrotational forceps: 483 - Nonrotational vacuums: 254 - Rotational births: 124 Caesarean section after	Indirectness: Study population is not restricted to low-risk women, although it did only include term, singleton pregnancies in cephalic vertex presentation. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	0 - 30 minutes: 182 (20.7) > 30 minutes: 37 (30.8) OR 0.58 (95% CI 0.38 to 0.88) e. Second stage of labour > 2 hours 0 - 15 minutes: 59 (10.6) > 15 minutes: 102 (23.1) OR 0.39 (95% CI 0.28 to 0.55) 0 - 30 minutes: 114 (13.0) > 30 minutes: 47 (39.2) OR 0.23 (95% CI 0.15 to 0.35) f. Perineal/pudendal infiltration 0 - 15 minutes: 195 (35.0) > 15 minutes: 91 (20.6) OR 2.07 (95% CI 1.55		national recording purposes. The time of making the decision to deliver and the actual time of birth were noted on the computer record by the operator. Similar information was also entered by the midwife and in the operating room records; therefore, allowing for validation. Handwritten medical records were reviewed if there was a discrepancy or missing data. Statistical analysis Decision to delivery intervals were calculated as means and standard deviations and as medians and IQRs (the latter being to take account of outliers). Differences between groups were evaluated using Student's t-test.	failed operative vaginal birth: 17/878 (1.9) [Note: Of the completed operative vaginal births, 770 were in the labour room and 91 were in the operating room] c. DDI > 30 minutes (n = 120) Completed operative vaginal birth: 104/120 - Nonrotational forceps: 45 - Nonrotational vacuums: 14 - Rotational births: 45 Caesarean section after failed operative vaginal birth: 16/120 [Note: Of the completed operative vaginal births, 28 were in the labour room and 76 were in the operating room] * The % reported here	

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	to 2.77) 0 - 30 minutes: 278 (31.7) > 30 minutes: 8 (6.7) OR 6.49 (95% CI 3.12 to 13.48) g. Epidural analgesia 0 - 15 minutes: 384 (68.9) > 15 minutes: 338 (76.6) OR 0.68 (95% CI 0.51 to 0.90) 0 - 30 minutes: 625 (71.2) > 30 minutes: 97 (80.8) OR 0.59 (95% CI 0.36 to 0.94) h. Spinal anaesthesia 0 - 15 minutes: 18 (3.2) > 15 minutes: 53 (12.0) OR 0.24 (95% CI 0.14 to 0.42)		Univariate analyses were done comparing the odds of having an outcome with different DDI thresholds. Odds ratios and 95% CI are reported. The authors report that with the sample size available, an OR of 1.5 for fetal acidosis (defined as pH < 7.10) could be detected for the comparison of the group delivered in excess of 15 minutes and those delivered within 15 minutes. Outcomes reported - Mode of birth: reported for the attempted operative vaginal deliveries, split by DDI - Tears: third degree tear was recorded where tearing involved the anal sphincter muscle; fourth degree tear	have been calculated by the technical team. They do not match those reported in the paper, because the % in the paper are as a proportion of the total births delivered by that mode of birth (as reported below), rather than the total births delivered in a particular DDI category. Third or fourth degree tear (n/total (%)) 0 - 15 minutes: 19/557 (3.4) > 15 minutes: 23/441 (5.2) OR 0.64 (95% CI 0.35 to 1.19) 0 - 30 minutes: 36/878 (4.1) > 30 minutes: 6/120 (5.0) OR 0.81 (95% CI 0.34 to 1.97)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	0 - 30 minutes: 38 (4.3) > 30 minutes: 33 (27.5) OR 0.12 (95% CI 0.07 to 0.20) i. General anaesthesia 0 - 15 minutes: 0 (0) > 15 minutes: 4 (0.9) OR: not reported 0 - 30 minutes: 1 (0.1) > 30 minutes: 3 (2.5) OR 0.04 (95% CI 0.01 to 0.43) j. Male baby 0 - 15 minutes: 302 (54.2) > 15 minutes: 236 (53.5) OR 1.03 (95% CI 0.80 to 1.32) 0 - 30 minutes: 482 (54.9) > 30 minutes: 56		was recorded where tearing involved the anal mucosa - Cord blood gas values: cord blood was taken from the umbilical artery and vein; pH < 7.10 and base excess < -12.0 were taken as markers for adverse neurodevelopmental outcome - Admission to NICU - Neonatal resuscitation: included bag and mask ventilation, intubation with intermittent positive pressure ventilation and full cardiac arrest procedures - Neonatal trauma: composite outcome that included bruising, cephalhematoma, lacerations, intra- or extra-cranial	Cord blood gas values (n/total (%)) a. pH umbilical artery < 7.10 0 - 15 minutes: 50/557 (9.0) > 15 minutes: 31/441 (7.0) OR 1.24 (95% CI 0.78 to 1.99) 0 - 30 minutes: 77/878 (8.8) > 30 minutes: 4/120 (3.3) OR 2.76 (95% CI 0.98 to 7.71) b. Base excess umbilical artery < -12.0 0 - 15 minutes: 55/557 (9.9) > 15 minutes: 42/441 (9.5) OR 1.00 (95% CI 0.65 to 1.53) 0 - 30 minutes: 90/878 (10.3) > 30 minutes: 7/120	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(46.7) OR 1.39 (95% CI 0.95 to 2.04) k. Birth weight > 4.0 kg 0 - 15 minutes: 44 (7.9) > 15 minutes: 42 (9.5) OR 0.82 (95% CI 0.52 to 1.27) 0 - 30 minutes: 75 (8.5) > 30 minutes: 11 (9.2) OR 0.93 (95% CI 0.48 to 1.80) l. Meconium-stained liquor 0 - 15 minutes: 112 (20.1) > 15 minutes: 78 (17.7) OR 1.17 (95% CI 0.85 to 1.61) 0 - 30 minutes: 164 (18.7) > 30 minutes: 26		haemorrhage, facial nerve palsy, brachial plexus injury, or fractures (note: forceps marks were not considered traumatic, nor was a chignon, unless there was additional bruising or lacerations) - Perinatal death - Severe neonatal morbidity: adverse events are discussed in the text [Note: neonatal outcomes were available up until the point of discharge]	(5.8) OR 1.81 (95% CI 0.82 to 4.03) Admission to NICU (n/total (%)) 0 - 15 minutes: 15/557 (2.7) > 15 minutes: 22/441 (5.0) OR 0.53 (95% CI 0.27 to 1.03) 0 - 30 minutes: 29/878 (3.3) > 30 minutes: 8/120 (6.7) OR 0.48 (95% CI 0.21 to 1.07) Neonatal resuscitation (n/total (%)) 0 - 15 minutes: 138/557 (24.8) > 15 minutes: 109/441 (24.7) OR 1.00 (95% CI 0.75 to 1.34) 0 - 30 minutes: 210/878 (23.9)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(21.7) OR 0.83 (95% CI 0.52 to 1.32) m. Fetal blood sample performed 0 - 15 minutes: 176 (31.6) > 15 minutes: 172 (39.0) OR 0.72 (95% CI 0.56 to 0.94) 0 - 30 minutes: 291 (33.1) > 30 minutes: 54 (47.7) OR 0.55 (95% CI 0.37 to 0.81) Inclusion criteria Booked for care at Ninewells Hospital and requiring an operative delivery for fetal distress during the second stage of labour Term (at least 37			> 30 minutes: 37/120 (30.8) OR 0.70 (95% CI 0.46 to 1.07) Neonatal trauma (n/total (%)) 0 - 15 minutes: 19/557 (3.4) > 15 minutes: 43/441 (9.8) OR 0.33 (95% CI 0.19 to 0.57) 0 - 30 minutes: 44/878 (5.0) > 30 minutes: 18/120 (15.0) OR 0.30 (95% CI 0.17 to 0.54) Perinatal death (n/total (%))** 0 - 15 minutes: 2/557 (0.4) > 15 minutes: 0/441 (0) 0 - 30 minutes: 2/878 (0.2) > 30 minutes: 0/120 (0)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	weeks gestation) Live singleton pregnancy in cephalic, vertex presentation Exclusion criteria None reported			[Note: - The first baby was delivered in a labour room by forceps for a fetal bradycardia due to vasa previa. The DDI was 3 minutes, but the bradycardia had first occurred in a peripheral midwifery unit resulting in a 55 minute transfer time. The baby had no cardiac output for 20 minutes, but was resuscitated and transferred to NICU. The baby then had multiorgan failure and died 2 days later. - The second baby had a DDI of 11 minutes. The baby was delivered by forceps in the operating room for bradycardia, and was declared stillborn following a lengthy resuscitation attempt.]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Severe neonatal morbidity (n/total (%))** 0 - 15 minutes: 1/557 (0.2) > 15 minutes: 0/441 (0) 0 - 30 minutes: 1/878 (0.1) > 30 minutes: 0/120 (0) [Note: The baby was born with a DDI of 3 minutes by lift out forceps in the labour room for a fetal bradycardia secondary to placental abruption. The baby was resuscitated and taken to NICU, where it developed severe hypoxic ischemic encephalopathy (HIE) and was diagnosed with cerebral palsy at follow-up.] ** The adverse events of mortality and severe	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				morbidity are discussed in the text. As the DDI are reported, the NCC-WCH were able to report the risks of the outcomes for each subgroup of DDI that is designated for the other outcomes. SUBGROUP ANALYSIS BY THOSE ATTEMPTED IN A LABOUR ROOM ONLY (n = 800) Note: data are only reported for a threshold of 15 minutes, not for a threshold of 30 minutes Third/fourth degree tear (n/total (%)) 0 - 15 minutes: 18/526 (3.4) > 15 minutes: 13/274 (4.7) OR 0.71 (95% CI 0.34 to 1.47)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Cord blood gas values (n/total (%)) a. pH umbilical artery < 7.10 0 - 15 minutes: 46/526 (8.7) > 15 minutes: 23/274 (8.4) OR 0.99 (95% CI 0.58 to 1.68) b. Base excess umbilical artery < -12.0 0 - 15 minutes: 53/526 (10.1) > 15 minutes: 28/274 (10.2) OR 0.93 (95% CI 0.57 to 1.52) Neonatal resuscitation (n/total (%)) 0 - 15 minutes: 128/526 (24.3) > 15 minutes: 56/274 (20.4) OR 1.25 (95% CI 0.88 to 1.78) Neonatal trauma (n/total	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(%)) 0 - 15 minutes: 16/526 (3.0) > 15 minutes: 20/274 (7.3) OR 0.40 (95% CI 0.20 to 0.78) Admission to NICU (n/total (%)) 0 - 15 minutes: 13/526 (2.5) > 15 minutes: 10/274 (3.6) OR 0.67 (95% CI 0.29 to 1.55)	
Full citation Okunwobi-Smith,Y., Cooke,I., MacKenzie,I.Z., Decision to delivery intervals for assisted vaginal vertex delivery, BJOG: An International Journal of Obstetrics and Gynaecology, 107, 467-471, 2000 Ref Id 239772 Country/ies where the study was carried out Not definitively stated authors are based in England and Ireland	Sample size N = 225 attempted operative vaginal deliveries Characteristics The following were reported according to type of vaginal delivery attempted Success and type of attempted vaginal	Interventions Decision to delivery interval	Details Setting The study was conducted in a large district teaching obstetric unit. Protocol for instrumental vaginal births The diagnosis of fetal distress was made using the judgement of the clinician managing the case, almost always using interpretation of the	Results Decision to delivery for each planned mode of birth/minutes (mean ± SD) Forceps: 29.9 ± 19.0 (n = 90) - Fetal distress: 23.3 ± 14.3 (n = 41) - No fetal distress: 40.7 ± 20.7 (n = 49) Ventouse: 35.4 ± 17.1 (n = 135)	Limitations Choice of treatment unrelated to confounders (selection bias): Delivery was achieved more rapidly in the case of fetal distress; the type of anaesthetic used also had an effect Groups comparable at baseline: See above - the DDI was affected by characteristics of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Prospective observational study Aim of the study To describe the time interval between the decision for assisted vaginal delivery and the birth of the baby in different clinical circumstances Study dates November 1st 1997 to February 1st 1998 Source of funding None reported	delivery (n/total) Forceps - Successful at first attempt: 87/90 - Caesarean section (CS): 2/90 - Repeat forceps success: 1/90 Ventouse - Successful at first attempt: 113/135 - CS: 5/135 - Forceps following failed attempt(s): 17/135 Gestation/weeks (mean ± SD) Forceps: 39.7 ± 1.7 Ventouse: 39.6 ± 1.7 Maternal age/years (mean ± SD) Forceps: 28.9 ± 5.5 Ventouse: 29.2 ± 5.3 Maternal height/cm (mean ± SD) Forceps: 165 ± 7		cardiotocograph. The primary indication for intervention was recorded as the more major one if there was more than one indication; distress was taken as the more major if it was identified. For the 134 cases with no fetal distress, the primary indication was delay in the second stage of labour (n = 125), maternal distress (n = 7), and for prophylaxis with a history of intracranial haemorrhage (n = 2). Generally, births were conducted by year 1-3 trainees or senior house officers (SHOs) under the supervision of more senior obstetricians. Rotational deliveries, other than those occurring with ventouse, were supervised or conducted by year 4-5	- Fetal distress: 29.2 ± 13.2 (n = 50) - No fetal distress: 39.1 ± 18.1 (n = 85) [Note: overall DDI for all deliveries was 34.4 ± 18.3 (range 5 to 101); for all those with fetal distress regardless of mode it was 26.5 ± 14.0; for all those without fetal distress regardless of mode it was 39.5 ± 19.0] Perineal trauma It is reported that the decision to delivery interval did not affect trauma rates; however no further details are given. Cord blood gas values, split by DDI and indication for expedited birth (mean [n in each category not reported]) a. Cord artery pH	the woman's labour Groups received same/similar care (apart from intervention): Yes Blinding of those assessing outcomes: Yes - the staff were unaware that a study was happening Missing data/loss to follow-up: 25 (11.1%) babies did not have cord blood gas values taken Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Unclear where data on cord blood gas values were collected from Intention-to-treat analysis performed: Not applicable - this was a study just reporting the association of different DDIs with outcomes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Ventouse: 163 ± 12 Maternal weight/kg (mean ± SD) Forceps: 68.1 ± 13.2 Ventouse: 66.3 ± 15.4 Length of first stage labour/minutes (mean ± SD) Forceps: 454 ± 287 Ventouse: 456 ± 248 Length of second stage of labour/minutes (mean ± SD) Forceps: 131 ± 74 Ventouse: 147 ± 63 Birthweight/grams (mean ± SD) Forceps: 3365 ± 522 Ventouse: 3482 ± 472 Inclusion criteria Operative vaginal deliveries of live, singleton pregnancies in vertex presentation		trainees or consultants. More experienced SHOs performed nonrotational forceps and ventouse deliveries without supervision if judged appropriate following discussion with their senior colleague. Data collection Staff engaged in clinical provision of the service were not aware of the study in advance or during the collection of data. The policy of the unit was that the timing of all decisions for operative birth (instrumental or CS) was recorded in the patient record, as well as the timing of birth. Statistical analysis Chi-squared test, Student's t-test and one way ANOVA were used to analyse data.	≤ 10 minutes - Distress: 7.20 - No distress: 7.23 11 - 20 minutes - Distress: 7.17 - No distress: 7.19 21 - 30 minutes - Distress: 7.20 - No distress: 7.23 31 - 40 minutes - Distress: 7.16 - No distress: 7.23 41 - 50 minutes - Distress: 7.13 - No distress: 7.21 51 - 60 minutes - Distress: 7.24 - No distress: 7.22 ≥ 61 minutes - Distress: 7.19 - No distress: 7.16 b. Cord artery base excess (nmol/litre)	Indirectness: Study was not restricted to low risk women Other information This study was included in the 2007 guideline

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Not reported		Outcomes reported - Mode of birth: reported for attempted instrumental vaginal births - Cord blood gas values: arterial pH and arterial base excess are reported - Perineal trauma - Admission to special care baby unit	≤ 10 minutes - Distress: -7.0 - No distress: -6.2 11 - 20 minutes - Distress: -8.7 - No distress: -5.5 21 - 30 minutes - Distress: -8.0 - No distress: -7.0 31 - 40 minutes - Distress: -8.9 - No distress: -6.3 41 - 50 minutes - Distress: -11.3 - No distress: -7.4 51 - 60 minutes - Distress: -5.1 - No distress: -5.5 ≥ 61 minutes - Distress: -7.2 - No distress: -7.0 [Note: the authors report that, in babies	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				with fetal distress, over the first hour the longer the DDI the more acidaemic the arterial values became although it did not reach statistical significance (p = 0.4). They report that there were too few births after 60 minutes to evaluate it further than that. For babies without fetal distress, the authors report that increasing acidaemia was not observed until the interval was greater than 60 minutes] Admission to special care baby unit 21 babies were initially admitted to the special care baby unit. 11 babies were delivered within 30 minutes of the decision, and 4 were delivered after at least 60 minutes. Unfortunately because	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				the number of births within each DDI category is not reported (there are missing data in the table) it is not possible to interpret these figures in a helpful way.	
Full citation Olagundoye,V., MacKenzie,I.Z., The impact of a trial of instrumental delivery in theatre on neonatal outcome, BJOG: An International Journal of Obstetrics and Gynaecology, 114, 603-608, 2007 Ref Id 239775 Country/ies where the study was carried out England Study type Prospective observational study Aim of the study To observe the effect of a trial of instrumental delivery in theatre on outcome for mother and baby	Sample size N = 229 Characteristics Mode of birth, split by initial instrument of choice (n/total (%)) Ventouse: 134/229 (58.5) - Successful initial attempt: 104 - Forceps following failed ventouse: 21 - Repeat ventouse: 2 - caesarean section (CS) following failed ventouse: 7 Forceps: 95/229 (41.5) - Successful initial	Interventions Decision to delivery interval	Details Setting No details given. Protocol for instrumental vaginal births Deliveries were managed by senior house officers or year 1-3 registrars, under the supervision of a senior obstetrician depending on experience. Rotational forceps were always supervised or managed by year 4-5 registrars or consultants. The indication for delivery was taken as that documented by the accoucheur. Fetal	Results Decision to delivery interval/minutes split by first choice of instrument and by indication (mean ± SD) a. All Forceps: 28.7 ± 21.5 (n = 95) Ventouse: 33.4 ± 22.3 (n = 134) [p = 0.11] b. Dystocia Straight forceps: 27.4 ± 19.4 - Median (1st - 3rd quartile): 22 (17 - 30) Ventouse: 38.0 ± 23.4 - Median (1st - 3rd quartile): 27 (20 - 52)	Limitations Choice of treatment unrelated to confounders (selection bias): Unclear - the different characteristics of the women were only reported for the comparison of ventouse and forceps, not the different DDI groups Groups comparable at baseline: Unclear - the different characteristics of the women were only reported for the comparison of ventouse and forceps, not the different DDI groups Groups received

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates 3 months from 1st June 2005 Source of funding None reported	attempt: 91 - Ventouse following failed forceps: 2 - CS following failed forceps: 2 Indication for expedited birth (n/total (%)) Fetal distress: 78/229 (34.1) Delay in second stage: 147/229 (64.2) Maternal distress: 4/229 (1.7) [Note: the authors report that their analysis later classified women as having fetal distress (n = 78) or dystocia (n = 151)] Characteristics according to first choice instrument a. Nulliparous (n/total) Forceps: 78/95 Ventouse: 105/134		distress was almost always diagnosed using interpretation of the cardiotocograph (CTG). Data collection Demographic data were recorded. The time at which the decision was made to expedite delivery was that documented on the first occasion that the recommendation was written in the contemporaneous clinical records. The DDI could be calculated accordingly from the time recorded for birth of the baby. Statistical analysis Results were analysed using Student's t-test, Fisher's exact test quoting odds ratios and 95% CI, Mann-Whitney U test and linear regression analyses.	Rotational forceps: 59.8 ± 25.1 - Median (1st - 3rd quartile): 57 (41 - 71) c. Fetal distress Straight forceps: 18.9 ± 12.2 - Median (1st - 3rd quartile): 17 (10 - 22) Ventouse: 24.2 ± 16.7 - Median (1st - 3rd quartile): 21 (14 - 27) Rotational forceps: 31.5 ± 14.5 - Median (1st - 3rd quartile): 34 (24 - 42) DDI (in minutes) split by whether delivery occurred in labour room or was a trial in theatre and split by indication where possible a. Mean ± SD Labour room: 21.2 ± 9.0 (n = 169) - Distress: 18.1 ± 8.1 (n = 64)	same/similar care (apart from intervention): Yes Blinding of those assessing outcomes: Apart from the authors, staff providing clinical care were not aware of the study during data collection Missing data/loss to follow-up: 49 (21.4%) of babies had cord blood gas values missing Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Not applicable - the study just reports the DDI for different modes of birth/outcomes Indirectness: Study was not restricted to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	b. Induction of labour (n/total) Forceps: 33/95 Ventouse: 47/134 c. Fetal distress as indication (n/total) Forceps: 33/95 Ventouse: 45/134 d. Maternal age/years (mean ± SD) Forceps: 29.8 ± 6.1 Ventouse: 31.7 ± 8.6 [p = 0.07] e. Gestation/weeks (mean ± SD) Forceps: 39.3 ± 1.7 Ventouse: 40.0 ± 1.1 [p = 0.0002] f. Length of first stage of labour/hours (mean ± SD) Forceps: 7.27 ± 4.09 Ventouse: 7.25 ± 4.21 [p = 0.9]		Outcomes reported - Mode of birth: DDI according to first choice of instrument - Cord blood gas values: correlation of DDI and pH and base excess is reported; also DDI for babies acidotic at birth, defined as cord arterial pH ≤ 7.10 and cord arterial base excess < -12 [Note: in the text, the definition is reported as > -12. However, this does not seem to be correct as a more extreme (i.e. more negative) base excess indicates acidaemia. This also does not match the paper that they reference for the definition.]	- Dystocia: 23.1 ± 9.0 (n = 105) Trial in theatre: 59.2 ± 20.4 (n = 60) - Distress: 44.1 ± 22.1 (n = 14) - Dystocia: 63.7 ± 18.1 (n = 46) b. Median (1st - 3rd quartile) Labour room: 20 (15 - 25) Trial in theatre: 58 (47 - 70) [p < 0.0001] c. Proportion delivered within 46 minutes (n/total (%)) Labour room: 168/169 (99.4) Trial in theatre: 15/60 (25.0) [Note: In the labour room group, 1 woman with a BMI of 30.1 delivered 60 minutes	low risk women although only singleton pregnancies in vertex presentation were included; 34.9% of women had induction of labour Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	g. Length of second stage of labour/hours (mean ± SD) Forceps: 2.11 ± 1.14 Ventouse: 2.21 ± 1.11 [p = 0.3] Inclusion criteria Consecutive instrumental vaginal vertex deliveries of live singleton pregnancies Exclusion criteria None reported			after a failed ventouse delivery of a baby weighing 3719 g in OP position.] Correlation of DDI (split into 10 minute intervals) with mean cord blood gas values a. pH r2 = 0.0222 n: 189 values b. Base excess r2 = 0.0611 n: 179 values Association of mean DDIs and mean cord blood gas values Babies with fetal distress delivered in labour room (n = 64): - DDI (mean ± SD): 18.1 ± 8.1 - Cord artery pH (mean ± SD): 7.20 ± 0.09 - Base excess (mean ± SD): -8.1 ± 3.4	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Babies with dystocia delivered in labour room (n = 105): - DDI (mean ± SD): 23.1 ± 9.0 - Cord artery pH (mean ± SD): 7.24 ± 0.08 - Base excess (mean ± SD): -6.5 ± 3.4 Babies with fetal distress delivered after a trial in theatre (n = 14): - DDI (mean ± SD): 44.1 ± 22.1 - Cord artery pH (mean ± SD): 7.18 ± 0.10 - Base excess (mean ± SD): -8.2 ± 4.0 Babies with dystocia delivered after a trial in theatre (n = 46): - DDI (mean ± SD): 63.7 ± 18.1 - Cord artery pH (mean ± SD): 7.22 ± 0.09 - Base excess (mean ± SD): -7.8 ± 3.5	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Proportion of babies acidotic at birth The authors report that 12 babies were acidotic at birth (all of which were delivered vaginally). They report that the DDI was < 15 minutes in 3 babies, 15-30 minutes in 7 babies, and longer than that in 2 babies (47 minutes and 60 minutes). Unfortunately, 49 babies had one or more of the cord blood gas values missing and therefore their data are not available (and it is not reported what DDI they had). The only data reported on the number of babies in DDI classification groups are the proportion of babies within 46 minutes and over 46 minutes (as	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				reported above). Therefore, the following denominators incorporate an unknown quantity of missing data (totalling to 49) across the two groups: Proportion of babies acidotic (n/total (%)) DDI ≤ 46 minutes (delivered within 46 minutes): 10/183 (5.5) DDI > 46 minutes: 2/46 (4.3) Admission to NICU It is reported that 7 babies were admitted to NICU but not what their DDIs were	

1.1.21 Is active management of the third stage of labour more effective than physiological management?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation de Groot,A.N., van,Roosmalen J., van Dongen,P.W., Borm,G.F., A placebo-controlled trial of oral ergometrine to reduce postpartum hemorrhage, Acta Obstetricia et Gynecologica Scandinavica, 75, 464-468, 1996 Ref Id 155644 Country/ies where the study was carried out The Netherlands Study type Randomised controlled trial Aim of the study To evaluate oral ergometrine compared with placebo for the third stage of labour Study dates	Sample size N = 367 (However, the population for the comparison of interest is N = 221) Characteristics Maternal age/years (mean±SD) Oxytocin: 30±4 Placebo: 30±4 The groups were also comparable in the proportion that were primiparous, the length of the 1st, 2nd and 3rd stages of labour, and the proportion of women having an episiotomy. Inclusion criteria Not developing exclusion criteria (no further details given) Exclusion criteria	Interventions Oxytocin (n = 78) Placebo (n = 143)	Details Note: The study was designed to be a trial of oral ergometrine vs. placebo, with a third arm receiving intramuscular oxytocin, representing the standard regimen. However, ergometrine alone is currently not a comparator of interest, and therefore, only data for the comparison of oxytocin and placebo (the latter representing physiological management) will be reported here. Randomisation Randomisation was performed in a 2:2:1 design. The hospital pharmacy supplied number boxes containing ergometrine, placebo tablets or 5 IU oxytocin according to a computer generated randomisation list. The contents of the boxes was concealed. Recruitment	Results Incidence of postpartum haemorrhage (number of women/total (%)) a. Blood loss ≥ 500 ml Oxytocin: 25/78 (32.1) Placebo: 55/143 (38.5) b. Blood loss ≥ 1000 ml Oxytocin: 7/78 (9.0) Placebo: 16/143 (11.2) Need for further intervention (number of women/total (%)) a. Further oxytocics Oxytocin: 14/78 (17.9) Placebo: 26/143 (18.2)	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes No information provided about timing of cord clamping.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
July 1993 to July 1994 Source of funding Not reported	Woman declined to participate Any cardiovascular disease (hypertension) Multiple pregnancies Non-cephalic presentation Polyhydramnios Tocolysis 2 hours prior to delivery Anticoagulant therapy Stillbirth Antepartum haemorrhage Chemical induction or augmentation (oxytocin, prostaglandins) Instrumental/operative birth Anaemia (Hb < 6.8) Former complication in the		Informed consent was sought early in labour; however, only women who did not develop exclusion criteria participated. 371 women were included, but 4 women with exclusion criteria (3 forceps extractions and 1 augmentation) were mistakenly randomised initially, and therefore were excluded from analysis. Treatment allocation was performed just before birth of the baby's head. Management of the third stage Tablets or injection were given immediately after birth. When the mother felt contractions or there were signs of separation, she was encouraged to deliver the placenta via maternal effort and adopt a position to aid gravity. A hand could be placed on the mother's abdomen to act as a brace. If the placenta did not deliver spontaneously,	b. Manual removal of the placenta Oxytocin: 1/78 (1.3) Placebo: 0/143 (0) c. Blood transfusion Oxytocin: 2/78 (2.6) Placebo: 3/143 (2.1) Birth weight/g (mean±SD) Oxytocin: 3534±410 Placebo: 3498±444	This trial was designed to be blinded for the comparison of ergometrine vs. placebo. It is not blinded for the comparison of oxytocin vs. placebo; however, there would have been no way for the participants or staff to figure out whether the comparison arm were receiving placebo or another active agent (ergometrine), therefore this may reduce the risk of bias resulting from changes in management as a result of lack of blinding. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	third stage		the staff waited. However, if haemorrhage occurred, additional oxytocics were given, or the placenta was removed by other means, such as controlled cord traction. Outcomes reported 1. Postpartum haemorrhage: Blood loss ≥ 500 and ≥ 1000 ml are reported. Blood loss was measured by placing a fresh perineal pad under the perineum to absorb the blood or fluid. All gauzes and pads were collected until 1 hour after delivery, and were weighed (a 100 gram increase in weight was considered to represent 100 ml). Attempts were made to minimise the blood not collected (i.e. on gowns or drapes); however, the authors state that there is likely to be a constant error of about 10%. 2. Need for further intervention: Use of further oxytocics was reported, as was the incidence		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			of manual removal and the need for a blood transfusion 3. Birth weight: This is reported as a characteristic of the population in the study; however, it will be reported as an outcome for the review		
Full citation Prendiville,W.J., Harding,J.E., Elbourne,D.R., Stirrat,G.M., The Bristol third stage trial: active versus physiological management of third stage of labour, BMJ, 297, 1295-1300, 1988 Ref Id 78375 Country/ies where the study was carried out UK Study type Randomised controlled trial	Sample size N = 1695 Characteristics Maternal age/years (mean (SD)) Active: 27.2 (5.1) Physiological: 27.4 (5.1) Primiparous (number/total (%)) Active: 409/846 (48.3) Physiological: 372/849 (43.8) Previous third stage problems (number/total (%))	Interventions Active management (n = 846) Physiological management (n = 849)	Details Recruitment and participants Women expected to give birth vaginally were recruited in the antenatal clinic. On admission to the labour ward, eligible women who agreed to participate were entered into the trial register. Correspondingly numbered, sealed opaque envelopes were placed in the women's notes. When the obstetrician or midwife was ready to prepare for birth, the envelope was opened and revealed treatment allocation. All women for whom the envelope was opened were considered to have entered the	Results Postpartum haemorrhage (number/total (%)) a. Blood loss ≥ 500 ml Active: 50/846 (5.9) Physiological: 152/849 (17.9) b. Blood loss ≥ 1000 ml Active: 7/846 (0.8) Physiological: 26/849 (3.1) Maternal haemoglobin	Limitations Appropriate randomisation: Method of randomisation not reported Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No, but not really possible Blinding of staff providing care: No, but not really possible Blinding of outcome assessors: No

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare the effects on fetal and maternal morbidity of routine active management of the third stage of labour and expectant (physiological) management, in particular to determine whether active management reduced incidence of postpartum haemorrhage Study dates January 1st 1986 to 31st January 1987 Source of funding South Western Regional Health Authority Maternity and Child Division at WHO, Geneva DHSS	Active: 38/437 (8.7) Physiological: 47/477 (9.9) Variables of labour (number/total (%)) a. Spontaneous onset Active: 717/846 (84.8) Physiological:731/849 (86.1) b. Oxytocic for induction or augmentation Active: 232/846 (27.4) Physiological: 205/849 (24.1) c. Number who had cord clamped before birth of baby Active: 115/846 (13.6) Physiological: 98/849 (11.5) d. Spontaneous birth Active: 722/846 (85.3) Physiological: 743/849 (87.5)		trial. Women who became ineligible after being entered into the register but before the envelope was opened were deemed not to have entered the trial, and their envelope was returned unopened to the trial coordinator. The criteria for exclusion was noted, and they were not analysed. Management protocol Active management: - One ampule of the oxytocic was given immediately after birth of the anterior shoulder. The oxytocic was routinely syntometrine (5 units oxytocin and 0.5 mg ergometrine maleate) but was 10 IU of synthetic oxytocin if the woman had raised blood pressure. - Cord clamping 30 seconds after birth of the baby - When the uterus contracted, deliver the placenta by controlled cord traction with a protective hand on the	in g/l* a. Haemoglobin (mean±SD) Active: 117±22 [n = 685] Physiological: 111±14 [n = 694] p ≤ 0.001 b. Number with haemoglobin ≤ 90 g/l at 24-48 hours postpartum (number/total (%)) Active: 27/685 (3.9) Physiological: 51/694 (7.3) c. Fall in haemoglobin from 34-37 weeks gestation (mean±SD) Active: 1±21 [n = 634] Physiological: 6±13 [n = 627] p ≤ 0.001	Missing data/loss to follow-up: Unexplained missing data for neonatal packed cell volume and for maternal haemoglobin. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Method of measuring blood loss is not reported Intention-to-treat analysis performed: Yes Indirectness: less than 50% of the women allocated to physiological management actually received full physiological management Trial was stopped early and therefore did not meet its intended sample size; however, the interim analysis was pre-specified.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Gestational age < 37 weeks (number/total (%)) Active: 21/846 (2.5) Physiological: 17/849 (2.0) There were also no significant differences in number married, number with haemoglobin < 90 g/l, number with low risk first and second stages, and numbers of males. Inclusion criteria Expected to give birth vaginally Exclusion criteria Woman declined to participate Cardiac disease Antepartum haemorrhage Breech presentation Multiple pregnancy		abdomen helping to shear off the placenta and prevent uterine inversion - No special instructions about posture Special circumstances: If the placenta was retained after one hour, the protocol was to ensure that the bladder was emptied, reattempt delivery by active management, then remove placenta manually under general anaesthesia or epidural block. Physiological management: - No oxytocic - Leave the cord attached to the baby until the placenta is delivered - No CCT or any manual interference with the uterus at the fundus - Encourage the mother to feel for the next contraction or urge to push - At the point of contraction or if there are signs of separation, encourage the woman to adopt	* this was converted by the technical team into g/dl for use in the meta-analysis, for consistency with the other studies Need for further intervention (number/total (%)) a. Blood transfusion Active: 18/846 (2.1) Physiological: 48/849 (5.7) b. Therapeutic oxytocics Active: 54/846 (6.4) Physiological: 252/849 (29.7) c. Manual removal of the placenta Active: 16/846 (1.9) Physiological: 22/849	The trial does not specify that uterotonic was given intramuscularly (IM); however, as it was syntometrine and at the birth of the anterior shoulder, it has been assumed to be IM. Other information Actual management of the third stage among those allocated to each arm (number/total (%)) Active Management actually as allocated: 840/846 (99.3) Prophylactic oxytocic given: 838/846 (99.1) Cord clamped before placental delivery: 838/846 (99.1) Cord traction: 839/846 (99.2) Mother adopted position to aid gravity: 217/846 (25.7)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Intrauterine death The following were added after an interim analysis: - Ritodrine given within 2 hours before birth - Anticoagulant treatment given - Any condition known before the opening of the envelope that would necessitate a particular management of the third stage		a position aiding gravity Special circumstances: - If the placenta does not deliver spontaneously, wait, put the baby to the breast and encourage maternal effort - If the cord had to be clamped and cut before placental delivery (e.g. meconium stained liquor, cord around the neck), blood was released from the placental end into a kidney dish - In the case of a forceps birth, episiotomies were repaired first and then the third stage was managed physiologically - If an epidural was necessary, the midwife rested a hand on the fundus but did not intervene - If the placenta was retained after an hour: the bladder was emptied, physiological delivery was reattempted with gentle fundal pressure; active management of the third stage; manual removal under general anaesthetic or epidural block.	(2.6) d. Subsequent evacuation of retained products of conception Active: 11/846 (1.3) Physiological: 16/849 (1.9) Maternal side effects (number/total (%)) a. Vomiting Active: 102/846 (12.1) Physiological: 55/849 (6.5) b. Headache Active: 13/846 (1.5) Physiological: 8/849 (0.9) c. Diastolic pressure > 100 mm Hg in labour ward	Physiological: Management actually as allocated: 403/849 (47.5) Prophylactic oxytocic given: 168/849 (19.8) Cord clamped before placental delivery: 437/849 (51.5) Cord traction: 336/849 (39.6) Mother adopted position to aid gravity: 416/849 (49.0) The reasons for the discrepancy between allocation and actual management in the physiological arm were: heavy bleeding (n = 95), cord cut before baby delivered (n = 94), meconium (n = 68), resuscitation of the baby (n = 59), placenta not delivered after one hour (n = 57), late maternal decline

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Data collection and analysis A sample size calculation based on a reduction in PPH (≥ 500 ml) from 7.5% with physiological management to 5% with active management found that a sample size of 3900 would give an 80% chance of detecting the difference at p ≤ 0.05. An independent data monitoring committee was set up, and an interim analysis after roughly 1500 women was planned. Data on outcomes, the trial population and actual management were available from the computerised data collection system. Files were analysed in a separate unit. Information on the need for subsequent surgical evacuation was obtained from the local hospital. Continuous data were analysed with the t-test, categorical data	Active: 17/846 (2.0) Physiological: 8/849 (0.9) Apgar score ≤ 6 at 5 minutes Active: 8/846 (0.9) Physiological: 8/849 (0.9) Birth weight/grams (mean±SD) Active: 3337±451 Physiological: 3422±444 (p ≤ 0.001) Neonatal packed cell volume (number/total (%)) a. Packed cell volume < 0.50	of treatment allocation (n = 30), and reason not given (n = 15). In the active group there were one woman who declined treatment allocation at a late stage, three other reasons (not reported) and two women without a reason given.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			with chi-squared with Yates's correction, and other outcomes with odds ratios. Interim analyses Due to high rates of PPH in the physiological arm, there was a meeting of the data monitoring committee after 425 deliveries. The incidence of PPH was found to be significantly higher in the physiological arm, but a disproportionate number among women who had been allocated to physiological management but for whom it had not been possible, for example those who had to have early cord clamping and cutting due to it being around the baby's neck, worries about MAS or the poor condition of the baby at birth. Early breast feeding was reported for only a small proportion of the group. The committee then recommended that there was	Active: 19/127 (15.0) Physiological: 11/166 (6.6) b. Packed cell volume > 0.65 Active: 15/127 (11.8) Physiological: 64/166 (38.6) Neonatal admission (number/total (%)) a. Admitted to special care nursery Active: 48/846 (5.7) Physiological: 64/849 (7.5) b. Admitted for respiratory problems Active: 14/846 (1.7) Physiological: 15/849 (1.8)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			sufficient evidence to adapt the trial protocol and add new exclusion criteria (see above). Also, if a woman had been allocated to physiological but there was an obvious need to interrupt this (i.e. condition of the baby indicating early clamping) the management became active. The data committee met three later times, and recommended that the trial be stopped early. Outcomes reported 1. Postpartum haemorrhage: blood loss ≥ 500 ml or ≥ 1000 ml 2. Maternal haemoglobin: mean, mean fall from 34-37 weeks gestation, and number with haemoglobin ≤ 90 g/l at 24-48 hours postpartum 3. Need for further intervention: blood transfusion, therapeutic oxytocic, manual removal,	Jaundice (bilirubin > 428 micromoles / litre) Active: 39/846 (4.6) Physiological: 54/849 (6.4) Breastfeeding (number/total (%)) a. Baby put to breast within 10 minutes Active: 63/846 (7.4) Physiological: 225/849 (26.5) (note: this was part of the trial protocol for physiological management, and therefore will not be reported as an outcome in the GRADE table) b. At discharge	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			subsequent evacuation of retained products of conception 4. Side effects: vomiting, headaches, diastolic pressure > 100 mm Hg in labour ward 5. Apgar score ≤ 6 at 5 minutes 6. Birth weight 7. Packed cell volume: number with < 0.50 and > 0.65 8. Admission to special care nursery 9. Jaundice: defined as bilirubin > 428 micromoles/litres 10. Breastfeeding: number put to breast within 10 minutes, breastfeeding at discharge	Active: 637/846 (75.3) Physiological: 632/849 (74.4) Secondary analysis The authors reported doing a pre-specified sub-group analysis by whether the women had a low risk first and second stage. The stages were defined as low risk if there was spontaneous onset of labour, augmentation and epidural not necessary, labour lasted < 12 hours, and birth was spontaneous. They reported that: - the incidence of adverse events was lower overall in low risk women - the direction of the effect (i.e. favouring	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				active management) was the same, but tended to be greater in the low risk women	
Full citation Rogers,J., Wood,J., McCandlish,R., Ayers,S., Truesdale,A., Elbourne,D., Active versus expectant management of third stage of labour: the Hinchingbrooke randomised controlled trial, Lancet, 351, 693-699, 1998 Ref Id 156392 Country/ies where the study was carried out UK Study type Randomised controlled trial	Sample size N = 1512 Characteristics Maternal age/years (mean (SD)) Active: 28.7 (4.9) Expectant: 28.5 (4.4) Primiparous (n (%)) Active: 295 (39.4) Expectant: 280 (36.6) Gestational age < 37 weeks (n (%)) Active: 23 (3.1) Expectant: 15 (2.0)	Interventions Active management (n = 748) Expectant management (n = 764)	Details Prior to the trial beginning, midwives were surveyed to assess their confidence in using each method of third stage management. Those who identified themselves as needing further training in either method were assisted by experienced midwives who remained present until completion of the third stage. Meetings were also held to prepare staff. Recruitment and randomisation Between 24 and 32 weeks gestation, women were invited to join the trial through a letter distributed by a community	Results Postpartum haemorrhage (n/total (%)) a. Blood loss 500 - 999 ml Active: 38/748 (5.1) Expectant: 106/764 (13.9) b. Blood loss ≥ 1000 ml Active: 13/748 (1.7) Expectant: 20/764 (2.6) Maternal haemoglobin	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No Missing data/loss to follow-up: Missing data for admission to SCBU and jaundice (4.3% of women lost to follow up).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare the effects of active and expectant management of the third stage of labour on maternal and neonatal morbidity Study dates June 1993 to December 1995 Source of funding Grant from the Public Health and Operational Research Committee of the Anglia and Oxford Regional Health Authority Department of Health	Birth position (n (%)) a. Spontaneous vaginal Active: 746 (99.7) Expectant: 74 (98.7) b. Upright position Active: 202 (27.0) Expectant: 230 (30.1) c. In water Active: 11 (1.5) Expectant: 13 (1.7) Perineal tear requiring sutures (n (%)) a. None Active: 311 (41.6) Expectant: 324 (42.4) b. Sutured tear Active: 345 (46.1) Expectant: 351 (45.9)		midwife. Consent was obtained at a later antenatal visit. When women were admitted in established labour, consent and eligibility were confirmed, and, if appropriate, any women who had not previously been contacted were invited to join the study. During the trial, 6446 women gave birth at the hospital of which 976 declined to participate and 3958 were not eligible. 1512 women were randomised into the trial. Randomisation was using variably sized balanced blocks prepared in advance at the NPEU. Allocation was by choosing the next, sequentially number opaque sealed envelope containing details of treatment allocation. Entry to the trial occurred when the envelope was opened, at the point at which the midwife anticipated a normal, uncomplicated birth. Clinicians were instructed to carry out allocated management unless	(g/dl) a. Haemoglobin on the second postpartum day (mean (SE)) Active: 11.2 (0.04) [n = 702] Expectant: 10.7 (0.05) [n = 718] b. Haemoglobin change from 32 weeks (mean (SE)) Active: 0.9 (0.05) [n = 659] Expectant: -0.4 (0.06) [n = 677] c. Women with haemoglobin ≤ 10 g/dl (n/total (%)) Active: 107/702 (15.2) Expectant: 204/718 (28.4)	There is also missing data for change in haemoglobin (12%) and postpartum haemoglobin (6%). Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Blood loss was estimated Intention-to-treat analysis performed: Yes Indirectness: only 64% of women allocated to physiological management had full physiological management; dose/route of uterotonic is not reported Other information Actual third stage management received (n (%)) Active

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	c. Episiotomy Active: 92 (12.3) Expectant: 89 (11.6) The groups were also similar in: mean haemoglobin at 32 weeks, known history of depression, rhesus negative, expectation of good support at home, median duration of first and second stage of labour, % intending to breastfeed. Inclusion criteria Pregnant women expecting to give birth at Hinchingbrooke Hospital Low risk of haemorrhage Exclusion criteria Placenta praevia Previous PPH Antepartum haemorrhage after 20 weeks gestation		there was good reason to deviate. Management protocol Women were randomised to receive one of the following: - active management with supine posture - active management with upright posture - expectant management with supine posture - expectant management with upright posture Active management was defined as: - administration of prophylactic uterotonic (oxytocin+ergometrine or oxytocin) as soon as possible after birth of the anterior shoulder (within 2 minutes of birth) - immediate cord clamping and cutting - delivery of the placenta by controlled cord traction or maternal effort	Need for further intervention (n/total (%)) a. Therapeutic oxytocic ≥ 2 minutes after birth of baby Active: 24/748 (3.2) Expectant: 161/764 (21.1) b. Manual removal of the placenta Active: 15/748 (2.0) Expectant: 13/764 (1.7) c. Blood transfusion Active: 4/748 (0.5) Expectant: 20/764 (2.6) d. Evacuation of retained products of conception Active: 9/748 (1.2)	Full active management: 699/748 (93.4) Full expectant: 2/748 (0.3) Mixture: 47/748 (6.2) Oxytocic < 2 minutes after birth: 707/748 (94.5) - Oxytocin: 146/748 (19.5) - Oxytocin + ergometrine: 561/748 (75.0) Clamping before placental delivery: 748/748 (100) Clamping and cutting before pulsation stopped: 699/748 (93.4) CCT at any time: 347/748 (46.4) Primary reason why allocated management was not fully achieved (n): - ineligible after envelope opened: 1

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Anaemia (haemoglobin < 10 g/dl or mean corpuscular volume < 75 fl) Non-cephalic presentation Multiple pregnancy Intrauterine death Epidural anaesthesia Parity > 5 Uterine fibroid Oxytocin infusion Anticoagulation therapy Intended instrumental/operative birth Duration of gestation less than 32 weeks Any other circumstances deemed by the clinical to be overwhelming		Expectant management was defined as: - no use of uterotonic drugs - no clamping of the cord until pulsations had ceased - delivery of the placenta within 1 hour by maternal effort If care was not as allocated, the reason was recorded by the midwife on the data sheet. Data collection and analysis Questionnaires were used for data collection: - One was completed by the midwife present at the birth, with details of labour and postnatal events before transfer to the postnatal ward - One was completed by the midwife who discharged the woman home, and detailed events since birth - Women answered a questionnaire prior to discharge, regarding her experience	Expectant: 6/764 (0.8) e. Readmitted for bleeding problems Active: 12/748 (1.7) Expectant: 5/764 (0.7) Maternal side effects (n/total (%)) a. Systolic blood pressure > 160 mmHg Active: 8/748 (1.1) Expectant: 3/764 (0.4) b. Diastolic blood pressure > 100 mmHg Active: 6/748 (0.8) Expectant: 1/764 (0.1) c. Nausea Active: 86/748 (11.5) Expectant: 45/764 (5.9)	- mother's or midwife's request, or mothers' tiredness or distress: 11 - baby's health: 9 - other: 8 - no reason given: 20 Expectant Full expectant: 488/764 (63.9) Full active management: 19/764 (2.5) Mixture: 257/764 (33.6) Oxytocic < 2 minutes after birth: 19/764 (2.5) - Oxytocin: 5/764 (0.7) - Oxytocin + ergometrine: 14/764 (1.8) Clamping before placental delivery: 556/764 (72.8) Clamping and cutting before pulsation stopped: 226/764 (29.6) CCT at any time: 92/764 (12.0)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	contraindications to any of the management		- 6 weeks after birth a questionnaire was sent to the woman asking about emotional and psychological well-being, with a follow-up letter if there was no response after 3 weeks and then a telephone call if there was no response 2 weeks after that. Additional information on characteristics and postnatal outcomes were collected from case notes by investigators. Sample size calculations estimated that 2000 women would be needed to have a 90% chance of detecting a reduction in PPH from 10% to 6% with 5% significance. Data analysis was carried out at the NPEU based on an intention-to-treat analysis, with pre-specified sub-group analysis by posture and initial confidence of midwives with expectant management. Two-sided t-tests and median tests were used for continuous data, and chi-	d. Vomiting Active: 47/748 (6.3) Expectant: 17/764 (2.2) e. Headache Active: 5/748 (0.7) Expectant: 3/764 (0.4) Birth weight/grams (mean (SE)) Active: 3454 (17) Expectant: 3521 (17) Phototherapy for jaundice (number/total (%)) Active: 32/716 (4.5) Expectant: 25/731 (3.4) Admission to SCBU (number/total (%))	Primary reason why allocated management was not fully achieved (n): - ineligible after envelope opened: 15 - instructions followed by oxytocic given after 1 hour: 16 - therapeutic uterotonic because of bleeding: 38 - mother's or midwife's request, or mothers' tiredness or distress: 34 - baby's health: 115 - other: 17 - no reason given: 41 Confidence of midwives with each mode of management Active management (%): - Very confident: 84 - Fairly confident: 15 - Not very confident: 1 Expectant management

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			squared for categorical data. Outcomes reported 1. Postpartum haemorrhage: defined as blood loss ≥ 500 ml or ≥ 1000 ml, as estimated by the attending midwife 2. Maternal haemoglobin: measurement taken on the second postpartum day 3. Need for further intervention: blood transfusion, manual removal, evacuation of retained products of conception 4. Side effects: nausea, vomiting, headache and hypertension (diastolic > 100 mmHg or systolic > 160 mmHg) 5. Birth weight 6. Jaundice: reported as the need for phototherapy for jaundice, as reported by the	Active: 20/716 (2.7) Expectant: 20/731 (2.6) Breastfeeding (number/total (%)) a. Baby put to breast within 10 minutes of birth Active: 13/748 (1.7) Expectant: 61/764 (8.0) b. Baby put to breast 10 - 120 minutes after birth Active: 474/748 (63.4) Expectant: 436/764 (57.1) c. At discharge - Fully Active: 546/748 (73.0) Expectant: 531/764	(%): - Very confident: 41 - Fairly confident: 37 - Not very or not at all confident: 22 Full compliance with allocated management was similar regardless of initial confidence. Standard errors were reported by the authors. These were converted to standard deviations by the technical team for use in the meta-analysis

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			mother 7. Admission to SCBU: as reported by the mother 8. Breastfeeding 9. Women's satisfaction and experience: after third stage, and at 6 weeks postpartum	(69.5) - Partially Active: 8/748 (1.1) Expectant: 11/764 (1.4) d. At 6 weeks - Fully Active: 265/748 (37.0) Expectant: 272/764 (37.2) - Partially Active: 142/748 (19.8) Expectant: 120/764 (16.4) [Note: the baby was put to breast within 10 minutes of birth in 1.7% of active arm and 8.0% of expectant arm. The baby was put to breast within 10-120 minutes of birth in 63.4% of active arm and 57.1% of expectant arm]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Women's perceptions and experiences (number/total (%)) a. Satisfied with third stage management Active: 721/745 (96.8) Expectant: 718/762 (94.2) b. Felt in control during third stage Active: 621/745 (83.4) Expectant: 667/762 (87.5) General health at 6 weeks postpartum (number/total (%)) a. Worse than pregnancy Active: 64/716 (8.9) Expectant: 66/731 (9.0)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				b. Blues Active: 313/716 (43.7) Expectant: 343/731 (46.9) c. Depressed Active: 55/716 (7.7) Expectant: 46/731 (6.3) d. Help for depression Active: 107/716 (14.9) Expectant: 104/731 (14.2) (Note: 1 women in the active arm was admitted to hospital for depression) e. No health problems, as reported at 6 weeks Active: 529/716 (73.9) Expectant: 566/731	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(77.4) The outcomes at 6 weeks were not significantly different in the two arms.	
Full citation Thilaganathan,B., Cutner,A., Latimer,J., Beard,R., Management of the third stage of labour in women at low risk of postpartum haemorrhage, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 48, 19-22, 1993 Ref Id 156421 Country/ies where the study was carried out UK Study type Randomised controlled trial	Sample size N = 193 Characteristics The authors report that there were no significant differences between the two groups in terms of maternal age, birth weight or parity, but no further details are given. Inclusion criteria Pregnant women attending the antenatal clinic at 36 weeks gestation were considered eligible. They were randomised if they consented and then presented in labour at 37-42 weeks gestation in spontaneous labour.	Interventions Active management (n = 103) Physiological management (n = 90)	Details Recruitment and randomisation Pregnant women attending the antenatal clinic at 36 weeks gestation and without any exclusion criteria were considered eligible and approached for written informed consent. Previously consenting women presenting in spontaneous labour at 37-42 weeks were randomly allocated using standard randomisation tables. The midwife responsible for managing the patient was not aware of the allocation until her patient was entered into the study. Management protocol	Results Retained placenta (number/total (%)) Active: 1/103 (0.97) Physiological: 0/90 (0) Need for further intervention (number/total (%)) a. Manual removal Active: 1/103 (0.97) Physiological: 0/90 (0) b. Blood transfusion Active: 1/103 (0.97) Physiological: 0/90 (0)	Limitations Appropriate randomisation: Yes, randomised using tables Allocation concealment: Unclear Groups comparable at baseline: Unclear, very few details are given. Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No Missing data/loss to follow-up: rates of PPH not reported, despite saying that in the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare active management with physiological management of the third stage of labour in women at low risk of postpartum haemorrhage Study dates January 1988 to February 1990 Source of funding None stated	Exclusion criteria Grand multiparity Malpresentation Multiple pregnancy Previous caesarean section or postpartum haemorrhage Pregnancy induced hypertension Intrauterine death Augmentation of labour Instrumental or operative delivery Third degree tears Cervical lacerations		Active management: - 1 ml of syntometrine was injected as soon as the baby delivered - Cord was immediately clamped - Placenta was delivered with controlled cord traction Physiological management: - Cord was not cut or clamped until pulsations ceased. If the maternal end has to be clamped for any reason (e.g. cord was around the neck tightly), the clamp was removed from the maternal end as soon as possible to allow drainage. - Upon signs of placental separation, the mother was encouraged to adopt and erect position and bear down. When the placenta was in the vagina, the midwife could assist delivery In the case of a delay in delivery of the placenta beyond 30 minutes, the bladder was	c. Further oxytocics Active: 1/103 (0.97) Physiological: 7/90 (7.8) Maternal haemoglobin a. Postpartum haemoglobin in g/dl (median [IQR]) Active: 11.7 (10.9 - 12.6) Physiological: 11.7 (10.7 - 12.6) p = 0.41 b. Fall in haemoglobin in g/dl (median [IQR]) Active: 0.5 (-0.1- 1.2) Physiological: 0.7 (-0.3 - 1.4) p > 0.5 c. Number with postpartum haemoglobin ≥ 9 g/dl	physiological group, 7 women received oxytocics for presumed PPH. Also, not reported how many people were initially randomised, and why the arms are so uneven. Precise definition of outcomes: Definition of retained placenta is not clear. Also, it is not clear what time interval the fall in haemoglobin is being reported in. Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Unclear - not reported how many women received their allocated intervention Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			emptied and medical assistance summoned. If the delivery was not considered imminent, a manual removal was done. In the case of excessive blood loss at any stage, medical assistance was sought and PPH was managed in the standard way. Outcomes reported 1. Retained placenta: definition is not clear, as they report that at 30 minutes assistance was sought; however, 14 women had a third stage > 30 minutes but only 1 retained placenta is reported. 2. Need for further intervention: manual removal, blood transfusion, further oxytocics 3. Haemoglobin: reported as mean postpartum (measured on the third day postpartum), fall in haemoglobin, and number with Hb ≥ 9 g/dl	(number/total (%)) Active: 102/103 (99.0) Physiological: 85/90 (94.4) p = 0.16	

1.1.22 Does early cord clamping in active management of the third stage of labour improve maternal and neonatal outcomes compared to late or delayed cord clamping?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation McDonald,Susan J., Middleton,Philippa, Effect of timing of umbilical cord clamping of term infants on maternal and neonatal outcomes, Cochrane Database of Systematic Reviews, , -, 2013 Ref Id 66839 Country/ies where the study was carried out Various Study type Systematic review of RCTs Aim of the study To determine the maternal and neonatal	Sample size N = 3911 mothers and their babies (from 15 trials) Characteristics Al-Tawil 2012 Definition of early cord clamping: Within first 30 seconds of birth Definition of late cord clamping: 3 minutes after birth Oxytocic: Administration of uterotonic not clear The level baby held prior to cord clamping: Baby place on mother's abdomen until placenta was delivered Anderson 2011 Definition of early cord clamping: At or	Interventions Early cord clamping Late cord clamping	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by contacting the Trials Search Co-ordinator. CENTRAL, MEDLINE were searched, and hand searching of 30 journals and conference proceedings was done. No language restrictions were applied. Selection of studies At least two review authors independently assessed the full text of all potential studies for inclusion and methodological quality. Data extraction and management Two authors extracted the data	Results 1. PPH/blood loss 500 ml or more Studies: 4 n= 2260 RR 1.17 (0.94 to 1.44) p = 0.93 1.1 uterotonic before clamping Studies: 2 n = 1032 RR 1.11 (0.74 to 1.67) p = 0.60 1.2 uterotonic at, or after, clamping Studies: 3 n = 956 RR 1.22 (0.90 to 1.65) p = 0.20 1.3 use of uterotonic not specified Studies: 1 n = 272	Limitations No serious limitations Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
effects of different policies for the timing of cord clamping in the third stage of labour. Study dates Assessed as up-to-date: 14 March 2013 Source of funding Discipline of Obstetrics and Gynaecology, The University of Adelaide, Australia and Department of Health and Ageing, Australia.	before10 seconds of birth Definition of late cord clamping: 3 minutes after birth Oxytocic: IV Oxytocin 10 IU given immediately after the cord clamping The level baby held prior to cord clamping:Baby were hold 20 cm below the vulva for 30 secs and then place on mother's abdomen Jahazi 2008 Definition of early cord clamping: 30 seconds of birth Definition of late cord clamping: 3 minutes after birth Oxytocic: IM Oxytocin 10 IU given immediately after the cord clamping The level baby held prior to cord clamping:Baby were hold supine at the level of introitus Philip 1973 Definition of early cord clamping: At or before		separately and double checked it for discrepancies. Statistical analysis was done using RevMan. Where information was unclear, the reviewers attempted to contact the original authors. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Selection bias - Allocation concealment - Blinding - Incomplete outcome data - Sequence generation - Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, weighted mean difference were used. Fixed-effect analysis was performed in the absence of	RR 1.13 (0.73 to 1.74) p = 0.58 2. Severe PPH/blood loss 1000 ml or more Studies: 5 n = 2066 RR 1.04 (0.65 to 1.65) p = 0.91 2.1 uterotonic before clamping Studies: 1 n = 480 RR 1.16 (0.46 to 2.96) p = 0.75 2.2 uterotonic at, or after, clamping Studies: 3 n = 956 RR 1.06 (0.57 to 1.95) p = 0.86 2.3 use of uterotonic not specified Studies: 2 n = 630 RR 0.85 (0.29 to 2.49) p = 0.76 3 Mean blood loss	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	5 seconds of birth (never >15 sec) Definition of late cord clamping: > 10 secs after birth Oxytocic: Administration of uterotonic not clear The level baby held prior to cord clamping:Baby were hold 15 cm below the perineum Cernadas 2006 Definition of early cord clamping: Within first 15 seconds of birth Definition of late cord clamping: 1 to 3 minutes after birth Oxytocic: Interpret as no oxytocic? The level baby held prior to cord clamping: The infant was placed in the mother's arm while awaiting cord clamping. If a caesarean birth, the infant was placed on the mother's lap while awaiting cord clamping		significant heterogeneity. In the presence of heterogeneity sensitivity analysis followed by random effects analysis was performed. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis, with the denominator being set as the number randomised minus any participants whose outcomes were known to be missing. Analysis If high levels of heterogeneity (> 50%) were identified, pre-specified sensitivity analysis was done according to the quality of the trials. Subgroup analyses performed: 1. whether uterotonics were used as part of the third stage management 2. whether the infant was held above or below the abdomen	(ml) Studies: 2 n = 1345 Mean Difference 5.11 (-23.18 to 33.36) p = 0.55 3.1 uterotonic before clamping Studies: 1 n = 480 Mean Difference 22.01 (-40.16 to 84.16) p = 0.49 3.2 uterotonic at, or after, clamping Studies: 2 n = 865 Mean Difference 0.70 (-31.06 to 32.46) p = 0.97 4 Maternal haemoglobin (g/dl) 24 to 72 hours postpartum Studies: 3 n = 1128 Mean Difference -0.12 (-0.30 to 0.06)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Chaparro 2006 Definition of early cord clamping: 10 seconds of birth Definition of late cord clamping: 2 minutes after birth Oxytocic: NR What level baby held prior to cord clamping: Baby were hold at the level of perinum (data extracted from the original paper) Emhamed 2004 Definition of early cord clamping: 10 seconds of birth Definition of late cord clamping: When cord pulsation ceased Oxytocic: Given after cord clamped The level baby held prior to cord clamping: The infant was placed on the mother's abdomen (data extracted from the		prior to cord clamping 3. the extent of control for selection bias.	p = 0.19 4.1 uterotonic before clamping Studies: 1 n = 480 Mean Difference: Not estimable p = 1.0 4.2 uterotonic at, or after, clamping Studies: 1 n = 483 Mean Difference -0.10 [-0.42 to 0.22] p = 0.54 4.3 use of uterotonic not specified Studies: 2 n = 165 Mean Difference -0.28 (-0.60 to 0.04) p = 0.089 5 Need for blood transfusion Studies: 2 n = 1345 RR 1.02 (0.44 to 2.37) p = 0.59	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	original paper) Geethanath 1997 Definition of early cord clamping: As soon as infant was born Definition of late cord clamping: After placenta descended into the vagina Oxytocic: NR The level baby held prior to cord clamping: Held 10 cm below the vaginal introitus Gupta 2002 Definition of early cord clamping: As soon as infant was born Definition of late cord clamping: After placenta descended into the vagina Oxytocic: NR The level baby held prior to cord clamping: Held 10 cm below the vaginal introitus			5.1 uterotonic before clamping Studies: 1 n = 480 RR 1.55 (0.26 to 9.20) p = 0.63 5.2 uterotonic at, or after, clamping Studies: 2 n = 865 RR 0.89 (0.34 to 2.35) p = 0.82 6 Need for manual removal of placenta Studies: 2 n = 1515 RR 1.59 (0.78 to 3.26) p = 0.20 6.1 uterotonic before clamping Studies: 2 n = 1032 RR 2.17 (0.94 to 5.01) p = 0.06 6.2 uterotonic at, or after, clamping Studies: 1 n = 483	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	McDonald 1996 Definition of early cord clamping: As soon as infant was born Definition of late cord clamping: When cord pulsation ceased or 5 minutes if pulsation has not already ceased Oxytocic: Early uterotonic administration was at the time of birth of the anterior shoulder of the baby; late uterotonic administration was after the birth of the baby (literally) and if the cord clamping allocation was early, then it was allocated to be after the cord was clamped (i.e. not within 30 seconds). The level baby held prior to cord clamping: NR Oxford midwives 1991 Definition of early cord clamping: As soon as infant was born			RR 0.49 (0.09 to 2.65) p = 0.41 7 Length of third stage > 30 minutes Studies: 2 n = 1345 RR 1.18 (0.55 to 2.52) p = 0.36 7.1 uterotonic before clamping Studies: 1 n = 480 RR 3.10 (0.32 to 29.61) p = 0.33 7.2 uterotonic at, or after, clamping Studies: 2 n = 865 RR 1.01 (0.44 to 2.29) p = 0.32 8 Length of third stage > 60 minutes Studies: 2 n = 865 RR 1.11 (0.33 to 3.74) p = 0.95	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Definition of late cord clamping: 3 minutes after birth Oxytocic: NR The level baby held prior to cord clamping: NR Saigal 1972 Definition of early cord clamping: Within 5 seconds of birth Definition of late cord clamping: 1 minute after birth Oxytocic: Given after cord clamped The level baby held prior to cord clamping: Held 30 cm below the perineum Spears 1966 Definition of early cord clamping: Within 20 minute of birth (60% were clamped within 30 secs) Definition of late cord clamping: 3 minutes after birth			8.1 uterotonic before clamping Studies: 1 n = 480 RR 1.03 (0.34 to 3.16) p = 0.95 8.2 uterotonic at, or after clamping Studies: 2 n = 865 RR 1.68 (0.09 to31.66) p = 0.73 9 Need for therapeutic uterotonics Studies: 1 n = 963 RR 0.94 (0.74 to 1.20) p = 0.62 9.1 uterotonic before clamping Studies: 1 n = 480 RR 1.10 (0.78 to 1.55) p = 0.60 9.2 uterotonic at, or after, clamping	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Oxytocic: NR The level baby held prior to cord clamping: Held level with mother's perineum Van Rheenen 2007 Definition of early cord clamping: Within 20 seconds of birth Definition of late cord clamping: When cord pulsation ceased Oxytocic: Given after cord clamped The level baby held prior to cord clamping: Held 10 cm below the vaginal introitus Nelson 1980 Definition of early cord clamping: Within 1 minute of birth Definition of late cord clamping: When cord pulsation ceased Oxytocic: Given after cord clamped			Studies: 1 n = 483 RR 0.81 (0.58 to 1.14) p = 0.22 10 Maternal ferritin (microgams/l) Studies: 1 n = 107 Mean Difference 9.10 (7.86 to 10.34) p < 0.00001 10.1 use of uterotonic not specified Studies: 1 n = 107 Mean Difference 9.10 (7.86 to 10.34) p < 0.00001 11 Apgar score < 7 at 5 min Studies: 3 n = 1399 RR 1.23 (0.73 to 2.07) p = 0.43 11.1 uterotonic before clamping Studies: 1 n = 480	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	The level baby held prior to cord clamping: The infant was placed on the mother's abdomen (data extracted from the original paper) Inclusion criteria Randomised trials comparing different strategies for the timing of umbilical cord clamping of term infants during the third stage of labour. Exclusion criteria Quasi-randomised studies were excluded			RR 1.72 (0.42 to 7.13) p = 0.45 11.2 uterotonic at, or after, clamping Studies: 2 n = 540 RR 1.96 (0.60 to 6.42) p = 0.27 11.3 use of uterotonic not specified Studies: 1 n = 379 RR 0.97 (0.51 to 1.85) p = 0.94 12 Admission to SCN or NICU Studies: 4 n = 1675 RR 0.79 (0.48 to 1.31) p = 0.36 12.1 uterotonic before clamping Studies: 1 n = 480 RR 1.45 (0.47 to 4.50) p = 0.52 12.2 uterotonic at, or	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				after,clamping Studies:2 n = 865 RR 0.74 (0.37 to 1.46) p = 0.38 12.3 use of uterotonic not specified Studies: 2 n = 330 RR 0.57 (0.20 to 1.60) p = 0.28 13 Respiratory distress Studies: 3 n = 835 RR 0.70 (0.22 to 2.19) p = 0.53 14 Jaundice requiring phototherapy Studies: 7 n = 2324 RR 0.62 (0.41 to 0.96) p = 0.03 14.1 uterotonic before clamping Studies: 2 n = 1032 RR 0.59 (0.32 to 1.11) p = 0.1	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				14.2 uterotonic at, or after,clamping Studies: 4 n = 1112 RR 0.64 (0.35 to 1.18) P = 0.16 14.3 use of uterotonic not specified Studies: 1 n = 90 RR 1.00 (0.06 to 15.74) p = 1.0 15 Clinical jaundice Studies: 6 n = 2098 RR 0.84 (0.66 to 1.07) p = 0.15 15.1 uterotonic before clamping Studies: 2 n = 1022 RR 0.86 (0.62 to 1.18) p = 0.34 15.2 uterotonic at, or after, clamping Studies: 2 n = 576 RR 0.87 (0.57 to 1.31) p = 0.49	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				15.3 use of uterotonic not specified Studies: 23n = 500 RR 0.64 (0.29 to 1.39) p = 0.26 16. Polycythaemia Studies: 5 n = 1025 RR 0.39 (0.12 to 1.27) p = 0.12 16.1 uterotonic at, or after, clamping Studies: 3 n = 577 RR 0.38 (0.06 to 2.48) p = 0.31 16.2 use of uterotonic not specified Studies: 2 n = 448 RR 0.40 (0.09 to 1.80) p = 0.23 17. Cord haemoglobin (g/dL) Studies: 4 n= 314 Mean Difference 0.42	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(0.03 to 0.80) p = 0.03 17.1 uterotonic at, or after, clamping Studies: 2 n = 149 Mean Difference 0.66 (0.13 to 1.19) p = 0.01 17.2 use of uterotonic not specified Studies: 2 n = 165 Mean Difference 0.15 (-0.42 to 0.71) p = 0.61 18 Newborn haemoglobin (g/dL) Studies: 3 n = 671 Mean Difference -2.17 (-4.06 to-0.28) p = 0.02 18.1 uterotonic at, or after, clamping Studies: 1 n = 45 Mean Difference -4.45	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(-5.33 to -3.57) p < 0.00001 18.2 use of uterotonic not specified Studies: 2 n = 626 Mean Difference -1.07 (-2.03 to -0.12) p = 0.02 19 Infant haemoglobin at 24-48 hours (g/dL) Studies: 2 n = 382 Mean Difference -1.34 (-1.80 to -0.88) p < 0.00001 19.1 uterotonic at, or after, clamping Studies: 1 n = 104 Mean Difference -1.40 (-2.17 to -0.63) p < 0.0003 19.2 use of uterotonic not specified Studies: 1 n = 278 Mean Difference -	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.31 (-1.88 to -0.74) p < 0.00001 20 Infant haemoglobin at 2-4 months (g/dL) Studies: 3 n = 256 Mean Difference -0.30 (-1.25 to 0.65) p = 0.45 20.1 uterotonic at, or after,clamping Studies: 1 n = 91 Mean Difference -0.30 (-0.88 to 0.28) p = 0.31 20.2 use of uterotonic not specified Studies: 2 n = 165 Mean Difference -0.27 (-1.94 to 1.390) p = 0.75 21 Infant haemoglobin at 6 months (g/dL) Studies: 2 n = 447 Mean Difference 0.03	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(-0.17 to 0.230) p = 0.78 21.1 uterotonic at, or after, clamping Studies:1 n = 91 Mean Difference 0.40 (-0.35 to 1.15) p = 0.29 21.2 use of uterotonic not specified Studies: 1 n = 356 Mean Difference: Not estimable 22 Infant haematocrit < 45% at 6 hours Studies:1 272 RR 16.18 (2.05 to 127.37) p = 0.008 22.1 use of uterotonic not specified Studies:1 n = 272 RR 16.18 (2.05 to 127.37)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				p = 0.008 23 Infant haematocrit < 45% at 24-48 hours Studies: 1 n = 268 RR 6.03 (2.27 to 16.07) p = 0.0003 23.1 use of uterotonic not specified Studies: 1 n = 268 RR 6.03 (2.27 to 16.07) p = 0.0003 24 Infant haemoglobin > 2 SDs below 10.3 g/dL at 4 months Studies: 1 n = 91 RR 1.84 (0.96 to 3.54) p = 0.06 24.1 uterotonic at, or after clamping Studies: 1 n = 91 RR 1.84 (0.96 to 3.54) p = 0.06	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				25 Infant haemoglobin at 6 months Studies: 2 n = 447 RR 1.05 (0.75 to 1.48) p = 0.76 26 Infant ferritin (micrograms/l) 26.1 at 3 months: use of uterotonic not specified Studies: 1 n = 107 Mean Difference -17.90 (-19.21 to -16.59) p < 0.0001 26.2 at 6 months: use of uterotonic not specified Studies: 1 n = 315 Mean Difference -11.80 (-19.53 to 4.07) p = 0.002 27 Not breastfeeding	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				27.1 at discharge Studies: 4 n = 1633 RR 1.11 (1.00 to 1.20) p = 0.32 27.2 1 month Studies: 1 n = 268 RR 1.10 (1.00 to 1.20) p = 0.05 27.4 2 months Studies: 1 n = 84 RR 0.21 (0.01 to 4.24) p = 0.31 27.5 3 months: use of uterotonic not specified Studies: 2 n = 144 RR 0.93 (0.36 to 2.42) p = 0.89 27.6 4 months: use of uterotonic not specified Studies: 2 n= 391 RR 0.88 (0.74 to 1.04)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				p = 0.13 27.7 6 months: use of uterotonic not specified Studies: 2 n = 430 RR 0.99 (0.89 to 1.11) p = 0.90	
Full citation Jahazi,A., Kordi,M., Mirbehbahani,N.B., Mazloom,S.R., The effect of early and late umbilical cord clamping on neonatal hematocrit, Journal of Perinatology, 28, 523-525, 2008 Ref Id 121477 Country/ies where the study was carried out Iran Study type Randomised control trial Aim of the study To compare the effect of	Sample size Early cord clamping (ECC): n = 34 Late cord clamping (LCC): n = 30 Characteristics Maternal age: LCC group (21.3 ± 3.7) ECC group (23 ± 4.7) p < 0.05 Gestational age: LCC group (39.6 ± 1.2) ECC group (39.3 ± 0.9) p = 0.25 Neonatal birth weight (g):	Interventions Early cord clamping (ECC): cord clamped 30 sec after birth Late cord clamping (LCC): cord clamped 3 min after birth	Details Just immediately before vaginal birth, infants were randomised to ECC or LCC groups by tossing a coin. A midwife controlled and recorded the cord clamping time using a stopwatch. In both groups neonates were held at the level of vaginal introitus before the cord clamping. A unit of 1 ml blood was collected from umbilical vein into ethylene diamie tetraacetic acid (1.2 mg ml _1) immediately after the cord clamping (before the delivery of the placenta). A unit of 1 ml antecubital blood was collected at 2 and 18 hours (± 10 min) after birth.	Results Duration of the third stage (min) LCC = 10.5 ± 2.7 ECC = 9.4 ± 2.6 p = 0.05 5 min Apgar score (range) LCC = 9 (9 - 10) ECC = 10 (8 - 10) p < 0.001 Hematocrit value (%) Cord blood: LCC = 50 ± 4.4 ECC = 51.2 ± 3.4 p = 0.24 2 hours of life:	Limitations Appropriate randomisation: Randomisation performed by tossing a coin Allocation concealment: not clear Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: not clear Blinding of staff providing care: not clear Blinding of outcome assessors: not clear Missing data/loss to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
early and late umbilical cord clamping on neonatal haematocrit. Study dates From 7th October 2002 to 9th February 2003 Source of funding Funding was provided from "The research deputy of Mashad University of Medical science"	LCC group (3272.4 ± 329) ECC group (3008.7 ± 573) p < 0.05 Inclusion criteria Women with uncomplicated pregnancy, term, uncomplicated delivery (38 - 42 weeks) Exclusion criteria Infants were excluded with apgar score < 7 (1 or 5 min), congenital abnormality, small for gestational age (< 10 percentile) or large gestational age (> 90 percentile), cord blood hematocrit < 40 or > 65		Oxytocin 10 IU was injected intramuscularly to all mothers after the cord clamping. Infants were assessed for polycythemia (tachypnea, cyanosis, tachycardia, lethargy, irritability, tremors, vomiting and poor feeding) at the time of blood sample taking (2 and 18 hours after birth) and 5 days after birth Statistical analysis Based on the power calculation, n = 23 infants in each group were needed to detect an increase in the mean hematocrit by 6.4% with a power of 90% and confidence interval of 95%. The data were analysed by using SPPS (v13.0). Student's T test was used to compare the mean value in ECC and LCC groups. For nonparametric variables, X2 and Mann-Whitney tests were used.	LCC = 62.6 ± 4.5* ECC = 61 ± 4.9* p = 0.61 * p < 0.001 when compared with values at birth 18 hours of life: LCC = 56.2 ± 3.9† ECC = 56.9 ± 4.1† p = 0.53 † p < 0.001 when compared with values at 2 hours of life in each group Polycythemia at 2 hours, 18 hours and 5 days of life: LCC = 0 ECC = 0 Frequency of asymptomatic polycythemia at 2 hours of life: LCC = 20%	follow-up: not reported Precise definition of outcomes: Not clear if the cord was clamped precisely at 30 sec in ECC group or it was clamped immediately after birth up to 30 sec Valid and reliable method of outcome assessment: Yes Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				ECC = 23% p = 0.73 No infants developed asymptomatic polycythemia at 18 hours of life.	
Full citation Jaleel,R., Deeba,F., Khan,A., Timing of umbilical cord clamping and neonatal haematological status, JPMA - Journal of the Pakistan Medical Association, 59, 468-470, 2009 Ref Id 151106 Country/ies where the study was carried out Pakistan Study type Randomised control trial Aim of the study To determine the effect of delayed umbilical	Sample size Total n = 200 women Group A: Early cord clamping n = 100 women Group B: Late cord clamping n = 100 women Characteristics Baseline characteristics of women in two group were comparable: Women's age mean ± SD Group A: 27.6 ± 4.9 Group B: 28.2 ± 5.3 Parity mean ± SD Group A: 2.45 ± 2 Group B: 2.9 ± 2.6	Interventions Group A: the umbilical cord was clamped immediately after birth Group B: the umbilical cord clamping was delayed until the pulsation in the cord stopped	Details Women were randomly allocated to group A and group B. Following the birth, the baby was kept at the same level as the placenta between the mother's legs. After cutting the cord, a blood sample from the cut end of the umbilical cord was collected for neonatal haemoglobin and bilirubin levels. The second sample of blood was taken 6 hours following birth, from antecubital vein for serum bilirubin. Blood samples were sent to the laboratory without delay. Neonates were regarded anaemic if the cord blood Hb was < 14 g/dl (normal range: 14 -20 g/dl and 14 -24 g/dl). Mothers were advised to attend	Results Mean neonatal Hb at Birth: Group A: 14.1 g/dl Group B: 15.2 g/dl p = 0.008 Neonatal Hb < 14 at 6 hours following birth: Group A: n = 49% Group B: n = 39% Cord blood bilirubin: Group A: 1.8 mg/dl Group B: 1.9 mg/dl p = 0.186 Serum bilirubin checked at 6 hours after birth: Group A: 2.5 mg/dl	Limitations Appropriate randomisation: not clear Allocation concealment: not clear Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: not clear Blinding of staff providing care: not clear Blinding of outcome assessors: not clear Missing data/loss to follow-up: reported; women with incomplete data were excluded Precise definition of outcomes: adequate

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
cord clamping on Hb (haemoglobin) and bilirubin levels of neonates and to identify newborn babies with anaemia and refer them for treatment Study dates Between 1st November 2006 and 15th July 2007 Source of funding Not reported	Antenatal booking % Group A: 36 Group B: 45 Number of antenatal visits mean ± SD Group A: 2 ± 2.1 Group B: 2.5 ± 2.1 Maternal Hb mean ± SD Group A: 9.75 ± 0.97 Group B: 9.95 ± 0.87 Delivery by caesarean section % Group A: 21 Group B: 26 Gestational age mean ± SD Group A: 38.4 ± 1.3 Group B: 38.7 ± 1.2 Birth weight (kg) mean ± SD Group A: 3.06 ± 0.39 Group B: 3.15 ± 0.55		paediatrics outpatient for further evaluation. Data analysis Data were entered and analysed using SPSS version 11. Mean values with standard deviation were calculated for quantitative variables while percentiles were verified for categorical variables. Student's t test was used to determine significance of the results	Group B: 2.7 mg/dl p = 0.095 Rise in bilirubin in group B vs. group A: p = 0.186	Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: not clear Paper indicates, when the second serum bilirubin were taken (6 hours of life), majority of the women were not available. But the number of losses was not reported Other information Women were included in the study irrespective of mode of delivery (in Group A: 21% gave birth by caesarean section and in group B: 26% gave birth by caesarean section). After the birth the baby was kept at the same level as placenta between the mother's

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Sex of Newborns Male % Group A: 53 Group B: 65 Sex of Newborns Female % Group A: 47 Group B: 35 Inclusion criteria Women with singleton, term pregnancy who were admitted to labour ward Exclusion criteria Women with: Rhesus negative blood group Multiple pregnancy Diabetes Pre-eclampsia and eclampsia In-utero growth restriction Fetal death and premature birth				legs. Use of uterotonic was not specified.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Andersson,O., Hellstrom-Westas,L., Andersson,D., Domellof,M., Effect of delayed versus early umbilical cord clamping on neonatal outcomes and iron status at 4 months: a randomised controlled trial, BMJ, 343, d7157-, 2011 Ref Id 152053 Country/ies where the study was carried out Sweden Study type Randomised controlled trial Aim of the study To compare the effects of delayed and early cord clamping on iron status, including haemoglobin, at 4 months of age in	Sample size Total: n = 382 infants Early cord clamping n = 166 Delayed cord clamping n = 168 Characteristics No statistically significant differences observed between the two groups in maternal age, parity, weight at first antenatal visit, body mass index, Hb at first antenatal visit, percentage of women with Rh negative blood group, and mode of birth. No statistically significant differences were observed in infants gestational age, sex, Apgar score of 7 - 10 at 1 minute, head circumference, and	Interventions Delayed cord clamping ≥ 180 seconds after birth Early cord clamping ≤ 10 seconds after birth	Details Women were randomised using a sealed, numbered, opaque envelope to be in either early clamping or late clamping group. In both intervention arms, midwives were instructed to hold the newborn at the level about 20 cm lower to vulva for thirty seconds and then place the baby on the mothers abdomen. Babies born by caesarean section were placed in mothers lap before cord clamping. 10 IU Oxytocin was administered intravenously immediately after cord clamping. Cord clamping time was measured by midwife using a stopwatch. In the delayed cord clamping group, the venous and cord arterial sample were taken within 30 seconds from the unclamped cord. In the early clamping group this was taken with 10 minutes from the double clamped segment of umbilical cord. The remaining fetal blood in	Results Blood count at 2 days (Early n = 160, Delayed n = 162) Haemoglobin: Early: 175 (19) Delayed: 189 (17) Differences (95% CI): 13.5 (9.6 to 17.5) p < 0.001 Packed cell volume (fL) Early: 50 (5) Delayed: 53 (5) Differences (95% CI): 3.5 (2.4 to 4.6) p < 0.001 Mean cell haemoglobin concentration (g/l) Early: 98.3 (3.8) Delayed: 98.4 (3.7) Differences (95% CI): 0.1 (-0.7 to 0.9) p = 0.82 Reticulocyte count (x10°/l)	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: not clear Blinding of staff providing care: Yes Blinding of outcome assessors: Yes Missing data/loss to follow-up: not reported Precise definition of outcomes: yes Valid and reliable method of outcome assessment: Yes All analysis made on an intention to treat basis except for 12 cases that were mistakenly included in the study despite not meeting the inclusion criteria (n = 4 in delayed

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
healthy, term Swedish infants. Study dates April 2008 to September 2009 Source of funding Supported by grants from the Regional Scientific Council of Halland; the HASNA Foundation, Halmstad; HRH Crown Princess Lovisa's Foundation for Child Care, Stockholm; and the Framework of Positive Scientific Culture, Hospital of Halland, Halmstad	infant's length. Infants in early clamping group had statistically significant higher birth weight than infants in delayed cord clamping group (p = 0.05). Infants in early clamping group also had higher umbilical cord haemoglobin and umbilical cord packed cell volume compared with infants in delayed cord clamping (p = 0.01, p = 0.01 respectively). Inclusion criteria Healthy pregnant women with singleton, term pregnancy (37 to 41+6 weeks): Non-smoking No haemolytic disease No treatment with anticonvulsants, antidepressants, thyroid hormone, insulin, chemotherapy, or cortisone normal No pre-eclampsia		placenta was measured by placing the free end of the cut umbilical cord in a measuring glass and then elevating the placenta until all blood was drained. Follow up Infants were assessed 1 and 6 hours following birth by a midwife for breast feeding and respiratory symptoms. All infants were examined by a physician within 72 hours. At 48 to 72 hours following birth, routine venous blood samples were taken by a midwife or neonatal nurse. The results from the study samples were reviewed once a week by a physician and appropriate action was taken if needed. At 6 month of age infants were scheduled for a follow up visit including blood sampling and weight and length measurement. Enquiries were made about infant's feeding before the visit. Parents	Early: 171 (47) Delayed: 168 (44) Differences (95% CI): -3 (-13 to 7) p = 0.54 Iron status at 2 days (Early n = 160, Delayed n = 162) Iron (micromol/l) Early: 9.9 (2.9) Delayed: 9.9 (2.7) Differences (95% CI): -0.1 (0.7 to 0.6) p = 0.88 Transferrin (g/l) Early: 1.76 (0.26) Delayed:1.76 (0.22) Differences (95% CI): 0.0 (-0.05 to 0.05) p = 0.99 Transferrin receptors Early: 5.35 (1.60) Delayed: 5.44 (1.64) Differences (95% CI): 0.09 (-0.26 to 0.45) p = 0.61	cord clamping and n = 8 in early cord clamping). Other information Definitions At 2 days: Anaemia: haemoglobin < 145 g/l Polycythaemia: packed cell volume > 0.65 Hyperbilirubinaemia: bilirubin > 257 micromol/l At 4 months: Anaemia: haemoglobin < 105 g/l Iron deficiency: ≥ 2 indicators of iron status outside reference range

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	No diabetes No prolonged rupture of membranes or signs of infection Expected vaginal delivery with cephalic presentation Understand Swedish and live close to the hospital and willing to return for follow-up after four months. Exclusion criteria Serious congenital malformations, syndromes, or other congenital diseases that could affect the outcome measures		were asked to fill in a three day feeding questionnaire regarding infants feeding (breast feeding, bottle feeding). Randomisation Performed by computer in block of 20 using the random number generator in MS Excel Blinding Physicians performing the neonatal examination, staff collecting blood samples and laboratory staff performing blood sample analysis were blinded to infant's allocation group. Statistical analysis For variables with normal distribution, Student's t test was used. Mann-Whitney U test was used when variables had skewed distribution. Hodge and Lehmann were used for confidence intervals across groups. Ferritin concentration	Transferrin saturation Early: 23 (7) Delayed: 23 (7) Differences (95% CI): 0.4 (-1.9 to 1.2) p = 0.65 Geometric mean (range) ferritin (micrograms/l) Early: 300 (44 - 628) Delayed: 312 (110 - 1029) Differences (95% CI): 4.0 (-6.5 to 15.1) p = 0.45 logTfR/Fer Early: 1.41 (0.27) Delayed: 1.40 (0.25) Differences (95% CI): -0.01 (-0.07 to 0.05) p = 0.74 Total body iron (mg/kg) Early:11.7 (2.2) Delayed:11.8 (2.1) Differences (95% CI): 0.1 (-0.4 to 0.6)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			was log transformed for analysis. Categorical variables were compared using Fisher's exact test. SPSS version 18.0 and JavaStat calculator were used for number to treat, relative risk reduction and their confidence intervals. A $p < 0.05$ was considered significant.	p = 0.74 Blood count at 4 months (Early n = 175, Delayed n = 168) Haemoglobin: Early:113 (7) Delayed: 113 (8) Differences (95% CI): 0.0 (-1.6 to 1.6) p = 0.98 Packed cell volume (fL) Early: 33 (2) Delayed:33 (2) Differences (95% CI): -0.2 (-.07 to 0.2) p = 0.28 Mean cell haemoglobin concentration (g/l) Early: 334 (0.8) Delayed: 347 (0.8) Differences (95% CI): 2.6 (0.9 t0 4.3) p = 0.002 Reticulocyte count	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(x10°/l) Early: 37 (11) Delayed: 40 (11) Differences (95% CI): 2.5 (0.1 to 4.8) p = 0.04 Iron status at 4 months (Early n = 175, Delayed n = 168)Iron (micromol/l) Early: 9.3 (2.9) Delayed:10.2 (3.0) Differences (95% CI): 0.9 (0.2 to 1.5) p = 0.007 Transferrin (g/l) Early: 2.41 (0.34) Delayed: 2.28 (0.31) Differences (95% CI): -0.12 (-0.19 to -0.06) p < 0.001 Transferrin receptors Early: 3.97 (0.80) Delayed: 3.73 (0.69) Differences (95% CI): -0.24 (-0.40 to -0.08) p = 0.003	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Transferrin saturation Early: 16 (6) Delayed: 18 (6) Differences (95% CI): 2.4 (1.2 to 3.7) p < 0.001 Geometric mean (range) ferritin (micrograms/l) Early: 81 (6 - 780) Delayed: 117 (20 - 880) Differences (95% CI): 45 (23 to 71) p < 0.001 logTfR/Fer Early: 1.85 (0.43) Delayed: 1.66 (0.33) Differences (95% CI): -0.19 (0.27 to 0.11) p < 0.001 Total body iron (mg/kg) Early: 8.1 (3.5) Delayed: 9.6 (2.7) Differences (95% CI): 1.6 (0.9 to 2.3)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				p < 0.001 Hyperbilirubinaemia and need for phototherapy at 2 days (Early n = 189, Delayed n = 192) Mean (SD) bilirubin (micromol/l) Early: 144(62) Delayed: 145 (67) Mean difference (95% CI): 0.4 (15.2 to 16.1) p = 0.96 Bilirubin > 257 micromol/l Early: 7 (5.4) Delayed: 4 (2.9) Differences (95% CI): 0.46 (-0.70 to 0.83) p = 0.37 Treated with Phototherapy Early: 2 (1.1) Delayed: 1 (0.5) Relative risk reduction (95% CI):	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				0.52 (-2.7 to 0.94) p = 0.62 Proportion of infants who had iron status indicators outside reference limit at 4 months (Early n = 175, Delayed n = 172) Ferritin < 20 micromol/l Early: 13 (7.4) Delayed: 0 (0.0) Relative risk reduction (95% CI): 1.0 (0.71 to 1.00) Number needed to treat (95% CI): 14 (14 to 25) p < 0.001 Iron deficiency Early: 10 (5.7) Delayed: 1 (0.6) Relative risk reduction (CI): 0.90 (0.38 to 0.98) Number needed to treat (95% CI): 20 (17	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 67) p = 0.01 Anaemia Early: 21 (1.2) Delayed: 21 (1.25) Relative risk reduction (CI): -0.04 (-0.83 to 0.41)	

1.1.23 Is oxytocin 10 IU im the most effective drug/route/dose to use in the active management of the third stage of labour?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation McDonald,Susan J., Abbott,Jo M., Higgins,Shane P., Prophylactic ergometrine-oxytocin versus oxytocin for the third stage of labour, Cochrane Database of Systematic Reviews, -, 2009 Ref Id 143494 Country/ies where the study was carried out	Sample size Six trials were analysed in this review, with a total of 9332 women. Characteristics Choy 2002 Population: Total n = 991 women with singleton pregnancy and vaginal birth. Women who received oxytocin infusion in the first stage of labour were also included. The infusion stopped at the end of	Interventions Intervention: prophylactic ergometrine-oxytocin Comparison: oxytocin	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by contacting the Trials Search Coordinator (30 April 2007). Quarterly searches of CENTRAL and monthly searches of MEDLINE were conducted, and hand searching of 30 journals and proceedings of major conferences performed. Language restrictions were not applied. Data extraction and management Methodological quality of each trial was	Results Ergometrine-oxytocin versus oxytocin (any dose) Blood loss ≥ 500 ml 6 trials 9332 women Ergometrine-oxytocin: n = 392/4661 Oxytocin: n =	Limitations No major limitations The authors assessed risk of bias for each of the individual studies: - Method of randomisation: 5 were at low risk of bias, 1 had unclear risk of bias - Allocation concealment: 3

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Various (Australia, Finland, HongKong, Uk and Emirates) Study type Systematic review - meta-analysis Aim of the study To compare the effects of ergometrine-oxytocin with oxytocin in reducing the risk of PPH (blood loss of at least 500 ml) and other maternal and neonatal outcomes. Study dates Updated 2009 Source of funding Not reported	2nd stage. Interventions: 1 ml of oxytocin (10 iu) intravenously vs. 1 ml of oxytocin-ergometrine IM. The injection was given at the birth of anterior shoulder. Khan 1995 Population: Total n = 2040 women with singleton pregnancy and vaginal birth. Women undergoing operative delivery were excluded. Interventions: 1 ml of oxytocin (10 iu) IM vs. 1 ml of oxytocin-ergometrine IM. The injection was given at the birth of anterior shoulder. No intention to treat analysis. 12 women were excluded after randomisation. McDonald 1993 Population: Total n = 3497 women with singleton pregnancy in whom a vaginal birth was anticipated. Women undergoing planned caesarean section were excluded.		assessed independently by each member of review group. The information was entered only if a consensus had been reached. Subgroup analysis was performed based on the dosage. Study authors were contacted when additional information was needed. Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals using a fixed effect model. In the presence of significant heterogeneity a random effects model was also used. Dealing with missing data Not reported Outcome Measures: Maternal outcomes (1) 'Moderate' postpartum haemorrhage (PPH) (clinically estimated blood loss of at least 500 ml); (2) 'severe' PPH (blood loss of at least 1000 ml); (3) manual removal of the placenta; (4) blood transfusion; (5) elevation of diastolic blood pressure;	469/4671 Odds Ratio 95% CI 0.82 [0.71 to 0.95] Blood loss ≥ 1000ml 5 trials 7954 women Ergometrine-oxytocin: n = 86/3972 Oxytocin: n = 111/3982 Odds Ratio 95% CI 0.78 [0.58 to 1.03] Manual removal of the placenta 6 trials 9332 women Ergometrine-oxytocin: n = 130/4661 Oxytocin: n =	were at low risk of bias, 3 had an unclear risk of bias - Blinding: 5 were at low risk of bias, 1 had unclear risk of bias - Incomplete outcome data: 2 were at high risk of bias and 4 were at low risk of bias - Overall quality: 5 were rated as being of high methodological quality, and in 1 study there was insufficient information Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Interventions: 1 ml of oxytocin (10 iu) IM vs. 1 ml of oxytocin-ergometrine IM. The injection was given at the birth of anterior shoulder. Mitchell 1993 Population: Total n = 461 women with singleton pregnancy in whom a vaginal birth was anticipated. Women undergoing planned caesarean section were excluded. Interventions: 1 ml of oxytocin (5 iu) IM vs. 1 ml of oxytocin-ergometrine IM. The injection was given at the birth of anterior shoulder. Nieminen 1963 Population: Total n = 1378 women confined at the 2 obstetrics and gynaecology hospitals. Interventions: 1 ml of oxytocin (10 iu) IM vs. 1 ml of OCM505 (equivalent product to oxytocin-ergometrine) IM. The injection was given at the birth		(6) vomiting; (7) nausea; (8) use of therapeutic uterotonics; (9) third stage of labour lasting more than 30 minutes; (10) third stage of labour lasting more than 60 minutes. Neonatal outcomes (1) Apgar score equal to or less than six at five minutes; (2) jaundice; (3) not breastfed at discharge; (4) admission to neonatal intensive care unit;	127/4671 Odds Ratio 95% CI 1.03 [0.80 to 1.33] Blood transfusion 4 trials 7482 women Ergometrine-oxytocin: n = 49/3735 Oxytocin: n = 36/3747 Odds Ratio 95% CI 1.37 [0.89 to 2.1] Elevation of diastolic blood pressure 4 trials 7486 women Ergometrine-oxytocin: n = 65/3737 Oxytocin: n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	of anterior shoulder. Yuen 1995 Population: Total n = 991 women with singleton pregnancy in whom a vaginal birth was anticipated. Women who received oxytocin infusion in the first stage of labour were also included. The infusion stopped at the end of 2nd stage. Interventions: 1 ml of oxytocin (10 iu) IM vs. 1 ml of oxytocin-ergometrine IM. The injection was given at the birth of anterior shoulder. No intention to treat analysis. Inclusion criteria The women recruited to the trials included in this review were in labour expecting to have a vaginal birth. In one trial (Khan 1995) the participants had only spontaneous vaginal birth.			26/3749 Odds Ratio 95% CI 2.40 [1.58 to 3.64] Vomiting 3 trials 5458 women Ergometrine-oxytocin: n = 373/2721 Oxytocin: n = 66/2737 Odds Ratio 95% CI 4.92 [4.30 to 6.00] Vomiting + nausea combined 4 trials 7486 women Ergometrine-oxytocin: n = 874/3737 Oxytocin: n = 198/3749	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Not reported			Odds Ratio 95% CI 5.71 [4.97 to 6.57] Therapeutic oxytocics 3 trials 5465 women Ergometrine-oxytocin: n = 397/2726 Oxytocin: n = 466/2739 Odds Ratio 95% CI 0.83 [0.72 to 0.96] 3rd stage > 30 minutes 5 trials 7304 women Ergometrine-oxytocin: n = 80/3645 Oxytocin: n = 75/3659 Odds Ratio 95% CI	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.07 [0.78 to 1.48] 3rd stage > 60 minutes 2 trials 4861 women Ergometrine-oxytocin: n = 34/2419 Oxytocin: n = 31/2442 Odds Ratio 95% CI 1.11 [0.68 to 1.81] Apgar score ≤ 6 at 5 minutes 2 trials 5468 women Ergometrine-oxytocin: n = 48/2729 Oxytocin: n = 48/2739 Odds Ratio 95% CI 1.00 [0.67 to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.50] Jaundice 2 trials 5468 women Ergometrine-oxytocin: n = 453/2729 Oxytocin: n = 466/2739 Odds Ratio 95% CI 0.97 [0.84 to 1.12] Not breastfed at discharge 1 trial 3440 women Ergometrine-oxytocin: n = 252/1713 Oxytocin: n = 253/1727 Odds Ratio 95% CI 1.10 [0.90 to 1.33]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Admission to neonatal intensive care unit 1 trial 3440 women Ergometrine-oxytocin: n = 317/1713 Oxytocin: n = 309/1727 Odds Ratio 95% CI 1.04 [0.88 to 1.24] Ergometrine-oxytocin versus oxytocin (5 iu) Blood loss ≥ 500 ml 2 trials 1839 women Ergometrine-oxytocin: n = 11/919 Oxytocin: n = 26/920 Odds Ratio	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				95% CI 0.43 [0.23 to 0.83] Blood loss ≥ 1000ml 1 trial 461 women Ergometrine-oxytocin: n = 0/230 Oxytocin: n = 1/231 Odds Ratio 95% CI 0.14 [0.00 to 6.85] Manual removal of the placenta 2 trials 1839 women Ergometrine-oxytocin: n = 23/919 Oxytocin: n = 19/920 Odds Ratio	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				95% CI 1.55 [0.80 to 2.99] 3rd stage > 30 minutes 2 trials 1839 women Ergometrine-oxytocin: n = 9/919 Oxytocin: n = 12/920 Odds Ratio 95% CI 0.75 [0.32 to 1.77] 3rd stage > 60 minutes 1 trial 1378 women Ergometrine-oxytocin: n = 4/689 Oxytocin: n = 6/689 Odds Ratio 95% CI	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				0.67 [0.19 to 2.32] Ergometrine-oxytocin versus oxytocin (10 iu) Blood loss ≥ 500 ml 4 trial 7493 women Ergometrine-oxytocin: n = 372/3742 Oxytocin: n = 432/3751 Odds Ratio 95% CI 0.85 [0.73 to 0.98] Blood loss ≥ 1000 ml 4 trials 7493 women Ergometrine-oxytocin: n = 86/3742	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Oxytocin: n = 110/3751 Odds Ratio 95% CI 0.78 [0.59 to 1.04] Manual removal of the placenta 4 trials 7493 women Ergometrine-oxytocin: n = 107/3742 Oxytocin: n = 112/3751 Odds Ratio 95% CI 0.96 [0.73 to 1.26] Blood transfusion 4 trials 7482 women Ergometrine-oxytocin: n = 49/37435	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Oxytocin: n = 36/3747 Odds Ratio 95% CI 1.37 [0.89 to 2.10] Elevation diastolic blood pressure 4 trials 7486 women Ergometrine-oxytocin: n = 65/3737 Oxytocin: n = 26/3749 Odds Ratio 95% CI 2.40 [1.58 to 3.64] Vomiting 3 trials 5458 women Ergometrine-oxytocin: n = 373/2721 Oxytocin: n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				66/2737 Odds Ratio 95% CI 4.92 [4.03 to 6.00] Nausea 3 trials 5458 women Odds Ratio 95% CI Ergometrine-oxytocin: n = 487/2721 Oxytocin: n = 128/2737 4.07 [3.43 to 4.84] Vomiting + nausea combined 4 trials 7486 women Ergometrine-oxytocin: n = 874/3737 Oxytocin: n = 198/3749	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Odds Ratio 95% CI 5.71 [4.94 to 6.57] Therapeutic oxytocics 3 trials 5465 women Ergometrine-oxytocin: n = 397/2726 Oxytocin: n = 466/2739 Odds Ratio 95% CI 0.83 [0.72 to 0.96] 3rd stage > 30 minutes 3 trials 5465 women Ergometrine-oxytocin: n = 71/2726 Oxytocin: n = 63/2739 Odds Ratio	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				95% CI 1.14 [0.81 to 1.60] Apgar ≤ 6 at 5 minutes 2 trials 5468 women Ergometrine-oxytocin: n = 48/2729 Oxytocin: n = 48/2739 Odds Ratio 95% CI 1.00 [0.67 to 1.50] Jaundice 2 trials 5468 women Ergometrine-oxytocin: n = 435/2729 Oxytocin: n = 466/2739 Odds Ratio 95% CI 0.97 [0.84	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 1.12] Not breastfed at discharge 1 trial 3440 women Ergometrine-oxytocin: n = 252/1713 Oxytocin: n = 235/1727 Odds Ratio 95% CI 1.10 [0.90 to 1.33] Admission to neonatal intensive care unit 1 trial 3440 women Ergometrine-oxytocin: n = 317/1713 Oxytocin: n = 309/1727 Odds Ratio 95% CI	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.04 [0.88 to 1.24]	

1.1.24 What is the most effective management of retained placenta in women who have had active management of the third stage of labour: a) with PPH b) without PPH

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Van,BeekhuizenH, Tarimo,V., Pembe,A.B., Fauteck,H., Lotgering,F.K., A randomized controlled trial on the value of misoprostol for the treatment of retained placenta in a low-resource setting, International Journal of Gynecology and Obstetrics, 122, 234-237, 2013 Ref Id 273583 Country/ies where the study was carried out Tanzania Study type Double blind randomised control trial	Sample size N = 95 Characteristics Age = 27 - 28.5 Parity Misoprostol = 2.3 Placebo = 2.6 Hemoglobin third trimester, g/dl Misoprostol = 10.7 Placebo = 10.3 Mean time oxytocin administered, min Misoprostol = 5.7	Interventions Orally administered Misoprostol, 800micrograms Comparator Orally administered placebo in form mimicking Misoprostol in terms of taste and dissolvability.	Details Potential participants were identified in delivery rooms 20 minutes postpartum. Bladder catheterised and cannula inserted for delivery of normal saline. 2:1 randomisation by balanced variable blocks. Misoprostol: N = 65; Placebo: N = 30 Over-encapsulation technique used for both sets of oral capsules. CCT performed every 10 mintutes following randomisation. Blood loss measured by weighing matresses.	Results Primary outcome: Manual removal of placenta Misoprostol = 26 (40) Placebo = 10 (33) P = 0.53 Secondary outcomes: Postpartum hemorrhage >1l Misoprostol = 19 (29) Placebo = 11 (37) P = 0.47 Blood transfusion Misoprostol = 10 (15) Placebo = 7 (23) P = 0.35 Haemoglobin at discharge,	Limitations Low-resource setting affected communication between centres. 14/83 women received the trial medication too early (Less than 30 minutes after birth). Trial stopped with 22 too few women for ethical reasons: continuation would not alter the interim conclusion that misoprotol was ineffective. "Best case situation" was calculated.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To evaluate the efficacy and safety of misoprostol among patients with retained placenta in a low resource setting. Study dates April 2008 - November 2011 Source of funding Not stated	Placebo = 2.9 Controlled cord traction (CCT) performed before inclusion Misoprostol = 61 Placebo = 26 Blood loss before inclusion (ml) Misoprostol = 262 Placebo = 270 Inclusion criteria Active management of third stage of labour Placenta not expelled after 30 minutes from birth of neonate Exclusion criteria Haemoglobin < 100g/l Blood loss > 750mls Pulse rate > 120 beats per minute		Manual removal of placenta (MRP) (including curettage) was performed if blood loss > 1500ml or placenta not expelled after 30 minutes.	g/dl Misoprostol = 8.8 (8.8) Placebo = 10.7 (10.7) P = 0.31	Other information Drug side effects not part of study

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Samanta,A., Roy,S.G., Mistri,P.K., Mitra,A., Pal,R., Naskar,A., Bhattacharya,S.K., Pal,P.P., Pande,A., Efficacy of intra-umbilical oxytocin in the management of retained placenta: a randomized controlled trial, Journal of Obstetrics and Gynaecology Research, 39, 75-82, 2013 Ref Id 273632 Country/ies where the study was carried out India Study type Single centre randomised control trial Aim of the study To determine the efficacy of umbilical injection of oxytocin as a treatment modality for retained placenta.	Sample size N = 58 Characteristics Some women delivered before being admitted to the study centre. Age (years): Oxytocin: 24.55 (± 3.77) Normal saline: 24.62 (± 3.88) p = 0.945 Parity: Oxytocin: 1 (0-3) Normal saline: 1 (0-3) p = 0.881 Gestational age in weeks: Oxytocin: 37.9 ± 1.57 Normal saline: 38.17 ± 1.54 p = 0.501 Induction/augmentation	Interventions Intraumbilical injection of oxytocin (50 IU diluted with NS to a volume of 30 ml) Comparator Intraumbilical injection of NS (30ml)	Details The diagnosis of retained placenta was made at 30 minutes following birth. Randomisation was generated using a table of random numbers and one copy was kept seperately on the labour ward. Blood was collected after consent for blood count and grouping. Following randomisation blood was collected via fracture bedpan, and ceftriaxone was injected intravenously. Oxytocin/NS was injected into the umbilical vein through a No.10 infant feeding tube - tied at the end to avoid backflow. Gentle cord traction was applied 30 mins after trial entry if spontaneous delivery had not ensued. If above unsuccessful, vaginal exam took place	Results Placenta expelled within 30 mins: Oxytocin: 15 Saline: 6 p = 01014 Blood loss in ml: Oxytocin: 210.34 ± 110.50 Saline: 332.76 ± 158.27 p = 0.001 Fall in Hb% from pre randomisation to 24 hours later: Oxytocin: 1.61 ± 1.45 Saline: 3.64 ± 3.06 p = 0.002 PPH: Oxytocin 1 Saline 5 p = 0.085 Blood transfusion: Oxytocin 1 Saline 4	Limitations Single blinded study. Only the participants were blinded. Heterogeneous study population in respect to the duration of the retained placenta prior to randomisation, though no statistical diffrence in their distribution in the two intervention arms. This was due to a large proportion of participants being referred cases from other hospitals. Single centre based study. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates June 2010 - May 2011 Source of funding Not stated.	(p = 0.410): Oxytocin: 16 Normal saline: 18 Previous abortion, curettage/manual removal of placenta/endometritis: Oxytocin: 0 Normal saline: 1 p = 0.313 Referred cases: Oxytocin: 11 Normal saline: 10 p = 0.785 Duration of retained placenta prior to randomisation: Oxytocin: 1.52 (± 1.28) Normal saline: 1.31 (± 1.13) p = 0.516 Inclusion criteria - Over 18 years old - Singleton		to ease placenta trapped in cervical os. If above unsuccessful, placenta was removed surgically.	p = 0.160 Requirement for extra oxytocics for continued bleeding: Oxytocin 3.45 ± 6.69 Saline 16.90 ± 12.85 p < 0.001 Postpartum fever: Oxytocin 3 Saline 2 p = 0.364 Pre-discharge antibiotics: Oxytocin 2 Saline 2 p = 640 Hospital stay in days: Oxytocin 2-3 Saline 2-4 p = 0.361	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	pregnancies - Gestation of > 34 weeks - Vaginal deliveries with no placenta delivery after 30 mins of active management. Exclusion criteria - Maternal hemodynamic instability - Postpartum haemorrhage (PPH) requiring immediate intervention - Multiple pregnancy - Pre-eclampsia - Stillborn baby - Severe anaemia - Previous placenta praevia - Known uterine malformations - Previous cesarean delivery				
Full citation van,Stralen G.,	Sample size	Interventions Misoprostol	Details During the 2 hours (the	Results Manual removal: Misoprostol	Limitations Number of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Veenhof,M., Holleboom,C., van,Roosmalen J., No reduction of manual removal after misoprostol for retained placenta: a double-blind, randomized trial, Acta Obstetricia et Gynecologica Scandinavica, 92, 398-403, 2013 Ref Id 273669 Country/ies where the study was carried out Netherlands Study type Double blind, multi centre randomised control trial Aim of the study To test the effect of 800micrograms of misoprostol orally on the prevention of manual removal of retained placenta (MRRP). Study dates Feb 2008 - Sep 2011	n = 99 Characteristics Mean age ± SD range (p = 0.74): Misoprostol group 32 ± 4.15 (21-40); Placebo group 33 ± 4.42 (20-41) Nulliparous (p = 0.003): Misoprostol group 35; Placebo group 23 Prior cesarean section (CS) (p = 0.34): Misoprostol group 1; Placebo group 3 Prior postartum haemorrhage (PPH) (p = 0.36): Misoprostol group 4; Placebo group 2 Prior manual removal of placenta (p = 0.70): Misoprostol	800micrograms Comparator Oral placebo	half life of side effects is 20-40 mins) following administering study medication, women were asked to report complaints of nausea, vomiting, abdominal pain, headache, dyspepsia, shaking & dizziness. All women had clinical review exam 6 - 8 weeks postpartum to identify postpartum endometritis, late haemorrhage and placental remnants. Blood loss was measured by collecting and weighing including swabs. It was possible to retrieve information about whether misoprostol or placebo had been administered by opening an enclosed 'safety envelope'. 2 proportions power analysis were performed based on pilot study: 40 women were needed in	group 24 (50%); Placebo group 28 (55%); RR (95% CI) 0.91 (0.62 to 1.34) Blood transfusion: Misoprostol group 6 (13%); Placebo group 9 (18%); RR (95% CI) 0.83 (0.52 to 1.32) PPH, >1000ml: Misoprostol group 18 (38%); Placebo group 24 (47%); RR (95% CI) 0.83 (0.57 to 1.21) Average blood loss (p = 0.39): Misoprostol group 970±771 (200-3000); Placebo group 1120±949 (200-5000) Average interval medication/birth placenta, min ± SD (p = 0.35): Misoprostol group 59±33; Placebo group 66±39 Side effects of Misoprostol: Nausea (p = 0.10): Misoprostol group 6/42; Placebo group 1/32 Vomiting (p = 0.12): Misoprostol group 3/42; Placebo group 0/32	nulliparous participants is statistically significant. Participants' self reports of side effects is unvalidated. Statisticians were not blinded. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding No special funding	group 2; Placebo group 3 Mean gestational age ±SD (p = 0.84): Misoprostol group 39 weeks and 10.74 days (35+4 - 41+6); Placebo group 39 weeks and 13.48 days (34+2 - 42+0) Mean interval birth neonate-medication ± SD, min (range): Misoprostol group 67 ± 13.3 (41-105); Placebo group 2 68 ± 11.3 (55-104) Misprostol group (n = 48): - Mean age = 32; - Prior CS = 1; - Nulliparous = 35; - Prior PPH = 4; - Prior MRRP = 2; - Mean gestation = 39+2		each group.	Abdominal pain (p = 0.54): Misoprostol group 8/42; Placebo group 8/32 Headache (p = 0.54): Misoprostol group 1/42; Placebo group 1/32 Dizziness (p = 0.73): Misoprostol group 5/42; Placebo group 3/32 Dyspepsia (p = 0.07): Misoprostol group 4/42; Placebo group 0/32 Shivering (p = 0.001): Misoprostol group 15/42; Placebo group 1/28	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Placebo group (n = 51): - Mean age = 33; - Nulliparous = 23; - Prior CS = 3; - Prior MRRP = 3; - Mean gestation = 39+3. Inclusion criteria Over 18, fluent in Dutch. Women with retained placenta (60 mins post childbirth) at least 25 weeks pregnant. Consent requested 45 minutes into 3rd stage labour. Women for whom controlled cord traction had failed 60 mins after birth. Exclusion criteria Women who had a PPH within 60 mins after birth.				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Chongsomchai,Chompilas, Lumbiganon,Pisake, Laopaiboon,Malinee, Prophylactic antibiotics for manual removal of retained placenta in vaginal birth, Cochrane Database of Systematic Reviews, -, 2011 Ref Id 244362 Country/ies where the study was carried out Study type Aim of the study Study dates Source of funding	Sample size Characteristics Inclusion criteria Exclusion criteria	Interventions Comparator	Details	Results	Limitations Other information
Full citation Harara,R., Hanafy,S., Zidan,M.S., Alberry,M., Intraumbilical injection of three different uterotonics	Sample size N = 78 Characteristics Age / years (mean ±	Interventions Oxytocin: 20 IU in 30 ml saline (n = 26)	Details Recruitment The diagnosis of retained placenta was made when signs of	Results Need for manual removal of the placenta (number/total (%)) Oxytocin: 7/26 (26.9)	Limitations Appropriate randomisation: Randomisation is appropriate, but it is

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
in the management of retained placenta, Journal of Obstetrics and Gynaecology Research, 37, 1203-1207, 2011 Ref Id 143478 Country/ies where the study was carried out Egypt Study type Randomised controlled trial Aim of the study To compare the effect of umbilical vein injection of three different uterotonic solutions in the management of retained placenta Study dates April 2008 to March 2009 Source of funding None stated	SD (range)) Ergometrine: 22.4 ± 3.8 (18 - 30) Oxytocin: 25.7 ± 6.1 (19 - 35) Misoprostol: 26.3 ± 5.2 (18 - 35) (NS) Gestational age / weeks (mean ± SD (range)) Ergometrine: 39.2 ± 2.7 (32 - 41) Oxytocin: 37.6 ± 5.2 (26 - 42) Misoprostol: 38.0 ± 4.1 (32 - 42) (NS) Parity (median (range)) Ergometrine: 1 (0 - 2) Oxytocin: 1 (0 - 3) Misoprostol: 1 (0 - 4) (NS) Number of previous curettages (median (range)) Ergometrine: 1 (0 - 1) Oxytocin: 1 (0 - 2)	Comparator Ergometrine: 0.2 mg in 30 ml saline (n = 27) Misoprostol: 800 mg dissolved in 30 ml saline (n = 25)	spontaneous placental separation had not occurred 30 minutes after the delivery of the fetus. All women had uterotonics (5 IU of oxytocin + 0.2 mg methyl ergometrine) after delivery of the anterior shoulder. Gentle uterine massage was also routinely performed after delivery of the baby, before the diagnosis of retained placenta. 78 women were randomised (using a computer-generated randomisation system) to receive one of the following: - 20 IU of oxytocin in 30 ml saline - 0.2 mg of ergometrine in 30 ml saline - 800 mg of misoprostol dissolved in 30 ml saline Protocol	Ergometrine: 10/27 (37.0) Misoprostol: 5/25 (20) p > 0.05 Postpartum haemorrhage (number/total (%)) Oxytocin: 0/26 (0) Ergometrine: 0/27 (0) Misoprostol: 0/25 (0) Interval between injection and spontaneous separation / minutes (mean ± SD) Oxytocin: 13.1 ± 3.76 (n = 19) Ergometrine: 22.5 ± 4.37 (n = 17) Misoprostol: 7.0 ± 2.2 (n = 20) p < 0.001 (Note: these data are only reported for women who did not have a manual removal) Maternal side effects (number/total (%)) Oxytocin: 0/26 (0)	not clear at what point the women were randomised and at what point women consented Allocation concealment: Unclear - no details are given Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: Unclear - blinding is not reported Blinding of staff providing care: Unclear - blinding is not reported Blinding of outcome assessors: Unclear - blinding is not reported Missing data/loss to follow-up: No Precise definition of outcomes: The amount of blood loss

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Misoprostol: 1 (0 - 2) (NS) Birth weight / grams (mean ± SD (range)) Ergometrine: 3520 ± 484.3 (2200 - 3800) Oxytocin: 2990 ± 996.1 (1000 - 4000) Misoprostol: 3201 ± 827.2 (1750 - 4000) (NS) Placental weight / grams (mean ± SD (range)) Ergometrine: 495.5 ± 54.8 (350 - 550) Oxytocin: 477 ± 84.4 (280 - 550) Misoprostol: 473 ± 73.7 (NS) Cord length / cm (mean ± SD (range)) Ergometrine: 50.2 ± 2.6 (45 - 55) Oxytocin: 51.09 ± 2.7 (48 - 54) Misoprostol: 51.4 ± 2.2 (48 - 55)		When spontaneous separation of the placenta had not occurred after 25 minutes, the last 5 minutes were used to prepare the solution. The solution was discarded if spontaneous separation occurred in the last 5 minutes. A size-10 nasogastric suction catheter was inserted along umbilical vein. When resistance was felt, it was retracted by 1-2 cm and then pushed as far as possible. The solution was injected after clamping of the cord. If spontaneous separation had not occurred within 30 minutes of the injection, or if significant bleeding occurred, then manual removal was done.	Ergometrine: 0/27 (0) Misoprostol: 0/25 (0) (Note: no further details about side effects are given, except to specifically state that no women experienced closure of the cervix and subsequent entrapment of the placenta)	constituting a postpartum haemorrhage is not defined. Valid and reliable method of outcome assessment: Yes in most cases; however it is unclear how and when side effect data were collected Intention-to-treat analysis performed: Yes Indirectness: - Only excludes women of less than 20 weeks gestation; therefore some women will be outside of the scope of the guideline - Injection to separation interval is reported; however the actual outcome of interest is duration of third stage

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(NS) Catheter tip-to-placenta distance/cm (mean ± SD (range)) Ergometrine: 10 ± 2.6 (8 - 12) Oxytocin: 10.9 ± 2.1 (9 - 12) Misoprostol: 9.9 ± 2.3 (8 - 12) (NS) Inclusion criteria Prolonged third stage of labour Exclusion criteria Less than 20 weeks gestation Multiple pregnancy Vaginal birth after caesarean		Outcomes reported 1. Need for manual removal of the placenta 2. Incidence of postpartum haemorrhage (PPH) 3. Injection to separation interval: for women whose placenta separated spontaneously 4. Maternal side effects: reported after administration of uterotonics Statistical analysis ANOVA was used to compare means of the three arms. Chi-squared was used to compare categorical data.		Other information Population: women with active management and no PPH
Full citation Lim,P.S., Singh,S., Lee,A., Muhammad Yassin,M.A.,	Sample size N = 61	Interventions Oxytocin: 100 IU in 30 ml of 0.9%	Details Management of third stage of labour	Results Manual removal of the placenta (n/total (%))	Limitations Appropriate randomisation: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Umbilical vein oxytocin in the management of retained placenta: an alternative to manual removal of placenta?, Archives of Gynecology and Obstetrics, 284, 1073-1079, 2011 Ref Id 156038 Country/ies where the study was carried out Malaysia Study type Randomised controlled trial Aim of the study To evaluate the effectiveness of intraumbilical vein injection of oxytocin compared to controlled cord traction (CCT) in reducing the need for manual removal of the placenta Study dates December 2002 to March 2004	Characteristics Age/years (mean ± SD) Oxytocin: 30.0 ± 4.40 Control: 28.3 ± 6.1 Multiparous (n (%)) Oxytocin: 20 (66.7) Control: 18 (58.1) Induction of labour (n (%)) Oxytocin: 3 (10) Control: 4 (12.9) Instrumental birth (n (%)) Oxytocin: 2 (6.7) Control: 1 (3.2) Previous scar (n (%)) Oxytocin: 4 (13.3) Control: 4 (12.9) History of D&C (n (%)) Oxytocin: 12 (40) Control: 6 (19.4) History of retained placenta (n (%)) Oxytocin: 2 (6.7) Control: 4 (12.9)	sodium chloride (n = 30) Comparator Controlled cord traction (n = 31)	All women had active management of the third stage of labour - 1 ml of syntometrine was given intramuscularly (IM) during delivery of the anterior shoulder or crowning of the head. Syntocinon (10 IU) was given in the case of hypertension or cardiac disease. The umbilical cord was clamped and cut immediately. CCT was done in all patients where there were signs of separation. In cases without signs of separation, gentle traction combined with counter traction were attempted at 5 minutes after birth. It was repeated every 2-3 minutes if the third attempt failed. No fundal pressure was used. Recruitment and randomisation Retained placenta was	Oxytocin: 9/30 (30) Control: 21/31 (67.7) Postpartum haemorrhage (n/total (%)) a. At least 500 ml Oxytocin: 6/30 (20) Control: 11/31 (35.5) b. More than 1000 ml Oxytocin: 1/30 (3.3) Control: 1/31 (3.2) Need for further intervention (n/total (%)) a. Blood transfusion Oxytocin: 2/30 (6.7) Control: 3/31 (9.7) b. Uterine curettage Oxytocin: 0/30 (0) Control: 1/31 (3.2) c. Uterotonic drugs Oxytocin: 10/30 (33.3) Control: 20/31 (64.5) Drop in haemoglobin/g per dl Oxytocin: 0.75 (0 - 2.18) Control: 1.00 (0 - 1.80)	Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No Missing data/loss to follow-up: No Precise definition of outcomes: It is unclear whether the drop in haemoglobin is a mean or a median; also not reported at what point "time to deliver placenta" was measured from Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported	Pre-birth haemoglobin (mean ± SD) Oxytocin: 11.4 ± 1.28 Control: 11.8 ± 1.14 Management of third stage (n (%)) - Syntocinon Oxytocin: 1 (3.3) Control: 3 (9.7) - Syntometrine Oxytocin: 29 (96.7) Control: 28 (90.3) Interval between birth of baby and commencement of oxytocin injection or CCT/minutes (mean (range)) Oxytocin: 35 (30.75 - 41.75) Control: 33 (20 - 38) Inclusion criteria Singleton pregnancy > 28 weeks		defined as failure to deliver the placenta 20 minutes after delivery of the baby. Eligible women were then randomised using a box containing equal numbers of envelopes (50 each) with either group 1 or group 2. Women were allocated by opening one of the sealed opaque envelopes (taken randomly from the box). The envelopes were prepared by a staff member not involved in the study and who kept those involved in recruitment unaware of what allocation had already occurred. Protocol Women were managed as follows: - Oxytocin group 100 ml of oxytocin diluted in 30 ml of 0.9%	p > 0.05 [Note: it is not reported whether these figures represent means or medians] Time needed to deliver placenta/minutes (median) Oxytocin: 5 (4 - 10*) Control: 15 (10.75 - 21.75*) * It is not reported whether these values are ranges, IQR, or confidence intervals. 60% of the oxytocin group were delivered within 10 minutes; 25.8% of control group were delivered within 20 minutes.	Yes - all women for whom an envelope was opened were followed up regardless of subsequent management. Indirectness: - Includes women > 28 weeks; therefore an unknown proportion of women are outside the scope of the guideline - Reported time to deliver placenta is reported, when actual outcome of interest is duration of the third stage of labour Other information Population: women with active management and no PPH

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Vaginal birth Failure to deliver the placenta after 20 minutes of birth Active management of third stage Exclusion criteria Placenta previa Primary postpartum haemorrhage (PPH) Snapped umbilical cord Emergency caesarean section (CS) in labour Haemodynamic instability or illness Severe anaemia Chorioamnionitis Refusal to participate		sodium chloride solution and was injected into the vein of the umbilical cord via a 40 cm infant feeding tube. Oxytocin was infused through the tube into the umbilical vein up to 5 cm from the insertion of the cord. The cord was occluded with finger pressure around the cathether during injection. Following injection of the solution, the cord was clamped with the catheter in position. Intermittent (every 2-3 minutes) controlled cord traction was then stared 1 minutes after the injection. - CCT group Intermittent controlled cord traction was done following randomisation. Administration of oxytocin and CCT were done by a single		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			operator in order to eliminate operator bias. Manual removal was done if the placenta had not been expelled after 30 minutes. IV infusion of oxytocin (40 units in 500 ml of saline) was started if bleeding occurred. Outcomes reported 1. Need for manual removal of the placenta: to avoid bias, there was a strict protocol that failure to deliver the placenta within 30 minutes constituted treatment failure 2. Postpartum haemorrhage: blood loss of 500 ml or more within 24 hours of birth; measured by collecting all blood and closts in a graduated container and counting swabs and linen		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			3. Need for further intervention: blood transfusion, curettage and uterotonic drugs are reported 4. Drop in haemoglobin 5. Time needed to deliver placenta: unclear at what point this was measured from Statistical analysis Power calculation was based on manual removal of the placenta - assuming 63% of the control group and 28% of the oxytocin group would need a manual removal, 28 patients were needed in each group to detect a difference (p = 0.05) with 80% power. Fisher's exact test and ANOVA were used to assess comparability of groups at baseline. Chi-		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			squared, Fisher's exact test, and ANOVA were used to compare outcomes as appropriate		
Full citation Nardin,J.M., Weeks,A., Carroli,G., Umbilical vein injection for management of retained placenta. [Update of Cochrane Database Syst Rev. 2001;(4):CD001337; PMID: 11687109], Cochrane Database of Systematic Reviews, 5, CD001337-, 2011 Ref Id 143495 Country/ies where the study was carried out Various Study type Systematic review of RCTs Aim of the study To determine the possible risks and benefits of the	Sample size N = 1704 (from 15 trials) Characteristics Bider 1996 Definition of retained placenta: 60 minutes Limit time for manual removal: 30 minutes Gestational age: not reported (NR) Interventions: - UVI prostaglandin F2-alpha 20 mg + 20 ml saline solution - UVI oxytocin 30 IU in 3 ml + 20 ml solution - UVI saline 20 ml Calderale 1994 Definition of retained	Interventions UVI of oxytocin plus saline Comparator Expectant management UVI of saline only UVI of plasma expander UVI of prostaglandin plus saline	Details Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by contacting the Trials Search Coordinator. CENTRAL, MEDLINE, EMBASE were searched, and hand searching of journals and conference proceedings was done. No language restrictions were applied. Selection of studies Two review authors independently assessed all potential studies for inclusion. Any disagreement was resolved through	Results The following meta-analyses all use fixed effects model, and are as presented in the Cochrane review. OXYTOCIN SOLUTION VS. EXPECTANT MANAGEMENT (Comparison 2 from review) Maternal mortality (number/total) Oxytocin: 0/45 Expectant: 0/48 RR 0.0 (95% CI 0.0 to 0.0) Heterogeneity: Chi2 = 0.0, df = 0 (P < 0.00001); I2 = 0.0% Test for overall effect: Z = 0.0 (P < 0.00001) (2 trials: Gazvani et al., 1998; Kristiansen et al.,	Limitations Using the NICE methodology checklist for systematic reviews, there are no major limitations to this systematic review. The authors assessed risk of bias for each of the individual studies: - Method of randomisation: 6 were at low risk of bias, 9 had unclear risk of bias - Allocation concealment: 9 were at low risk of bias, 6 had an unclear risk of bias

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
use of umbilical vein injection (UVI) in the management of retained placenta Study dates Assessed as up-to-date on March 9th 2011 Source of funding Department of Reproductive Health and Research, WHO (Switzerland) and Secretaria de Salud Publica, Municipalidad de Rosario (Argentina) are reported as external sources of support	placenta: 30 minutes Limit time for manual removal: 30 minutes Gestational age: 34 - 42 weeks Interventions: - UVI oxytocin 10 IU in 1 ml + 20 ml saline solution - UVI placebo + saline solution 20 ml Carroli 1998 Definition of retained placenta: 30 minutes Limit time for manual removal: 30 minutes Gestational age: NR Interventions: - UVI oxytocin 20 IU in 2 ml + 18 ml saline solution - UVI saline 2 ml + 18 ml saline solution - Expectant management (Note: After the first 40 women, the injected volume was increased		consultation with a third person. Data extraction and management A form was designed to extract data, and two authors extracted it. It was analysed in RevMan. Where information was unclear, the reviewers attempted to contact the original authors. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Sequence generation - Allocation concealment - Blinding - Incomplete outcome data - Selective reporting bias	1987) Manual removal of the placenta (number/total) Oxytocin: 117/234 Expectant: 123/210 RR 0.87 (95% CI 0.74 to 1.03) Heterogeneity: Chi2 = 6.88, df = 4 (P = 0.14); I2 = 42% Test for overall effect: Z = 1.62 (P = 0.10) (5 trials: Carroli et al., 1998; Gazvani et al., 1998; Huber et al., 1991; Thiery, 1987; Kristiansen et al., 1987) Need for further intervention (number/total) a. Blood transfusion Oxytocin: 18/120 Expectant: 19/117 RR 0.89 (95% CI 0.50 to 1.58) Heterogeneity: Chi2 = 0.0, df = 0 (P = 1.00); I2 = 0.0% Test for overall effect: Z = 0.41 (P = 0.68)	- Blinding: 6 were at high risk of bias, 8 were at low risk of bias, and 1 study was not assessed on this criterion - Incomplete outcome data: 3 were at high risk of bias and 6 were at low risk of bias - Selective reporting: 1 was at high risk of bias, 5 were at low risk of bias - Overall quality: 8 were rated as being of high methdological quality, 5 were rated as being of poor methodological quality, and in 2 studies there was insufficient information Other information Details of the active management of the third stage, and whether or not

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	to 40 ml) Frappell 1988 Definition of retained placenta: 15 minutes Limit time for manual removal: 15 minutes Gestational age: NR Interventions: - UVI oxytocin 10 IU in 1 ml + 20 ml saline solution - UVI saline 1 ml + 20 ml saline solution Gazvani 1998 Definition of retained placenta: 30 minutes (point at which UVI was given) Gestational age: ≥ 28 weeks Interventions: - UVI oxytocin 20 IU in 2 ml + 20 ml saline solution - UVI saline solution 20 ml - No injection		- Other sources of bias Measures of effect Dichotomous outcomes were presented as a risk ratio with 95% confidence intervals. For continuous data, mean difference and standardised mean difference were used, depending on whether trials had measured outcomes on the same or different scales. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis, with the denominator being set as the number randomised minus any participants whose	(2 trials: Carroli et al., 1998; Gazvani et al., 1998) b. Surgical evacuation of RPoC Oxytocin: 23/94 Expectant: 31/88 RR 0.69 (95% CI 0.44 to 1.09) Heterogeneity: not applicable Test for overall effect: Z = 1.57 (P = 0.12) (1 trial: Carroli et al., 1998) Postpartum haemorrhage (number/total (%)) a. Blood loss ≥ 500 ml Oxytocin: 26/96 Expectant: 15/89 RR 1.51 (95% CI 0.87 to 2.60) Heterogeneity: Chi2 = 0.05, df = 1 (P = 0.82); I2 = 0.0% Test for overall effect: Z = 1.47 (P = 0.14)	women with PPH were included or excluded, were not consistently reported in the Cochrane review and therefore the full texts have been used for reference. See below for details that were extracted from the full text: Bider 1996 - Active management: 10 IU of oxytocin was injection IV after delivery if women had not received oxytocin in labour; cord was clamped. - PPH: Excluded. Calderale 1994 - Active management: Full paper is not in English; therefore no further details can be reported - PPH: Full paper is not in English; therefore no further

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Hansen 1987 Definition of retained placenta: 30 minutes Limit time for manual removal: 15 minutes PPH: Cochrane review reports that one woman with heavy bleeding was not entered. Gestational age: NR Interventions: - UVI oxytocin 10 IU in 1 ml + 20 ml saline solution - UVI saline 1 ml + 20 ml saline solution Huber 1991 Definition of retained placenta: 30 minutes Limit time for manual removal: based on clinical judgement Gestational age: ≥ 28 weeks Interventions:		outcomes were known to be missing. Analysis If high levels of heterogeneity (> 50%) were identified, pre-specified sensitivity analysis was done according to the quality of the trials. A random effects model was used as an overall summary where appropriate. Fixed-effect meta-analysis was used where trials were comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where heterogeneity was present or suspected.	(2 trials: Carroli et al., 1998; Gazvani et al., 1998) b. Blood loss ≥ 1000 ml Oxytocin: 6/70 Expectant: 4/60 RR 1.29 (95% CI 0.38 to 4.34) Heterogeneity: not applicable Test for overall effect: Z = 0.40 (P = 0.69) (1 trial: Carroli et al., 1998) Postnatal haemoglobin (mean ± SD) a. 24 - 48 hours postpartum Oxytocin: 9.7 ± 1.9 (n = 85) Expectant: 9.7 ± 2.1 (n = 81) Mean difference 0.0 (95% CI -0.61 to 0.61) Heterogeneity: not applicable Test for overall effect: Z = 0.0 (P = 1.0) (1 trial: Carroli et al., 1998)	details can be reported Carroli 1998 - Active management: 40 - 46% women had oxytocic in the third stage; 56 - 63% women had cord traction in the third stage; 67 - 71% had fundal pressure. All women had their cord clamped and cut. - PPH: No details given (although the Cochrane review reports that women with signs of hypovolaemic shock were excluded). - Gestational age: 16 - 20% of each arm had a gestational age < 37 weeks. The mean in each arm was 38 weeks (SD 4). Frappell 1988 - Active management: Syntometrine (5 IU

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	- UVI oxytocin 10 IU in 1 ml + 20 ml saline solution - UVI saline 1 ml + 20 ml saline solution - Expectant management Kristiansen 1987 Definition of retained placenta: 20 minutes Gestational age: NR Interventions: - UVI oxytocin 10 IU in 1 ml + 10 ml saline solution - UVI saline 10 ml - Expectant management Makkonen 1995 Definition of retained placenta: 30 minutes Limit time for manual removal: 30 minutes Gestational age: NR Interventions: - UVI oxytocin 50 IU in 5 ml + 15 ml saline			b. 40 - 45 days postpartum Oxytocin: 10.9 ± 1.7 (n = 47) Expectant: 10.4 ± 1.5 (n = 49) Mean difference 0.5 (95% CI -0.14 to 1.14) Heterogeneity: not applicable Test for overall effect: Z = 1.53 (P = 0.13) (1 trial: Carroli et al., 1998) Serious maternal morbidity (number/total) Oxytocin: 0/45 Expectant: 0/45 RR 0.0 (95% CI 0.0 to 0.0) Heterogeneity: Chi2 = 0.0, df = 0 (P < 0.00001); I2 = 0.0% Test for overall effect: Z = 0.0 (P < 0.00001) (2 trials: Gazvani et al., 1998; Kristiansen et al., 1987) Infection (number/total)	oxytocin with 0.5 mg ergometrine maleate) was given IM with the delivery of the anterior shoulder - PPH: No details given - Gestational age: Oxytocin arm had mean 38.5 (range 29 - 42); Placebo arm had mean 39 (range 25 - 41) Gazvani 1998 - Limit time for manual removal: If the placenta had not delivered by 15 minutes after the injection, a vaginal examination was done to ease the placenta trapped in the os, and if that was unsuccessful, a manual removal was arranged - Active management: 1 ml of Syntometrine (ergometrine maleate

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	solution - UVI plasma expander (Dextran 70) 20 ml Rogers 2007 Definition of retained placenta: 45 minutes Limit time for manual removal: 30 minutes Gestational age: > 37 weeks Interventions: - UVI oxytocin 50 IU in 5 ml + 25 ml saline solution - UVI prostaglandin E1 analogue (misoprostol) 800 micrograms + saline solution 30 ml - UVI saline 30 ml Selinger 1986 Definition of retained placenta: 20 minutes Limit time for manual removal: 15 minutes PPH: Excluded those who were bleeding heavily.			Oxytocin: 5/93 Expectant: 4/86 RR 1.16 (95% CI 0.32 to 4.16) Heterogeneity: not applicable Test for overall effect: Z = 0.22 (P = 0.82) (1 trial: Carroli et al., 1998) OXYTOCIN VS. SALINE SOLUTION (Comparison 3 from review) Maternal mortality (number/total) Oxytocin: 1/369 Saline: 0/355 RR 2.93 (95% CI 0.12 to 71.59) Heterogeneity: Chi2 = 0.0, df = 0 (P = 1.00); I2 = 0.0% Test for overall effect: Z = 0.66 (P = 0.51) (4 trials: Gazvani et al., 1998; Hansen et al., 1987; Kristiansen et al., 1987; Weeks et al., 2009)	0.5 mg and oxytocin 5 IU) IM after delivery of the anterior shoulder. Cords were clamped soon after delivery. After clinical signs of placental separation, maternal effort was encouraged to deliver the placenta, otherwise cord traction was used. - PPH: Excluded - women with PPH requiring immediate intervention were not included. - Gestational age: Median (range) were: 39 (37 - 40), 39 (38 - 40), 40 (36 - 40) Hansen 1987 - Active management: Full text is not in English; therefore no details can be accessed

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Gestational age: NR Interventions: - UVI oxytocin 10 IU in 1 ml + 19 ml saline solution - UVI saline 20 ml Sivalingam 2001 Definition of retained placenta: 20 minutes Limit time for manual removal: 30 minutes PPH: Excluded Gestational age: ≥ 28 weeks Interventions: - UVI oxytocin 30 IU in 3 ml + 27 ml saline solution - UVI saline 30 ml Thiery 1987 Definition of retained placenta: 15 minutes Limit time for manual removal: 15 minutes Active management: Personal communication stated			Manual removal of the placenta (number/total) Oxytocin: 355/655 Saline: 371/621 RR 0.91 (95% CI 0.82 to 1.00) Heterogeneity: Chi2 = 19.85, df = 11 (P = 0.05); I2 = 45% Test for overall effect: Z = 2.05 (P = 0.041) (12 trials: Calderale et al., 1994; Carroli et al., 1998; Frappell et al., 1988; Gazvani et al., 1998; Hansen et al., 1987; Huber et al., 1991; Kristiansen et al., 1987; Rogers et al., 2007; Selinger et al., 1986; Sivalingam & Surinder, 2001; Weeks et al., 2009; Wilken-Jensen et al., 1989) Need for further intervention (number/total) a. Additional therapeutic uterotonics Oxytocin: 43/346	Huber 1991 - Active management: 54 - 66% of women received oxytocin in the third stage. No further details given - PPH: No details given. - Gestational age: mean is 39 weeks in each arm Kristiansen 1987 - Limit time for manual removal: Not reported - Active management: No details given - PPH: No details given Makkonen 1995 - Active management: Yes. Oxytocin 5 IU IV and ergometrine maleate 0.2 mg IM after delivery of the fetus. - PPH: Unclear but they report that manual removal was

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	in Cochrane review; therefore no further details can be accessed PPH: Personal communication stated in Cochrane review; therefore no further details can be accessed Gestational age: NR Interventions: - UVI oxytocin 10 IU in 1 ml + 20 ml saline solution - Expectant management Weeks 2009 Definition of retained placenta: 30 minutes PPH: Excluded - only women not bleeding were eligible. Gestational age: > 34 weeks gestation or > 2 kg birth weight Interventions: - UVI oxytocin 50 IU			Saline: 46/332 RR 0.85 (95% CI 0.59 to 1.23) Heterogeneity: Chi2 = 5.82, df = 3 (P = 0.12); I2 = 48% Test for overall effect: Z = 0.85 (P = 0.39) (4 trials: Bider et al., 1996; Hansen et al., 1987; Sivalingam & Surinder, 2001; Weeks et al., 2009) b. Blood transfusion Oxytocin: 63/446 Saline: 52/434 RR 1.18 (95% CI 0.84 to 1.65) Heterogeneity: Chi2 = 0.41, df = 3 (P = 0.94); I2 = 0.0% Test for overall effect: Z = 0.95 (P = 0.34) (5 trials: Carroli et al., 1998; Gazvani et al., 1998; Selinger et al., 1986; Sivalingam & Surinder, 2001; Weeks et al., 2009)	preformed earlier if the haemorrhage was heavy - Gestational age: mean was 38.8 weeks in one arm and 39.2 weeks in the other Rogers 2007 - Active management: Yes. Syntometrine 1 ml IM or Syntocinon 10 units IV at delivery of the anterior shoulder, followed by early cord clamping. - PPH: Excluded - those with significant bleeding were not included Selinger 1986 - Active management: Yes. 1 ml of Syntometrine IM was given with the delivery of the anterior shoulder. - Gestational age: Mean was 39.4 (SD

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	in 5 ml + 25 ml saline solution - UVI placebo (5 ml sterile water) + 25 ml saline Wilken-Jensen 1989 Definition of retained placenta: 20 minutes Limit time for manual removal: 40 minutes Gestational age: NR Interventions: - UVI oxytocin 100 IU in 10 ml + 20 ml saline solution - UVI saline 30 ml Inclusion criteria Trials comparing UVI of saline solution with other fluids, with or without uterotonic drugs, either with expectant management or with an alternative solution or uterotonic, in the management of retained placenta.			c. Surgical evacuation of RPoC Oxytocin: 27/420 Saline: 29/406 RR 0.89 (95% CI 0.56 to 1.40) Heterogeneity: Chi2 = 1.00, df = 3 (P = 0.80); I2 = 0.0% Test for overall effect: Z = 0.50 (P = 0.61) (4 trials: Carroli et al., 1998; Selinger et al., 1986; Sivalingam & Surinder, 2001; Weeks et al., 2009) Postpartum haemorrhage a. Blood loss ≥ 500 ml Oxytocin: 131/424 Saline: 124/405 RR 1.01 (95% CI 0.83 to 1.24) Heterogeneity: Chi2 = 4.87, df = 4 (P = 0.30); I2 = 18% Test for overall effect: Z = 0.12 (P = 0.90) (5 trials: Carroli et al., 1998; Frappell et al., 1988;	1.7) in one arm and 39.8 (SD 1.0) in the other arm. Sivalingam 2001 - Active management: Yes. Syntometrine 1 ml (oxytocin 5 units + ergometrine 0.5 mg) given IM either during delivery of the anterior shoulder or during crowning of the head. Immediate cord clamping was done, and controlled cord traction was performed using the Brandt-Andrew technique. No fundal pressure was applied. Thiery 1987 - Personal communication stated in Cochrane review; therefore no further details can be accessed Weeks 2009

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Trials including women in whom the placenta was not delivered spontaneously at least 15 minutes after vaginal delivery of the baby. Exclusion criteria None reported			Gazvani et al., 1998; Sivalingam & Surinder, 2001; Weeks et al., 2009) b. Blood loss ≥ 1000 ml Oxytocin: 37/391 Saline: 33/375 RR 1.08 (95% CI 0.70 to 1.68) Heterogeneity: Chi2 = 1.77, df = 3 (P = 0.62); I2 = 0.0% Test for overall effect: Z = 0.34 (P = 0.73) (4 trials: Carroli et al., 1998; Selinger et al., 1986; Sivalingam & Surinder, 2001; Weeks et al., 2009) Postnatal haemoglobin a. 24 - 48 hours postpartum (mean ± SD) Oxytocin: 9.7±1.9 (n = 85) Saline: 9.8±2.4 (n = 82) Mean difference -0.10 (95% CI -0.76 to 0.56) Heterogeneity: not applicable Test for overall effect: Z =	- Limit time for manual removal: Cord traction was tried 30 minutes after injection, and if this was unsuccessful a manual removal was done. - Active management: Yes, but exact details not given. Reports excluding women requesting physiological management which is defined as no early cord clamping, no prophylactic oxytocics, no cord traction or fundal pressure. - Gestational age: 7.6% of one arm and 7.8% of one arm were < 37 weeks gestation Wilken-Jensen 1989 - Active management: Methylergometrine (0.2 mg) was given

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				0.30 (P = 0.77) (1 trial: Carroli et al., 1998) b. 40 - 45 days postpartum (mean ± SD) Oxytocin: 10.9 ± 1.7 (n = 47) Saline: 10.8 ± 1.6 (n = 44) Mean difference 0.10 (95% CI -0.58 to 0.78) Heterogeneity: not applicable Test for overall effect: Z = 0.29 (P = 0.77) (1 trial: Carroli et al., 1998) c. Haemoglobin levels fall (number/total) Oxytocin: 185/274 Saline: 178/267 RR 1.01 (95% CI 0.90 to 1.14) Heterogeneity: not applicable Test for overall effect: Z = 0.21 (P = 0.83) (1 trial: Weeks et al., 2009)	IM at delivery of the first shoulder - PPH: Excluded women with heavy bleeding requiring immediate removal

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Serious maternal morbidity (number/total) Oxytocin: 0/369 Saline: 1/355 RR 0.33 (95% CI 0.01 to 7.95) Heterogeneity: Chi2 = 0.0, df = 0 (P = 1.00); I2 = 0.0% Test for overall effect: Z = 0.69 (P = 0.49) (4 trials: Gazvani et al., 1998; Hansen et al., 1987; Kristiansen et al., 1987; Weeks et al., 2009) Infection (number/total) Oxytocin: 43/417 Saline: 31/403 RR 1.35 (95% CI 0.87 to 2.09) Heterogeneity: Chi2 = 0.56, df = 1 (P = 0.46); I2 = 0.0% Test for overall effect: Z = 1.36 (P = 0.17) (3 trials: Carroli et al., 1998; Hansen et al., 1987; Weeks	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				et al., 2009) Adverse effects (number/total) a. Nausea following injection Oxytocin: 0/32 Saline: 0/28 RR 0.0 (95% CI 0.0 to 0.0) Heterogeneity: not applicable Test for overall effect: Z = 0.0 (P < 0.00001) (1 trial: Hansen et al., 1987) b. Fever Oxytocin: 1/43 Saline: 0/35 RR 2.00 (95% CI 0.09 to 43.22) Heterogeneity: Chi2 = 0.0, df = 0 (P = 1.00); I2 = 0.0% Test for overall effect: Z = 0.44 (P = 0.66) (2 trials: Bider et al., 1996; Hansen et al., 1987) c. Headache following	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				injection Oxytocin: 0/32 Saline: 0/28 RR 0.0 (95% CI 0.0 to 0.0) Heterogeneity: not applicable Test for overall effect: Z = 0.0 (P < 0.00001) (1 trial: Hansen et al., 1987) d. Shivering following injection Oxytocin: 0/32 Saline: 0/28 RR 0.0 (95% CI 0.0 to 0.0) Heterogeneity: not applicable Test for overall effect: Z = 0.0 (P < 0.00001) (1 trial: Hansen et al., 1987) e. Hypertension following injection Oxytocin: 0/32 Saline: 0/28 RR 0.0 (95% CI 0.0 to 0.0)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Heterogeneity: not applicable Test for overall effect: Z = 0.0 (P < 0.00001) (1 trial: Hansen et al., 1987) Length of third stage of labour/minutes (mean ± SD) Oxytocin: 111.4±43.2 (n = 15) Saline: 95.2 ± 44.6 (n = 15) Mean difference 16.20 (95% CI -15.22 to 47.62) Heterogeneity: not applicable Test for overall effect: Z = 1.01 (P = 0.31) (1 trial: Selinger et al., 1986) OXYTOCIN VS. PLASMA EXPANDER (comparison 4 from review) Manual removal of the placenta (number/total) Oxytocin: 49/68 Plasma expander: 22/41 RR 1.34 (95% CI 0.97 to 1.85)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Heterogeneity: not applicable Test for overall effect: Z = 1.80 (P = 0.072) (1 trial: Makkonen et al., 1995) Blood loss ≥ 1000 ml (number/total) Oxytocin: 8/68 Plasma expander: 5/41 RR 0.96 (95% CI 0.34 to 2.75) Heterogeneity: not applicable Test for overall effect: Z = 0.07 (P = 0.95) (1 trial: Makkonen et al., 1995) PROSTAGLANDIN SOLUTION VS. OXYTOCIN SOLUTION (comparison 6 from review) Manual removal of the placenta (number/total) Prostaglandin: 9/31 Oxytocin: 21/31	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				RR 0.43 (95% CI 0.25 to 0.75) Heterogeneity: Chi2 = 1.71, df = 1 (P = 0.19); I2 = 42% Test for overall effect: Z = 2.96 (P = 0.0031) (2 trials: Bider et al., 1996; Rogers et al., 2007) Need for additional therapeutic uterotonics (number/total) Prostaglandin: 6/10 Oxytocin: 5/11 RR 1.32 (95% CI 0.58 to 3.00) Heterogeneity: not applicable Test for overall effect: Z = 0.66 (P = 0.51) (1 trial: Bider et al., 1996) Adverse effects: Fever (number/total) Prostaglandin: 1/10 Oxytocin: 1/11 RR 1.10 (95% CI 0.08 to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				15.36) Heterogeneity: not applicable Test for overall effect: Z = 0.07 (P = 0.94) (1 trial: Bider et al., 1996) Time from injection to placental delivery/minutes (mean±SD) Prostaglandin: 7 ± 3.2 (n = 10) Oxytocin: 13 ± 3.3 (n = 11) Mean difference -6.00 (95% CI-8.78 to -3.22) Heterogeneity: not applicable Test for overall effect: Z = 4.23 (P = 0.000024) (1 trial: Bider et al., 1996) SALINE SOLUTION VS. EXPECTANT MANAGEMENT (comparison 1 in review) Maternal mortality (number/total) Saline: 0/42	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Expectant: 0/45 RR 0.0 (95% CI 0.0 to 0.0) Heterogeneity: Chi2 = 0.0, df = 0 (P<0.00001); I2 = 0.0% Test for overall effect: Z = 0.0 (P < 0.00001) (2 trials: Gazvani et al., 1998; Kristiansen et al., 1987) Need for manual removal of the placenta (number/total) Saline: 114/206 Expectant: 113/197 RR 0.99 (95% CI 0.84 to 1.16) Heterogeneity: Chi2 = 0.93, df = 3 (P = 0.82); I2 = 0.0% Test for overall effect: Z = 0.12 (P = 0.91) (4 trials: Carroli et al., 1998; Gazvani et al., 1998; Huber et al., 1991; Kristiansen et al., 1987) Need for further intervention (number/total)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				a. Blood transfusion Saline: 15/118 Expectant: 19/117 RR 0.76 (95% CI 0.41 to 1.39) Heterogeneity: Chi2 = 0.0, df = 0 (P = 1.00); I2 = 0.0% Test for overall effect: Z = 0.90 (P = 0.37) (2 trials: Carroli et al., 1998; Gazvani et al., 1998) b. Surgery to remove RPoC Saline: 25/90 Expectant: 31/88 RR 0.79 (95% CI 0.51 to 1.22) Heterogeneity: not applicable Test for overall effect: Z = 1.06 (P = 0.29) (1 trial: Carroli et al., 1998) Postpartum haemorrhage (number/total) a. Blood loss ≥ 500 ml	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Saline: 15/88 Expectant: 15/89 RR 0.98 (95% CI 0.52 to 1.82) Heterogeneity: Chi2 = 0.40, df = 1 (P = 0.53); I2 = 0.0% Test for overall effect: Z = 0.08 (P = 0.94) (2 trials: Carroli et al., 1998; Gazvani et al., 1998) b. Blood loss ≥ 1000 ml Saline: 3/62 Expectant: 4/60 RR 0.73 (95% CI 0.17 to 3.11) Heterogeneity: not applicable Test for overall effect: Z = 0.43 (P = 0.67) (1 trial: Carroli et al., 1998) Postnatal haemoglobin (mean ± SD) a. 24 - 48 hours postpartum Saline: 9.8 ± 2.4 (n = 82) Expectant: 9.7 ± 2.1 (n = 81)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Mean difference 0.10 (95% CI -0.59 to 0.79) Heterogeneity: not applicable Test for overall effect: Z = 0.28 (P = 0.78) (1 trial: Carroli et al., 1998) b. 40 - 45 days postpartum Saline: 10.8 ± 1.6 (n = 44) Expectant: 10.4 ± 1.5 (n = 49) Mean difference 0.40 (95% CI -0.23 to 1.03) Heterogeneity: not applicable Test for overall effect: Z = 1.24 (P = 0.22) (1 trial: Carroli et al., 1998) Serious maternal morbidity (number/total) Saline: 0/42 Expectant: 0/45 RR 0.0 (95% CI 0.0 to 0.0) Heterogeneity: Chi2 = 0.0, df	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				= 0 (P < 0.00001); I2 = 0.0% Test for overall effect: Z = 0.0 (P < 0.00001) (2 trials: Gazvani et al., 1998; Kristiansen et al., 1987) Infection (number/total) Saline: 2/90 Expectant: 4/86 RR 0.48 (95% CI 0.09 to 2.54) Heterogeneity: not applicable Test for overall effect: Z = 0.87 (P = 0.39) (1 trial: Carroli et al., 1998) PROSTAGLANDIN SOLUTION VS. SALINE SOLUTION (comparison 5 in review) Need for manual removal of the placenta (number/total) Prostaglandin: 9/31 Saline: 14/20 RR 0.42 (95% CI 0.22 to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				0.82) Heterogeneity: Chi2 = 5.56, df = 1 (P = 0.02); I2 = 82% Test for overall effect: Z = 2.53 (P = 0.011) (2 trials: Bider et al., 1996; Rogers et al., 2007) Need for additional therapeutic uterotonics (number/total) Prostaglandin: 6/10 Saline: 4/7 RR 1.05 (95% CI 0.46 to 2.38) Heterogeneity: not applicable Test for overall effect: Z = 0.12 (P = 0.91) (1 trial: Bider et al., 1996) Fever (number/total) Prostaglandin: 1/10 Saline: 0/7 RR 2.18 (95% CI 0.10 to 46.92) Heterogeneity: not	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				applicable Test for overall effect: Z = 0.50 (P = 0.62) (1 trial: Bider et al., 1996)	
Full citation van Beekhuizen,H.J., de Groot,A.N., De,Boo T., Burger,D., Jansen,N., Lotgering,F.K., Sulprostone reduces the need for the manual removal of the placenta in patients with retained placenta: a randomized controlled trial, American Journal of Obstetrics and Gynecology, 194, 446-450, 2006 Ref Id 121578 Country/ies where the study was carried out The Netherlands Study type Randomised controlled trial (phase 1) with an additional, non-comparative second phase	Sample size N = 50 Characteristics Nulliparous (number/total (%)) - Phase 1: Sulprostone: 13/24 (54.2) Placebo: 12/26 (46.2) - Phase 2: 37/53 (69.8) Obstetric history (number/total (%)) a. Manual removal of placenta - Phase 1 Sulprostone: 2/24 (8.3) Placebo: 3/26 (11.5) - Phase 2: 1/53 (1.9) b. Caesarean birth	Interventions Sulprostone (n = 24) (Note: a further 53 women received sulprostone in phase 2, the non-comparative phase) Comparator Placebo (n = 26)	Details Recruitment and participants Women with retained placenta were recruited from 6 hospitals, and included both women who were admitted for a hospital delivery and women who had been referred because of retained placenta following home delivery. Patients who delivered in hospital all received active management of labour: oxytocin 10 IU was given intramuscularly immediately after delivery of the infant, and controlled cord traction was performed	Results PHASE 1: RCT Need for manual removal of the placenta (number/total (%)) Sulprostone: 11/24 (45.8) Placebo: 22/26 (84.6) (Note: 2 of these patients, one from each arm, required a uterine relaxant during the manual removal) Need for a blood transfusion (number/total (%)) Sulprostone: 6/24 (25) Placebo: 8/26 (30.8) Need for a hysterectomy (number/total (%)) Sulprostone: 0/24 Placebo: 0/26 Reported side effects	Limitations Appropriate randomisation: Yes. Allocation concealment: unclear whether envelopes were opaque Groups comparable at baseline: Some details are reported Groups received same care (apart from intervention): unclear whether proportion of women with a home birth (who received slightly different care) was the same in each arm Blinding of participants: unclear, but probably as clinicians were blinded

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To determine the extent to which sulprostone administration reduces the need for manual removal of the placenta in women with retained placenta Study dates Phase 1: July 2002 to September 2003 Phase 2: September 2003 to August 2004 Source of funding None reported	- Phase 1 Sulprostone: 1/24 (4.2) Placebo: 1/26 (3.8) - Phase 2: 1/53 (1.9) c. Curettage - Phase 1 Sulprostone: 2/24 (8.3) Placebo: 5/26 (19.2) - Phase 2: 8/53 (15.1) Inclusion criteria Retained placenta Exclusion criteria Blood loss ≥ 1000 ml Reduction in diastolic blood pressure ≥ 20 mm Hg Tachycardia ≥ 120 beats per minute Gynecologic infection Age < 18 years or > 40 years Gestational age ≤ 28		at the first uterine contraction. If the placenta could not be expelled, the bladder was catheterised and after 30 minutes controlled cord traction was attempted again. If the placenta was retained at 45 minutes after delivery of the infant, the patient was asked to participate in the trial. Patients who were referred from home received the same treatment once they arrived in hospital. 60 patients were asked to participate in phase 1 of the study, of which 1 refused and 9 could not be included (1 withdrew consent, 1 had a contraindication following inclusion, 3 expelled the placenta before trial medication,	(number/total (%)) a. Painful contractions Sulprostone: 3/24 (12.5) Placebo: 2/26 (7.7) b. Dizziness Sulprostone: 1/24 (4.2) Placebo: 1/26 (3.8) c. Flushes Sulprostone: 0/24 Placebo: 1/26 (3.8) d. Nausea Sulprostone: 0/24 Placebo: 1/26 (3.8) PHASE 2: Non-comparative study Need for manual removal of the placenta: 28/53 (52.8%) (Note: 0 patients required a uterine relaxant during manual removal) Need for a blood transfusion: 10/53 (18.9%) (Note: all blood transfusions were in women requiring a	Blinding of staff providing care: Yes Blinding of outcome assessors: Yes Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: includes women giving birth over 28 weeks therefore an unknown proportion of women are outside the scope of the guideline. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	weeks Asthma, bronchitis Epilepsy Cardiac disease Hypertension, pre-eclampsia, HELLP syndrome, Liver failure, renal failure Stomach ulcer, ulcerative colitis Sickle cell anaemia, beta-thalassemia Glaucoma		and 4 had blood loss over 1000 ml before medication). 55 patients were eligible for phase 2 of the study, of which 53 received sulprostone. (1 withdrew consent, and 1 had a technical failure of the pump) Study treatment and randomisation Administration of study medication began if the placenta was retained at 60 minutes after delivery of the infant. Patients received 30 minutes of intravenous infusion of either: - Sulprostone (250 micrograms) - Placebo In phase 1, randomisation was done in blocks of 4, and the allocation of sealed	manual removal) Need for a hysterectomy: 0/53 (0%) Reported side effects: - Abdominal cramps: 8/53 (15.1) - Nausea: 3/53 (5.7) - Shivering: 2/53 (3.8) (Note: The non-comparative data are not reported in the GRADE evidence profile, as the review is restricted to comparative data.)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			envelopes as in the sequence of randomisation. The physician was blinded to treatment. In phase 2, all women received sulprostone and there was no blinding. During the 30 minutes of medication, controlled cord traction was done once every 10 minutes. Medication was ceased immediately after placental delivery. If the placenta had not been expelled after the full dose of medication, or if blood loss exceeded 1500 ml during treatment, a manual removal was done. Analysis A truncated sequence probability test was used to include a maximum of 100 patients. Interim analyses were done		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			after every 5 patients. The procedure was designed to have a power of 80% to detect a 25% difference in success rate of expulsion between the placebo arm and the sulprostone arm. The study was designed so that if the interim analysis were to indicate superiority of sulprostone, all remaining patients would receive sulprostone to test its safety and efficacy (phase 2 of the study) Outcomes reported 1. Manual removal of the placenta 2. Need for further intervention: Need for a blood transfusion, need for a hysterectomy 3. Adverse effects: painful contractions,		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			dizziness, flushes and nausea are reported		
Full citation Visalyaputra,S., Prechapanich,J., Suwanvichai,S., Yimyam,S., Permpolprasert,L., Suksopee,P., Intravenous nitroglycerin for controlled cord traction in the management of retained placenta, International Journal of Gynaecology and Obstetrics, 112, 103-106, 2011 Ref Id 122448 Country/ies where the study was carried out Thailand Study type Randomised controlled trial Aim of the study To determine the effect of 200 micrograms of intravenous nitroglycerin	Sample size N = 40 Characteristics Age / years (mean ± SD) Nitroglycerin: 28.4 ± 5.9 Placebo: 28.0 ± 6.2 (p = 0.85) Gestational age / weeks (mean ± SD) Nitroglycerin: 38.4 ± 2.1 Placebo: 37.5 ± 2.5 (p = 0.45) Estimated blood loss / ml (mean ± SD) a. Before injection Nitroglycerin: 217.5 ± 107.5 Placebo: 176.3 ± 87.2 (p = 0.20) b. After injection	Interventions Nitroglycerin: 200 micrograms in 10 ml of saline intravenously (n = 20) Comparator Placebo: 10 ml of saline intravenously (n = 20)	Details Management of the third stage Immediately following vaginal delivery of the fetus, 10 units of oxytocin in 1000 ml of 0.45% saline with 5% dextrose was administered intravenously at rates of 200-300 ml in the first few minutes and then 100 ml/hour. If the placenta had not separated after 15 or 20 minutes, then 5 more units were given IV. If the placenta still was not delivered, a Kelly clamp was attached and controlled cord traction was done. Recruitment and randomisation If the placenta was	Results Need for a manual removal of the placenta (number/total (%)) Nitroglycerin: 17/20 (75) Placebo: 16/20 (80) Need for further intervention (number/total (%)) a. Repeat manual removal or curettage for retained products Nitroglycerin: 3/20 (15) Placebo: 0/20 (0) (Note: 3 women needed a second procedure because placental parts were incompletely removed during the first manual removal. Of these women, 1 eventually needed a uterine curettage.) b. Need for a blood transfusion Nitroglycerin: 1/20 (10) Placebo: 1/20 (10)	Limitations Appropriate randomisation: Yes Allocation concealment: Unclear. They report that allocation was concealed in an envelope, but not whether the envelope was opaque. Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: Yes Blinding of staff providing care: Yes Blinding of outcome assessors: Yes Missing data/loss to follow-up: No Precise definition of outcomes: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
for the release of retained placenta by cord traction Study dates January 1st 2008 to June 30th 2009 Source of funding The study was supported by the research development fund of Siriraj Hospital and the Faculty of Medicine of Mahidol University, Thailand	Nitroglycerin: 263.9 ± 178.9 Placebo: 230.6 ± 225.7 (p = 0.63) There was also no significant difference between: maternal height, maternal weight, number of abortions, volume of fluid infused before injection, volume of fluid infused after injection, amount of fentanyl used, and postoperative haematocrit. Type of retained placenta (number/total (%)) - Trapped placenta Nitroglycerin: 3/20 (15) Placebo: 3/20 (15) - Placenta adherens Nitroglycerin: 14/20 (70) Placebo: 13/20 (65)		retained after 30 minutes following the delivery of the baby, 500 ml of crystalloid solution was given IV, and an ECG, pulse oximetry and blood pressure monitoring were started. Eligible women were then approached, and verbal consent was obtained for participation in the trial. Of the 47 women initially eligible, 5 were not approached as cord traction had already been done and 2 opted for immediate anaesthesia. The Research Randomizer programme was used to randomise 40 successive eligible women, using a bloc-of-4 method. Group assignments was enclosed in a numbered envelope.	Side effects (number/total (%)) a. Severe hypotension Nitroglycerin: 2/20 (10) Placebo: 2/20 (10) (p = 0.96) b. Headache Nitroglycerin:1/20 (5) Placebo: 0 (0) (p = 0.32) c. Palpitations Nitroglycerin: 1/20 (5) Placebo: 1/20 (5) (p = 0.97) d. Dizziness Nitroglycerin: 1/20 (5) Placebo: 1/20 (5) (p = 0.97)	Valid and reliable method of outcome assessment: Yes in most cases, although it is unclear how side effect data was collected and at what point it was assessed. Intention-to-treat analysis performed: Yes Indirectness: only excludes women < 28 weeks, therefore an unknown proportion of women are not at term and are outside the scope of the guideline. Other information Population: women with active management of the third stage. Not reported whether women with PPH were included or excluded.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	- Not identified (due to successful procedure) Nitroglycerin: 3/20 (15) Placebo: 4/20 (20) There were also no significant differences in maternal height or weight, number of abortions Inclusion criteria Singleton pregnancy No cardiac, pulmonary, or other form of disease requiring treatment Placenta retained for 30 minutes or longer following the vaginal delivery of the fetus Exclusion criteria Pre-eclampsia Gynecologic infection Uterine scar		Trial protocol Prior to the administration of saline or nitroglycerin, 50 to 100 micrograms of fentanyl citrate was given for analgesia. Norepinephrine bitartrate was given to those with hypotension. A nurse not involved in the rest of the study opened the envelope and prepared the syringes. Women were randomised to one of two interventions: - The study group received 200 micrograms of nitroglycerin intravenously, 100 micrograms at a time, in normal saline solution made up to 10 ml - The control group received 10 ml of saline intravenously The first 100		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Placenta accreta Gestation < 28 weeks Hypotension (defined as systolic BP < 100 mmHg and a pulse rate > 100 beats per minute) Umbilical cord disruption		micrograms of solution (2 ml of the solution, after dilution) were injected, and 80 seconds later the obstetrician began to gently pull the cord. If the placenta did not separate within 1 minute, and the patient was not hypotensive, the second 100 microgram bolus (from the same syringe) was given. Cord traction was then performed for no longer than 2 further minutes. If the placenta was not released after 3 minutes of controlled cord traction, the procedure was considered to have failed. For those in whom the procedure was successful, oxytocin or ergometrine was given. The investigators who administered the		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			injections and monitored blood pressure, the clinicians who performed the controlled cord traction, and the participants were all blinded to allocation. Outcomes reported 1. Manual removal of the placenta: manual removal under general anaesthesia was done if the placenta was not released after 3 minutes of controlled cord traction 2. Need for further intervention: uterine curettage or repeat manual removal 3. Side effects: incidence of hypotension (defined as systolic ≤ 80 mmHg), headache, palpitations and dizziness are reported		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Statistical analysis A sample size calculation based on an expected difference in success rate of 50% calculated that 20 participants were needed per group for a 2-side type 1 error of 0.01 and 80% power. Statistical analysis was done using chi-square test or Fisher's exact test, as appropriate.		

1.1.25 What are the most effective interventions in managing primary PPH (arresting bleeding) due to uterine atony including: a) medical interventions

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Mousa,Hatem A., Alfirevic,Zarko, Treatment for primary postpartum haemorrhage, Cochrane Database of Systematic Reviews, -, 2009 Ref Id	Sample size Total n = 462 Characteristics Gambia 2004 n = 160 Gestational age: over 28 weeks	Interventions Misoprostol versus oxytocin/ergometrine Misoprostol versus placebo	Details Searching criteria: Search performed in the Cochrane Pregnancy and Childbirth Group Trials Register by contacting the Trials Search Co-ordinator (31 October 2006). The Cochrane Pregnancy and	Results Misoprostol versus oxytocin/ergometrine Hysterectomy 1 Study n = 64 Misoprostol n = 0/32 Oxytocin/ergometrine n = 1/32 RR 0.33 (95% CI 0.01	Limitations No major limitations to this systematic review. The authors assessed risk of bias for each of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
60605 Country/ies where the study was carried out Various (Gambia, South Africa) Study type Systematic review Aim of the study To determine the effectiveness and safety of pharmacological, surgical and radiological interventions used for the treatment of primary postpartum haemorrhage Study dates Assessed as up-to-date on November 2006 Source of funding Not reported	PPH defined: blood loss > 500 ml Interventions: Routine active management of third stage of labour with oxytocin 10 IU or syntometrine 1 ampule (5 ml) All participants had standard management of PPH (rubbing the uterus, commencing intravenous infusion, administering oxytocics, delivering the placenta if undelivered, and emptying the bladder). Trial tablets (misoprostol 200 micrograms or placebo) were administered: 1 orally and 2 sublingually. South Africa 2001 n = 64 Gestational age: not reported PPH defined: blood loss > 500 ml Interventions: Syntometrine + syntocinon intravenous		Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from: 1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL); 2. monthly searches of MEDLINE; 3. hand searches of 30 journals and the proceedings of major conferences; 4. weekly current awareness search of a further 37 journals. Trials identified through the searching activities described above were given a code (or codes) depending on the topic. The codes were linked to review topics. The trials search co-ordinator searched the register for each review using these codes rather than keywords. No language restrictions applied.	to 7.89) Persistent haemorrhage 1 Study n = 64 Misoprostol n = 2/32 Oxytocin/ergometrine n = 11/32 RR 0.18 (95% CI 0.04 to 0.76) Additional uterotonics 1 Study n = 64 Misoprostol n = 2/32 Oxytocin/ergometrine n = 11/32 RR 0.18 (95% CI 0.04 to 0.76) Surgical co-interventions (excluding hysterectomy) 1 Study n = 64 Misoprostol n = 2/32 Oxytocin/ergometrine n = 2/32 RR 1.00 (95% CI 0.15 to 6.67)	the individual studies: - Method of randomisation: All 3 included studies were at low risk of bias for method of randomisation - Allocation concealment: All included studies had adequate allocation concealment - Blinding: 1 was at high risk of bias and 2 were at low risk of bias. - Assessment bias: 1 was at high risk of bias and 2 were at low risk of bias - Selective reporting: 1 was at high risk of bias, 2 were at

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	infusion + 4 placebo tablets per rectum versus 800 micrograms (4 tablets) misoprostol per rectum + a placebo normal saline 2 ml intramuscular injection + placebo crystalloid intravenous infusion. South Africa 2004 n = 244 Gestational age: not reported PPH defined: unclear definition Intervention: Routine active management of the third stage of labour with oxytocin 10 units or syntometrine one ampule soon after birth. All participants were given all the routine treatment for PPH (intravenous infusion, uterotonics, etc.) from a special 'PPH Trolly'. Trial tablets (misoprostol 200 micrograms or placebo) were administered: 1 orally, 2 sublingually and 2			Misoprostol versus placebo Maternal death 2 studies n = 398 Misoprostol n = 3/196 Oxytocin/ergometrine n = 0/202 RR 7.24 (95% CI 0.38 to 138.60) Hysterectomy 2 studies n = 398 Misoprostol n = 3/196 Oxytocin/ergometrine n = 2/202 RR 1.24 (95% CI 0.04 to 40.78) Additional uterotonics 2 studies n = 398 Misoprostol n = 66/190 Oxytocin/ergometrine n = 68/193 RR 0.98 (95% CI 0.78 to 1.24) Surgical co-	low risk of bias Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	rectally. Inclusion criteria All randomised controlled trials of treatment of primary postpartum haemorrhage (PPH). Exclusion criteria Quasi-randomised controlled trials.			interventions (excluding hysterectomy) Not reported Blood loss 500 ml or more after enrolment 2 studies n = 397 Misoprostol n = 19/196 Oxytocin/ergometrine n = 34/201 RR 0.57 (95% CI 0.34 to 0.96) Blood loss 1000 ml or more after enrolment 2 studies n = 397 Misoprostol n = 3/196 Oxytocin/ergometrine n = 5/201 RR 0.65 (95% CI 0.17 to 2.44) Average blood loss after enrolment	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				2 studies n = 397 Misoprostol n = 196 Oxytocin/ergometrine n = 201 Mean difference -19.10 (95% CI -58.68 to 20.48) Hb < 6 or blood transfusion 2 studies n = 386 Misoprostol n = 32/189 Oxytocin/ergometrine n = 29/197 RR 1.15 (95% CI 0.73 to 1.82) Shivering 2 studies n = 394 Misoprostol n = 86/195 Oxytocin/ergometrine n = 38/199 RR 2.31 (95% CI 1.68 to 3.18) Nausea 1 Study n = 160 Misoprostol n = 3/79	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Oxytocin/ergometrine n = 5/81 RR 0.62 (95% CI 0.15 to 2.49) Headache 1 Study n = 160 Misoprostol n = 7/79 Oxytocin/ergometrine n = 11/81 RR 0.65 (95% CI 0.27 to 1.60) Maternal pyrexia (38.5°C or more) 2 studies n = 392 Misoprostol n = 15/193 Oxytocin/ergometrine n = 2/199 RR 6.40 (95% CI 1.71 to 23.96) Manual removal of the placenta 2 studies n = 398 Misoprostol n = 4/196 Oxytocin/ergometrine n = 7/202	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				RR 7.24 (95% CI 0.38 to 138.60) Evacuation of retained products of conception 1 study n = 238 Misoprostol n = 2/117 Oxytocin/ergometrine n = 0/121 RR 5.17 (95% CI 0.25 to 106.55) Blood transfusion 2 studies n = 394 Misoprostol n = 31/194 Oxytocin/ergometrine n = 24/200 RR 1.33 (95% CI 0.81 to 2.18)	
Full citation Baruah,M., Cohn,G.M., Efficacy of rectal misoprostol as second-line therapy for the treatment of primary postpartum hemorrhage, Journal of	Sample size Treatment group (misoprostol) n = 40 Control group (methylergonovine maleate) n = 18	Interventions Treatment group received misoprostol rectally (800 to 1000 micrograms) Control group received	Details All women initially received 20 ml oxytocin after delivery of placenta for the prevention and treatment of of PPH. If PPH (bleeding > 500ml) diagnosed women in	Results The second line therapy is defined as any intervention needed to manage PPH following the failure of	Limitations Choice of treatment unrelated to confounders (selection bias): unclear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Reproductive Medicine, 53, 203-206, 2008 Ref Id 121380 Country/ies where the study was carried out USA Study type Retrospective cohort study Aim of the study To assess the efficacy of rectal misoprostol as second-line therapy in the management of primary postpartum hemorrhage (PPH) as compared to methylergonovine maleate Study dates From July 2000 to February 2005 Source of funding Not reported	Characteristics No significant differences observed between the two groups in maternal age, gestational age, parity or type of birth Inclusion criteria Women with: Term pregnancy (37 and 42 weeks) Singleton pregnancy Vaginal birth Diagnosed with PPH Uterotonic received as a second line management after a failed initial oxytocin (20 IU in 1 litre of lacted Ringer's solution following delivery of placenta) Exclusion criteria No clear exclusion criteria reported. One woman was excluded as her bleeding was due to cervical laceration	methylergonovine maleate intramuscularly (0.2 mg)	treatment group received misoprostol and women in the control group received methylergonovne maleate received as a second line treatment	initial oxytocin treatment The second line therapy referred to intervention needed to manage failed second line therapy. Need for blood transfusion Misoprostol group n= 5/40 (12.5%) Methylergonovine maleate group n= 0/18 (0%) p = 0.11 Need for third-line medical therapy Misoprostol group n = 22/40 (55%) Methylergonovine maleate group n = 10/18 (55.5%) p = 0.961 Need for any surgical intervention Misoprostol n = 5/40	Groups comparable at baseline: yes Groups received same/similar care (apart from intervention): yes Blinding of those assessing outcomes: unclear Missing data/loss to follow-up: no Precise definition of outcomes: yes Valid and reliable method of outcome assessment: unclear Intention-to-treat analysis performed: unclear A retrospective study with high risk of bias (no blinding of participants, staf f providing care

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(12.5%) Methylergonovine maleate n = 4/18 (22.2%) p = 0.51 Need for third-line therapy (medical/surgical) Misoprostol group n = 27/40 (67.5%) Methylergonovine maleate group n = 14/18 (77.7%) p = 0.961 Surgical intervention in both groups Dilatation and curettage Misoprostol group n = 8/40 (20%) Methylergonovine maleate group n = 4/18 (22%) p = 0.84 Uterine packing Misoprostol group n =	and outcome assessors) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				2/40 (5%) Methylergonovine maleate group n = 0/18 (0%) p = 0.92 Uterine artery symbolisation Misoprostol group n = 1/40 (3%) Methylergonovine maleate group n = 0/18 (0%) p = 0.49 Uterine artery ligation Misoprostol group n = 1/40 (3%) Methylergonovine maleate group n = 1/18 (6%) p = 0.55 Hysterectomy Misoprostol group n = 1/40 (3%) Methylergonovine maleate group n = 1/18 (6%) p = 0.55	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Blum,J., Winikoff,B., Raghavan,S., Dabash,R., Ramadan,M.C., Dilbaz,B., Dao,B., Durocher,J., Yalvac,S., Diop,A., Dzuba,I.G., Ngoc,N.T., Treatment of post-partum haemorrhage with sublingual misoprostol versus oxytocin in women receiving prophylactic oxytocin: a double-blind, randomised, non-inferiority trial, Lancet, 375, 217-223, 2010 Ref Id 121396 Country/ies where the study was carried out Burkina Faso, Egypt, Turkey, and Vietnam Study type Randomised controlled trial Aim of the study To examine if sublingual	Sample size Total n = 809 Misoprostol n = 407 Oxytocin n = 402 Characteristics Women were comparable in the two groups on age, marital status, number of live births, pregnancy gestation, haemogolobin before delivery and suturing after birth. None of the participants received induction, augmentation or prophylactic oxytocics. Known previous PPH Misoprostol: n = 9/488 (2%) Oxytocin: n = 19/490 (4%) Early cord clamping Misoprostol: n = 362/488 (74%) Oxytocin: n = 366/490 (75%)	Interventions Treatment: 800 micrograms sublingual misoprostol (four 200 microgram tablets) placed under tongue for 20 min Control: 40 IU oxytocin in a litre of intravenous solution over 15 min	Details Study conducted in five hospitals in Burkina Faso, Egypt, Turkey, and Vietnam (two secondary-level and three tertiary-level facilities). 809 (3%) women were diagnosed with post-partum haemorrhage and were randomly assigned to misoprostol or intravenous oxytocin group. Women were screened for inclusion at admission to labour ward. Blood loss for all included women was assessed once after birth and haemoglobin measured. Blood loss assessment: Blood loss was measured by placing a flexible calibrated drape under buttocks after birth of the baby. Blood collection continued for 20 min or until active bleeding stopped. Measurement recorded at the time of PPH	Results Misoprostol: total n = 407 Oxytocin: total n = 402 Maternal death Miosprostol: n = 1 (<1%) Oxytocin: n = 1 (<1%) RR 0.99 (95% CI 0.06 to 15.73) p = ns Bleeding was controlled within 20 min after initial treatment Misoprostol: n = 363 (89%) Misoprostol Oxytocin: n = 360 (90%) RR 0.99, (95% CI 0.95 to 1.04) Crude difference 0.4%, (95% CI 3.9 to 4.6) p = ns	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: yes Blinding of staff providing care: yes Missing data/loss to follow-up: yes Precise definition of outcomes: yes Valid and reliable method of outcome assessment: Blood loss and side effect assessment are

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
misoprostol is non-inferior to intravenous oxytocin for treatment of post-partum haemorrhage (PPH) in women receiving prophylactic oxytocin Study dates Between August 2005 and January 2008 Source of funding Grant from the Bill & Melinda Gates Foundation.	Controlled cord traction Misoprostol: n = 316/488 (65%) Oxytocin: n = 366/490 (75%) Uterine massage Misoprostol: n = 277/488 (57%) Oxytocin: n = 264/490 (54%) Mean time to placental delivery, min (SD) Misoprostol: 9.4 (9.1) Oxytocin: 9.2 (8.4) Mean blood loss at the time of PPH, ml (SD) Misoprostol: 765 (185) Oxytocin: 744 (150) Inclusion criteria Labouring women who gave consent at the hospital admission to participate in the study Exclusion criteria		diagnosis, at time of treatment, 20 mins after treatment, and when active bleeding stopped. If bleeding did not cease within 20 min after the treatment, providers were instructed to give standard care. Need for treatment was by a clinical judgement or blood loss 700 ml in the calibrated drape Randomisation Randomisation performed immediately after a PPH was diagnosed using sealed and numbered opaque boxes which contained the treatment allocation and were opened in numeric sequence. Computer generated random allocation sequence in blocks of ten was not revealed until data collection and cleaning were completed. Data collection Data were collected and	Additional blood loss of 300 ml or greater after treatment Misoprostol: n = 139 (34%) Oxytocin: n = 123 (31%) RR 1.12 (95% CI 0.92 to 1.37) p = ns Additional blood loss of 500 ml or greater after treatment Misoprostol: n = 58 (14%) Oxytocin: n = 53 (13%) RR 1.029 (95% CI 0.77 to 1.54) p = ns Additional blood loss of 1000 ml or greater after treatment Misoprostol: n = 11 (3%) Oxytocin: n = 3 (1%) RR 3.62 (95% CI 1.02 to 12.89)	subjective Intention-to-treat analysis performed: not clear Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Known allergy to prostaglandin Uterotonic drug in labour Had a caesarean birth PPH not due to uterine atony Gave birth outside the study sites		recorded by trained staff and reviewed by designated midwife or physician at every hospital. Data were translated and entered locally onto a centralised online data base. Analysis performed using SPSS (version 15.0)	p = 0.06 Additional interventions Hysterectomy Miosprostol: n = 4 (1%) Oxytocin: n = 2 (<1%) RR 1.98 (95% CI 0.36 to 10.73) p = ns Other surgery Miosprostol: n = 6(1%) Oxytocin: n = 7 (2%) RR 0.85 (95% CI 0.29 to 2.50) p = ns Blood transfusion Miosprostol: n = 24(6%) Oxytocin: n = 18 (4%) RR 1.32 (95% CI 0.73 to 2.39) p = ns Side effects Shivering Misoprostol: n =152	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(37%) Oxytocin: n = 59 (15%) RR 2.54, (95% CI 1.95 to 3.32) p = 0.0003 Fever Miosprostol: n = 88 (22%) Oxytocin: n = 59 (15%) RR 1.47 (95% CI 1.09 to 1.99) p = 0.007	
Full citation Widmer,M., Blum,J., Hofmeyr,G.J., Carroli,G., bdel-Aleem,H., Lumbiganon,P., Nguyen,T.N., Wojdyla,D., Thinkhamrop,J., Singata,M., Mignini,L.E., bdel-Aleem,M.A., Tran,S.T., Winikoff,B., Misoprostol as an adjunct to standard uterotonics for treatment of post-partum	Sample size Misoprostol: n = 705 Placebo: n = 717 Characteristics The two groups were compatible in maternal characteristics (Misoprostol: total n = 705, Placebo: total n = 717):	Interventions 600 micrograms misoprostol sublingually (three tablets of 200 micrograms; GyMiso, HRA Pharma, Paris, France) or matching placebo	Details Randomisation A computer-generated randomisation sequence was used. Women were randomised to receive 600 micrograms misoprostol sublingually (three tablets of 200 micrograms) or matching placebo; both groups received standard uterotonics (in most cases 10 IU oxytocin given	Results Maternal death Misoprostol: n = 2/704 (<1%) Placebo: n = 0/717 (0%) Severe morbidity (hysterectomy, or admission to maternal intensive care unit) Misoprostol: n = 8/704 (1%)	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: yes Groups received same care (apart from intervention): yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
haemorrhage: a multicentre, double-blind randomised trial, Lancet, 375, 1808-1813, 2010 Ref Id 121590 Country/ies where the study was carried out Argentina, Egypt, South Africa, Thailand, and Vietnam Study type A multicentre, double blind randomised trial Aim of the study To examine the effectiveness of misoprostol as an extra to standard uterotonics compared with standard uterotonics alone for treatment of post-partum haemorrhage Study dates Between July 2005 and	Age (years) mean (SD) Misoprostol: 26 (5.6%) Placebo: 26 (6.0%) Nulliparous Misoprostol: n = 287 (41%) Placebo: n = 290 (40%) Type of uterotonic given during active management of third stage of labour Oxytocin Misoprostol: n = 688 (98%) Placebo: n = 701 (98%) Ergometrine Misoprostol: n = 44 (6%) Placebo: n = 49 (7%) Prostaglandins Misoprostol: n = 8 (1%) Placebo: n = 6 (1%) Any uterotonic taken before study drug Misoprostol: n = 645 (91%) Placebo: n = 647 (90%)		intramuscularly or by slow intravenous injection). The use of uterine massage was not consistent. Participating trial centre members of the study team, were blinded to the randomisation code until the trial was closed. Placebo tablets were identical in shape, colour, weight, feel, and taste to misoprostol tablets. Allocation concealment was maintained by sealed treatment boxes. After diagnosis of post-partum haemorrhage, standard uterotonics were given immediately as per standard practice at participating hospitals. Participants were then randomly allocated to treatment, and received the study drug as soon as possible after standard uterotonics. Providers and participants were both blinded to the treatment allocation.	Placebo: n = 10/717 (1%) RR 0.81 (95% CI 0.32 to 2.00) Blood loss ≥ 500 ml within 60 min after randomisation Misoprostol: n = 100/704 (14%) Placebo: n = 100/717 (14%) RR 1.02 (95% CI 0.79 to 1.32) Blood loss ≥ 500 ml within 90 min after randomisation Misoprostol: n = 149/704 (21%) Placebo: n = 162/717 (23%) RR 0.93 (95% CI 0.77 to 1.14) Blood loss ≥ 1000 ml within 60 min after randomisation Misoprostol: n = 9/704 (1%)	Blinding of participants: yes Blinding of staff providing care: yes Blinding of outcome assessors: not clear Missing data/loss to follow-up: yes Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: yes Side effects were reported by women or observation by the providers No record of Hb before birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
August 2008 Source of funding Funded by the Bill & Melinda Gates Foundation through a grant to Family Care International and Gynuity Health Projects. Additional funds were supplied by the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction.	Birth weight of neonate (g) Misoprostol: 3148 (589) Placebo: 3164 (557) Inclusion criteria All women with vaginal birth were eligible to participate in the study if they were diagnosed with post-partum haemorrhage that was suspected to be due to uterine atony, and they needed additional uterotonics. Exclusion criteria Birth by caesarean section If misoprostol could not be given sublingually Any severe allergic or bleeding disorders (e.g. haemophilia) Temperature was higher than 38.5°C If the birth was categorised as a miscarriage according to local gestational age limits.		Treatments 1422 women were randomly allocated to receive 600 micrograms misoprostol sublingually plus standard uterotonics (n = 705 participants), or placebo plus standard uterotonics (n = 717). Blood loss at 60 min and 90 min after randomisation, side-effects and all other interventions were obtained and recorded on paper forms by trained study staff at the time of the delivery; data were reviewed by the principal investigator at each hospital. All data entry forms were stored at the participating hospital. Data were entered locally into a centralised online database. All data were available for viewing by designated study monitors throughout the trial. Practitioners assessed the side effects by direct observation or asking the participants directly. Any	Placebo: n = 9/717 (1%) RR 1.02 (95% CI 0.41 to 2.55) Blood loss ≥ 1000 ml within 90 min after randomisation Misoprostol: n = 17/704 (2%) Placebo: n = 22/717 (3%) RR 0.78 (95% CI 0.42 to 1.47) Blood transfusion after randomisation Misoprostol: n = 103/704 (15%) Placebo: n = 117/717 (16%) RR 0.89 (95% CI 0.72 to 1.14) Haemoglobin < 80 g/l ml within 24 h postpartum or need for blood transfusion Misoprostol: n = 121/691 (18%)	Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			side effects that needed treatment were categorised as severe. Blood loss assessment Blood collection was started immediately after the drug given. A fresh non-absorbent sheet was placed under the women's buttocks. A low profile plastic fracture bedpan was positioned under women perineum to collect all subsequent blood loss. The blood from the sheet or gauze swabs, or both were transferred to a jar and the volume was measured. In one centre blood was collected into a calibrated plastic sheet that was placed under the woman's buttocks immediately after she took the drug. Statistical analysis Calculation for the sample size made based on a	Placebo: n = 139/710 (20%) RR 0.89 (95% CI 0.72 to 1.11) Within 60 min after randomisation Shivering (any) Misoprostol: n = 455/704 (65%) Placebo: n = 230/717 (32%) RR 2.01 (95% CI 1.79 to 2.27) Number needed to harm 3.1 (95% CI 2.7 to 3.6) Shivering (severe) Misoprostol: n = 80/704 (11%) Placebo: n = 7/717 (1%) RR 11.64 (95% CI 5.41 to 25.03) Number needed to harm 9.6 (95% CI 7.8 to 12.6)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			systematic review of previous trials. Based on the estimation that additional blood loss of 500 ml or more would occur in about 16% of women on placebo, n = 691 women per group would be needed to detect a reduction to 10% in women receiving misoprostol at a 5% significance level (two-sided test) with 90% power. Therefore 1400 women were needed. Intention to treat was performed. Comparability ensured by comparisons between treatment groups for baseline characteristics and between study groups to identify any possible confounding factors. Stratified analyses were done with the Cochrane Mantel-Haenszel statistic. To assess the association between outcomes and treatment across participating countries	Temperature (≥ 38°C) Misoprostol: n = 303/704 (43%) Placebo: n = 107/717 (15%) RR 2.88 (95% CI 2.37 to 2.50) Number needed to harm 3.6 (95% CI 3.1 to 4.2) Temperature (≥ 40°C) Misoprostol: n = 18/704 (3%) Placebo: n = 3/717 (<1%) RR 6.11 (95% CI 1.81 to 20.65) Number needed to harm 46.7 (95% CI 29.4 to 113.6) Diarrhoea (any) Misoprostol: n = 2/704 (<1%) Placebo: n = 3/717 (<1%) RR 0.68 (95% CI 0.11 to 4.05) Number needed to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			homogeneity tests (Breslow-Day) were done. If a significant difference was recorded for side effects, the number needed to harm (95% CI) was calculated.	harm: not reported Diarrhoea (severe) Misoprostol: n = 0/704 (%) Placebo: n = 0/717 (%) RR: NA Number needed to harm: NA Vomiting (any) Misoprostol: n = 36/704 (5%) Placebo: n = 16/717 (2%) RR 2.30 (95% CI 1.28 to 4.09) Number needed to harm 34.7 (95% CI 20.7 to 107.5) Vomiting (severe) Misoprostol: n = 2/704 (<1%) Placebo: n = 2/717 (<1%) RR 1.02 (95% CI 0.14 to 7.21) Number needed to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				harm: NA Nausea (any) Misoprostol: n = 45/704 (6%) Placebo: n = 35/717 (5%) RR 1.31 (95% CI 0.85 to 2.01) Number needed to harm: NA Nausea (severe) Misoprostol: n = 2/704 (<1%) Placebo: n = 1/717 (<1%) RR 2.04 (95% CI 0.18 to 22.41) Number needed to harm: NA Within 90 min after randomisation Shivering (any) Misoprostol: n = 514/704 (73%) Placebo: n = 252/717 (35%) RR 2.08 (95% CI	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				1.86 to 2.32) Number needed to harm 2.6 (95% CI 2.3 to 3.0) Shivering (severe) Misoprostol: n = 95/704 (13%) Placebo: n = 13/717 (2%) RR 7.44 (95% CI 4.21 to 13.16) Number needed to harm 8.6 (95% CI 6.9 to 1.1) Temperature (≥ 38°C) Misoprostol: n = 406/704 (58%) Placebo: n = 137/717 (19%) RR 3.00 (95% CI 2.55 to 3.53) Number needed to harm 2.6 (95% CI 2.3 to 3.0) Temperature (≥ 40°C) Misoprostol: n = 48/704 (7%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Placebo: n = 3/717 (<1%) RR 16.21 (95% CI 5.07 to 51.78) Number needed to harm 15.6 (95% CI 11.6 to 22.3) Diarrhoea (any) Misoprostol: n = 6/704 (1%) Placebo: n = 5/717 (1%) RR 1.22 (95% CI 0.37 to 3.99) Number needed to harm: not reported Diarrhoea (severe) Misoprostol: n = 0/704 (0%) Placebo: n = 0/717 (0%) RR: NA Number needed to harm: not reported Vomiting (any) Misoprostol: n = 45/704 (6%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Placebo: n = 25/717 (3%) RR 1.83 (95% CI 1.14 to 2.96) Number needed to harm 34.4 (95% CI 19.6 to 153.8) Vomiting (severe) Misoprostol: n = 2/704 (<1%) Placebo: n = 2/717 (<1%) RR 1.02 (95% CI 0.14 to 7.21) Number needed to harm: not reported Nausea (any) Misoprostol: n = 60/704 (9%) Placebo: n = 49/717 (7%) RR 1.25 (95% CI 0.87 to 1.79) Number needed to harm: not reported Nausea (severe) Misoprostol: n = 2/704	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(<1%) Placebo: n = 1/717 (<1%) RR 2.04 (95% CI 0.18 to 22.41) Number needed to harm: not reported Blood loss of ≥ 500 ml within 60 min	
Full citation Winikoff,B., Dabash,R., Durocher,J., Darwish,E., Nguyen,T.N., Leon,W., Raghavan,S., Medhat,I., Huynh,T.K., Barrera,G., Blum,J., Treatment of post-partum haemorrhage with sublingual misoprostol versus oxytocin in women not exposed to oxytocin during labour: a double-blind, randomised, non-inferiority trial, Lancet, 375, 210-216, 2010 Ref Id 121591 Country/ies where the	Sample size Misoprostol: n = 488 Intravenous oxytocin: n = 490 Characteristics Baseline characteristics did not differ between the two treatment groups. Median blood loss at time of treatment was 700 ml for both groups Inclusion criteria Women with diagnosed primary PPH	Interventions Treatment group: 800 micrograms misoprostol sublingual tablets an d IV saline solution Control: 40 IU intravenous oxytocin and four placebo tablets resembling misoprostol	Details n = 9348 women not exposed to prophylactic oxytocin had blood loss measured after vaginal delivery at four hospitals in Ecuador, Egypt, and Vietnam (two hospitals) (one secondary-level and three tertiary-level facilities). n = 978 (10%) women were diagnosed with primary post-partum haemorrhage and were randomly assigned to receive the treatments. Providers and women were blinded to treatment allocation.	Results Active bleeding controlled within 20 min with initial uterotonic treatment Misoprostol: n = 440/488 (90%) Oxytocin: n = 486/490 (96%) RR 0.94 (95% CI 0.91 to 0.98) p < 0.001 Additional blood loss ≥ 300 ml Misoprostol: n = 147/488 (30%) Oxytocin: n = 83/490	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: yes Blinding of staff providing care: yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study was carried out Ecuador, Egypt, and Vietnam Study type Randomised control trial Aim of the study To examine whether sublingual misoprostol was similarly effective as intravenous oxytocin for treatment of post-partum haemorrhage in women not exposed to oxytocin during labour Study dates From August 2005, to January 2008 Source of funding Funded by a grant from the Bill & Melinda Gates Foundation.	Exclusion criteria Allergy to prostaglandin Received any uterotonic drug in labour Had a caesarean section Gave birth outside the study site Women whose post-partum bleeding was not suspected to be due to atonic uterus		Treatment Oxytocin or saline solution (Boulevard Pharmaceutical Compounding Center, Worcester, MA, USA) was administered in a litre of intravenous solution over 15 min, and misoprostol or placebo tablets (GyMiso, HRA Pharma, Paris, France) were placed under the tongue for 20 min. Haemoglobin was measured by study staff with a handheld device (Hemocue, Angelholm, Sweden) and post-partum blood loss measured using a polyurethane receptacle with a calibrated funnel (Brasss-V Drapes, Excellent Fixable Drapes, Madurai, Tamil Nadu, India). All women had their haemoglobin concentration before delivery and blood loss, documented at one hour post-partum. Blood was collected by	(17.5%) RR 1.78 (95% CI 1.40 to 2.26) p < 0.0001 Additional blood loss after treatment given mean (SD) (ml) Misoprostol: 244 (186) Oxytocin: 190 (174) p < 0.0001 Additional blood loss ≥ 500 ml after treatment Misoprostol: n = 53/488 (11%) Oxytocin: n = 20/490 (4%) RR 2.84 (95% CI 1.63 to 5.01) p < 0.0001 Additional blood loss ≥ 1000 ml after treatment Misoprostol: n = 5/488 (1%) Oxytocin: n = 3/490	Blinding of outcome assessors: yes Missing data/loss to follow-up: Precise definition of outcomes: yes Valid and reliable method of outcome assessment: Blood loss assessment and assessment of side effects are subjective Intention-to-treat analysis performed: Not clear Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			placing a drape under the woman's buttocks. If the woman's bleeding exceeded 700 ml, the treatment was started immediately. Blood loss measures were recorded with the same drape at time of diagnosis of post-partum haemorrhage, treatment administration, 20 min after treatment, and when active bleeding stopped. For women whose active bleeding did not stop with first-line treatment or whose condition deteriorated within the first 20 min, providers were instructed to give care in accordance with hospital protocol. Side-effects after treatment and provision of any additional intervention were recorded. Before discharge, women were asked a series of questions to assess the acceptability of treatment and side-effects. Haemoglobin was measured before discharge, when	(1%) RR 1.67 (95% CI 0.40 to 6.96) p = 0.360 Drop in Hb ≥ 20 g/l or blood transfusion Misoprostol: n = 250/488 (51%) Oxytocin: n = 230/490 (47%) RR 1.09 (95% CI 0.96 to 1.24) p = 0.101 Drop in Hb ≥ 30 g/l or blood transfusion Misoprostol: n = 199/488 (41%) Oxytocin: n = 148/490 (3%) RR 1.35 (95% CI 1.14 to 1.60) p < 0.0001 Time to active bleeding controlled mean (SD) (min) Misoprostol: 13.4 (8.2)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			possible at least 12 h after removal of any intravenous line. Data were collected and recorded by trained staff and reviewed by a designated nurse midwife or physician at every hospital. Randomisation Women were observed one hour following birth, If post-partum haemorrhage diagnosed and suspected due to uterine atony, study staff immediately administered the next sequentially numbered allocated treatment packet. Every packet contained one active treatment (either one ampoule of 40 IU oxytocin or four tablets of 200 microgram misoprostol) and matching placebo (either one ampoule of saline solution or four placebo tablets resembling misoprostol), which were administered simultaneously. Randomisation performed	Oxytocin: 11.8 (6.6) p = 0.001 Shivering Misoprostol: n = 229/488 (47%) Oxytocin: n = 82/490 (17%) RR 2.80 (95% CI 2.25 to 3.49) p < 0.0001 Shivering (reported as intoleratable by women) Misoprostol: n = 55/488 (11%) Oxytocin: n = 1/490 (<1%) RR 55.02 (95% CI 7.70 to 397) p < 0.0001 Fever (any) Misoprostol: n = 217/488 (44%) Oxytocin: n = 27/490 (6%) RR 8.07 (95% CI 5.52	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			using a computer-generated random allocation sequence. Statistical analysis Data were entered locally onto a centralised online database. Data were reviewed by study monitors throughout the trial and transferred for analysis into SPSS (version 15.0). Characteristics of the two treatment groups were compared by use of χ2 or Fisher's exact test for categorical variables and continuous variables. Relative risks (RR) with 95% CI, t tests or Mann-Whitney U tests were calculated to measure treatment effects for main study outcomes. Stratified analyses by site were done as needed to explore statistical heterogeneity of effect between study sites. Crude relative risks were adjusted for sites by calculation of Mantel-Haenszel weighted	to 11.8) p < 0.0001 Fever (reported as intoleratable by women) Misoprostol: n = 45/488 (9%) Oxytocin: n = 0/490 (0%) RR: NC p < 0.0001 Temperature Misoprostol: n = 66/488 (14%) Oxytocin: n = 0/490 (%) RR: NC p < 0.0001 Temperature (reported as intoleratable by women) Misoprostol: n = 22/488 (5%) Oxytocin: n = 0/490 (%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			relative risks, with Greenland and Robbins 95% CIs. The Breslow and Day $\chi 2$ test was also used to assess homogeneity of outcomes by site. Power Calculation Made based on an assumption that Misoprostol has an 82% efficacy rate. On that basis a sample size of 870 women was needed. The sample was increased by 10% to account for any deviations in protocol resulting in un-analysable outcomes, thus 958 women (479 per group) were to be enrolled. The primary outcomes, which were individually calculated, were the proportion of women who ceased active bleeding within 20 min after study treatment alone and those who lost 300 ml or more of blood after treatment. The crude risk difference and 97.5% CI with a one-sided	RR: NC p < 0.0001 Nausea Misoprostol: n = 49/488 (10%) Oxytocin: n = 41/490 (8%) RR 1.20 (95% CI 0.81 to 1.78) p = 0.213 Nausea (reported as intoleratable by women) Misoprostol: n = 0/488 (0%) Oxytocin: n = 0/490 (0%) Vomiting Misoprostol: n = 24/488 (5%) Oxytocin: n = 7/490 (1%) RR 3.44 (95% CI 1.50 to 7.92) p < 0.0001	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			probability were calculated for the primary outcome of active bleeding cessation within 20 min.	Vomiting (reported as intoleratable by women) Misoprostol: n = 1/488 (<1%) Oxytocin: n = 0/490 (0%) RR: NC p = 0.499 Fainting Misoprostol: n = 4/488 (1%) Oxytocin: n = 4/490 (1%) RR 1.00 (95% CI 0.25 to 3.99) p = 0.635 Fainting (reported as intoleratable by women) Misoprostol: n = 0/488 (0%) Oxytocin: n = 0/490 (0%) Diarrhoea Misoprostol: n = 2/488	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(<1%) Oxytocin: n = 2/490 (<1%) RR 1.00 (95% CI 0.14 to 7.10) p = 0.686 Diarrhoea (reported as intoleratable by women) Misoprostol: n = 0/488 (0%) Oxytocin: n = 0/490 (0%) Other Misoprostol: n = 21/488 (4%) Oxytocin: n = 20/490 (4%) RR 1.05 (95% CI 0.58 to 1.92) p = 495 Other (reported other side effect intoleratable by women) Misoprostol: n =	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				21/488 (4%) Oxytocin: n = 20/490 (4%) RR 2.01 (95% CI 0.18 to 22.1) p = 498	
Full citation Zuberi,N.F., Durocher,J., Sikander,R., Baber,N., Blum,J., Walraven,G., Misoprostol in addition to routine treatment of postpartum hemorrhage: a hospital-based randomized-controlled trial in Karachi, Pakistan, BMC Pregnancy and Childbirth, Vol.8, pp.40, 2008., -, -32676 Ref Id 155935 Country/ies where the study was carried out Pakistan Study type Randomised control trial	Sample size Total n = 61 600 micrograms misoprostol sublingually n = 29 Placebo n = 32 Characteristics No statistical differences observed between the two groups in the amount and route of prophylactic oxytocin given. All women received prophylactic oxytocin at the delivery of baby's anterior shoulder (intravenous [IV] administration 88.5%; intramuscular [IM] administration 11.5%). At the two of the four study	Interventions 600 micrograms misoprostol sublingually Matching placebo	Details Four hospitals in Karachi, Pakistan participated in this study: a large tertiary level hospital; and three secondary level facilities. Each of these hospitals had approximately 2,000 deliveries per year. All women underwent routine active management of the third stage of labor with standard uterotonics, controlled cord traction after delivery of baby, and gentle uterine massage after delivery of the placenta. At the delivery of the anterior shoulder of baby, one of two uterotonic regimens was administered: intravenous 10 IU of oxytocin or 5 IU of	Results Misoprostol total n = 29 (n = 27 as two cases had incomplete blood loss measurements and were excluded from analysis) Placebo total n = 32 Total blood loss post-treatment (ml) mean ± SD (range) Misoprostol 175 ± 168 (10 to 700) Placebo 187 ± 207 (10 to 900) p = 0.809 Total blood ≥ 500 ml post- treatment n (%)	Limitations Appropriate randomisation: yes Allocation concealment: yes Groups comparable at baseline: yes Groups received same care (apart from intervention): yes Blinding of participants: yes Blinding of staff providing care: yes Blinding of outcome assessors: yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To examine whether 600 micrograms of misoprostol taken sublingually provides an additional benefit to a standard oxytocin regimen for treatment of postpartum haemorrhage (PPH). Study dates December 2005 to April 2007 Source of funding Funded by the Bill and Melinda Gates Foundation through a grant to Gynuity Health Projects and Family Care International.	sites, standard practice was the prophylactic use of ergometrine in addition to oxytocin. In half of the births (equally distributed across study arms), ergometrine was administered prophylactically (IV administration 60.0%; IM administration 40.0%) in conjunction with oxytocin. There were no statistically significant differences between the two groups in maternal age, parity, outcomes of birth (singleton, twins, stillbirth), episiotomy, manual removal of placenta, placental delivery within 5 minutes, pre-delivery haemogolobin, measured blood loss at diagnosis, time to diagnosis, use of oxytocics prior to study treatment and the use of oxytocics after the study treatment.		oxytocin plus 0.4 mg of ergometrine given either intramuscularly or intravenously. Immediately after baby's birth, blood loss was collected by placing a clean fracture bedpan directly under the woman's buttocks for a minimum of one hour. Women losing less than 500 ml were not entered into the trial. A clean bedpan was placed underneath their buttocks to collect blood lost after PPH diagnosis. A fresh, large perineal pad with plastic backing was positioned just below the bedpan to capture any spattering blood. Once the delivery attendant considered active bleeding to have stopped, the blood was transferred to a calibrated jar for measurement. Treatment All women with diagnosed PPH due to uterine atony,	Misoprostol n = 2/27 (7.4%) Placebo n = 4/32 (12.5%) RR 0.59 (95% CI 0.12 to 2.99) Postpartum haemogolobin measures Post delivery Hb mean ± SD (range) Misoprostol 9.0 ± 1.4 (5.9 to 11.3) Placebo 8.7 ± 1.2 (5.9 to 10.2) p = 0.291 Drop in Hb mean ± SD (range) Misoprostol 2.0 ± 1.1 (0.4 to 4.2) Placebo 2.2 ± 1.4 (0.1 to 5.1) p = 0.614 Post- treatment Hb ≥ 2 g/dl lower than predelivery Hb n (%) Misoprostol n = 12/27	Missing data/loss to follow-up: reported Precise definition of outcomes: yes Valid and reliable method of outcome assessment: yes Intention-to-treat analysis performed: unclear Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria All women who underwent routine active management of the third stage. Exclusion criteria Caesarean-section Gestational age less than 28 weeks at time of delivery		were given IV oxytocin as routine treatment for PPH treatment. Women were reminded of their consent to participate in the trial and a member of study team gave each woman the pills in the next randomised study envelope and instructed her to place the tablets under her tongue i.e. sublingually. Each study envelope contained three tablets of either misoprostol (200 micrograms × 3) (Gymiso, HRA Pharma, France) or matching placebo. All women, providers, and investigators were blinded to the treatment allocation. Concurrent to PPH treatment. Blood loss assessment Blood collection was restarted with a clean bedpan and fresh perineal pad placed underneath the woman. Blood loss measurement continued	(41%) Placebo n = 18/32 (56%) RR 0.74 (95% CI 0.43 to 1.25) Additional interventions Amount of IV fluids given 500 - 1000 ml Misoprostol n = 12/22 (76%) Placebo n = 17/32 (53%) RR: not reported >1000 ml Misoprostol n = 7/27 (24%) Placebo n = 15/32 (47%) RR 0.51 (95% CI 0.24 to 1.08) Blood transfusion n (%) Misoprostol n = 5/27 (17%) Placebo n = 6/32	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			until active bleeding ceased (or for a minimum of one hour). The additional blood lost after receiving PPH treatment and all used gauzes and pads were counted weighted. Hemoglobin levels were measured upon entry into labor ward and 12–24 hours post-delivery. Side effects were recorded by the delivery attendant as they were observed or reported. Throughout duration of the trial, delivery ward staff were regularly monitored and trained. Randomisation Sample size performed based on previous studies. To achieve 80% power at p = 0.05, a sample size of 420 women in each arm was needed. Randomisation was done using a computer-generated random sequence. Data analysis was conducted using the	(19%) RR 0.92 (95% CI 0.31 to 2.69) Uterine packing n (%) Misoprostol n = 2/27 (7%) Placebo n = 6/32 (19%) RR 0.37 (95% CI 0.8 to 1.68) Balloon tamponade n (%) Misoprostol n = 0/27 (0%) Placebo n = 1/32 (3%) RR 0.0 (95% CI 0.0 to 43) Referral for additional PPH care n (%) Misoprostol n = 1/27 (3.4%) Placebo n = 1/32 (3%) RR 1.1 (95% CI 0.7 to 16.9)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Statistical Package for the Social Sciences, version 13.0 (SPSS, Chicago, IL, USA). Categorical data were analysed using a computer-generated random sequence.		

1.1.26 What are the most effective SURGICAL interventions in managing primary PPH (arresting bleeding) due to uterine atony?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Chantrapitak,W., Srijanteok,K., Puangsa-art,S., Lower uterine segment compression for management of early postpartum hemorrhage after vaginal delivery at Charoenkrung Pracharak Hospital, Journal of the Medical Association of Thailand, 92, 600-605, 2009 Ref Id	Sample size Total n = 64 Characteristics No significant differences observed between the two groups in maternal age, parity, body weight, gestational age and previous PPH. Gestational age weeks median (range): Conventional treatment group: 39 (36 - 42)	Interventions Lower uterine compression	Details Method Participants were selected by unrestricted randomisation. n = 64 women met all inclusion criteria and were included in the present study. Women were equally divided into two groups and the treatment method was randomly assigned to each woman. Both groups received similar treatment including uterine massage, oxytocin (10-20 units	Results Amount of blood loss (ml) before treatment mean (SD) Conventional group: 845.3 (SD 243.0) Lower uterine compression group: 955.3 (SD 344.1) p = 0.15 Amount of blood loss (ml) after treatment median (range)	Limitations Appropriate randomisation: not clear Allocation concealment: not clear Groups comparable at baseline: not clear Groups received same care (apart from intervention):

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
121408 Country/ies where the study was carried out Thailand Study type Randomised trial Aim of the study To examine the efficacy of lower uterine compression method in the treatment of immediate postpartum haemorrhage (PPH). Study dates Between January and August 2008 Source of funding Not reported	Lower uterine compression group: 39 (31- 41) Inclusion criteria Pregnant women between 28-42 weeks gestational age, delivered vaginally and had PPH; blood loss > 500 ml after delivery Exclusion criteria Not reported		in 1,000 ml of intravenous solution, 200 ml/min), intravenous ergometrine (Methergin, 0.2 mg), placed cold pack on the uterus, and urinary catheterization. The experiment group received the additional lower uterine compression method for 10 minutes which started promptly together with other routine treatments. Bleeding was observed for 2 hours after birth. All soaking drapes and blood in bucket were weighed. The bleeding before and after treatments was measured. The result was recorded in a Record Form by well trained nurses. Lower uterine compression Performed in two techniques. The first technique was to compress at the lower segment only, which is suitable with a tense abdominal wall found in primiparous or obese women. The second technique was to compress the lower uterine	Conventional group: 225.0 (401.0) Lower uterine compression group: 120.0 (211.0) p = 0.026 Fundal cold pack n (%) Conventional group: n = 32/32 (100) Lower uterine compression group: n = 32/32 (100) p = 1.00 Uterine massage n (%) Conventional group : n =32/32 (100) Lower uterine compression group: n = 32/32 (100) p = 1.00 Urinary cauterisation n (%) Conventional group n (%): n = 32/32 (100) Lower uterine	Yes Blinding of participants: NA Blinding of staff providing care:NA Blinding of outcome assessors: not clear Missing data/loss to follow-up: not reported Precise definition of outcomes: yes Valid and reliable method of outcome assessment: not clear Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			segment with counteracting pressure from fundus, which is appropriate for women with a relaxed abdominal wall. Statistical analysis The data were analysed by using SPSS statistical software version 11.5 (SPSS, Chicago, IL). The difference in quantitative and qualitative measurements between the experiment and control group was tested by Student's t-test or Mann Whitney U-test and Chi-square or Fisher's exact test, respectively as appropriate.	compression group n (%): n = 30/32 (94) p = 0.0492 Received intravenous oxytocin n (%) Oxytoxin 10 units Conventional group: n = 9/32 (28.1) Lower uterine compression group: 10/32 (31.3) p = 0.79 Oxytoxin 20 units n (%) Conventional group: n = 23/32 (71.9) Lower uterine compression group: 22/32 (68.8) p = 0.79 Methergin 0.2 mg n (%) Conventional group: n = 29/32 (91) Lower uterine compression group: 30/32 (94)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				p = 1.00 Prostaglandin (Nalador) (%) (n = 5) Conventional group: n = 3/5 (60) Lower uterine compression group: 2/5 (40) p = 1.00 Blood transfusion (%) (n = 10) Conventional group : n = 3/10 (30) Lower uterine compression group: n = 7/10 (70) p = 0.17	
Full citation Soltan,M.H., Mohamed,A., Ibrahim,E., Gohar,A., Ragab,H., El-menia air inflated balloon in controlling atonic post partum hemorrhage, International Journal of Health Sciences, 1, 53-59, 2007	Sample size Group 1: n = 120 Group 2: n = 120 Characteristics Women in both groups had a similar condition regarding consciousness & shock at the hospital admission.	Interventions An air-inflated balloon	Details n = 240 women with diagnosis of atonic PPH following vaginal deliveries were randomly assigned to two groups. In Group 1 women received ecobolics and uterine massage, recommended by the WHO and in group 2 women	Results Women's condition on admission (shock) Group 1 (control): n = 78/120 (65%) Group 2 (Study) : n = 83/120 (69%) Maternal mortality	Limitations Appropriate randomisation: randomisation performed Allocation concealment: not clear Groups

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 155873 Country/ies where the study was carried out Egypt Study type Randomised Trial Aim of the study To examine and test an air-inflated balloon for the management of of atonic post partum hemorrhage (APPH). Study dates Between 2003 and 2004 Source of funding Not reported	No other characteristics reported. Inclusion criteria Women who delivered vaginally either in the hospital or at home and diagnosed with PPH and medical resuscitation approach. No more details reported Exclusion criteria Other causes of PPH rather than uterine aton Caesarean birth		were managed by WHO protocol plus El-Menia air inflated balloon. El-Menia balloon Composed of a latex balloon with a 0.19 mm wall thickness (manufactured in Italy) and a 15 cm long piece of rigid catheter (made in Malaysia). The catheter was introduced inside the balloon and was tied over tightly several times with a silk suture, to prevent air escape. Treatment In diagnosis of PPH women in both group received manual aortic compression around umbilicus. In addition to the compression, women in group 2 had an air inflated balloon inserted into the uterine cavity, under an aseptic condition. The balloon was inflated with air up to 140 mmHg. Cervical cerclage with a silk suture was undertaken under light	Group 1 (control): n = 0/120 Group 2 (Study) : n = 0/120 Hysterectomy Group 1 (control): n = 3/120 Group 2 (study): n = 0/120 Blood transfusion units Group 1 (control): mean ± SD: 7.4 ± 1.8 Group 2 (study): mean ± SD: 4.1 ± 0.86 p = 0.001 Maternal Hb at discharge Group 1 (control): mean ± SD: 8.8 ± 1.6 Group 2 (study): mean ± SD: 9.7 ± 0.2 p < 0.0001	comparable at baseline: not clear Groups received same care (apart from intervention): Yes Blinding of participants: NA Blinding of staff providing care: NA Blinding of outcome assessors: not clear Missing data/loss to follow-up: not reported Precise definition of outcomes: yes Valid and reliable method of outcome assessment: not clear Not clear how PPH was diagnosed and no definition of PPH

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			analgesia to prevent herniation of the inflated balloon. Following the arrest of the uterine bleeding (uterine tone palpated by hand), deflation of one half balloon pressure was performed. If bleeding restarted then the balloon was re-inflated to the previous level and in cases of no bleeding, the new pressure was kept for 2 hours and then deflated over 10 min. Women were given prophylactic antibiotics for 3 days thereafter. Data analysis Data were analysed using SPSS program version 11 for Windows. Independent means compared with Student's t-test. Data collection No details provided	Syntocinon unit used Group 1 (control): mean ± SD: 63.9* ± 23.3 Group 2 (study): mean ± SD: 37 ± 5.6 p = 0.001 *639 reported in the paper however as the reported range is 40 - 110, the correct number must be 63.9 ICU stay (days) Group 1 (control): mean ± SD: 1 ± 0 Group 2 (study): mean ± SD: 1.5 ± 0.5 p = 0.001 Hospital stay (days) Group 1 (control): mean ± SD: 2.3 ± 0.5 Group 2 (study): mean ± SD: 3.5 ± 0.5 p = 0.001 Maternal morbidities (surgical intervention;	is given Not clear who inserted the balloon and if the same practitioner assessed the outcomes Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				uterine and ovarian artery ligation, uterine compression suture, internal iliac artery ligation and abdominal, hysterectomy) Group 1 (control): n = 5/120 Group 2 (Study) : n = 0/120 Treatment success Group 1 (control) n = 19 failures to arrest APPH in the controls group; n = 14 cases responded to secondary application of El-Menia balloon, and n = 5 cases required surgical intervention. Group 2 (Study): n = 120/120 (100% success rate) Balloon use complications	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Cervical tears n = 2 Uterine size above umbilicus = 1	

1.1.27 Is air more effective than oxygen when used for neonatal resuscitation (a) initially and (b) after a period of no/poor response?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Bajaj,N., Udani,R.H., Nanavati,R.N., Room air vs. 100 per cent oxygen for neonatal resuscitation: a controlled clinical trial, Journal of Tropical Pediatrics, 51, 206-211, 2005 Ref Id 225418 Country/ies where the study was carried out India Study type Randomised controlled trial	Sample size N = 204 Characteristics Birth weight/grams (mean ± SD) Air: 2461 ± 602 Oxygen: 2319 ± 614 [p = 0.10] Gestational age/weeks (mean ± SD) Air: 38.3 ± 2.8 Oxygen: 37.4 ± 3.5 [p = 0.05] Heart rate at birth/beats per	Interventions Resuscitation with room air (n = 107) Resuscitation with 100% oxygen (n = 97)	Details Recruitment and randomisation The study was conducted in the level III neonatal intensive care unit of a tertiary care institute. Informed consent was obtained from parents at the point of admission into hospital. Of the 236 initially enrolled, 32 were excluded for lack of consent (5), congenital malformations (17) or low birth weight (10). Babies were allocated to	Results Hypoxic ischaemic encephalopathy (n/total (%)) a. Any Air: 36/107 (33.6) Oxygen: 33/97 (34.0) OR 0.98 (95% CI 0.55 to 1.76) b. Stage II or III Air: 29/107 (27.1) Oxygen: 24/97 (24.7) OR 1.13 (95% CI 0.60 to 2.12)	Limitations Appropriate randomisation: No. Allocation was based on odd/even date of birth. Allocation concealment: No. Allocation was based on odd/even date of birth. Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: Unclear - no details

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To evaluate whether use of room air would lead to a lower incidence of hypoxic ischaemic encephalopathy (HIE) and/or death before discharge Study dates April 2001 to June 2002 Source of funding None reported	minute (mean ± SD) Air: 96 ± 28 Oxygen: 100 ± 28 [p = 0.37] Primigravida (n (%)) Air: 58 (54.2) Oxygen: 50 (51.5) [p = 0.78] Pregnancy induced hypertension (n (%)) Air: 24 (22.4) Oxygen: 12 (12.4) [p = 0.33] Antepartum haemorrhage (n (%)) Air: 14 (13.1) Oxygen: 6 (6.2) [p = 0.79] Duration of labour/hours (mean ± SD) Air: 7.67 ± 4.52 (n = 94) Oxygen: 7.67 ± 4.34 (n = 83) [p = 0.94] Vaginal birth (n (%)) Air: 54 (51.5)		receive 100% oxygen or room air according to whether their date of birth was an odd or even date. Care protocol In both groups, the guidelines from the American Academy of Pediatrics and American Heart Association were followed. - Oxygen group Oxygen was delivered by connecting a corrugated reservoir to a bag with an oxygen source. The flow rate was set at 5-6 litres/minute. - Room air group The reservoir was not used and the bag was not connected. Any baby who had bradycardia (defined as heart rate < 100 bpm) and/or central cyanosis after birth was switched to oxygen supplementation.	Death (n/total (%)) a. Death before discharge Air: 17/107 (15.9) Oxygen: 17/97 (17.5) OR 0.89 (95% CI 0.43 to 1.86) b. Asphyxia related mortality Air: 8/107 (7.5) Oxygen: 9/97 (9.3) OR 0.79 (95% CI 0.29 to 2.14) Composite outcome (n/total (%)) a. HIE and/or death before discharge Air: 44/107 (41.1) Oxygen: 42/97 (43.3) OR 0.92 (95% CI 0.52 to 1.59) b. Stage II or III HIE and/or death before discharge Air: 38/107 (35.5)	given Blinding of staff providing care: No; therefore, there may have been a risk of bias in some subjective outcomes such as need for intubation and Apgar scores Blinding of outcome assessors: Yes for HIE and abnormal neurological signs Missing data/loss to follow-up: For the abnormal neurological examination outcome, there are missing data for 15 babies in the room air group Precise definition of outcomes: Yes, apart from the fact that treatment failure is not defined for the oxygen group Valid and reliable method of outcome assessment: Yes Intention-to-treat

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Oxygen: 57 (59.8) [p = 0.26] Meconium stained liquor (n (%)) Air: 38 (35.5) Oxygen: 30 (30.9) [p = 0.55] Inclusion criteria Newborn babies weighing at least 1000g Apnea or gasping respiration and/or heart rate less than 100 bpm requiring positive pressure ventilation after the initial steps of resuscitation Exclusion criteria Major congenital malformation Hydrops		Statistical analysis A sample size calculation was based on a 30% incidence of the primary outcome among newborns needing resuscitation. 73 babies in each group were needed to detect a 50% reduction with a power of 80% and an alpha of 0.05. Data were analysed using SPSS, using Student's t-test, Mann-Whitney U-test, Fisher's exact test and chi-squared as appropriate Outcomes reported - HIE: defined according to Sarnat & Sarnat staging. Babies were examined for HIE every 12 hours in the first 3 days of life by the senior resident. The maximum stage reached was noted, and the presence of HIE was confirmed by another blinded observer.	Oxygen: 34/97 (35.1) OR 1.02 (95% CI 0.57 to 1.81) Apgar score at 5 minutes (mean ± SD) Air: 6.8 ± 2.0 Oxygen: 7.1 ± 1.6 [p = 0.27] Rescuscitation failure (n/total (%)) Air: 4/107 (3.7) Oxygen: 4/97 (4.1) [p = 0.89] Need for further resuscitation/intervention (n/total (%)) a. Chest compressions Air: 7/107 (6.5) Oxygen: 9/97 (9.3) [p = 0.47] b. Adrenaline use Air: 2/107 (1.9) Oxygen: 3/97 (3.1) [p = 0.57]	analysis performed: Not explicitly stated, but no reason to suspect not Indirectness: outcome of interest was proportion of babies with Apgar score < 7 and only means are reported; study is not restricted to term babies (only those weighing 1000 grams or more). Mean gestational age is 38.3 weeks in the room air group and 37.4 weeks in the 100% oxygen group. Note: Study was not restricted to low risk women (17.6% of the study population had pregnancy induced hypertension; 9.8% of the study population had antepartum haemorrhage); however, it has been

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Death: rate of death before discharge, and rate of asphyxia related mortality are reported - Composite of HIE and/or death before discharge: the composite was their primary outcome - Apgar score: mean at 5 minutes - Resuscitation failure: reported that switching to oxygen from air was considered a failure, but not what the definition of failure in the oxygen group was - Further resuscitation or intervention: rate of chest compressions, adrenaline and intubation are reported - Abnormal neurological examination at discharge: A detailed neurological	c. Endotracheal intubation during resuscitation Air: 55/107 (51.4) Oxygen: 34/97 (35.1) [p = 0.04] Abnormal neurological examination at discharge (reported excluding babies who died) (n/total (%)) Air: 15/75 (20) Oxygen: 11/80 (13.8) [p = 0.60] Heart rate in beats/minute (mean ± SD) a. at 1 minute Air: 113 ± 26 Oxygen: 108 ± 29 [p = 0.20] b. at 5 minutes Air: 134 ± 15 Oxygen: 132 ± 14 [p = 0.53] Time to first breath/minutes (median (IQR)) Air: 2 (1 - 4)	agreed that for this review, high risk women can be included Other information Duration of resuscitation was median 2.3 (IQR 1-5) in both groups (p = 0.06)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			exam was performed by an independent and blinded observer at discharge. The need for anticonvulsants, hypotonia, hypertonia, or visual/hearing deficit at discharge (assessed by brainstem response) was considered abormal Secondary outcomes from review protocol: - Heart rate: mean reported at 1 and 5 minutes	Oxygen: 2 (1 - 4) [p = 0.32]	
Full citation Ramji,S., Ahuja,S., Thirupuram,S., Rootwelt,T., Rooth,G., Saugstad,O.D., Resuscitation of asphyxic newborn infants with room air or 100% oxygen, Pediatric Research, 34, 809-812, 1993 Ref Id 225816 Country/ies where the study was carried out	Sample size N = 84 Characteristics Antenatal care receieved (n (%)) Air: 20 (48) Oxygen: 19 (45) [Note: it was regarded as adequate if at least 3 hospital visits were made in the last 2 trimesters]	Interventions Resuscitation with room air (n = 42) Resuscitation with 100% oxygen (n = 42)	Details Recruitment and randomisation Babies born on even dates were allocated to room air and those born on odd dates were allocated to oxygen. 85 babies were initially enrolled, but 1 baby was born with no heart rate, could not be resuscitated and was declared a stillbirth. This baby was excluded from	Results Neonatal mortality (n/total (%)) Air: 3/42 (7.1) Oxygen: 4/42 (9.5) [Note: the 3 deaths in the air group and 3 of the deaths in the oxygen group were related to birth asphyxia; the other death in the oxygen group was due to respiratory distress. 6 of the deaths occurred	Limitations Appropriate randomisation: No - allocation was based on whether the baby was born on an odd or even day Allocation concealment: No - allocation was based on whether the baby was born on an odd or even day Groups comparable at

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
India Study type Quasi-randomised trial (allocation according to odd/even birth date) Aim of the study To investigate the short term effects of resuscitating asphyxiated newborn infants with either room air or 100% oxygen Study dates Not reported Source of funding None stated	Maternal disease* (n (%)) Air: 17 (41) Oxygen: 14 (33) * one or more of hypertension, anaemia, antepartum/accidental haemorrhage, or infection Abnormal fetal heart rate (n (%)) Air: 11 (26) Oxygen: 18 (43) Meconium stained liquor (n (%)) Air: 19 (45) Oxygen: 16 (38) Prolonged second stage (n (%)) Air: 3 (7) Oxygen: 5 (12) Vaginal breech (n (%)) Air: 5 (12) Oxygen: 5 (12) Caesarean section (n (%))		the analysis. Care protocol Babies were bagged with an AMBU Infant Resuscitator using a face mask and a ventilatory frequency of about 60/minute for as long as needed. - Air group Babies who were cyanosed and/or bradycardic after 90 seconds were switched to 100% oxygen. - Oxygen group 100% oxygen was delivered by connecting a corrugated tube reservoir to the bag with an oxygen flow rate of at least 4 litres/minute Statistical analysis Sample size calculation was based on Apgar score. It was calculated that 36 babies in each arm would	within the first 3 days of life, and the last occurred on day 6] Hypoxic ischaemic encephalopathy (n/total (%)) a. Any Air: 4/42 (9.5) Oxygen: 3/42 (7.1) b. Grade I Air: 0/42 (0) Oxygen: 1/42 (2.4) c. Grade II Air: 1/42 (2.4) Oxygen: 1/42 (2.4) d. Grade III Air: 3/42 (7.1) Oxygen: 1/42 (2.4) [Note: all of the babies with grade III HIE died] Abnormal neurology during the first week of life (n/total (%)) Air: 7/42 (16.7)	baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: Unclear - no details given Blinding of staff providing care: Unclear - no details given Blinding of outcome assessors: Blinding was done for abnormal neurological status and for HIE; there was no blinding for other outcomes Missing data/loss to follow-up: 14% of babies were lost by the follow up at 28 days; however, this does not affect the outcomes reported above Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Air: 10 (24) Oxygen: 9 (21) Birth weight/grams (mean ± SD) Air: 2410 ± 540 Oxygen: 2410 ± 660 Gestational age/weeks (mean ± SD) Air: 38.4 ± 1.9 Oxygen: 38.1 ± 2.6 Inclusion criteria Heart rate < 80 beats/minute and/or apnea at birth justifying resuscitation Birth weight > 999 g Exclusion criteria Lethal anomalies Hydrops fetalis Congenital cyanotic heart defects		be needed to have 80% power to detect a statistically significant difference of 1 in mean Apgar score at 5 minutes. Data were analysed using Mann-Whitney tests, chi-squared tests or Fisher's exact tests as appropriate. A two-tailed $p < 0.05$ was considered statistically significant. Outcomes reported - Mortality - HIE: defined according to Sarnat and Sarnat staging - Abnormal neurology: defined as the baby being hypo- or hypertonic, having reflex responses (Moro, sucking, rooting) inappropriate for gestation, or having convulsions - Apgar scores: median Apgar score at 5 minutes is	Oxygen: 5/42 (11.9) [Note: 36 babies in each group were available for follow-up at 28 days and all were neurologically normal] Apgar score at 5 minutes (median (25th and 75th percentile)) Air: 8 (7 - 9) Oxygen: 7 (6 - 8) [p = 0.03] Change in gas used for resuscitation (n/total (%)) Air: 6/42 (14.3) Oxygen: 0/42 (0) [Note: these babies failed to respond after 90 seconds and so were switched, according to the protocol] Additional intervention (n/total (%)) a. Intubated at birth Air: 6/42 (14.3)	Intention-to-treat analysis performed: Yes Indirectness: study was not restricted to term babies (although babies had to weigh more than 999g) - mean gestational age was 38.4 weeks in the room air group and 38.1 weeks in the 100% oxygen group; only 46% of women received antenatal care; outcome of interest was proportion of babies with Apgar score < 7 Note: study was not restricted to low risk women (37% of women had 'maternal disease') but for this review it was agreed that high risk women could be included.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			reported - Change in resuscitation: numbers of babies switching from air to oxygen and vice versa are reported - Additional intervention: number of babies intubated at birth and those ventilated and subsequently intubated are reported, as well as those needing supplementary oxygen by hood	Oxygen: 14/42 (33.3) [Note: all of the air group and 12 of the oxygen group were for meconium aspiration; the other 2 in the oxygen group were for heart rate < 60 bpm] b. Ventilated by face mask and subsequently intubated Air: 4/42 (9.5) Oxygen: 3/42 (7.1) [Note: this was between 1.5 and 3.0 minutes after birth, as a result of persistent bradycardia < 100 bpm] c. Receiving supplementary oxygen by hood for respiratory distress Air: 2/42 (4.8) Oxygen: 5/42 (11.9) Time to first breath (median (25th - 75th	Other information Median (25th - 75th percentile) duration of assisted ventilation was 2.4 (1.5 - 3.4) minutes in the room air group and 3.0 (2.0 - 4.0) minutes in the oxygen group [p = 0.14]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				percentile)) Air: 1.5 (1 - 2) Oxygen: 1.5 (1 - 2) [p = 0.59] All neonates except 1 in the room air group were breathing spontaneously by 10 minutes.	
Full citation Ramji,S., Rasaily,R., Mishra,P.K., Narang,A., Jayam,S., Kapoor,A.N., Kambo,I., Mathur,A., Saxena,B.N., Resuscitation of asphyxiated newborns with room air or 100% oxygen at birth: a multicentric clinical trial, Indian Pediatrics, 40, 510-517, 2003 Ref Id 225817 Country/ies where the study was carried out India Study type Quasi-randomised	Sample size N = 431 Characteristics Induction of labour (n (%)) Air: 38 (22.6) Oxygen: 31 (17.8) Complications during labour (n (%)) a. Fetal distress Air: 96 (45.7) Oxygen: 108 (48.9) b. Meconium stained liquor Air: 95 (45.2) Oxygen: 85 (38.5) c. Fetal distress and	Interventions Resuscitation with room air (n = 210) Resuscitation with 100% oxygen (n = 221)	Details Recruitment and randomisation The study was carried out at 4 centres in India. Babies born on even dates were resuscitated with room air and those born on odd dates were resuscitated with 100% oxygen. Care protocol Babies were ventilated with a neonatal resuscitation bag with a frequency of 40-60 breaths per minute. - Air group If babies remained bradycardic (< 100 bpm)	Results Mortality (n/total (%)) a. All mortality Air: 26/210 (12.4) Oxygen: 40/221 (18.1) OR 0.64 (95% CI 0.36 to 1.13) b. Asphyxia mortality Air: 21/210 (10.0) Oxygen: 30/221 (13.6) OR 0.71 (95% CI 0.73 to 1.08) HIE (n/total (%)) a. Any Air: 75/210 (35.7) Oxygen: 82/221 (37.1)	Limitations Appropriate randomisation: No - babies were allocated based on odd/even birth date Allocation concealment: No - babies were allocated based on odd/even birth date Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
controlled trial (allocated based on odd/even date of birth) Aim of the study To test the hypothesis that room air is as effective as 100% oxygen for resuscitation of asphyxiated newborns at birth Study dates 1995 to 1997 Source of funding Indian Council of Medical Research, New Delhi	meconium stained liquor Air: 82 (39.0) Oxygen: 83 (37.5) Duration of labour/hours (mean ± SD) Air: 9.27 ± 4.0 Oxygen: 8.82 ± 3.8 Mode of birth (n (%)) a. Spontaneous vertex Air: 70 (33.3) Oxygen: 72 (32.6) b. Vaginal breech Air: 35 (16.7) Oxygen: 27 (12.2) c. Forceps Air: 25 (11.9) Oxygen: 20 (9.0) d. Lower segment CS Air: 77 (36.7) Oxygen: 98 (44.3) Birth weight/grams (mean ± SD) Air: 2400 ± 563 Oxygen: 2529 ± 629		and/or cyanosed after 90 seconds, they were resuscitated with 100% oxygen. (They were analysed intention to treat) - Oxygen group The bag was connected to the oxygen reservoir, with flow at 4 litres/minute. For all babies, two trained personnel were available at birth. One monitored time and outcome measures - babies were assessed every 30 seconds until 90 seconds, and then at 3 minutes, 5 minutes, and 10 minutes. Statistical analysis A power calculation based on Apgar score at 5 minutes found that 144 babies would be needed in each group to detect a difference of 1 with a SD of 2, with a 5% error probability and 95% power.	OR 0.94 (95% CI 0.62 to 1.42) b. Grade I Air: 22.6% (raw data not reported) Oxygen: 16.7% (raw data not reported) c. Grade II Air: 8.9% (raw data not reported) Oxygen: 14.9% (raw data not reported) d. Grade III Air: 8.3% (raw data not reported) Oxygen: 9.8% (raw data not reported) Note: it is not clear why the % reported for each grade of HIE do not sum to the overall % reported Apgar score at 5 minutes (median (5 - 95 centile)) Air: 7 (3 - 10) Oxygen: 7 (2 - 10)	assessors: No Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: study was not restricted to term babies (although they had to weigh more than 1000g) - mean gestational age was 37.9 weeks in the room air group and 38.1 weeks in the oxygen group; outcome of interest was Apgar score < 7 Note: study is not restricted to low risk women, but for this review it was decided that high risk women

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Gestational age/weeks (mean ± SD) Air: 37.9 ± 2.9 Oxygen: 38.1 ± 2.6 Anaesthesia use* (n/total (%)) a. General Air: 37/168 (22.0) Oxygen: 43/174 (24.7) b. Spinal Air: 17/168 (10.1) Oxygen: 30/174 (17.2) * missing values because only 3 centres provided data Inclusion criteria Newborn babies weighing more than 1000 grams Heart beat of less than 100 bpm and/or apnoeic Unresponsive to nasopharyngeal suction and tactile stimuli		Chi-squared tests, Student's t-test, and Mann-Whitney tests were used as appropriate. Outcomes reported - Mortality: all deaths, and deaths related to asphyxia are reported - HIE: assessed using Sarnat and Sarnat's criteria - Apgar score: reported at 5 minutes - Treatment failure: bradycardic (< 100 bpm) and/or cyanosed after 90 seconds (note: those in air group were switched to oxygen; those in oxygen group were not switched but the numbers meeting the criteria for failure were recorded for comparability) Secondary outcomes reported	[p = 0.19] Treatment failure (n/total (%)) Air: 82/210 (39.0) Oxygen: 89/221 (40.3) OR 0.95 (95% CI 0.63 to 1.42) Heart rate/beats per minute (mean ± SD) a. at 1 minute Air: 94.4 ±26.1 Oxygen: 87.7 ± 27.6 b. at 5 minutes Air: 131.5 ± 17.7 Oxygen: 131.1 ± 14.3 [Note: the authors report that 2-way ANOVA with replications did not show a significant difference in the treatment groups, or an interaction between treatment and time] Time to first breath/minutes (median	could be included Other information Median (5 - 95 centile) duration of resuscitation was 2.0 (0.78 - 21.08) minutes in the air group and 3.0 (0.64 - 22.25) minutes in the oxygen group [p = 0.000076]

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Requiring assisted ventilation Exclusion criteria Lethal anomalies Hydrops fetalis Congenital pulmonary or cyanotic heart defects		- Heart rate: heart rate was recorded at 1 and 5 minutes	(5th - 95th centile)) Air: 1.5 (0.5 - 9.3) Oxygen: 1.5 (0.5 - 7.25) [p = 0.0694]	
Full citation Saugstad,O.D., Rootwelt,T., Aalen,O., Resuscitation of asphyxiated newborn infants with room air or oxygen: an international controlled trial: the Resair 2 study, Pediatrics, 102, e1-, 1998 Ref Id 225837 Country/ies where the study was carried out Multicentre (India, Egypt, Philippines, Estonia, Spain, Norway) Study type	Sample size N = 609 Characteristics Maternal anaemia (n/total (%)) Room air: 58/265 (21.9) Oxygen: 66/300 (22.0) Pre-eclampsia (n/total (%)) Room air: 52/280 (18.6) Oxygen: 61/312 (19.6) Vaginal birth (n/total (%)) Room air: 169/286 (59.1) Oxygen: 202/320 (63.1) Sedation (n/total (%))	Interventions Resuscitation with room air (n = 288) Resuscitation with 100% oxygen (n = 321)	Details Recruitment and randomisation An ethical committee approved the study. Informed consent was not obtained before enrollment, but consent was obtained from parents for participation in the follow-up study. The study was organised as a multicentre trial in 11 centres in 6 countries. Formal randomisation was not done, as there was a concern about delaying treatment and reducing the	Results Note: Multivariate analyses are adjusted for gender, gestational age and birth weight Death (n/total (%)) a. Within 7 days Room air: 35/288 (12.2) Oxygen: 48/321 (15.0) Univariate OR 0.79 (95% CI 0.49 to 1.26) Multivariate OR 0.82 (95% CI 0.50 to 1.35) b. Within 28 days (full denominator) Room air: 40/288 (13.9)	Limitations Appropriate randomisation: No - allocation was done based on odd/even birth date Allocation concealment: No - allocation was done based on odd/even birth date Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Quasi-randomised trial (allocated based on odd/even birth date) Aim of the study To test the hypothesis that room air is superior to 100% oxygen when asphyxiated newborns are resuscitated Study dates June 1st 1994 to May 31st 1996 Source of funding Laerdal Foundation for Acute Medicine Norwegian Council for Research	Room air: 41/272 (16.8) Oxygen: 43/312 (13.8) Use of pain relief (n/total (%)) Room air: 119/270 (44.1) Oxygen: 132/305 (43.3) Fetal bradycardia (n/total (%)) Room air: 104/273 (38.1) Oxygen: 118/301 (39.2) Premature (n/total (%)) Room air: 75/288 (26.0) Oxygen: 72/321 (22.4) Birth weight < 2500 g (n/total (%)) Room air: 115/288 (39.9) Oxygen: 137/321 (42.7) Meconium (n/total (%)) Room air: 119/280 (42.5) Oxygen: 140/316 (44.3) Intubated (n/total (%)) Room air: 73/288 (25.3) Oxygen: 82/321 (25.5)		inclusion of severely depressed babies. Therefore, babies born on even days were resuscitated with room air and those born on odd days were resuscitated with 100% oxygen. The study was not blinded. Forms for 703 babies were received by the steering committee. 86 of 94 babies from one centre had been included without meeting all of the inclusion criteria for resuscitation; therefore, all 94 from the centre were excluded. Of the remaining babies, 16 had been allocated to the wrong group accidentally because of a mistake in the dates (15) or because oxygen was not available (1). The babies were included in the group in which they had been treated. (Note: there were 107 further babies who would have been	Oxygen: 61/321 (19.0) Univariate OR 0.69 (95% CI 0.44 to 1.06) Multivariate OR 0.72 (95% CI 0.45 to 1.15) c. Within 28 days (excluding those lost to follow-up) Room air: 40/267 (15.0) Oxygen: 61/294 (20.7) Univariate OR 0.67 (95% CI 0.43 to 1.04) Multivariate OR 0.71 (95% CI 0.44 to 1.14) HIE Grade II or III Room air: 47/288 (16.3) Oxygen: 55/321 (17.1) Univariate OR 0.94 (95% CI 0.62 to 1.45) Multivariate OR 1.04 (95% CI 0.67 to 1.63) Heart rate (mean ± SD) a. at 1 minute Room air: 90 ± 31	providing care: No Blinding of outcome assessors: No Missing data/loss to follow-up: There were some missing data on characteristics (therefore 3.3% of babies were not incorporated in the multivariate analysis); 21 babies from the air group and 27 babies from the oxygen group had been lost to follow-up by 28 days; 8.1% of babies in the oxygen arm had missing data for 'treatment failure' Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Not completely clear how data were collected, but they were returned on forms to the steering committee. Intention-to-treat

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Study centre (n) - Delhi Room air: 64 Oxygen: 94 - Bombay Room air: 52 Oxygen: 71 - Madras Room air: 54 Oxygen: 46 - Cairo Room air: 47 Oxygen: 40 - Chandigarh Room air: 19 Oxygen: 28 - Mansoura Room air: 21 Oxygen: 13 - Manila Room air: 16 Oxygen: 10 - Tartu		eligible but were not enrolled, for example because the resuscitation team arrived too late or the obstetrician did not want the baby enrolled) Care protocol The existing protocol for resuscitation in each unit was followed. A face mask and bag were used and the babies were endotracheally intubated when needed. The ventilation techniques described by the American Heart Association were used as guidelines, aiming at a rate of mechanical ventilation of 40-60 breaths per minute. In each case, at least 2 trained personnel involved in the study took part in resuscitation. It was started immediately after the birth of the infant, when a stop watch was started by one of the team. - Room air group: if the	Oxygen: 93 ± 33 b. at 90 seconds Room air: 110 ± 27 Oxygen: 113 ± 30 The authors report that there were no significant differences between the two groups in heart rate over the first 30 minutes of life (repeated-measures ANOVA) and that the number of babies with heart rates < 60, 80 or 100 beats per minute did not differ between the two groups at any time Apgar score at 5 minutes a. Median (5 to 95 percentile) Room air: 8 (4 to 9) Oxygen: 7 (3 to 9) (p = 0.12) b. Apgar < 7 (n/total (%)) Room air: 71/286 (24.8) Oxygen: 102/321 (31.8)	analysis performed: Yes Indirectness: study was not restricted to term babies (although they had to be at least 1000g) - 26% of the room air group and 22% of the oxygen group were born < 37 weeks; outcome of interest was Apgar score < 7 Note: study was not restricted to low risk women (19% and 20% had pre-eclampsia; 22% of each group had anaemia); however, it was agreed that for this review, high risk women could be included Other information Median duration of resuscitation was 2.0 minutes in both groups

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Room air: 10 Oxygen: 16 - Valencia Room air: 4 Oxygen: 2 - Tønsberg Room air: 1 Oxygen: 1 Inclusion criteria Apnea or gasping with heart rate < 80 beats per minute necessitating resuscitation Exclusion criteria Birth weight < 1000 g Lethal anomalies Hydrops Cyanotic congenital heart defects Stillbirth (diagnosed when a heart rate was never established)		baby did not respond adequately to resuscitation within 90 seconds of birth, the baby was switched to 100% oxygen. Treatment failure was heart rate < 80 beats per minute, and/or central cyanosis at 90 seconds after birth. - Oxygen group: resuscitated with 100% oxygen; no further details given Resuscitation was withdrawn after 30-45 minutes if spontaneous breathing had not been established. Statistical analysis A sample size calculation found that 920 babies would be needed to detect a reduction in mortality and/or moderate to severe hypoxic ischemic encephalopathy (HIE) from 15% to 9%. A reduction	(p = 0.03) [Note: this difference in proportion of babies with Apgar < 7 was gone by 10 minutes, and there was also no significant difference in the proportion of babies with Apgar score < 4 at 5 or 10 minutes] "Treatment failures" (n/total (%)) Room air: 73/284 (25.7) Oxygen: 88/295 (29.8) Note: the room air failures were switched to oxygen; no change was made to oxygen group management but their data are reported for comparability. It is reported that these babies had high mortality at both 7 days (air: 33%; oxygen: 28% [NS]) and 28 days (air: 41%; oxygen 35%	(p = 0.09)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			from 15% to 8% would require 648 babies. Mann-Whitney, ANOVA, two-tailed t tests and chi-squared were used as appropriate. Logistic or Cox regression was used when the comparison was adjusted for gender, gestational age and birth weight. Interim analyses were performed after 150 and 300 enrolled babies. Because there was no significant difference in mortality, the trial continued. Outcomes reported - Neonatal death: death within 1 week and within 28 days are reported - HIE: graded according to Sarnat and Sarnat's criteria. Grade I (mild) includes irritability,	[NS]) It is reported that, at 30 minutes, 38 babies were on artificial ventilation but it is not reported what group these babies came from. Time to first breath/minutes (median (95% CI)) Room air: 1.1 (1.0 to 1.2) Oxygen: 1.5 (1.4 to 1.6) [p = 0.004]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			hyperalertness, mild hypotonia and poor sucking. Grade II (moderate) includes lethargy, seizures, marked abnormalities of tone and requirement of tube feeding. Grade III (severe) includes coma, prolonged seizures, severe hypotonia, and failure to maintain spontaneous respiration. - Apgar score at 5 minutes: - Treatment failure: heart rate < 80 beats per minute, and/or central cyanosis at 90 seconds after birth. Secondary outcomes: - Heart rate at 1 minute		
Full citation Saugstad,O.D., Ramji,S., Irani,S.F., El-Meneza,S., Hernandez,E.A., Vento,M., Talvik,T., Solberg,R., Rootwelt,T., Aalen,O.O., Resuscitation	Sample size N = 213 Characteristics Gestational age/weeks (median (5th - 95th	Interventions Resuscitation with air (21% oxygen) (n = 91)	Details For more details about the methodology of the original trial, see the entry of Saugstad et al., 1998. Of the 10 centres who	Results Missing development milestones at follow-up (n/total*) a. Not sitting	Limitations Appropriate randomisation: No - allocation was done based on odd/even birth date Allocation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
of newborn infants with 21% or 100% oxygen: follow-up at 18 to 24 months, Pediatrics, 112, 296-300, 2003 Ref Id 225840 Country/ies where the study was carried out Multicentre (India, Egypt, Philippines, Estonia, Spain, Norway) Study type Follow-up to a quasi-randomised trial Aim of the study To follow up children who had been resuscitated at birth with 21% or 100% oxygen. Study dates Not reported, but the original trial was conducted from June 1st 1994 to May 31st 1996 and this study is an 18 to	percentiles)) 21% oxygen: 38 (32 - 42) 100% oxygen: 39 (33 - 42) Birthweight/grams (median (5th - 95th percentiles)) 21% oxygen: 2650 (1490 - 4240) 100% oxygen: 2800 (1560 - 4300) Age at examination/months (median (5th - 95th percentiles)) 21% oxygen: 22 (18 - 25) 100% oxygen: 20 (17 - 24) [Note: 3 babies from the 21% oxygen group and 6 babies from the 100% oxygen group were examined at 12-18 months] Mother's age/years (median (5th - 95th percentiles)) 21% oxygen: 27 (20 - 41)	Resuscitation with 100% oxygen (n = 122)	participated in the original trial, 7 participated in the follow-up study. The 7 centres had enrolled 410 children in the original study - of these, 76 died during the neonatal period (30/186 [16%] in the air group and 46/224 [21%] in the oxygen group). (Note: A total of 75% died from a cause that could be directly linked to perinatal depression, such as asphyxia, bleeding or meconium aspiration). 3 babies died in the postneonatal period (between 3 and 5 months of age, of meningitis, SIDS and spinal muscle atrophy) and 8 further babies had parents who did not give informed consent for the follow-up. Therefore, 323 babies were eligible for follow-up (147 from air group and 176 from oxygen group), and 213 (66%) follow-up forms were	21% oxygen: 4/91 100% oxygen: 2/122 [Note: the authors additionally report that 95% of the air group and 94% of the oxygen group sat at 10 months] b. Not pulling-up 21% oxygen: 12/91 100% oxygen: 10/122 c. Not standing 21% oxygen: 10/91 100% oxygen: 11/122 d. Not walking 21% oxygen: 10/91 100% oxygen: 13/122 [Note: the authors additionally report that 96% of the air group and 98% of the oxygen group walked within 18 months, and that steady walking	concealment: No - allocation was done based on odd/even birth date Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: Unclear - the investigators were asked to perform examination without knowledge of allocation, but the study was not formally blinded. Missing data/loss to follow-up: Yes - 213/591 (36%) of the babies from the original trial were followed-up. Precise definition of outcomes: Yes Valid and reliable

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
24 month follow-up Source of funding The Laerdal Foundation for Acute Medicine and the Norwegian Council for Research suppored the study	100% oxygen: 26 (20 - 36) Father's education/years (median (5th - 95th percentiles)) 21% oxygen: 12 (0 - 21) 100% oxygen: 14 (0 -18) Mother's education/years (median (5th - 95th percentiles)) 21% oxygen: 10 (0 - 21) 100% oxygen: 12 (0 - 16) Inclusion criteria Apnea or gasping with heart rate < 80 beats per minute necessitating resuscitation Exclusion criteria Birth weight < 1000 g Lethal anomalies Hydrops Cyanotic congenital heart		received. Information about postneonatal development was obtained when the children were seen for a follow-up appointment between 18 and 24 months of age. Eight investigators (responsible for the Resair 2 study) performed the follow-up exams. They were asked to do this without knowing treatment allocation, but the study was not formally blinded. The investigators met once to try and standardise the follow-up protocol. The follow-up questionnaire was designed to detect obvious neurological delays. The age when development milestones were reached was noted. Statistical analysis	was identified in 83% of both groups] Time of reaching milestones, among those who reached them/months (median (5th - 95th percentiles)) a. Sitting 21% oxygen: 8 (6 - 11) 100% oxygen: 8 (6 - 11) b. Pulling up 21% oxygen: 10 (8 - 14) 100% oxygen: 10 (8 - 13) c. Standing 21% oxygen: 12 (10 - 15) 100% oxygen: 12 (10 - 16) d. Walking 21% oxygen: 14 (12 - 19) 100% oxygen: 14 (11 - 18)	method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: Original study was not restricted to term babies 26% of the room air group and 22% of the oxygen group were premature; mean gestational age of the babies who were followed up is 38 weeks in the room air group and 39 weeks in the oxygen group Note: the original trial was not restricted to low risk women (19% and 20% had pre-eclampsia; 22% of each group had anaemia) and the exact risk status of the follow-up population is not reported; however, it

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	defects Stillbirth (diagnosed when a heart rate was never established)		Statistical analyses were performed with SPSS. Mann-Whitney and 2-tailed t-tests were used as appropriate. Outcomes reported - Cerebral palsy: diagnosed if the examiner found the child spastic with increased deep tendon reflexes - Long term neurological outcomes: milestones such as sitting, pulling up, standing and walking (considered normal if it was steady and unsupported), language skill (checked by counting number of words in their vocabulary and whether they could speak in 2-word sentences) and hearing (assessed by evaluating the child's turning of their head to a bell)	Note: the authors report that there were no significant differences between the two groups regarding the age at which important milestones were reached Language development (n/total (%)) a. Having no words 21% oxygen: 6/91 (7) 100% oxygen: 3/122 (2.5) [NS; p-value not reported] b. Three or more words 21% oxygen: 80% (raw data NR) 100% oxygen: 81% (raw data NR) c. Sentences with only one identifiable word 21% oxygen: 38% (raw	was decided that for this review, high risk women could be included Other information Apgar score and heart rate are reported in this paper for the follow-up population; however, they are reported for the whole study population in the original study and therefore will not be reported here. Duplication of reports When registering the follow-up forms, it was discovered that 18 babies (8 from the air group and 10 from the oxygen group) from Saugstad et al. had been registered twice; therefore, the number of babies should have been 591 not 609. This

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Abnormal neurodevelopment: the examiner was asked to judge overall whether the child had developed normally - Time when milestones were reached: median point of reaching sit, pull-up, stand and walk milestones	data NR) 100% oxygen: 36% (raw data NR) [NS; p-value not reported] Abnormal hearing (n/total*) 21% oxygen: 3/91 100% oxygen: 2/122 * the numbers of children are reported in the text without actual stated denominators; therefore, it has been assumed to match the number of available children for follow-up Cerebral palsy (n/total (%)) 21% oxygen: 9/91 (10) [7 spastic di/hemiplegia, 1 spastic quadriplegia and 1 mixed cerebral palsy]	did not affect the baseline characteristics, and it is reported here that the OR for neonatal mortality changed very little (the reported % in each arm were the same at 15% in the room air group and 21% in the oxygen group). Originally reported OR for oxygen compared with air: 0.67 (95% CI 0.43 to 1.04) Revised OR: 0.68 (95% CI 0.44 to 1.06)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				100% oxygen: 8/122 (7) [6 spastic diplegia, 2 mixed cerebral palsy] Note: there was also a child with hemiparesis (following a capsula interna insult) in the oxygen group Abnormal development overall (n/total (%)) 21% oxygen: 14/91 (15) 100% oxygen: 12/122 (10%) OR 1.67 (95% CI 0.73 to 3.80); p = 0.22 [In addition to the babies with CP, this included 5 babies in the room air group and 4 babies in the oxygen group who had other developmental issues such as gross motor delay or mental retardation]	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Vento,M., Asensi,M., Sastre,J., Garcia-Sala,F., Pallardo,F.V., Vina,J., Resuscitation with room air instead of 100% oxygen prevents oxidative stress in moderately asphyxiated term neonates, Pediatrics, 107, 642-647, 2001 Ref Id 225962 Country/ies where the study was carried out Spain Study type Randomised controlled trial Aim of the study To test the hypothesis that use of room air in the resuscitation of asphyxiated newborns might reduce the generation of oxygen free	Sample size N = 40 [Note: 26 further babies were also included, but they were non-asphyxiated controls and therefore their details have not been reported here] Characteristics Intubation (n/total (%)) Room air = 0/19 (0%) Oxygen = 0/26 (0%) Gestational age/weeks (mean ± SD) Room air = 38.6 ± 1.7 Oxygen = 40.2 ± 0.8 Birth weight/grams (mean ± SD) Room air = 3380 ± 318 Oxygen = 3190 ± 245 Fetal bradycardia <80bpm (n/total (%)) Room air = 10/19 (52.6%) Oxygen = 12/21 (57.1%)	Interventions Resuscitation with room air (n = 19) Resuscitation with 100% oxygen (n = 21)	Details Recruitment and randomisation An ethical committee approved the study protocol. Written consent was obtained from the parents when each case was admitted to the obstetric ward before birth. Gas sources were connected to an oxygen blender which was invisible to the resuscitation team. The nurse in charge switched from 21% to 100% oxygen after an aleatoric number corresponding to one or the other was given in a sequential manner. Nurses provided the neonatologists with a bag and mask for resuscitation which were connected to the corresponding gas mixture. Therefore, the resuscitation team were unaware of the type of gas	Results Switching gas due to failure of resuscitation (n/total (%)) Room air: 0/19 Oxygen: 0/21 Apgar score at 5 minutes (Median (5th to 95th percentiles)) Room air: 8 (7 - 9) Oxygen: 7 (5 - 8) (Not statistically significant - p-value not reported) It is reported that there were no differences found in the follow-up evaluation conducted at 28 days (regarding clinical and neurological condition) between the two groups but no further details are given. Note: Babies resuscitated with oxygen took significantly longer to	Limitations Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes (between the two interventions) Groups received same care (apart from intervention): Yes Blinding of participants: Yes Blinding of staff providing care: Yes Blinding of outcome assessors: Unclear Missing data/loss to follow-up: Unclear Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: outcome of interest was 5

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
radicals and thus oxidative stress, allowing a more rapid and harmless recovery. Study dates Not stated (participants were recruited over a 24-month period) Source of funding - Fondo de Investigaciones Sanitarias de la Seguridad - Comisión Interministerial de Ciencia y Tecnología - Annual Research Grant of the Sociedad Española de Neonatología	Meconium stained amniotic fluid (n/total (%)) Room air = 5/19 (26.3%) Oxygen = 7/21 (33.3%) *All infants were born by vaginal delivery under epidural analgesia. Inclusion criteria Term neonates (37-40 weeks gestation) Clinical signs of asphyxia (hypotonia and apnea unresponsive to external stimuli, pale skin, mucous colour and bradycardia < 80 bpm) Biochemical signs of asphyxia (hypoxia, hypercarbia and acidosis in umbilical blood) Exclusion criteria		used on each infant. Out of 245 eligible patients, 40 newborn infants (16.3%) were enrolled in the study. Care protocol After birth, babies were put under a radiant heating unit and then were resuscitated following the nursery's usual procedures. Each infant was given a specific gas mixture at random. To avoid differences between infants, the maximal gas flow was limited to 6 l/min, the inspiratory pressure was limited to 40 mbar and the ventilation frequency was kept below 30 rpm. When the initial resuscitating procedures (around 1 minute) stabilised the patient, the nurses placed the probes to monitor the infants' clinical parameters. Statistical analysis	reach a sustained respiratory pattern (p < 0.05) than babies resuscitated with room air. The exact numbers are not reported, the data are just depicted on a bar graph.	minute Apgar score < 7; no indirectness identified in population as study was restricted to term babies Note: there is no detailed description of the baseline health status or demographic information of the participating mothers were given, therefore it is unclear if they are low risk; however, it was agreed for this review that high risk women could be included Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	No informed consent from parents No aleatoric number assigned (or unsuccessful blinding) No complete blood testing No follow-up clinical examination		Because the data did not having normal distribution, analysis was performed using non-parametric tests - Mann-Whitney test was used for non-paired samples and Kruskal-Wallis test was used for > 2 non-paired samples. Outcomes reported - Failure of resuscitation leading to gas switching - Apgar score: reported at 5 minutes		
Full citation Vento,M., Asensi,M., Sastre,J., Lloret,A., Garcia-Sala,F., Vina,J., Oxidative stress in asphyxiated term infants resuscitated with 100% oxygen.[Erratum appears in J Pediatr. 2003 Jun;142(6):616], Journal of Pediatrics, 142, 240-246, 2003 Ref Id	Sample size N = 106 [Note: 22 further non-asphyxiated babies were also included as controls; however, they are not the population of interest and therefore their data have not been reported here] Characteristics Intubation for suctioning	Interventions Resuscitation with room air (n = 51) Resuscitation with oxygen (n = 55)	Details Recruitment and randomisation Parents were informed of the trial in the hospital by the attending obstetrician. Their written informed consent was obtained for all cases before birth after admission to the obstetric ward. Randomisation was performed by assigning a	Results 5-min Apgar score (median (5th to 95th percentiles)) Room air = 6 (5-8) Oxygen = 6 (4-8) Supplementary oxygen therapy (n/total (%)) Room air: 0/51 (0%) Oxygen: 2/55 (3.6%)	Limitations Appropriate randomisation: Yes Allocation concealment: Yes - not reported whether envelopes were opaque, but they were sealed Groups comparable at baseline: Yes Groups received same care (apart from

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
225965 Country/ies where the study was carried out Spain Study type Randomised controlled trial Aim of the study To test the hypothesis that resuscitation of asphyxiated infants with pure oxygen causes hyperoxemia and oxidative stress. Study dates Not stated Source of funding Partially from the Annual Research Grant of the Sociedad Española de Neonatologia	and/or ventilation (n/total (%)) Room air = 5/51 (9.8) Oxygen = 7/55 (12.7) Gestational age/weeks (mean ± SD) Room air = 38.9 ± 1.6 Oxygen = 40.5 ± 1.1 Birth weight/grams (mean ± SD) Room air = 3160 ± 240 Oxygen = 3220 ± 168 Vaginal/Caesarean delivery Room air = 16/35 Oxygen = 14/41 Epidural analgesia/General analgesia Room air = 16/35 Oxygen = 14/41 Fetal bradycardia < 80 beats/min (n) Room air = 34 Oxygen = 32		sealed envelope containing a computer generated random number plus a statement indicating the corresponding group. A nurse opened the sealed envelope and switched the gas source according to the instruction. The resuscitating team was blinded from the oxygen concentration; however, the gas mixture could be changed if requested by the neonatologist. Care protocol The asphyxiated newborns were resuscitated immediately after birth following standard procedures. Meconium-stained amniotic fluid was directly suctioned from the trachea. Endotracheal intubation was performed in cases of ineffective ventilation. Neonatal nurses placed probes to	Time to onset of spontaneous respiration (not requiring additional intervention by the resuscitation team)/minutes (mean ± SD) Room air: 5.3 ± 1.5 Oxygen: 6.8 ± 1.2 [p < 0.05]	intervention): Yes Blinding of participants: Uncertain Blinding of staff providing care: Yes Blinding of outcome assessors: Uncertain Missing data/loss to follow-up: Uncertain - the denominator is reported inconsistently; however, it is unclear whether this was a typo or missing data. Heart rate is referenced in the methods but there are no outcome data reported. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis eprformed: No - babies who were switched from air to oxygen or vice-versa were excluded Indirectness: Outcome

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Meconium-stained amniotic fluid (n) Room air = 10 Oxygen = 13 Inclusion criteria Term neonates (37-40 weeks gestation) Born with evident signs of asphyxia (hypotonic, apneic, non-responsive to external stimuli, pale, bradycardia < 80 bpm, acidotic pH ≤ 7.05) Exclusion criteria Not fulfilling the biochemical requirements Having insufficient blood for analytical purposes Switched from room air to 100% oxygen or vice versa Not blindly resuscitated		monitor the clinical variables (temperature, heart rate, respiratory frequency and pulse oximetry). The nurses also recorded the Apgar scores at 1, 5 and 10 minutes after birth; the time until the first cry; and the time elapsed until the onset of spontaneous respiration. The neonatologist obtained the first blood sample from umbilical vessels just before detachment from placenta. Statistical analysis Due to non-normal distribution, non-parametric tests were applied - Mann-Whitney U test was used for non-paired samples; Kruskall-Wallis test was used for >2 non-paired samples. Simple and multiple regression analyses were used to assess the effect of variations in biochemical		of interest was 5 minute Apgar < 7 and only median was reported; no particular indirectness of population identified because study was restricted to term babies Note: No detailed description of the baseline health status or demographic information of the participating mothers were given, therefore it is unclear whether women who were low risk. However, it was agreed that for this review high risk women could be included Other information Time of ventilation needed until the onset of a sustained respiratory pattern (mean ± SD)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			parameters. Outcomes reported - Apgar scores at 5 minutes - Use of supplementary oxygen therapy: this is not defined		Room air: 5.3 ± 1.5 Oxygen: 6.8 ± 1.2 (p < 0.05) A previous study by this author has been included in this review - there does not appear to be cross-over in the study populations, as it is directly reported in the introduction as work done previously
Full citation Vento,M., Sastre,J., Asensi,M.A., Vina,J., Room-air resuscitation causes less damage to heart and kidney than 100% oxygen, American Journal of Respiratory and Critical Care Medicine, 172, 1393-1398, 2005 Ref Id 225966 Country/ies where the	Sample size N = 39 [Note: 22 further babies are reported in the study, but they are the non-asphyxiated controls and are not relevant for this review question] Characteristics Intubation for suctioning or ventilation (n/total (%)) Air: 7/17 (41.2) Oxygen: 8/22 (36.4)	Interventions Resuscitation with air (n = 17) Resuscitation with 100% oygen (n = 22)	Details Recruitment and randomisation Informed consent was obtained from parents on admission. A random number was assigned to each record, stating whether room air or 100% oxygen should be used. When the babies were born, the attending team evaluated them and if the baby was asphyxiated, a blood sample was taken	Results Death in the first 4 weeks of life (n/total (%)) Air: 2/17 (11.8) Oxygen: 4/22 (18.2) 5 minute Apgar score (median (5 to 95 percentiles)) Air: 5 (3 -5) Oxygen: 4 (3 - 5) [p < 0.05]	Limitations Appropriate randomisation: No details about how 'random numbers' were assigned to the records, i.e. whether the assigner was blinded to characteristics of the pregnancy etc. Allocation concealment: Unclear Groups comparable at baseline: Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
study was carried out Spain Study type Randomised controlled trial Aim of the study To compare damage caused to heart and kidneys on reoxygenation in severely asphyxiated term babies resuscitated with room air or 100% oxygen Study dates 1999 to 2002 Source of funding Supported in part by the Annual Research Award for Outstanding Research 2003-2004 of the Asociacon Espanola de Pediatria	Gestational age/weeks (mean ± SD) Air: 39.6 ± 1.6 Oxygen: 39.2 ± 1.1 Birth weight/grams (mean ± SD) Air: 3320 ± 180 Oxygen: 3110 ± 90 Fetal bradycardia at birth [defined as < 80 bpm] (n (%*)) Air: 11 (64.7) Oxygen: 14 (63.6) Meconium stained amniotic fluid (n (%*)) Air: 4 (23.5) Oxygen: 5 (22.7) * % calculated by NCC-WCH technical team based on numerators and denominators reported Inclusion criteria Severely asphyxiated newborn babies born during		from the umbilical cord and resuscitation was initiated with air or oxygen as per randomisation. Care protocol Babies were resuscitated according to established guidelines (based on the Paediatric Working Group of the International Liaison Committee on Resuscitation). The babies were monitored for heart and respiratory rate, skin temperature and oxygen saturation using pulse oximetry. The gas mixture could be changed at request if ventilation was not successful. A further cord blood sample was obtained at 24 hours and 48 hours and then an electrocardiogram (ECG) was done within 48 hours of birth. An echocardiogram was taken of babies with ECG or		Groups received same care (apart from intervention): Yes Blinding of participants: Unclear - no details given Blinding of staff providing care: No - the authors report that the gas could be changed at request, implying they were not blinded Blinding of outcome assessors: Unclear - no details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: No - the exclusion criteria that are listed in the study imply that babies could be excluded following randomisation (e.g. if the gas was

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	the study period (defined as pale colour, presence of bradycardia of < 80 beats/minute, nonresponsiveness to stimuli, cord pH of 7.0 or less at birth, and an Apgar score of 5 or less for more than 5 minutes) Exclusion criteria The following are listed as exclusion criteria: - not meeting entry criteria [n = 3] - change of the gas mixture [n = 4] - improperly randomised [n = 3] - incompletely studied (clinically or analytically) [n = 2] - needed supplemental oxygen [n = 5]		clinical signs of myocardial damage. Statistical analysis Statistical analyses were done using nonparametric statistics. Outcomes reported - Mortality: death in the first 4 weeks of life is reported - 5 minute Apgar score: median Apgar score		changed), and this could have been associated with a risk of bias. 30% of babies that were eligible were excluded. Indirectness: study was not restricted to term babies but the mean gestational age was 39.6 weeks (SD 1.6) in the room air group and 39.2 (SD 1.1) in the oxygen group therefore most were likely to have been term babies; outcome of interest was 5 minute Apgar < 7 Note: the study was not restricted to low risk women (unclear what proportion of women were higher risk: however, for this review it was agreed that high risk women could be included)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Other information Mean duration of resuscitation (defined as interval until the end of intervention by the resuscitating team) was 8.3 ± 1.9 in the air group and 9.8 ± 2.5 in the oxygen group ($p < 0.05$) Two further studies by this author have been included in this review - there does not appear to be cross-over in the study populations, as the other studies are reported in the introduction as 'previous studies'.

1.1.28 Is routine paired blood gas analysis predictive of perinatal or longer term outcome?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Hefler,L.A., Tomovski,C., Waibel,V., Brugger,C., Heim,K., Reinthaller,A., Tempfer,C., Concin,H., Umbilical arterial pH levels after delivery and adult intelligence: a hospital-based study, Acta Obstetricia et Gynecologica Scandinavica, 86, 1404-1406, 2007 Ref Id 243896 Country/ies where the study was carried out Austria Study type Retrospective cohort Aim of the study To examine the hypothesis that umbilical artery cord pH ≥ 7 is correlated with adult intelligence	Sample size n = 1,236 male newborns with arterial pH ≥ 7 Characteristics There was no significant differences between the two groups (pH < 7.12 and pH ≥ 7.12) in gestational age at birth operative delivery rate, parity, % of smoker in pregnancy and birth weight. Newborns in pH < 7.1 group had significantly lower Apgar score at 1 min, 5 min, and 10 min. Inclusion criteria - Singleton birth - Male newborns - Male infants born during the study period and attended military draft reported at age 18 Exclusion criteria - Premature newborns < 32	Interventions Umbilical cord artery pH	Details A hospital-based study performed in Bregenz-Austria investigating the umbilical arterial pH level of all male newborns. Study conducted in a primary care hospital. Maternal and neonatal data were extracted from chart review. As a routine practice paired samples were taken from the umbilical cord. All males in Austria, without severe mental or physical disability are required to appear before the draft board at the age of 18. Various tests are used by the Austrian military assessing the draftees' performance on a Stanine scale (score range 1 - 9, mean 5), designed to meet the needs of the Austrian military. The following factors are investigated: overall performance, overall intelligence, technical understanding, concentration, operation accuracy, working speed, and hand-eye co-	Results Number of infants with pH < 7.12 (from 7.0 - 7.12) n = 37 Number of infants with pH ≥ 7.12 n = 1199 Follow up at age 18 Overall performance mean (SD) Overall values: 5.1 (1.8) pH < 7.12: 5.3 (2.1) pH ≥ 7.12: 5.1 (1.9) p = 0.6 Overall intelligence mean (SD) Overall values: 4.9 (1.8) pH < 7.12: 5.2 (2.0) pH ≥ 7.12: 5.0 (1.8) p = 0.5 Technical understanding mean (SD) Overall values: 5.0 (2.0)	Limitations - Data collected from draft records (inadequate measure of adult intelligence) - Validity of various tests assessing the draftees' performance, is unclear. - Subtle differences can not be detected by a scale from 1 to 9 (a crude measurement) - n = 560 male infants were excluded from the study as they were drafted elsewhere - Study includes only male infants - Uneven number of infants in the two groups - Limited demographic factors investigated - Infants with pH < 7.0 were excluded (n = 89) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates From 1st January 1983 to 31st December 1985 Source of funding Not specified	weeks		ordination. All the socio-economic background and parental social status were considered as possible confounders. Analysis pH values were compared using X2 test, Pearson's correlation analysis, and t-tests, where appropriate. P values of < 0.05 were considered statistically significant and an SPSS statistical software system was used for statistical analysis.	pH < 7.12: 5.1 (2.3) pH ≥ 7.12: 5.0 (2.0) p = 0.7 Overall performance mean (SD) Overall values: 5.1 (1.8) pH < 7.12: 5.3 (2.1) pH ≥ 7.12: 5.1 (1.9) p = 0.6 Concentration mean (SD) Overall values: 4.8 (1.8) pH < 7.12: 4.5 (2.1) pH ≥ 7.12: 4.8 (1.8) p = 0.5 Operation accuracy mean (SD) Overall values: 6.2 (1.9) pH < 7.12: 6.5 (2.3) pH ≥ 7.12: 6.2 (1.9) p = 0.5 Working speed mean (SD) Overall values: 3.9 (1.6) pH < 7.12: 3.9 (1.9)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				pH ≥ 7.12: 3.8 (1.5) p = 0.7 Hand-eye co-ordination mean (SD) Overall values: 5 (2.0) pH < 7.12: 5.5 (2.1) pH ≥ 7.12: 5.0 (2.1) p = 0.3	
Full citation Keski-Nisula,L., Putus,T., Pekkanen,J., Umbilical artery pH values at birth and risk of asthma at 5 to 6 years of age, Journal of Investigational Allergology and Clinical Immunology, 22, 48-54, 2012 Ref Id 209622 Country/ies where the study was carried out Finland Study type Case control	Sample size n = 222 asthmatic children n = 183 control children aged 5 to 6 years with umbilical artery pH values recorded at birth Characteristics No significant differences observed between the two groups (asthmatic cases and controls) in the primary study population on: - availability of data on pH - gestational age at birth - preterm birth, Apgar at 1 min - antibiotics during the first week - maternal age and parity	Interventions Umbilical cord artery pH	Details The study is based on a previously reported asthma case control study. Birth information was collected from the Finnish Birth Registry (STAKES). n = 800 children were randomly selected from the register. Cases and controls were matched for age and sex. A questionnaire was sent to the parents of n = 1600 children. The response rate was 80.4% (n = 1287). The questionnaire included questions on the children's clinical history, their biological and social environments and parental demographics. A child was considered asthmatic if	Results Umbilical arterial pH values at birth and asthma, allergic rhinitis, and atopic eczema in children aged 5 - 6 years Umbilical artery pH ≥ 7.26 - 7.29 no. (%) Asthma 32/77 (41.6) OR 1 Allergic Rhinitis 27/75 (36.0) OR 1 Atopic Eczema	Limitations - The study is based on a previously reported asthma case control study - Unclear whether neonates in the included studies had paired blood sample (arterial and venous) taken at birth since it is optimal that both arterial and venous samples are obtained as this allows confirmation of which vessel was sampled - No exclusion criteria reported hence high risk of selection bias - Neonatal birth data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To investigate the association between umbilical arterial pH values at birth and asthma, allergic rhinitis, and atopic eczema in children Study dates September 1992 to August 1993 Source of funding Not specified	- breast feeding rate - spontaneous vaginal birth - elective Caesarean section - maternal education - maternal current and - smoking during the pregnancy - maternal age - family income Significant differences observed between the two groups on: Birth weight Cases: mean 3469 (SD 575)gr Control: mean 3580 (SD 536)gr p = 0.03 Admission to neonatal intensive care unit Cases: n = 15/222 (6.8%) Control: n = 3/183 (1.6%) p = 0.01 Maternal asthma		he/she was on the register for reimbursement of asthma medication. A child was considered to have allergic rhinitis if parents answered yes to the question Has your child ever had hay fever or another form of allergic rhinitis? A child was considered to have atopic eczema if parents answered yes to the question Has your child ever had atopic eczema?. Data for parental allergy, including maternal and paternal allergic rhinitis, asthma, atopic eczema were acquired from the questionnaire. Analysis The statistical analysis considered the possible risk factors for allergic diseases such as current age, maternal parity, maternal current smoking, education, gestational age at birth, mode of birth, need for neonatal intensive care unit, season of birth and parental allergy.	42/77 (54.5) OR 1 Umbilical artery pH ≥ 7.34 no. (%) Asthma 50/92 (54.3) OR 1.86 (95% CI 0.95 to 3.64) Allergic Rhinitis 27/89 (30.3) OR 0.48 (95% CI 0.21 to 1.12) Atopic Eczema 40/91 (44.0) OR 0.41 (95% CI 0.20 to 0.85) Umbilical artery pH ≥ 7.30 - 7.33 no. (%) Asthma 43/77 (55.8) OR 1.77 (95% CI 0.89 to 3.53) Allergic Rhinitis 25/75 (33.3) OR 0.52 (95% CI 0.22	collected from birth registry Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Cases: n = 40/221 (18.1%) Control: n = 12/179 (6.7%) p = 0.001 Maternal hay fever Cases: n = 121/221 (54.8%) Control: n = 61/179 (34.1%) p = 0.001 Maternal allergic eczema Cases: n = 93/217 (52.9%) Control: n = 53/178 (29.8%) p = 0.007 Paternal allergy Cases: n = 196/222 (88.3%) Control: n = 122/183 (66.7%) p = 0.0001 Current allergic rhinitis Cases: n = 124/216 (57.4%) Control: n = 20/179 (11.2%)		Logistic regression analysis was used to investigate the relationships between the presence of allergic diseases and adjusted effect of various predictors variables. The statistical significance was investigated using the Chi square test, Fisher's exact test and Mann-Whitney test.	to 1.22) Atopic Eczema 33/76 (43.4) OR 0.41 (95% CI 0.19 to 0.85) Umbilical artery pH ≥ 7.20 - 7.25 no. (%) Asthma 53/86 (61.6) OR 2.62 (95% CI 1.31 to 5.23) Allergic Rhinitis 40/84 (47.6) OR 1.13 (95% CI 0.49 to 2.62) Atopic Eczema 53/86 (61.6) OR 0.89 (95% CI 0.42 to 1.86) Umbilical artery pH ≤ 7.19 no. (%) Asthma 44/73 (60.3) OR 3.22 (95% CI 1.51	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	p = 0.001 Current atopic eczema Cases: n = 143/222 (64.4%) Control: n = 57/180 (31.7%) p = 0.001 Inclusion criteria - Available umbilical cord artery pH - Singleton birth Exclusion criteria Not specified			to 6.87) Allergic Rhinitis 25/72 (34.7) OR 0.67 (95% CI 0.27 to 1.66) Atopic Eczema 37/72 (44.4) OR 0.47 (95% CI 0.21 to 1.02)	
Full citation Malin,G.L., Morris,R.K., Khan,K.S., Strength of association between umbilical cord pH and perinatal and long term outcomes: systematic review and meta-analysis. [104 refs], BMJ, 340, c1471-, 2010 Ref Id 244033	Sample size N = 51 trials included in the systematic review. Result from n = 13 studies with the desired population reports here for the purpose of this review Characteristics Baenzinger 1999 (pH < 7.00) Included: All ventilated	Interventions Umbilical cord pH	Details Electronic searches The following electronic searches performed: Cochrane (2008 issue), MEDLINE (1966 - August 2008), EMBASE (1980 - August 2008) and Medion for relevant published articles. To identify grey literature SIGLE, Web of Science, the national research register, and medical	Results Association of low arterial cord pH with neonatal mortality Baenzinger 1999 (pH 7.00) n = 10 True positive/total events: n = 1/2 True negative/total with no events: n = 6/8 OR 3.0 (95% CI 0.1 to	Limitations Unclear whether neonates in the included studies had paired blood sample (arterial and venous) taken at birth since it is optimal that both arterial and venous samples are obtained as this allows confirmation of which vessel was sampled

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Various Study type Systematic review of observational studies Aim of the study To examine the association between umbilical cord pH at birth and long term neonatal outcomes Study dates Searched from 1966 to 2008 Source of funding First author funded by Mary Crosse Fellowship, Birmingham Women's Foundation. One other author funded by Medical Research Council/Royal College of Obstetrics and Gynaecology clinical	neonates; risk factors for hypoxic ischemic encephalopathy (HIE), including meconium liquor, abnormal cardiotocogram, low Apgar score or pH and gestational age > 34 weeks Yudkin 1994 (pH < 7.15) Included: Apgar score ≤ 3 at 1 minute, gestation > 37 weeks Excluded: multiple pregnancies and death related to congenital anomalies or rhesus diseases Heller 2003 (pH ≤ 7.00) Excluded: congenital anomalies Ingemarrson 1997 (pH ≤7.00) Population characteristics unreported Ghosh 2003 (pH 7.15) Included: gestation > 37		conference register were searched. Hand searching of journals and conference proceedings was performed. No language restrictions were applied. Selection of studies Two review authors independently assessed all potential studies for inclusion. Data extraction and management Two authors extracted the data and entered onto an Excel spreadsheet. Data were used to construct 2 x 2 table. Where information was unclear, the reviewers attempted to contact the original authors. Assessment of risk of bias Two review authors assessed methodological quality of studies using STARD and QUADAS checklists. A study was considered high quality if it had at least four of the following items: adequate	73.6) Yudkin 1994 (pH 7.10) n = 122 True positive/total events: n = 3/3 True negative/total with no events: n = 94/119 OR 25.9 (95% CI 1.3 to 518.6) Casey 2001 (pH 7.20) n = 1691 True positive/total events: n = 11/18 True negative/total with no events: n = 912/1673 OR 1.9 (95% CI 0.7 to 4.9) Heller 2003 (pH 7.00) n = 464,345 True positive/total events: n = 11/206 True negative/total with no events: n = 462,597/464,139 OR 16.2 (95% CI 9.2 to	Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
research fellowship.	weeks, singleton Excluded: rhesus diseases, maternal anaemia, or diabetes mellitus Gonzalez de Dios 2000 (pH 7.00) Included: At least one risk factor for asphyxia (i.e. Apgar score > 6, pH > 7) Excluded: congenital anomalies, sepsis, metabolic disorder, postnatal depression and gestation < 37 weeks Baenzinger 1999 (pH < 7.00) Included: All ventilated neonates; risk factors for HIE, including meconium liquor, abnormal cardiotocogram, low Apgar score or pH and gestational age > 34 weeks Yudkin 1994 (pH < 7.15) Included: Apgar score ≤ 3 at 1 minute, gestation > 37 weeks		description of the population, adequate description of the test and outcomes, consecutive recruitment, > 90% of completion of follow up, blinding of investigators assessing the outcomes, and a statement on the use of intervention between index test and outcome Measures of effect 2 x 2 table used to compute an odds ratio with 95% confidence intervals for each pair of index test and outcome. Analysis Heterogeneity was regarded substantial if T2> 0 and/or 12 > 30% or p < 0.1. Fixed-effect meta-analysis was used where trials were comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where heterogeneity was present or	31.1) Ingemarrson 1997 (pH 7.00) n = 308 True positive/total events: n = 2/2 True negative/total with no events: n = 247/306 OR 20.8 (95% CI 1.0 to 439.0) Ghosh 2003 (pH 7.15) n = 75 True positive/total events: n = 2/2 True negative/total with no events: n = 49/73 OR 10.1 (95% CI 0.5 to 218.7) Association of low arterial cord pH with cerebral palsy Ingemarrson 1997 (pH 7.00) n = 202 True positive/total events: n = 0/2	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Excluded: multiple pregnancies and death related to congenital anomalies or rhesus diseases Heller 2003 (pH ≤ 7.00) Excluded: congenital anomalies Ingemarrson 1997 (pH ≤ 7.00) Population characteristics unreported Ghosh 2003 (pH 7.15) Included: gestation > 37 weeks, singleton Excluded: rhesus diseases, maternal anaemia, or diabetes melitus Silva 2008 (pH 7.00) Included: gestation ≥ 34 weeks Excluded: congenital anomalies Engle 1999 (pH 7.00) Included: neonates		suspected.	True negative/total with no events: n = 139/200 OR 0.5 (95% CI 0.02 to 9.6) Association of low arterial cord pH and HIE (hypoxic ischaemic encephalopathy) Baenzinger 1999 (pH 7.00) n = 10 True positive/total events: n = 2/5 True negative/total with no events: n = 4/5 OR 2.7 (95% CI 0.02 to 45.1) Gonzalez de Dios 2000 (pH 7.00) n = 10 True positive/total events: n = 12/41 True negative/total with no events: n = 133/139 OR 9.2 (95% CI 3.2 to 26.5)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	admitted to neonatal unit directly from delivery suite, gestation ≥ 37 weeks Socol 1994 (pH 7.00) Included: Apgar score ≤ 3 at 5 minutes, Excluded: Birth weight < 2000g, gestation < 34 weeks Blackwell 2001 (pH 7.20) Included: all neonates requiring ventilation > 48 hours for meconium aspiration, gestation > 37 weeks Casey 2001 (pH 7.20) Included: neonates who developed respiratory symptoms postnataly requiring ventilation > 48 hours, gestation > 37 weeks Gilstrap 1989 (pH 7.00) Included: gestation > 37 weeks, cephalic			Ingemarrson 1997 (pH 7.00) n = 308 True positive/total events: n = 8/10 True negative/total with no even 154*/298 OR 18.5 (95% CI 3.8 to 89.6) Silva 2008 (pH 7.00) n = 174 True positive/total events: n = 2/2 True negative/total with no events: n = 156/172 OR 47.4 (95% CI 2.2 to 1030.3) Ghosh 2003 (pH 7.15) n = 75 True positive/total events: n = 10/10 True negative/total with no events: n = 49/55 OR 63.0 (95% CI 3.5 to 1135.0) *Different values	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	presentation, birth weight > 2500g Excluded: congenital anomalies or rhesus Perlman and Risser 1996 (pH 7.00) Included: gestation > 37 weeks Van den Berg 1996 (pH 7.00) Excluded: major congenital anomalies or intrauterine infection Inclusion criteria Population: - infants with the cord blood taken at birth Index text: - cord blood examined for arterial or venous pH or base excess Outcome: - any measure of compromise of neonatal			reported in the article that do not match the 2x2 data reported. The article's first author contacted and correct figure obtained then reported here. Association of low arterial cord pH and HIE plus seizures Engle 1999 (pH 7.00) n = 73 True positive/total events: n = 7/7 True negative/total with no events: n = 49/56 OR 42.4 (95% CI 2.3 to 782.1) Association of low arterial cord pH and seizures Socol 1994 (pH 7.00) n = 28 True positive/total events: n = 3/3 True negative/total with no events: n = 17/25 OR 14.4 (95% CI 0.7 to	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	wellbeing Study design - observational studies that allowed generation of 2 x 2 table Exclusion criteria Studies with 5 or fewer cases			311.8) Blackwell 2001 (pH 7.20) n = 8 True positive/total events: n = 1/1 True negative/total with no events: n = 5/7 OR 1.0 (95% CI 0.8 to 4.2) Casey 2001 (pH 7.20) n = 1691 True positive/total events: n = 47/66 True negative/total with no events: n = 900/1625 OR 3.1 (95% CI 1.8 to 5.3) Gilstrap 1989 (pH 7.00) n = 2736 True positive/total events: n = 2/2 True negative/total with no events: n = 2718/2734 OR 169.9 (95% CI 22.5	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				to 1281.4) Perlman and Risser 1996 (pH 7.00) n = 95 True positive/total events: n = 5/5 True negative/total with no events: n = 75/90 OR 50.3 (95% CI 2.7 to 955.6) Van den Berg 1996 (pH 7.00) n = 168 True positive/total events: n = 9/10 True negative/total with no events: n = 83/158 OR 10.0 (95% CI 1.2 to 80.5)	
Full citation Svirko,E., Mellanby,J., Impey,L., The association between cord pH at birth and intellectual function in childhood, Early Human Development, 84, 37-41,	Sample size Results from at least one of the three tests were available for n = 563. n = 11 excluded because they were < 36 weeks gestation. n = 13 excluded because of elective caesarean	Interventions Intellectual function tests	Details Data were collected retrospectively from children who were involved in a longitudinal project in three Oxfordshire primary schools investigating factors that predict literacy development	Results Ascertainment of cases: Cord gas analysis and obstetric details of all births prospectively was recorded in the hospital's data base called OXMAT. Result	Limitations - The author specified that the exact numbers of excluded children are unavailable - Limited confounding factors investigated; therefore, it is not

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
2008 Ref Id 244206 Country/ies where the study was carried out UK Study type Retrospective cohort study Aim of the study To examine if pH at birth is related to established tests of intellectual function Study dates Not specified Source of funding Not specified	section. Umbilical cord pH data were available for n = 116, n = 113 and n = 87 children undergoing TROG (Test for Compression of Grammar), NNAT (Naglieri Non verbal Ability) and WORD (Wechsler Objective Reading Dimensions) respectively. Characteristics Not specified. Inclusion criteria - School children aged 6–8, for whom obstetric data were available - Had been delivered after labour at term - Had an umbilical cord arterial pH > 7.00 Exclusion criteria - Children moving from the area - Children with persistent illness - Parents declined testing		and remediation programmes. Children at age 6 to 8 (in year 1 to 3 school year). About 90% of children entering year 1 of each school were tested. The results of the tests were then cross-referenced with the details of their births. Assessment Comprised tests of: - Non-verbal intelligence (Naglieri Non verbal Ability, NNAT): performed at age 6 - 8 years, mainly involves completing pattern grids from a choice of 5 possible pieces. - Grammar comprehension (Test for Compression of Grammar, TROG): performed at age 5 - 7 years, uses multiple choice pictorial format - Literacy (Wechsler Objective Reading Dimensions, WORD): assessed at age 6 - 8 years, includes single word reading, spelling, and a reading comprehensive exercise. The results of all three tests	from at least one of the three test were available for n = 563 children. About half had data available in OXMAT TROG In OXMAT with pH data n = 116 (52%) In OXMAT with pH > 7.00 n = 111 (50%) Mean score PH taken: 94.5 Mean score pH not taken: 95.3 p = 0.59 NNAT In OXMAT with pH data n = 113 (54%) In OXMAT with pH > 7.00 n = 107 (51%) Mean score PH taken: 99.7 Mean score pH not taken: 101.6 p = 0.51 WORD	possible to evaluate whether cord pH was the only element impacting on children's intelligence - Unclear if women had low risk pregnancy - Validity of various tests assessing the Intellectual function is unclear. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			were calculated as an age-standardised score In the participating hospitals, obstetric and cord gas analysis details of all births were prospectively recorded in a data base (OXMAT). The cord blood gas analysis was performed in about 50% of births. It was usually undertaken at caesarean birth, births outside hospital, or where the birth attendants were too busy. All children with cord blood analysis result were included. After birth, the cord was immediately double clamped and blood taken from umbilical artery. Analysis performed immediately and entered directly into OXMAT by a midwife. Analysis Relationships between pH and cognitive measures were analysed with parametric	In OXMAT with pH data n = 87 (52%) In OXMAT with pH > 7.00 n = 84 (50%) Mean score PH taken: 96.4 Mean score pH not taken: 103.7 p = 0.02 Mean arterial pH value: 7.20 (range 6.86 to 7.37, SD 0.09) Correlation between cord pH and cognitive measures NNAT: Non verbal intelligence TROG: Grammar comprehension WORD: Literacy Cord pH ≥ 7.0 WORD n = 84 Pearson's r: -0.30 p = 0.005 TROG n = 111 Pearson's r: -0.13 p = 0.18	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			correlations. Partial correlations were used to examine these relationships, controlling for possible confounding factors	NNAT n = 107 Pearson's r: -0.23 p = 0.01 Cord pH adjusted WORD n = 78 Pearson's r: -0.36a p = 0.001 TROG n = 105 Pearson's r: -0.09b p = 0.366 NNATn = 101 Pearson's r: -0.21c p = 0.033 aControlling for social class, breast feeding, maternal age and epidural/spinal bControling for social class, breast feeding, and single parent cControling for breast feeding, maternal age and single parent	
Full citation White,C.R., Doherty,D.A., Henderson,J.J., Kohan,R.,	Sample size n = 19,646 babies Characteristics Change in the population	Interventions Paired umbilical cord blood gas analysis	Details All births ≥ 20 weeks' gestation at a tertiary obstetric hospital during the study period were evaluated for inclusion. Paired	Results Nursery admissions 2003 n = 706/2906 (24.3%) 2006 n = 858/3808	Limitations Data retrospectively collected from the institution’s electronic database

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Newnham,J.P., Pennell,C.E., Benefits of introducing universal umbilical cord blood gas and lactate analysis into an obstetric unit, Australian and New Zealand Journal of Obstetrics and Gynaecology, 50, 318-328, 2010 Ref Id 235280 Country/ies where the study was carried out Australia Study type Retrospective case series Aim of the study To evaluate the impact of introducing universal umbilical cord blood gas analysis (UC-BGA) at birth on perinatal outcome	demographics, during the study period (year 2003 to year 2006): There was no significant changes in previous caesarean section delivery and women's parity during the study period (p = 0.126 and p = 0.124 respectively) The proportion of women younger than 20 years decreased (p = 0.005). There was a significant increase in preterm birth < 37 weeks (p = 0.001). There was a reduction in the use of intermittent auscultation and small changes in electronic fetal monitoring and fetal scalp blood sampling. Small but significant increase in meconium stained liquor and intrapartum hemorrhage (p < 0.05) An increase in the use of narcotics, nitrous analgesia and regional analgesia/anaesthesia (p <	(UC-BGA)	UC-BGA was performed on 97% of births (n = 19,646). Detailed information on all births was recorded in the institutional electronic database. Paired umbilical and venous blood samples were collected from a double clamped umbilical cord segment, immediately after birth ideally prior to neonate's first breath. Paired blood gas analysis were performed via blood gas analyser by those who collected the samples (usually midwifery staff). Statistical analysis Univariate comparison of outcomes between study years was conducted using chi-square test for categorical outcomes and analysis for variance for continuous outcomes. Binary logistic regression was used to identify simultaneous factors predictive of non validated cord gases. Logistic regression was used	(22.5%) OR 0.90 (0.80 to 1.01) OR adjusted* 0.74 (0.63 to 0.87) Special care nursery admissions 2003 n = 520/2906 (17.9%) 2006 n = 575/3808 (15.1%) OR 0.81 (0.71 to 0.92) OR adjusted* 0.75 (0.65 to 0.86) Neonatal intensive care unit admissions 2003 n = 186/2906 (6.4%) 2006 n = 283/3808 (7.4%) OR 1.17 (0.96 to 1.42) OR adjusted* 1.13 (0.86 to 1.47) Term nursery admissions 2003 n = 297/2906 (10.2%)	Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Between January 2003 and December 2006. Source of funding The first author was supported by a Bachelor of Medical Science scholarship from King Edward Memorial Hospital, Perth, Australia	0.00) Operative and instrumental birth increased with a corresponding decrease in spontaneous vaginal birth (p < 0.015) Inclusion criteria - All births > 20 weeks gestation during the study period Exclusion criteria - Therapeutic abortion for fetal abnormality - Fetal death in utero prior to labour		to assess likelihood of cord arterial blood gases falling outside predefined thresholds and also to assess the likelihood of admission to neonatal nursery.	2006 n = 285/3808 (7.5%) OR 0.71 (0.59 to 0.84) OR adjusted* 0.65 (0.54 to 0.78) Term neonatal intensive care unit admissions 2003 n = 35/2906 (1.2%) 2006 n = 40/3808 (1.1%) OR 0.87 (0.55 to 1.37) OR adjusted* 0.77 (0.47 to 1.26) *Adjusted for maternal age, gestational age, fetal presentation, induction and augmentation, mode of birth, mode of anaesthesia, and/or analgesia, obstetric, fetal and intrapartum complications, maternal medical and obstetrics history, and parity	
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Wiberg,N., Kallen,K., Herbst,A., Olofsson,P., Relation between umbilical cord blood pH, base deficit, lactate, 5-minute Apgar score and development of hypoxic ischemic encephalopathy, Acta Obstetricia et Gynecologica Scandinavica, 89, 1263-1269, 2010 Ref Id 244273 Country/ies where the study was carried out Sweden Study type Retrospective case series Aim of the study To assess the accuracy of arterial umbilical cord blood lactate, pH and base deficit to reflect a low 5-minute Apgar score and hypoxic	n = 13,735 neonates Characteristics Not specified Inclusion criteria - Appropriate obstetric and neonatal information (only cases with assured pairing of clinical and chemical data were included) - Singleton pregnancy - Women aiming for vaginal birth - pH validation (blood samples where pH were at least 0.02 units lower than in the vein to exclude mixed-up samples) Exclusion criteria Not specified	Cord blood gas pH	Study conducted at a university hospital (in Malo and Lund) where umbilical cord blood gas analysis at birth is a routine procedure. Immediately after birth and before baby's first breath, the umbilical cord was double clamped and arterial and venous blood samples obtained and analysed within 15 minutes. Acid base and lactate data during the study period were retrieved from the blood gas analyser and paired with obstetrics and neonatal data from regional database. Lactate, pH and pCO2 were measured directly by the blood gas analyser, whereas base deficit in the blood (BD) and in the extracellular fluid were calculated post hoc from determinations of pH and pCO2. Individual pH and lactate values were adjusted for gestational age of 40 weeks. Statistical analysis	HIE stage 2 - 3 pH < 7.10 Exposed cases (HIE with abnormal pH) n = 3 Exposed non-cases (HIE with normal pH) n = 3 Non exposed cases (no HIE with abnormal pH) n = 560 Exposed cases (no HIE with normal pH) n = 12,363 pH < 7.00 Exposed cases (HIE with abnormal pH) n = 0 Exposed non-cases (HIE with normal pH) n = 6 Non exposed cases (no HIE with abnormal pH) n = 41 Exposed cases (no HIE with normal pH) n = 12,882 pH < 7.00 and BD > 12	- No exclusion criteria reported hence high risk of selection bias - No details about women's characteristics are reported; therefore, it is not possible to evaluate what effect this had on the babies - Unclear whether women had low risk pregnancy. Babies' gestational week not reported Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
ischemic encephalopathy (HIE) stage 2-3. Study dates April 2000 to December 2006 Source of funding Supported by grants from Medical Faculty at Lund University, Region Skane, The Evy and Gunnar Sandberg Foundation and The Birgit and Sven Hakan Ohlsson Foundation			ROC curves created to estimate the area under curve (AUC) of both the actual and GA adjusted values of pH, BD, and lactate for each neonatal outcome parameter. To reflect adverse outcomes, odds ratios for both individual acid base parameters and parameters in combination were calculated.	Exposed cases (HIE with abnormal pH) n = 0 Exposed non-cases (HIE with normal pH) n = 6 Non exposed cases (no HIE with abnormal pH) n = 41 Exposed cases (no HIE with normal pH) n = 12,882 pH < 7.05 and BD > 12 Exposed cases (HIE with abnormal pH) n = 2 Exposed non-cases (HIE with normal pH) n = 4 Non exposed cases (no HIE with abnormal pH) n = 157 Exposed cases (no HIE with normal pH) n = 12,766 lactate > 10 Exposed cases (HIE with abnormal pH) n = 3 Exposed non-cases	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(HIE with normal pH) n = 3 Non exposed cases (no HIE with abnormal pH) n = 314 Exposed cases (no HIE with normal pH) n = 12,609	
Full citation Wildschut,J., Feron,F.J., Hendriksen,J.G., van,Hall M., Gavilanes-Jiminez,D.W., Hadders-Algra,M., Vles,J.S., Acid-base status at birth, spontaneous motor behaviour at term and 3 months and neurodevelopmental outcome at age 4 years in full-term infants, Early Human Development, 81, 535-544, 2005 Ref Id 244274 Country/ies where the study was carried out Netherlands Study type	Sample size n = 84 (n = 43 boys, n = 41 girls) Characteristics Birth weight Hb < 7.1 (median ± S.D.) 3130 ± 569 g Birth weight Hb ≥ 7.10 and pH < 7.20 3405 ± 479 g Birth weight pH ≥ 7.20 3520 ± 374 g Inclusion criteria - Known umbilical artery pH - Born at post menstrual	Interventions Umbilical cord blood gas analysis	Details Out of a birth cohort of 100 children, born during the study period, n = 84 infants were included. n = 32 infants with pH < 7.10 and 52 infants with pH ≥ 7.10. To analyse pH, arterial umbilical blood was drawn from a double clamped segment of the umbilical cord. Blood gas analysis performed within 15 min after collection. Umbilical artery pH was used as selection criterion in this study. Evaluation of the quality and quantity of GMs at birth Spontaneous motor behaviour at term was recorded on video	Results Median score of M-ABC and Hempel test in relation to pH at age 3 months Movement (manual dexterity, ball skills, balance) - ABC pH < 7.0 (n = 7) total score: 12.5 pH 7.0 to 7.1 (n = 13) total score: 6.0 pH ≥ 7.1 (n = 23) total score: 6.0 p = 0.05 Neurodevelopment - Hempel examination pH < 7.0 n = 8 score: 5.0	Limitations - Validity of various tests is unclear - About 50% of data loss in follow up Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Cohort Aim of the study To assess the relationship between acid-base status and quality and quantity of General Movements (GMs) at birth, quality of GMs at age 3 months, and motor, cognitive and behavioural functioning at the age of 4 years. Study dates February 1994 and November 1996 Source of funding Supported by a grant from the University Hospital Maastricht fund for outstanding and competitive clinical research, Het Profileringsfonds'.	age of 37—42 weeks - Birth weight between the 2.3rd and 97.7th percentiles of Kloosterman intra-uterine growth curves - Born in vertex position - Stay in the hospital at least 3 days after birth Exclusion criteria - Children with hypoxia—ischaemia other than caused by perinatal adverse conditions as measured from umbilical artery pH - Children with meconium aspiration - Respiratory distress and infections - Complicated pregnancy - Malformations (e.g. hernia diaphragmatica, lissenencephaly) - Maternally reported use of medication, alcohol or drugs during pregnancy - Children with abnormal pH values, caused by metabolic disorders		by a fellow in neurology. All infants were video recorded between the third and eighth postnatal day. At the beginning of the observation session, the head was held in the midline until no lateral pressure was felt. Each recording lasted 3h. Most of the observation sessions started 1h before a feed. During observation sessions, neonates were not sedated, needed no ventilator support, nor did they have infusion lines. The quality of GMs at 3 months (12 weeks) One hour video recording was performed. During all these recording sessions, infants were placed in supine position. They lay in a box or on a carpet on the floor. The infants were observed from each video, three GMs were selected. GMs with a minimal duration of 20s were selected from the video recordings for analysis.	pH 7.0 to 7.1 n = 13 score: 4.0 pH ≥ 7.1 n = 23 score: 3.0 p = 0.21 Median score of M-ABC and Hempel test in relation to pH at age 4 years Movement (manual dexterity, ball skills, balance) - ABC pH < 7.1 (n = 20) total score: 7.75 pH ≥ 7.1 (n = 23) total score: 6.0 p = 0.79 Neurodevelopment - Hempel examination pH < 7.1 n = 21 score: 4.0 pH ≥ 7.1 n = 23 score: 3.0 p = 0.109	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			GMs during crying, sucking, hiccups and manipulation were excluded from analysis. The final quality of GMs This was judged on the basis of these three GMs. Four different qualities of GMs were distinguished: two forms of normal (N) GMs (normal-optimal and normal suboptimal) and two forms of abnormal GMs [mildly abnormal (MA) and definitely abnormal (DA). The quality of each GM was assessed separately. A child could obtain one of the nine possible combinations of scores. Normal classfied as: the combinations N—N—N, MA—N—N, MA—MA—N Abnormal: the combinations DA—DA—DA, MA—DA—DA, and MA—MA—DA Mildly normal: all other combinations Two observers (one a child		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			neurologist, and other one a developmental neurologist) scored the GMs. Interobserver agreement on the classification of the quality of GMs into three categories was determined on the basis of a random sample of videos by the two observers who were unaware of the child's history and outcome. Interscorer agreement was good (Cohen's Kappa > 0.8). Outcomes at the age of 4 years The obtained overall scores were related to outcome at the age of 4 years and the umbilical artery pH. At 4 years n = 44/84 children participated in the study: n = 20 girls and n = 24 boys n = 21 children with pH < 7.10 and n = 23 children with pH ≥ 7.10 n = 40 loss to follow up (n= 11 children had moved to an unknown address, parents of n = 6 children refused to consent and files of n = 23 children		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			were lost. All reminded n = 44 children had a neuromotor examination, and n = 38 had a neuropsychological examination. At the age of 4 years, an experienced physiotherapist assessed quantitative motor functioning with the Movement-ABC test and qualitative motor functioning with the Hempel test: The Movement- ABC test (M-ABC): The test is a standardised motor test for children between 4 and 12 years old. The test provides a separate measure of manual dexterity, ball skills and static and dynamic balance. The best total score is 0 and the worst is 40. A score of 0 to 9 is a normal score, 9.5 to 16 a suspect and more than 16 an abnormal score.		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			The Hempel test The test is a standardised observation technique for spontaneous qualitative motor behaviour of children from 1 1/2 to 4 years old, developed in the Netherlands. The child is observed during reaching and grasping, sitting, crawling, standing and walking, and the following aspects are scored in discrete scales: fine and gross motor behaviour, posture, coordination of trunk and extremities, fluency and adequacy of mobility, indications for developmental delay, muscle tone, reflexes and responses. The results of the Hempel tests were analysed by scoring each item on a 2-, 3-, 4- or 5-point scale, where a score of 0 was the optimal score. The sum of the scores was the total score. Analysis The Movement-ABC and the optimality scores of the		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Hempel test were evaluated with non-parametric statistics by comparing groups with specific infancy characteristics. Medians of subscores and total scores were used. GMs and outcome was studied in two different ways. For the non-parametric tests Mann Whitney U and Kruskal Wallis were used. The statistical analyses were performed with SPSS 11.0.		
Full citation Yeh,P., Emary,K., Impey,L., The relationship between umbilical cord arterial pH and serious adverse neonatal outcome: analysis of 51,519 consecutive validated samples, BJOG: An International Journal of Obstetrics and Gynaecology, 119, 824-831, 2012 Ref Id 244287	Sample size n = 51,519 Characteristics Not specified Inclusion criteria - Singleton - Term - Neonates with validated umbilical cord arterial pH values Exclusion criteria - Neonates with major	Interventions Paired umbilical cord blood gases	Details Data were collected from maternity data base (OXMAT), from all women delivered during the study period, in the John Radcliffe Hospital, Oxford and the three community hospitals and at home. Based on the unit's policy, paired cord acid-bass analysis was performed on women who had been monitored electronically in labour, or where there was meconium, or antenatal complications.	Results Encephalopathy with seizures and/or death The pH range 7.26 - 7.30 which was above the median, used for comparison as an ideal pH range for all outcome pH ≤ 7.00 Total n = 1120 (2.17%) n = 33 pH ≥ 7.26 - 7.30 Total n = 12369 (24.01%)	Limitations Other information - No details about women's characteristics are reported; therefore, it is not possible to evaluate what effect this had on the babies' outcomes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out UK Study type Retrospective cohort Aim of the study To assess the relationship between umbilical cord pH at term and serious neonatal outcomes Study dates From January 1991 to December 2009 Source of funding None	congenital abnormalities - All where only one sample taken (not paired) and where the values were non physiological and where the arterial-venous pH difference was less than the fifth centile.		Analysis The cord was double clamped immediately after birth and both artery and vein were sampled and were analysed within 15 minutes. The incidence of seizure was calculated according to whether umbilical cord blood samples were taken or not. This was because these incidences might differ according to whether acid-base status had been determined (reflecting the higher risk pregnancies undergoing EFM [electronic fetal monitor] and a potential bias that cord blood sample was more likely to be taken if risk factors were present). There were n = 138,658 births during the study period. Umbilical cord vessels were sampled in n = 64,506 (52%) and n = 58,801(91.2%) of these were paired samples. The cases with less than fifth centile difference in	n = 20 RR 18.20 (95% CI 10.5 to 31.70) NNH*: 36 pH 7.01 - 7.05 Total n = 1364 (2.65%) n = 8 pH ≥ 7.26 - 7.30 Total n = 12,369 (24.01%) n = 20 RR 3.63 (95% CI 1.60 to 8.22) NNH*: 236 pH 7.06 - 7.10 Total n = 3071 (5.96%) n = 11 pH ≥ 7.26 - 7.30 Total n = 12369 (24.01%) n = 20 RR 2.2 (95% CI 1.06 to 4.62) NNH*: 509 pH 7.11 - 7.15 Total n = 5622 (10.91%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			arteriovenous pH were excluded leaving n = 51,519 validated cord blood pH for analysis.	n = 16 pH ≥ 7.26 - 7.30 Total n = 12,369 (24.01%) n = 20 RR 1.76 (95% CI 0.91 to 3.39) NNH*: NS pH 7.16 - 7.20 Total n = 9707 (19.02%) n = 19 pH ≥ 7.26 - 7.30 total n = 12369 (24.01%) n = 20 RR 1.20 (95% CI 0.64 to 2.25) NNH*: NS** pH 7.21 - 7.25 Total n = 12,903 (25.05%) n = 34 pH ≥ 7.26 - 7.30 Total n = 12,369 (24.01%) n = 20 RR 1.63 (95% CI 0.94 to 2.83) NNH*: NS**	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				pH 7.31 - 7.35 Total n = 4581 (8.89%) n = 8 pH ≥ 7.26 - 7.30 Total n = 12,369 (24.01%) n = 20 RR 1.08 (95% CI 0.48 to 2.45) NNH*: NS** pH ≥ 7.36 Total n = 692 (1.34%) n = 3 pH ≥ 7.26 - 7.30 Total n = 12369 (24.01%) n = 20 RR 2.67 (95% CI 0.80 to 8.96) NNH*: NS** Neonatal Unit admission pH ≤ 7.00 n = 392 pH ≥ 7.26 - 7.30 n = 679	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				RR 6.38 (95% CI 5.72 to 7.10) NNH*:4 pH 7.01 - 7.05 n = 208 pH ≥ 7.26 -7.30 n = 679 RR 1.63 (95% CI 1.38 to 1.93) NNH*: 11 pH 7.06 - 7.10 n = 287 pH ≥ 7.26 - 7.30 n = 679 RR 1.70 (95% CI 1.49 to 1.94) NNH*: 26 pH 7.11 - 7.15 n = 441 pH ≥ 7.26 - 7.30 n = 679 RR 1.43 (95% CI 1.27 to 1.60) NNH*: 43 pH 7.16 - 7.20	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				n = 644 pH ≥ 7.26 - 7.30 n = 679 RR 1.20 (95% CI 1.08 to 1.33) NNH*: 93 pH 7.21 - 7.25 n = 754 pH ≥ 7.26 - 7.30 n = 679 RR 1.06 (95% CI 0.96 to 1.18) NNH*: NS** pH 7.31 - 7.35 n = 237 pH ≥ 7.26 -7.30 n = 679 RR 0.94 (95% CI 0.82 to 1.09) NNH*: NS** pH ≥ 7.36 n = 28 (1.34%) pH ≥ 7.26 - 7.30 n = 679 RR 0.74 (95% CI 0.51 to 1.07)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				NNH*: NS** * NNH, number needed to harm, ** NS, not statistically significant	

1.1.29 What is the appropriate care of babies born with meconium-stained liquor?

details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Daga,S.R., Dave,K., Mehta,V., Pai,V., Tracheal suction in meconium stained infants: a randomized controlled study, Journal of Tropical Pediatrics, 40, 198-200, 1994 Ref Id 217436 Country/ies where the study was carried out India Study type Randomised controlled trial	Sample size N = 49 Characteristics Gestational age (n/total (%)) 34 - 37 weeks Oropharyngeal suction only: 9/23 (39) Tracheal and oropharyngeal suction: 13/26 (50) Over 37 weeks Oropharyngeal suction only: 14/23 (61) Tracheal and	Interventions Oropharyngeal suction (n = 23) Combined oropharyngeal and tracheal suction (n = 26)	Details Recruitment and randomisation Babies were 'randomly' (no further details given) assigned to the two groups Care protocol The basic treatment for both groups was reported to be identical and so was the protocol followed on the nursery. This included oxygenation, thermal control, nutrition, antibiotic therapy and management of pneumothorax. Babies received either	Results Death (n/total (%)) Oropharyngeal suction only: 0/23 (0) Tracheal and oropharyngeal suction: 1/26 (3.8) Pneumothorax (n/total (%)) Oropharyngeal suction only: 2/23 (8.7) Tracheal and oropharyngeal suction: 1/26 (3.8) HIE (n/total (%)) Oropharyngeal	Limitations Appropriate randomisation: Unclear - method of randomisation not stated Allocation concealment: Unclear - no details given about concealment of treatment allocation Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No details given Blinding of staff providing care: No details given Blinding of outcome assessors: No details given Missing data/loss to follow-up:

details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To evaluate the use of tracheal suction in unasphyxiated babies Study dates February 1991 to September 1991 Source of funding None reported	oropharyngeal suction: 13/26 (50) Birth weight (n/total (%)) Less than 2 kg Oropharyngeal suction only: 1/23 (4.3) Tracheal and oropharyngeal suction: 4/26 (15.4) 2-2.5 kg Oropharyngeal suction only: 8/23 (34.8) Tracheal and oropharyngeal suction: 5/26 (19.2) More than 2.5 kg Oropharyngeal suction only: 14/23 (60.9) Tracheal and oropharyngeal suction: 17/26 (65.4) Antepartum		oropharyngeal suctioning or combined oropharyngeal and tracheal suctioning. No further details are given about care. Statistical analysis No details given. Outcomes reported - Death: number of babies dying prior to discharge is reported - Pneumothorax - Hypoxic ischemic encephalopathy (HIE) - Duration of oxygen administration: proportion of babies requiring oxygen for 0-3 days and for 4-7 days were reported	suction only: 0/23 (0) Tracheal and oropharyngeal suction: 1/26 (3.8) Duration of oxygen administration (n/total (%)) 0-3 days Oropharyngeal suction only: 11/23 (47.8) Tracheal and oropharyngeal suction: 14/26 (53.8) 4-7 days Oropharyngeal suction only: 12/23 (52.2) Tracheal and oropharyngeal suction: 12/26 (46.2)	No Precise definition of outcomes: Unclear what criteria were used to judge HIE; type of oxygen administration is not reported Valid and reliable method of outcome assessment: No details given Intention-to-treat analysis performed: Unclear as no details given, but no reason to suspect not Indirectness: 45% of the study population were born preterm (at 34-37 weeks) Other information Only includes babies with thick meconium staining

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	haemorrhage (n/total (%)) Oropharyngeal suction only: 1/23 (4.3) Tracheal and oropharyngeal suction: 6/26 (23.1) Premature rupture of membranes (PROM) (n/total (%)) Oropharyngeal suction only: 1/23 (4.3) Tracheal and oropharyngeal suction: 1/26 (3.8) Mode of birth (n/total (%)) Caesarean section (CS) Oropharyngeal suction only: 6/23 (26.1) Tracheal and oropharyngeal suction: 8/26 (30.8)				

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Forceps Oropharyngeal suction only: 2/23 (8.7) Tracheal and oropharyngeal suction: 4/26 (15.4) Fetal heart rate abnormality (n/total (%)) Normal Oropharyngeal suction only: 19/23 (82.6) Tracheal and oropharyngeal suction: 17/26 (65.4) Tachycardia Oropharyngeal suction only: 0/23 (0) Tracheal and oropharyngeal suction: 2/26 (7.7) Bradycardia Oropharyngeal suction only: 4/23				

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(17.4) Tracheal and oropharyngeal suction: 7/26 (26.9) Inclusion criteria Passing meconium in utero (the abstract additionally reports that this was thick meconium) Not asphyxiated at birth Exclusion criteria Not stated				
Full citation Linder,N., Aranda,J.V., Tsur,M., Matoth,I., Yatsiv,I., Mandelberg,H., Rottem,M., Feigenbaum,D., Ezra,Y., Tamir,I., Need for endotracheal intubation and suction in meconium-stained neonates, Journal of Pediatrics, 112, 613-615, 1988	Sample size N = 572 Characteristics Birth weight/grams (mean ± SD) Intubated: 3300 ± 435 Not intubated: 3420 ± 319	Interventions Intubation (n = 308) No intubation (n = 264)	Details Recruitment and randomisation The study was designed so that the paediatricians were randomised, rather than the babies. Randomisation was based on the alphabetic order of their names. Half of the paediatricians were	Results Death (n/total (%)) Intubation: 0/308 (0) No intubation: 0/264 (0) Meconium aspiration syndrome (n/total (%)) Intubation: 4/308 (1.3) No intubation: 0/264	Limitations Appropriate randomisation: No - method of randomisation is not reported, and it was the paediatricians that were randomised not the babies Allocation concealment: No - the physicians were randomised and therefore would be aware of the treatment allocation before

details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 217356 Country/ies where the study was carried out Unclear - the authors came from Canada and Israel Study type Quasi-randomised trial (paediatricians not babies were randomised) Aim of the study To determine whether routine tracheal suctioning is indicated in all meconium stained but otherwise vigorous babies Study dates June 1984 to December 1986 Source of funding None stated	Gestational age/weeks (mean ± SD) Intubated: 39.8 ± 1.1 Not intubated: 39.6 ± 1.4 Particulate/pea soup amniotic fluid (n (%)) Intubated: 122 (39.6) Not intubated: 92 (34.8) Inclusion criteria Gestational age > 37 weeks Birth weight > 2500 g Normal vaginal delivery 1-minute Apgar score > 8 Breathing spontaneously before being handed over to paediatrician		instructed to intubate and suction all meconium stained babies born during their attendance, whereas the other half were instructed to refrain from doing so. On days when physicians not participating in the study were on duty, babies with meconium-stained liquor (MSL) were managed according to the standard protocol (tracheal aspiration was done). These babies were included in the intubation group, despite not being part of the randomisation. Informed consent was gained from parents whose babies were not being suctioned - all gave consent. Care protocol Suctioning of the babies' mouth and nose was done	(0) Stridor (n/total (%)) Intubation: 2/308 (0.65) No intubation: 0/264 (0) Need for oxygen (n/total (%)) Intubation: 4/308 (1.3) No intubation: 0/264 [Note: 2 babies with MAS needed FIO2 > 0.21 over 48 hours and the other two needed FIO2 > 0.4] Pneumothorax (n/total (%)) Intubation: 1/308 (0.32) No intubation: 0/264 (0) [Additional details reported: All 4 babies needing	enrolling babies into the trial Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Unclear - very few details given Intention-to-treat analysis performed: Yes Babies treated by non-participating physicians were included in the intubation group. Indirectness: None identified - babies born to high risk women were included but it was prespecified in the

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Caesarean section Instrumental birth Delayed first inspiration Estimated birth weight < 2500g Gestational age < 37 weeks 1 minute Apgar score < 8		with a DeLee catheter while the head was on the perineum. - Intubation group (group I in study report) Aspiration of the upper and lower airways was done using a 2.5 to 3.0 mm orotracheal tube. Suction was continued during tube removal. If aspirate continued to contain meconium, the procedure was repeated until airways were cleared. - No intubation (group II in study report) Only suctioning on the perineum was done Chest radiographs were only done if there was evidence of respiratory distress. In these babies, an umbilical catheter was inserted and oxygen concentration increased as needed. At the same time,	supplementary oxygen recovered within 9 days, and follow-up at 6 months showed no respiratory abnormalities. One of the babies with stridor had recurrent episodes of respiratory distress for which he was hospitalised at 1 and 3 months. Both babies with stridor had residual hoarseness at 6 months of age]	protocol that this was acceptable for this review question. Preterm babies were excluded Other information Meconium could be of any consistency

details	Participants	Interventions	Methods	Outcomes and Results	Comments
			vibration of the chest wall and repeated tracheal lavage were started. All of the paediatricians were skilled in neonatal resuscitation and had at least 3 years experience. The authors report that interphysician variability was likely to be minimal, given their comparable experience. Statistical analysis Fisher's exact test was done; $p < 0.05$ was considered significant Outcomes reported - Death - Meconium aspiration syndrome (MAS): clinical diagnosis was only made when there was meconium staining combined with neonatal oxygen dependency and chest radiograph consistent with		

details	Participants	Interventions	Methods	Outcomes and Results	Comments
			MAS - Stridor - Need for oxygen - Pneumothorax		
Full citation Liu,W.F., Harrington,T., The need for delivery room intubation of thin meconium in the low-risk newborn: a clinical trial, American Journal of Perinatology, 15, 675-682, 1998 Ref Id 216983 Country/ies where the study was carried out USA Study type Randomised controlled trial Aim of the study To determine if the intubation and intratracheal suctioning of apparently	Sample size N = 169 [Note: a further 163 women were also studied but were not randomised] Characteristics Birth weight/grams (mean ± SD) Intubated: 3484 ± 509 Not intubated: 3348 ± 404 Gestational age (mean ± SD) Intubated: 40.0 ± 1.0 Not intubated: 40.1 ± 1.1 [Note; 6.4% of the	Interventions Intubation (n = 77) No intubation (n = 92)	Details Recruitment and randomisation Women receiving prenatal care were informed about the study and given consent forms with their standard prenatal information. Mothers with meconium stained liquor (MSL) were identified by the obstetric staff following rupture of membranes. Babies meeting the inclusion criteria were ranomdised to either 'routine management' which involved intubation or 'no intubation' group. Randomisation was	Results Any respiratory symptoms (n/total (%)) Intubated: 2/77 (2.6) Not intubated: 1/92 (1.1) Respiratory symptoms requiring oxygen (n/total (%)) Intubated: 1/77 (1.3) Not intubated: 0/92 (0) (Note: the baby requiring supplemental oxygen was weaned to room air in 7 hours)	Limitations Appropriate randomisation: Yes - randomised based on random number table Allocation concealment: Unclear - babies were assigned using a random number table by whether the next consecutive number was odd/even. The assignments were written on self-adhesive labels kept in the nursery; therefore, it seems likely that staff could have seen what was up next Groups comparable at baseline: The authors report that there were more babies with some degree of meconium staining in the intubation group

details	Participants	Interventions	Methods	Outcomes and Results	Comments
vigorous infants born through thin meconium, with an otherwise low-risk pregnancy, would result in a difference in the presence of newborn respiratory symptoms Study dates May 27th 1994 to June 9th 1997 Source of funding None stated	intubated group and 5.4% of the non-intubated group were born > 41 weeks] Mode of birth (n (%)) a. caesarean section (CS) Intubated: 6 (7.8) Not intubated: 7 (7.6) b. Instrumental vaginal birth Intubated: 10 (13) Not intubated: 3 (3.3) Delivery room management (n (%)) a. Obstetrician suctioned pharynx before delivery Intubated: 66 (86.8) Not intubated: 67 (77) [Note: 7 further babies in the intubation group and 11 babies in the not intubated group were suctioned after delivery, with the		performed using a random number table - eligible patients were randomised consecutively based on whether the next number was odd or even. The assignment was written on labels which were stuck to the data sheet of the babies. Care protocol At the time, the department endorsed uniform management for all deliveries with MSL. This included oronasopharyngeal suction at the perineum, and the attendance of a resuscitation team (neonatal intensive care unit [NICU] respiratory therapist and nurse) at each delivery with MSL. The respiratory therapists cared only for sick babies and were certified in intubation skills.		Groups received same care (apart from intervention): Yes Blinding of participants: Unclear - no details given Blinding of staff providing care: Obstetricians were blinded; NICU team were not Blinding of outcome assessors: Chest x-rays were interpreted by a blinded radiologist. Otherwise, outcome assessors were not blinded because it is reported that the NICU team assessed neonatal outcomes Missing data/loss to follow-up: No Precise definition of outcomes: No - the criteria for diagnosing respiratory symptoms is not clear Valid and reliable method of outcome assessment: Unclear Intention-to-treat analysis performed: Yes Indirectness: None identified - preterm babies are excluded. The study was stopped early

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	remainder not suctioned at all] b. Stomach suctioned by obstetrician Intubated: 5 (6.5) Not intubated: 2 (2.2) c. Stomach suctioned by team - before 5 minutes Intubated: 12 (15.8) Not intubated: 18 (23.7) - after 5 minutes Intubated: 64 (83.1) Not intubated: 58 (63.0) Use of continuous positive airway pressure (CPAP) or positive pressure ventilation (PPV) (n/total (%)) Intubated: 8/77 (10.4) Not intubated: 3/92 (3.3)		- Intubation group [group I in study report] Babies were intubated with a 3.0 or 3.5 endotracheal tube and suctioned with a 6.0 or 8.0-Fr suction catheter. Suction was set at 100 mmHg and continued until clear, as tolerated. The baby's heart rate was monitored, and oxygen and ventilation were provided between suctioning if bradycardia developed or it was otherwise indicated. Saline lavage (sterile 0.9 normal saline without preservative at room temperature) was started at the team's discretion. The meconium aspirator was placed on the endotracheal (ET) tube and suction applied as the tube was removed. If significant meconium was noted in the pharynx or below the cords, the stomach was also suctioned (if possible, after		when it became clear that they would not reach their sample size. The authors also report that given the lack of blinding, there may have been a bias in who was recruited. For example, if the clinician believed the baby would benefit from intubation, they could call an initially floppy baby 'depressed' which would lead to them being excluded and therefore being able to move straight to intubation. Other information This only includes babies with thin meconium There are two further groups of babies reported in this study, who were excluded from each group due to non-medical exclusion criteria (lack of consent, clinician request). However, given that they were not randomised, their outcomes are not reported here.

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria Meconium stained amniotic fluid Exclusion criteria Preterm gestation (< 37 weeks) Suspected intrauterine growth restriction (IUGR) Drug abuse Maternal hypertensive disorders Fetal distress, as indicated by a nonreassuring fetal heart rate (FHR) resulting in caesarean section secondary to fetal indications Presence of moderate (particulate) or thick ("pea soup") meconium		5 minutes of age). - No intubation group [group II in study report] Oronasopharyngeal suctioning was done with a bulb syringe. Supplemental oxygen was given as indicated. If there was a significant amount of meconium, the stomach could be suctioned with a 8.0 or 10-Fr suction catheter (if possible, after 5 minutes of age). The obstetrician and staff were blinded to the randomisation; the NICU team were not blinded. Statistical analysis A retrospective chart review was used to calculate expected rate of MSL and MAS. Based on detecting an increased in respiratory symptoms of 50%, 743 babies would be needed in each group. To		

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Clinical neonatal depression (defined as a hypotonic newborn who was not initiating adequate respiratory effort after 15 seconds of routine delivery room management) Attending physician request that baby not be intubated Maternal refusal of consent Late arrival of the team		detect a 50% decrease in MAS, a sample size of 502 would be needed (not clear if this is per arm or total). Chi-square or Fisher's exact tests were used for categorical variables, as appropriate. Kruskal-Wallis ANOVA and Mann-Whitney U-test, and ANOVA and t-tests were used for continuous data. p < 0.05 was considered significant. Outcomes reported - Respiratory symptoms: definition unclear - Use of continuous positive airway pressure (CPAP) or positive pressure ventilation (PPV)		
Full citation Vain,N.E., Szyld,E.G., Prudent,L.M., Wiswell,T.E., Aguilar,A.M., Vivas,N.I.,	Sample size N = 2514 Characteristics	Interventions Suctioning of the orophraynx and nasopharynx	Details Recruitment and randomisation This was a multicentre trial	Results Note: all of their relative risks are reported for no	Limitations Appropriate randomisation: Yes Allocation concealment: Yes

details	Participants	Interventions	Methods	Outcomes and Results	Comments
Oropharyngeal and nasopharyngeal suctioning of meconium-stained neonates before delivery of their shoulders: multicentre, randomised controlled trial, Lancet, 364, 597-602, 2004 Ref Id 209200 Country/ies where the study was carried out Multicentre (Argentina, USA) Study type Randomised controlled trial Aim of the study To assess the efficacy of intrapartum suctioning for the prevention of meconium aspiration syndrome Study dates March 13th 2000 to October 1st 2001	Maternal age/years (mean ± SD) Suction: 27.4 ± 6.3 No suction: 27.3 ± 6.3 Primiparous (n (%)) Suction: 523 (41) No suction: 511 (41) Poor prenatal care (< 5 visits) Suction: 310 (24) No suction: 318 (25) Low socioeconomic group (n (%)) Suction: 782 (62) No suction: 792 (63) Complications of pregnancy (n (%)) Any Suction: 186 (15) No suction: 169 (14) Hypertension (systolic > 140 mmHg or diastolic > 90 mmHg) Suction: 65 (5) No suction: 65 (5)	(including hypopharynx) before delivery of the shoulders (n = 1263) No suctioning (n = 1251)	conducted at 11 sites in Argentina and 1 in USA. The hospitals included 6 public hospitals caring for patients from underserved populations who often failed to seek prenatal care and 6 private hospitals that cared for middle and upper socioeconomic classes who received high quality healthcare. Patients were enrolled under a "no informed consent" protocol. This was approved by the review boards of the participating institutions and an independent ethics committee. Obstetricians were given a letter to inform their patients about the study; however, women not receiving antenatal care would not have received this information. Women were randomised	suction compared with suction Mortality (n/total (%)) Suction: 9/1263 (1) No suction: 4/1251 (0.3*) [Note: the causes of death in the suction group were respiratory failure (4), congenital malformations (2) and sepsis (3); the causes of death in the no-suction group were respiratory failure (2), sepsis (1) and congenital malformation (1)] MAS (n/total (%)) Suction: 52/1263 (4) No suction: 47/1251 (4) RR 0.9 (95% CI 0.6 to 1.3)	Groups comparable at baseline: Yes Groups received same care (apart from intervention): Probably, although the care received by the control group is not completely clearly described Blinding of participants: Unclear Blinding of staff providing care: Those providing care for the baby subsequent to the delivery room were blinded Blinding of outcome assessors: Unclear who assessed the outcomes and therefore whether they were blinded Missing data/loss to follow-up: Some outcomes are only reported for babies with meconium aspiration syndrome Precise definition of outcomes: Yes, apart from respiratory disorders Valid and reliable method of outcome assessment: Unclear exactly how data

details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Sponsored in part by a grant from the American Academy of Pediatrics/American Heart Association Neonatal Resuscitation Program. [The funding was used to pay for data management and statistical analysis. The sponsors had no role in study design, data collection, data analysis, data interpretation, or writing of the report.]	Diabetes (pregestational fasting glucose > 5.55 mmol/l, or during pregnancy > 7.77 mmol/l 2 hours after a glucose tolerance test) Suction: 11 (1) No suction: 17 (1) Intrauterine growth restriction (IUGR) (fetal weight at or below 10th percentile by ultrasound) Suction: 13 (1) No suction: 10 (1) Oligohydramnios (n (%)) Suction: 17 (1) No suction: 20 (2) Abnormal fetal heart rate (FHR) during labour (n (%)) Suction: 145 (11) No suction: 130 (10)		using computer generated random numbers in blocks of 4. Random tables and evelopes were prepared by a statistician at the data collection centre. Assignments were drawn from consecutively numbered, sealed, opaque envelopes, which were opened immediately by the neonatalogist, before attendance at deliveries complicated by meconium staining. None of the resuscitation team at the hospitals were in charge of any subsequent patient care, and the babies' records only indicated partiicpation not allocation. Therefore, all investigators and the clinicians who subsequently cared for the babies outside the delivery room were unaware of group allocation and results. Care protocol	Need for mechanical ventilation for MAS (n/total (%)) Suction: 24/1263 (2) No suction: 18/1251 (1) RR 0.8 (95% CI 0.4 to 1.4) Endotracheal intubation, suction and PPV in the delivery room (n/total (%)) Suction: 106/1263 (8) No suction: 113/1251 (9) RR 1.1 (95% CI 0.8 to 1.4) Other respiratory disorders (n/total (%)) Suction: 61/1263 (5) No suction: 79/1251 (6) RR 1.3 (95% CI 0.9 to 1.8)	were collected (e.g. from charts or another method) Intention-to-treat analysis performed: Yes (Note: of those assigned to the suction group, 87 (7%) did not received it because the caregiver arrived late or there was an unexpected failure in the suction system. 26 (2%) of the no-suction group received intrapartum suctioning, mostly because the obstetrician demanded suctioning just as the child's head was being delivered) Indirectness: None identified - study is not restricted to low risk women (although some higher risk groups [e.g. preterm babies] are excluded) but it was prespecified for this review that babies born to higher risk women could be included Other information

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Consistency of meconium stained liquor (n (%)) Thin Suction: 774 (61) No suction: 761 (61) Moderately thick Suction: 337 (27) No suction: 322 (26) Thick Suction: 151 (12) No suction: 168 (13) Mode of birth (n (%)) Vaginal forceps assistance Suction: 40 (3) No suction: 37 (3) Caesarean section (CS) Suction: 401 (32) No suction: 398 (32) No labour (n (%)) Suction: 89 (7) No suction: 109 (9)		Suction group Intrapartum suctioning was carried out with an appropriately sized suction catheter (10-Fr to 13-Fr) connected to a negative pressure of 150 mmHg. Oropharyngeal suctioning was done first, followed by bilateral nasopharyngeal suctioning when possible. This was done after both vaginal birth and CS. No pharyngeal suctioning was done after delivery unless airway obstruction was clinically apparent. Thereafter, care was given according to the guidelines of the Neonatal Resuscitation Program of the American Academy of Paediatrics and the American Heart Association, which recommended tracheal suction followed by positive pressure ventilation (PPV) only in the care of non-	Pneumothorax (n/total (%)) Suction: 3/1263 (0.2*) No suction: 3/1251 (0.2*) RR 1.0 (95% CI 0.2 to 5.0) * calculated by the technical team, as not reported in the study Duration of oxygen treatment in babies with MAS/days (mean ± SD) Suction: 5.7 ± 8.8 [n = 52] No suction: 5.1 ± 7.1 [n = 47] (p = 0.91) Duration of mechanical ventilation in babies with MAS/days (mean	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Birthweight/grams (mean ± SD) Suction: 3413 ± 483 No suction: 3400 ± 496 Inclusion criteria Birth through meconium stained amniotic fluid of any consistency Gestational age of 37 weeks or more Cephalic presentation Exclusion criteria Major congenital malformations Inability to randomise before delivery Obstetrician not allowing their patients to participate [if obstetricians wanted to include some but		vigorous infants. Vigorous was defined as having strong respiratory efforts, good muscle tone, and a heart rate of > 100 bpm. [Note: it is not directly stated whether this applies to the control group too] Statistical analysis A sample size calculation found that at least 2286 patients (1143 per arm) would be needed to fulfil statistical equivalence between the suction and no-suction groups. This was based on an assumed incidence of meconium aspiration syndrome (MAS) of 7% with an equivalent limit difference of 3% (α = 0.05; β = 0.20). Data were analysed intention-to-treat (ITT). ANOVA, Mann-Whitney U test, chi-squared and Fisher's exact test were used as approriate. An	± SD) Suction: 5.1 ± 4.9 [n = 21] No suction: 4.2 ± 4.6 [n = 14] (p = 0.49) Duration of hospital care in babies with MAS/days (mean ± SD) Suction: 8.2 ± 10.7 [n =50] No suction: 9.0 ± 8.6 [n = 43] (p = 0.14) SUBGROUP ANALYSES a. Thick meconium (n = 319) - MAS Suction: 22/151 (15) No suction: 23/168 (14) RR 0.9 (95% CI 0.5 to	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	not all of their patients, they were not enrolled]		independent data safety and monitoring committee undertook interim analyses at two time-points, on enrolment of 400 and 1000 babies. 33 patients (18 suction, 15 no suction) were found not to meet the inclusion criteria following randomisation (e.g. due to congenital malformations) but their data were included in the ITT. Outcomes reported - Mortality - MAS: defined by: 1) respiratory distress (tachypnoea, retractions, or grunting) in a neonate born through MSL; 2) need for supplemental oxygen to maintain oxygen saturation at 92% or greater; 3) oxygen requirements starting during the first 2 hours of life and lasting for	1.6) - Mechanical ventilation for MAS Suction: 10/151 (7) No suction: 8/168 (5) RR 0.7 (95% CI 0.3 to 1.8) - Mortality Suction: 5/151 (3) No suction: 3/168 (2) RR 0.5 (95% CI 0.1 to 2.2) b. Caesarean section birth (n = 799) - MAS Suction: 19/401 (5) No suction: 20/398 (5) RR 1.1 (95% CI 0.6 to 2.0) - Mechanical ventilation for MAS Suction: 10/401 (2)	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
			12 hours or longer; 4) absence of congenital malformation of the airway, lung or heart. Severe MAS was defined as needing mechanical ventilation. - Endotracheal intubation, suction and PPV in the delivery room - Pneumothorax - Respiratory disorders: not defined what these are - Duration of oxygen treatment - Duration of mechanical ventilation: the indications for mechanical ventilation were 1) paO2 < 50 mmHg or O2 saturation < 92% in FiO2 or more than 0.7; 2) pCO2 > 60 mmHg or 3) clinically significant apnoea or clinical deterioration as determined by the attending neonatologist	No suction: 7/398 (2) RR 0.7 (95% CI 0.3 to 1.8) - Mortality Suction: 4/401 (1) No suction: 2/398 (1) RR 0.5 (95% CI 0.1 to 2.7) c. Caesarean section with no labour (n = 194) - MAS Suction: 2/87 (2) No suction: 4/107 (4) RR 1.6 (95% CI 0.3 to 8.7) d. Abnormal fetal heart rate during labour (n = 275) - MAS Suction: 19/145 (13) No suction: 17/130 (13)	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
			- Duration of hospital care	RR 1.0 (95% CI 0.5 to 1.8) - Mechanical ventilation for MAS Suction: 11/145 (8) No suction: 9/130 (7) RR 0.9 (95% CI 0.4 to 2.1) - Mortality Suction: 5/145 (3) No suction: 2/130 (2) RR 0.4 (95% CI 0 to 2.3) e. Need for PPV or more extensive resuscitation in delivery room (n = 219) - MAS Suction: 30/106 (28) No suction: 28/113 (25) RR 0.9 (95% CI 0.6 to 1.4)	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- Mechanical ventilation for MAS Suction: 13/106 (12) No suction: 12/113 (11) RR 0.9 (95% CI 0.4 to 1.8) - Mortality Suction: 6/106 (6) No suction: 4/113 (4) RR 0.6 (95% CI 0.2 to 2.2)	
Full citation Wiswell,T.E., Gannon,C.M., Jacob,J., Goldsmith,L., Szyld,E., Weiss,K., Schutzman,D., Cleary,G.M., Filipov,P., Kurlat,I., Caballero,C.L., Abassi,S., Sprague,D., Oltorf,C., Padula,M., Delivery room management of the apparently vigorous	Sample size N = 2094 Characteristics Gravidity (median (range)) Intubation: 2 (1 - 9) Expectant: 2 (1 - 13) Parity (median (range)) Intubation: 1 (0 - 8)	Interventions Intubation group (n = 1051) Expectant management group (n = 1043)	Details Recruitment and randomisation There was no informed consent protocol for this study. The rationale for this was that both universal and selective intubation policies are accepted standards of care, meconium is often not noted until very close to	Results Meconium aspiration syndrome (n/total (%)) a. Overall Intubation: 34/1051 (3.2) Expectant: 28/1043 (2.7) b. Subgroup analysis by degree of	Limitations Appropriate randomisation: Yes Allocation concealment: Yes, although babies could be excluded for not being vigorous after they had been randomised, which may have led to bias. Groups comparable at baseline: Yes - no significant differences were found

details	Participants	Interventions	Methods	Outcomes and Results	Comments
meconium-stained neonate: results of the multicenter, international collaborative trial, Pediatrics, 105, 1-7, 2000 Ref Id 217594 Country/ies where the study was carried out USA Study type Randomised controlled trial Aim of the study To assess whether intubation and suctioning of the apparently vigorous meconium stained baby reduces the incidence of meconium aspiration syndrome, and to determine the frequency of complications of intubation and suctioning Study dates July 1995 to September 1997	Expectant: 1 (0 - 12) Prenatal care (n (%)) < 5 visits Intubation: 130 (12.4) Expectant: 139 (13.3) ≥ 5 visits Intubation: 921 (87.6) Expectant: 904 (86.7) Presence of oligohydramnios (n (%)) Intubation: 28 (2.7) Expectant: 18 (1.7) Meconium consistency (n (%)) - Thin Intubation: 447 (42.5) Expectant: 453 (43.4) - Moderately thick Intubation: 301 (28.6) Expectant: 307 (29.4) - Thick Intubation: 303 (28.8) Expectant: 283 (27.1)		birth when it is too late to get consent, and there are inherent difficulties in getting informed consent from women in labour. The authors noted that with informed consent and not enrolling babies until that late, the study population might then not be representative (e.g. higher risk babies would be more likely to be excluded). This was a multicentre trial, including both clinical centres and university-affiliated hospitals. Randomisation was done using computer-generated random numbers. Allocation was contained in an opaque sealed envelope whcih was drawn and opened immediately before birth in deliveries complicated by meconium. If the baby was born and did not meet the criteria for apparent vigour, they were	meconium staining - Thin Intubation: 5/447 (1.1) Expectant: 2/453 (0.4) - Moderate Intubation: 7/301 (2.3) Expectant: 6/307 (2.0) - Thick Intubation: 22/303 (7.3) Expectant: 20/283 (7.1) [Note: it is reported that 30 of the babies with MAS needed either mechanical ventilation or continuous positive airway pressure (CPAP), but not what group these babies belonged to] Other respiratory disorders (n/total (%))	between the two study groups Groups received same care (apart from intervention): Yes Blinding of participants: No details given Blinding of staff providing care: No details given Blinding of outcome assessors: No details given Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: No particular indirectness identified, as preterm babies were excluded Other information Meconium could be of any consistency in this trial. It was defined as follows: - Thin: watery consistency fluid through which you could potentially read newspaper

details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Supported by grants from: - the Steering Committee of the American Heart Association / American Academy of Pediatrics Neonatal Resuscitation Program - American Pediatric Society / Society for Pediatric Research Multicenter Trials Initiative	Electronic fetal monitoring done (n (%)) Intubation: 820 (78.0) Expectant: 829 (79.5) Abnormal fetal heart rate during labour (n (%)) Intubation: 274 (33.4) Expectant: 269 (32.4) Use of amnioinfusion (n (%)) Intubation: 73 (6.9) Expectant: 65 (6.2) Mode of birth (n (%)) - Vacuum assisted Intubation: 52 (4.9) Expectant: 61 (5.8) - Forceps assisted Intubation: 54 (5.1) Expectant: 61 (5.8) - caesarean section (CS) Intubation: 234 (22.3)		excluded and the randomisation discarded. Care protocol The protocol was that all babies had suctioning of the oropharynx with either a catheter or a bulb syringe before delivery of the shoulders or trunk (95.6% of the intubation group and 95.4% of the expectant group did have suctioning before delivery of the shoulders). Babies were then randomised to one of the following groups: - Intubation Babies were intubated immediately after birth. A standard meconium suction device was connected to the proximal end of the endotracheal (ET) tube and attached to the wall suction, set at 80 to 120 mmHg. Suction was applied continuously for 1 to 5 seconds and as the	a. Overall Intubation: 40/1051 (3.8) Expectant: 47/1043 (4.5) [Note: the majority (n = 52) were transient tachypnea of the newborn, followed by delayed transition from fetal circulation (n = 16), sepsis or pneumonia (n = 10), persistent pulmonary hypertension of the newborn (n = 3), pulmonary oedema (n = 3), pneumothorax (n = 2), hypovolemia (n = 1), and blood aspiration (n = 1)] b. Subgroup analysis by degree of meconium staining - Thin Intubation: 6/447 (1.3)	print if the fluid was on paper - Moderate: opaque fluid without particles - Thick: fluid of pea-soup consistency or opaque fluid containing particulate material

details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Expectant: 221 (21.2) Inclusion criteria Meconium presence in the amniotic fluid Gestational age of ≥ 37 weeks Apparent vigour of the baby in the delivery room immediately after birth (defined by heart rate > 100 beats per minute, as well as presence of spontaneous respirations and reasonable tone) Exclusion criteria		tube was withdrawn. If meconium was suctioned from the trachea, the procedure was repeated until there was no more meconium stained fluid. Note: 17 (1.5%) were not intubated - generally due to excessively difficult intubation. - Expectant Babies had routine delivery room care. If the babies showed signs of respiratory distress, and clinicians felt it was indicated, the babies could be intubated and suctioned. 64 (6.1%) of the babies in this group ended up being intubated. Statistical analysis Antenatal, intrapartum and postnatal data were collected on a standardised form and forwarded on to a central facility for entry into a	Expectant: 8/453 (1.8) - Moderate Intubation: 10/301 (3.3) Expectant: 15/307 (4.9) - Thick Intubation: 24/303 (7.9) Expectant: 24/283 (8.5) Use of ECMO (n/total (%)) Intubation: 1/1051 (0.1) Expectant: 1/1043 (0.1) Death (n/total (%)) Intubation: 2/1051 (0.19) Expectant: 3/1043 (0.29) [Note: 4 were caused	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
			database. An independent data safety and monitoring committee assessed data at 1/3 and 2/3 way through enrolment. All other investigators remained blinded to the results until the end of the trial. Sample size calculation was based on a decrease in incidence from 3% to 1% with suctioning compared to expectant management. To demonstrate a difference with an alpha of 0.05 and power of 90%, 1029 babies were needed in each group. Univariate analyses, including a 2-group t-test, Wilcoxon rank sum test, two-tailed Fisher's exact test, and chi-squared were initially used to compare the groups. Stepwise logistic regression was then used to evaluate the effect of other factors on	by respiratory failure and 1 by overwhelming infection] Complications of intubation Out of the 1098 babies that were successfully intubated (1034 from intubation group and 64 from expectant group), 42 (3.8%) experienced complications of the procedure. These included bradycardia (n = 26), hoarseness or stridor (n = 14), laryngospasm (n = 6), apnea (n = 2), bleeding at the vocal cords (n = 2) and cyanosis (n = 1). Most were transient, lasting between 16 and 60 seconds. Hoarseness or stridor lasted between 2 minutes and 12 hours.	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
			incidence of meconium aspiration syndrome (MAS) or other respiratory disorders. Outcomes reported - Meconium aspiration syndrome: defined as respiratory distress in a baby born through meconium stained liquor (MSL) whose symptoms could not otherwise be explained and who had consistent radiographic findings (e.g. coarse, irregular infiltrates, hyperinflation, and/or segmental or lobar atelectasis) - Other respiratory disorders: includes transient tachypnea of the newborn, delayed transition from fetal circulation, sepsis or pneumonia, persistent pulmonary hypertension of the newborn, pulmonary	Respiratory support in 149 babies with fetal distress, split by degree of meconium staining (n (%)) a. Thin consistency (n = 900) No support: 12 (1.3) Oxygen only: 5 (0.6) CPAP only: 1 (0.1) Mechanical ventilation only: 3 (0.3) CPAP or mechanical ventilation: 4 (0.4) b. Moderately-thick consistency (n = 608) No support: 3 (0.5) Oxygen only: 29 (4.8) CPAP only: 2 (0.3) Mechanical ventilation only: 4 (0.7) CPAP or mechanical ventilation: 6 (1.0) c. Thick consistency (n = 586)	

details	Participants	Interventions	Methods	Outcomes and Results	Comments
			oedema, pneumothorax, hypovolemia, and other respiratory disorders - Use of extracorporeal membrane oxygenation (ECMO) - Death	No support: 2 (0.3) Oxygen only: 55 (9.4) CPAP only: 11 (1.9) Mechanical ventilation only: 22 (3.8) CPAP or mechanical ventilation: 33 (5.6) [Note: these data are not reported by what group the babies were assigned to, and therefore will not appear in GRADE. The data above are as reported in the study, with the % a proportion of all babies in that group]	