National Institute for Health and Care Excellence

Final

Addendum to Clinical Guideline CG190, Intrapartum care for healthy women and babies

Clinical Guideline Addendum 190.2

Methods, evidence and recommendations

November 2016

Developed by the National Institute for Health and Care Excellence

Disclaimer
Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and, where appropriate, their guardian or carer.

Contents

Clinical guidelines update

The NICE Clinical Guidelines Update Team update discrete parts of published clinical guidelines as requested by NICE's Guidance Executive.

Suitable topics for update are identified through the surveillance programme (see surveillance programme interim guide).

These guidelines are updated using a standing Committee of healthcare professionals, research methodologists and lay members from a range of disciplines and localities. For the duration of the update the core members of the Committee are joined by up to 5 additional members who are have specific expertise in the topic being updated, hereafter referred to as 'topic expert members'.

In this document where 'the Committee' is referred to, this means the entire Committee, both the core standing members and topic expert members.

Where 'standing committee members' is referred to, this means the core standing members of the Committee only.

Where 'topic expert members' is referred to this means the recruited group of members with topic expertise.

All of the core members and the topic expert members are fully voting members of the Committee.

Details of the Committee membership and the NICE team can be found in appendix A. The Committee members' declarations of interest can be found via appendix B.

1 Summary section

1.1 Update information

NICE published a guideline on intrapartum care of healthy women and their babies during childbirth in 2007 and this was partially updated in 2014 (https://www.nice.org.uk/guidance/cg190). In 2007 the original guideline group reviewed evidence on midwifery-led continuity models of care (specifically 'team midwifery' and 'caseload midwifery') with other models of care. That evidence review found that team midwifery was associated with a higher rate of perinatal mortality than other care models, and this led the guideline development group to recommend that team midwifery should not be offered. This section of the guideline was not reviewed as part of the update in 2014. During the consultation process for the updated guideline, stakeholders highlighted a Cochrane systematic review on midwife-led continuity models, which appeared to be inconsistent with the original recommendation on team midwifery. Unlike the original evidence review for the 2007 guideline, a subgroup analysis in the Cochrane review did not find any differences in outcomes between team midwifery and other models of care.

An initial assessment of the Cochrane review by the NICE surveillance team led to the commissioning of an update to specifically review midwifery-led continuity models. The Cochrane review included new evidence of midwifery-led continuity of care models and is consistent with the protocol of this guideline update. The aim of the update is to compare the effectiveness of midwifery-led continuity models of care (caseload or team) with other care models for the care of women in pregnancy and childbirth. The search and analysis in the Cochrane review was updated and this was used as the basis for this guideline update. In addition to the analysis undertaken in the Cochrane review, further subgroup analysis and GRADE was carried out for this guideline update by the NICE team.

Some recommendations can be made with more certainty than others. The committee makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the committee is confident that, given the information it has looked at, most people would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the person about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Patient-centred care').

Recommendations that must (or must not) be followed

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Recommendations that should (or should not) be followed– a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of people, following a recommendation will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer…') when we are confident that actions will not be of benefit for most people.

Recommendations that could be followed

We use 'consider' when we are confident that following a recommendation will do more good than harm for most people, and be cost effective, but other options may be similarly cost effective. The course of action is more likely to depend on the person's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the person.

1.2 Recommendations

1. **For guidance on ensuring continuity of care, see recommendation 1.4.1 in the NICE guideline on patient experience in adult NHS services [new 2016]**

1.3 Patient-centred care

This guideline offers best practice advice on the care of intrapartum care for women and babies.

Women have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.4 Methods

This update was developed based on the process and methods described in Developing NICE Guidelines: the manual 2014

2 Evidence review and recommendations

2.1 Introduction

During birth, women are cared for in one of four settings:

- Home
- A freestanding midwifery-led unit where care is provided in a unit located away from a hospital obstetric unit
- An alongside midwifery-led unit where care is provided in a unit located next to a hospital obstetric unit
- An obstetric unit.

Intrapartum care includes monitoring labour for normal progression, providing one-to-one support, provision of pain relief and birth of the baby and placenta. The way that maternity care is organised and delivered varies across England and Wales. Models of care can be divided according to the professional who takes the lead in care provision; common models include midwife-led, obstetrician-led and shared care approaches. GP-led care is also available in England and Wales, yet this is less common than other models of care.

Midwifery-led continuity of care is where a number of midwives are the lead professionals in the planning, organisation and delivery of care offered to a woman from initial booking to the postnatal period. Women may be offered these models of care with varying degree of continuity throughout pregnancy and birth. Among midwifery-led models, further subdivisions have been described:

- 'Team midwifery' describes a model of care where a group of midwives (usually five or more) take shared responsibility for a group of women throughout the antenatal, intrapartum and postnatal period.
- 'Caseload' models describe a model where care is provided throughout the antenatal, intrapartum and postnatal period primarily by one midwife known to the woman backed up by a few associate midwives, forming a group of four or less.

2.2 Review question

What is the effectiveness of midwife-led continuity models versus other models of care for childbearing women?

2.3 Clinical evidence review

2.3.1 Methods

This update made use of the aforementioned Cochrane review "Midwife-led continuity models versus other models of care for childbearing women". The Cochrane team were asked to update their review to ensure currency and also to provide additional data on outcome and subgroups where this data were not available. Outcome data were provided in a Review Manager 5 file for re-analysis by the CGUT technical analyst.

Searching

Quality assurance of this search was conducted by the NICE team and it was noted that the thesaurus term 'midwifery' was not included in the Medline strategy. In order to mitigate the risks of this, the Cochrane conducted a search of the specialised register to retrieve all studies with the term midwif$ (truncated search term to capture the variations 'midwife' or

'midwifery') that were not coded to the Cochrane review. An additional 474 references were retrieved which were then sifted by the NICE technical analyst and no additional references were included from this in the evidence review. See Appendix D and G for an overview of the Cochrane search strategy and NICE's quality assurance process. For full details of the Cochrane search, please see Sandall 2016 page 6. No additional searches were conducted by the NICE team.

Sifting

The Cochrane team updated their literature search of the Cochrane Specialised Register on 25 January 2016. Two review authors from the Cochrane team independently assessed the potential studies identified for inclusion and resolved any disagreement through discussion or, if required, consulted a third review author.

Data extraction

Two review authors from the Cochrane team extracted data into an agreed data extraction form and resolved through discussion or, if required, consulted a third review author. Summary information from the Cochrane systematic review was extracted into an evidence table (see Appendix G).

Critical appraisal

The quality of the Cochrane systematic review was assessed using the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) checklist.

Meta-analysis

When more than one study assessed an outcome for a given comparison, data were combined using pair-wise meta-analyses. The Mantel-Haenszel method was used for dichotomous outcomes. No continuous outcomes were included in this evidence review. A random effects model was chosen to average the range of possible treatment effects in different trials.

Quality and certainty of the evidence base

The quality of evidence for each outcome for each comparison was appraised using the approach recommended by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) working group.

Risk of bias

Risk of bias was assessed using the Cochrane risk of bias assessment available in the Cochrane review. This takes into account biases in study design, including selection bias, blinding, possible attrition bias (for example, clear differences in drop-out rates) and reporting bias. Lack of blinding and allocation concealment was not considered a risk of bias for objective outcomes including, for example, regional analgesia and caesarean section. However, lack of blinding or allocation concealment were considered a risk of bias for subjective outcomes, such as maternal satisfaction.

Indirectness

Indirectness was assessed on the applicability of the population, interventions and comparators and outcome of the included studies to the review protocol.

Inconsistency

Inconsistency was assessed on heterogeneity levels (I^2 result) of meta-analysis. This was considered serious if $I^2 \geq 50\%$ and very serious if $I^2 \geq 70\%$.

Imprecision

Published minimally important differences were sought for all outcomes via an internet search and through reference to the original NICE guideline on Intrapartum Care, but none were found. The GRADE default minimally important differences (MIDs) were used (0.75 and 1.25 for dichotomous outcomes). Imprecision was assessed using the MIDs as thresholds for 95% confidence intervals (CIs) of effect estimates (relative risk (RR) for dichotomous outcomes). Imprecision was considered serious and downgraded by one level if 95% CIs crossed one MID or very serious and downgraded by two levels if 95% CIs crossed both MIDs. Other factors such as publication bias were also considered, but none gave rise to serious uncertainty.

In all cases an explanation of the decision to downgrade or not was inserted into the modified GRADE profile as a footnote.

2.3.2 Results

One Cochrane review (Sandall 2016) was included (see evidence table in Appendix G) based on the criteria specified in the review protocol (Appendix C). The Cochrane team updated their literature search of the Cochrane Specialised Register in January 2016. Data available from the Cochrane review which met the criteria of this evidence review protocol was used and additional analysis, including subgroup analysis, was conducted. Sandall 2016 review included a total of 15 randomised control trials (RCTs), of which all were relevant to the review question identified for this update. Additional evidence was obtained for the subgroup of parity from 2 studies included in Sandall 2016 (Rowley 1995 and McLachlan 2012).

Evidence was available for the following comparisons included in the evidence review:

- Midwifery-led continuity of care versus Shared care (where responsibility for the delivery and organisation of care is shared between different health professionals during intrapartum period)
    - Evidence from 10 RCTs was included for this comparison.
- Midwifery-led continuity of care versus Physician-led care (where the physician / obstetrician is responsible for overlooking intrapartum care and midwives and/or nurses provide intrapartum care under medical supervision.
    - Evidence from 1 RCT was included for this comparison
- Midwifery-led continuity of care versus Physician provided care (where the majority of care is provided by the physician or obstetrician)
    - Evidence from 1 RCT was included for this comparison
- Midwifery-led continuity of care versus other mixed models of care (women have the option of receiving combination of shared care, physician-led care or physician provided care)
    - Evidence from 2 RCTs was included for this comparison

No evidence was identified for the comparison of midwifery-led continuity of care compared to midwifery-led care (varying degrees of continuity). Additionally none of the RCTs included models of care which offered home births. The evidence was analysed in accordance with the review protocol and where evidence was available, subgroup analyses based on midwifery-led model of care (caseload or team), variation in risk status (low or mixed risk) and variation in parity (first time mothers or women who have previously given birth) were performed.

Five RCTs (Flint 1999, McLachlan 2012, North Stafford 2000, Tracy 2013 and Turnbull 1996) included in Sandall 2016 used caseload midwifery where care was provided by a named midwife or a group of 4 midwives. Nine RCTs (Begley 2011, Biro 2000, Hicks 2003, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, Rowley 1995 and Waldenstrom

2001included in Sandall 2016) used team midwifery where care was provided by a team of 6 to 8 midwives.

To determine clinical effectiveness, where 95% CIs of an effect estimate crosses an MID, the effect of the intervention or control is uncertain. This uncertainty is captured in the evidence statements when the word ‘may’ is used (for example, may be higher). Where 95% CIs of an effect estimate crosses no effect, there may be no difference between intervention and comparison and this is highlighted in the evidence statement.

For a summary of included studies please see Table 1 (for the full evidence table, full GRADE profiles and forest plots please see appendices G, I and J respectively).

Table 1: Summary of included study

Study id	Studies included	Population	Intervention & comparator	Location	Outcomes reported
1 Cochrane systematic review (Sandall 2016)	Allen 2013 (no data included as trial was terminated) Begley 2011 Biro 2000 Flint 1989 Harvey 1996 Hicks 2003 Homer 2001 Kenny 1994 MacVicar 1993 McLachlan 2012 North Stafford 2000 Rowley 1995 Tracy 2013 Turnbull 1996 Waldenstrom 2001	Pregnant women	10 RCTs compared a midwifery-led continuity model of care to a shared model of care (Biro 2000; Flint 1989; Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993, North Stafford 2000; Rowley 1995, Tracy 2013, Turnbull 1996) 1 RCT compared a midwifery-led continuity model of care to physician-led care. (Begley 2011) 1 RCT compared a midwifery-led continuity model of care to physician provided care where the majority of care is provided by a physician. (Harvey 1996) 2 RCTs compared a midwifery-led continuity model of care to other mixed models of care such as having the option of receiving a combination of shared care and physician-led care . (McLachlan 2012 and Waldenstrom 2001)	8 RCTs were conducted in Australia, 5 in the UK, 1 in Ireland and 1 in Canada.	• Regional analgesia (epidural/spinal) • Caesarean birth • Instrumental vaginal birth (forceps/vacuum) • Spontaneous vaginal birth (as defined by trial authors) • Intact perineum • Preterm birth (less than 37 weeks) • Overall fetal loss and neonatal death • Maternal satisfaction • Augmentation of labour • Induction of labour • Breastfeeding initiation (indirect for breastfeeding on hospital discharge as in protocol) No studies reported on the outcome ‘transfer to physician led care’.

2.4 Health economic evidence review

2.4.1 Methods

Evidence of cost effectiveness

The Committee is required to make decisions based on the best available evidence of both clinical and cost effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits.

Evidence on cost effectiveness related to the key clinical issues being addressed in the guideline update was sought. The health economist extracted data from the economic studies included in the Cochrane systematic review (Sandall et al. 2016).

Economic literature review

The health economist:

- Critically appraised relevant studies using the economic evaluations checklist as specified in *Developing NICE Guidelines: the manual 2014*.
- Extracted key information about the studies' methods and results into full economic evidence tables (appendix N).
- Generated summaries of the evidence in economic evidence profiles.

Economic evidence profile

The economic evidence profile summarises cost-effectiveness estimates. It shows an assessment of the applicability and methodological quality for each economic evaluation, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from *Appendix H* of *Developing NICE Guidelines: the manual 2014*. It also shows the incremental cost, incremental effect and incremental cost-effectiveness ratio for the base case analysis in the evaluation, as well as information about the assessment of uncertainty.

The information contained in the economic evidence profile is explained in Table 2.

Table 2: Explanation of fields used in the economic evidence profile

Item	Description
Study	This field is used to reference the study and provide basic details on the included interventions and country of origin.
Applicability	Applicability refers to the relevance of the study to specific review questions and the NICE reference case. Attributes considered include population, interventions, healthcare system, perspective, health effects and discounting. The applicability of the study is rated as: • Directly applicable – the study meets all applicability criteria or fails to meet one or more applicability criteria but this is unlikely to change the conclusions about cost effectiveness. • Partially applicable – the study fails to meet one or more applicability criteria and this could change the conclusions about cost effectiveness. • Not applicable – the study fails to meet one or more of the applicability criteria and this is likely to change the conclusions about cost effectiveness. Such studies would usually be excluded from the review.
Limitations	This field provides an assessment of the methodological quality of the study. Attributes assessed include the relevance of the model's structure to the review question, timeframe, outcomes, costs, parameter sources, incremental

Item	Description
	analysis, uncertainty analysis and conflicts of interest. The methodological quality of the evaluation is rated as having: • Minor limitations – the study meets all quality criteria or fails to meet one or more quality criteria, but this is unlikely to change the conclusions about cost effectiveness. • Potentially serious limitations – the study fails to meet one or more quality criteria and this could change the conclusions about cost effectiveness • Very serious limitations – the study fails to meet one or more quality criteria and this is highly likely to change the conclusions about cost effectiveness. Such studies would usually be excluded from the review.
Other comments	This field contains particular issues that should be considered when interpreting the study, such as model structure and timeframe.
Incremental cost	The difference between the mean cost associated with one strategy and the mean cost of a comparator strategy.
Incremental effect	The difference between the mean health effect associated with the intervention and the mean health effect associated with the comparator. This is usually represented by quality-adjusted life years (QALYs) in accordance with the NICE reference case.
Incremental cost effectiveness ratio (ICER)	The incremental cost divided by the incremental effect which results in the cost per quality-adjusted life year gained (or lost). Negative ICERs are not reported as they could represent very different conclusions: either a decrease in cost with an increase in health effects; or an increase in cost with a decrease in health effects. For this reason, the word 'dominates' is used to represent an intervention that is associated with decreased costs and increased health effects compared to the comparator, and the word 'dominated' is used to represent an intervention that is associated with an increase in costs and decreased health effects.
Uncertainty	A summary of the extent of uncertainty about the ICER. This can include the results of deterministic or probabilistic sensitivity analysis or stochastic analyses or trial data.

Cost-effectiveness criteria

NICE's report *Social value judgements: principles for the development of NICE guidance* sets out the principles that GDGs should consider when judging whether an intervention offers good value for money. In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

- the intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- the intervention cost less than £20,000 per QALY gained compared with the next best strategy.

If the Committee recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'evidence to recommendations' section of the relevant chapter, with reference to issues regarding the plausibility of the estimate or to the factors set out in *Social value judgements: principles for the development of NICE guidance*.

In the absence of economic evidence

When no relevant economic studies were found from the economic literature review, and de novo modelling was not feasible or prioritised, the Committee made a qualitative judgement

about cost-effectiveness by considering expected differences in resource use between options and relevant UK NHS unit costs, alongside the results of the clinical review of effectiveness evidence. The UK NHS costs reported in the guideline were those presented to the Committee and they were correct at the time recommendations were drafted; they may have been revised subsequently by the time of publication. However, we have no reason to believe they have been changed substantially.

2.4.2 Results of the economic literature review

Data were extracted from the 7 studies included in the Cochrane systematic review. Table 4 contains the economic evidence profile for this review question summarising the results of the studies included in the systematic review. Full economic evidence tables are contained in appendix N.

A within-trial cost analysis of the MidU study (Kenny et al. 2015) compared midwifery-led care with consultant-led care in Ireland. The intervention appeared to be team midwifery although this is not stated. The average cost per birth was €2,598.06 for midwifery-led care and €2,780.00 for consultant-led care. Midwifery-led care was associated with a cost saving of €181.94 (95% CI 33 to 330) per birth. This study was partially applicable with potentially serious limitations.

A within-trial cost analysis (Tracy et al. 2013) compared caseload midwifery-led continuity of care to shared care with rostered midwives. Caseload midwifery care cost AUD$566.74 per birth (95% CI 106.17 to 1,027.30) less than the shared care model. This study was partially applicable with potentially serious limitations.

A within-trial cost analysis (Homer et al. 2001) compared community-based midwifery-led care with hospital-based shared care and found that midwifery-led care cost AUD$904 less. This study was partially applicable with potentially serious limitations.

A within-trial cost analysis (Young et al. 1997) compared caseload midwifery-led care with shared care. It found no statistically significant difference in cost between the arms for antenatal and intrapartum care and an increased cost of £118.81 associated with midwifery-led care for the postnatal care period. This study was partially applicable with potentially serious limitations.

A within-trial cost analysis (Rowley et al. 1995) compared team midwifery-led care with shared care. It found a cost saving of AUD$151 for midwifery-led care. This study was partially applicable with potentially serious limitations.

A within-trial cost analysis (Kenny et al. 1994) compared team midwifery-led care with shared care and found a cost saving of AUD$98 for midwifery-led care. This study was partially applicable with potentially serious limitations.

Flint et al. (1989) examined the costs for a subgroup of women and estimated costs for antenatal care was 20% to 25% cheaper for women in the midwifery-led continuity of care group due to differences in staff costs.

2.4.3 Unit costs

The original guideline (CG190) considered the costs of events relevant to birth from 2 sources: firstly from the Birthplace cost-effectiveness analysis and secondly from consensus of the guideline committee. These costs are summarised in Table 3. The cost of these events were considered by the committee because they relate to the outcomes specified in the review protocol. Further detail on how these costs were derived can be found in Appendix A of the original guideline available on the NICE website (Intrapartum Care, Clinical Guideline 190).

Table 3: Unit costs from original guideline (CG190)

Procedure	Birthplace analysis	Guideline committee consensus
Augmentation	£141.78	£52.27
Epidural	£253.33	£108.35
Spinal analgesia	£253.33	£67.38
General anaesthetic	£774.85	£160.58
Assisted delivery – ventouse	£389.36	£156.20
Assisted delivery – forceps	£479.11	£156.20
Emergency caesarean	££882.52	£488.50
Suturing – second degree tear	Not reported	£89.25
Suturing – third or fourth degree tear	£498.98	£322.95
Manual removal of placenta	£559.96	£139.80
Postpartum haemorrhage <1,500mL	Not reported	£55.42
Postpartum haemorrhage >1,500mL	Not reported	£871.98
Blood transfusion	£77.87	£63.71
Hysterectomy	Not reported	£2,278.15
Neonatal intubation	Not reported	£68.64

Table 4: Economic evidence profile

Study	Applicability	Limitations	Other comments	Average cost	Average effectiveness	Incremental cost	Incremental effectiveness	Incremental cost effectiveness ratio	Uncertainty
Kenny et al. 2015 Midwifery-led care vs. consultant-led care Ireland	Partially applicable [1,2]	Potentially serious limitations [3]	Within-trial cost analysis	Consultant-led: €2,780.00 Midwife-led: €2,598.06	Not applicable	-€181.94 (95% CI -33 to -330) or -£164.20 (2016)	Not applicable	Not applicable	1 additional midwife visit to mothers in the midwifery-led arm reduced cost savings to €170 (95% CI 20 to 231) Distribution of costs taken into account in the confidence interval around the mean difference
Tracy et al. 2013 Caseload midwifery-led care vs. shared care with rostered midwives Australia	Partially applicable [4,5]	Potentially serious limitations [6]	Within-trial cost analysis	Shared care: AUD$5,903.67 Caseload midwifery care: AUD$5,497.34	Not applicable	-AUD$566.74 (95% CI -106.17 to -1,027.30) or -£281.51 (2016)	Not applicable	Not applicable	One way sensitivity analysis not conducted Distribution of costs taken into account in the confidence interval around the mean difference
Homer et al. 2001 Team midwifery-led care vs. shared care Australia	Partially applicable [7,8]	Potentially serious limitations [9]	Within-trial cost analysis	Shared care: AUD$3,483 Midwifery-led care: AUD$2,579	Not applicable	-AUD$904 or -£686.99 (2016)	Not applicable	Not applicable	• Excluding costs associated with neonate special care nursery: reduced savings to AUD$139 • Excluding costs associated with neonate special care nursery and reducing the number of women seen in the midwifery-led clinical to 10 per week from 60: midwifery-led model cost more than the shared-care model

Study	Applicability	Limitations	Other comments	Average cost	Average effectiveness	Incremental cost	Incremental effectiveness	Incremental cost effectiveness ratio	Uncertainty
									• Excluding the costs associated with neonate special care nursery and increasing the caesarean section rate in the midwifery-led model to 20% while maintaining the rate of caesarean section at 17% for the shared-care model: models have similar cost
Young et al. 1997 Caseload midwifery-led care vs. shared care Scotland	Partially applicable [10,11]	Potentially serious limitations [12]	Within-trial cost analysis	Shared care Antenatal: £295.91 Intrapartum: £241.17 Postpartum: £352.03 Midwifery-led care Antenatal: £287.60 Intrapartum: £240.90 Postpartum: £470.34	Not applicable	- Antenatal: No difference Intrapartum: No difference Postpartum: +£118.31	Not applicable	Not applicable	Caseload increased to 39 women per midwife from 29, incremental cost: • Antenatal: £20.97 • Intrapartum: no difference • Postpartum: £52.14
Rowley et al. 1995 Team midwifery-led care vs. shared care	Partially applicable [13,14]	Potentially serious limitations [15]	Within-trial cost analysis	Shared care: AUD$3,475 Midwifery-led care: AUD$3,324	Not applicable	-AUD$151 or -£129.23 (2016)	Not applicable	Not applicable	Univariate and probabilistic sensitivity analysis not conducted

Study	Applicability	Limitations	Other comments	Average cost	Average effectiveness	Incremental cost	Incremental effectiveness	Incremental cost effectiveness ratio	Uncertainty
Australia									
Kenny et al. 1994 Team midwifery-led care vs. shared care Australia	Partially applicable [16,17]	Potentially serious limitations [18]	Within-trial cost analysis	Shared care Antenatal: AUD$167 Intrapartum: AUD$219 Postpartum: AUD$833 Midwifery-led care Antenatal: AUD$158 Intrapartum: AUD$219 Postpartum: AUD$745	Not applicable	- Total difference: -AUD$98 or -£84.79 (2016)	Not applicable	Not applicable	Univariate and probabilistic sensitivity analysis not conducted

Flint et al. 1989 could not be obtained. Narrative summary from Cochrane review provided in section 2.4.2.

1 *Costs may be different in the Irish healthcare system*
2 *Models of care may be different in the Irish healthcare system*
3 *The time horizon of perinatal care may not capture all the important health and cost consequences*
4 *Costs may be different in the Australian healthcare system*
5 *Models of care may be different in the Australian healthcare system*
6 *The time horizon of perinatal care may not capture all the important health and cost consequences*
7 *Costs may be different in the Australian healthcare system*
8 *Models of care may be different in the Australian healthcare system*
9 *The time horizon of perinatal care may not capture all the important health and cost consequences*
10 *Costs may be different in the Scottish healthcare system*
11 *Models of care may be different in the Scottish healthcare system*
12 *The time horizon of perinatal care may not capture all the important health and cost consequences*
13 *Costs may be different in the Australian healthcare system*
14 *Models of care may be different in the Australian healthcare system*
15 *The time horizon of perinatal care may not capture all the important health and cost consequences*
16 *Costs may be different in the Australian healthcare system*
17 *Models of care may be different in the Australian healthcare system*

2.5 Evidence statements

2.5.1 Clinical evidence statements

2.5.1.1 Midwifery-led continuity of care versus other models of care

- Low quality evidence from 14 RCTs with 17674 participants using midwifery-led continuity of care showed less use of regional analgesia (epidural or spinal) compared to other models of care, yet this effect did not reach minimum important difference.
- Moderate quality evidence from 14 RCTs with 17658 participants showed there may be no difference in caesarean birth.
- Moderate quality evidence from 13 RCTs with 17965 participants using midwifery-led continuity of care showed less instrumental vaginal birth compared to other models of care.
- Moderate quality evidence from 12 RCTs with 16687 participants showed more spontaneous vaginal birth with using midwifery-led continuity of care.
- Low quality evidence from 10 RCTs with 13186 participants showed there may be no difference in intact perineum.
- Low quality evidence from 8 RCTs with 13238 participants showed there may be lower preterm births (< 37 weeks) with midwifery-led continuity of care.
- Moderate quality evidence from 13 RCTs with 17527 participants showed there may be lower perinatal mortality defined as all fetal loss before and after 24 weeks plus neonatal death with midwifery-led continuity of care. However, very low quality evidence from 12 RCTs with 10359 participants showed no difference perinatal mortality defined as fetal loss equal to/after 24 weeks and neonatal death.
- Very low quality evidence from 12 RCTs with 15196 participants showed lower augmentation / artificial oxytocin during labour with midwifery-led continuity of care yet this effect did not reach minimum important difference.
- Low quality evidence from 12 RCTs with 15856 participants showed no difference in induction of labour.
- Very low quality evidence from 2 RCTs with 2050 participants showed there may be no difference in breastfeeding initiation although a clinically important reduction, or increase, cannot be excluded.
- Very low evidence from 1 RCT with 623 participants showed greater maternal satisfaction with midwifery-led continuity of care.

2.5.1.1.1 Variation in midwifery-led model of care (caseload / team)

Caseload model (4 or fewer midwives)

- Very low quality evidence from 5 RCTs with7783 participants showed there may be no significant difference in regional analgesia (epidural or spinal).
- Moderate quality evidence from 5 RCTs with 7783 participants showed no difference in the caesarean birth and instrumental vaginal birth (using forceps or vacuum) and there may be no difference in spontaneous vaginal birth.
- Low quality evidence from 4 RCTs with 5476 participants showed there no difference in intact perineum.
- Low quality evidence from 3 RCTs with 2970 participants showed that preterm birth may be lower with midwifery-led continuity of care caseload model.
- Low quality evidence from5 RCTs with 7749 participants showed there may be no difference in perinatal mortality defined as all fetal loss before and after 24 weeks

plus neonatal death. Very low quality evidence found there may be no difference perinatal mortality defined as fetal loss equal to/after 24 weeks and neonatal death.
- Very low quality evidence 4 RCTs with 5476 participants showed there may be no difference in augmentation / artificial oxytocin during labour
- Low quality evidence 5 RCTs with7783 participants showed there may be lower levels of induction of labour with midwifery-led caseload model of care.

Team model (5 or more and up to 8 midwives)

- Moderate quality evidence from 9 RCTs with 9891 participants showed lower use of regional analgesia with midwifery-led continuity of care team model compared to other models of care yet this effect did not reach minimum important difference and no difference in caesarean birth.
- Moderate quality evidence from 8 RCTs with 10182 participants showed lower instrumental vaginal birth (using forceps or vacuum) with midwifery-led continuity of care team model yet this effect did not reach minimum important difference.
- Moderate quality evidence from 7 RCTs with 8904 participants showed more spontaneous vaginal birth with midwifery-led continuity of care team model yet this effect did not reach minimum important difference.
- Low quality evidence from 6 RCTs with 7710 participants showed there may be no difference in intact perineum.
- Very low quality evidence from 5 RCTs with 7961 participants showed there may be no difference in preterm birth.
- Moderate quality evidence from 8 RCTs with 9778 participants showed there no difference in perinatal mortality defined as all fetal loss before and after 24 weeks plus neonatal death.
- Low quality evidence from 7 RCTs with 9576 participants showed inconclusive evidence for perinatal mortality defined as fetal loss equal to/after 24 weeks and neonatal death.
- Very low quality evidence from 8 RCTs with 9718 participants showed there may be no difference in augmentation / artificial oxytocin during labour.
- Moderate quality evidence from these 7 RCTs with 8073 participants showed no difference in induction of labour.
- Very low quality evidence from 2 RCT with 2050 participants showed there may be no difference in breastfeeding.
- Moderate quality evidence from 1 RCT with 523 participants showed there may be higher maternal satisfaction in midwifery-led continuity of care team model compared to other models of care.

2.5.1.1.2 Variation in risk status (low risk/ mixed risk)

Exclusively women at low risk of complications

- Very low quality evidence from 8 RCTs with11096 participants found there may be lower use of regional analgesia (epidural / spinal) in women at low risk of complications receiving midwifery-led continuity of care compared to other models of care.
- Moderate quality evidence from 8 RCTs with 11096 participants showed there may be no difference in caesarean birth.
- Moderate quality evidence from 7 studies with 10923 participants showed lower instrumental vaginal birth using forceps or vacuum yet this effect did not reach minimum important difference.
- Moderate quality evidence from 7 RCTs with 10923 participants showed more spontaneous vaginal birth in women at low risk of complications receiving midwifery-led continuity of care compared to other models of care yet this effect did not reach minimum important difference.

- Low quality evidence from 6 RCTs with 8616 participants showed there may be no difference in intact perineum.
- Low quality evidence from 7 RCTs with 10895 participants showed there may be no difference in perinatal mortality defined as all fetal loss before and after 24 weeks plus neonatal death. Very low quality evidence was inconclusive for perinatal mortality defined as fetal loss equal to/after 24 weeks and neonatal death.
- Very low quality evidence from 6 studies with 8616 participants showed there may be a lower augmentation / artificial oxytocin during labour in women at low risk of complications receiving midwifery-led continuity of care yet this effect did not reach minimum important difference.
- Moderate quality evidence from 7 RCTs with10921 participants showed lower induction of labour in women at low risk of complications receiving midwifery-led continuity of care yet this effect did not reach minimum important difference.
- Low quality evidence from 5 RCTs with 9726 participants showed there may be no difference in preterm birth in women at low risk of complications receiving midwifery-led continuity of care.

Women at low or high risk of complications

- Moderate quality evidence from 6 RCTs with 6578 participants showed no difference in regional analgesia (epidural/spinal) in mixed risk women receiving midwifery-led continuity of care compared to other models of care.
- Moderate and low quality evidence from 6 RCTs with 6578 participants showed no difference in caesarean birth.
- Low quality evidence from 6 RCTs with 6578 participants showed there may be no difference in instrumental vaginal birth using forceps or vacuum.
- Low quality evidence from 6 RCTs with 6632 participants showed there may be lower perinatal mortality defined as all fetal loss before and after 24 weeks plus neonatal death in women with mixed risk of complications women receiving midwifery-led continuity of care. However, very low quality evidence from these studies was inconclusive for perinatal mortality defined as fetal loss equal to/after 24 weeks and neonatal death.
- Moderate quality evidence from 5 RCTs with 5764 participants showed greater spontaneous vaginal birth with midwifery-led continuity of care yet this effect did not reach minimum important difference.
- Moderate quality evidence from 4 RCTs with 4570 participants showed no difference in intact perineum.
- Low quality evidence from 3 RCTs with 3512 participants showed there may be no difference in preterm birth.
- Low quality evidence from 6 RCTs with 6578 participants showed no difference in augmentation / artificial oxytocin during labour.
- Moderate quality evidence from 6 RCTs with 6578 participants showed no difference in induction of labour.
- Very low quality evidence from 1 RCT with 405 participants showed there may be higher levels of breastfeeding initiation in women with mixed risk of complications receiving midwifery-led continuity of care compared to other models of care.
- Moderate quality evidence from 1 RCT with 523 participants showed that maternal satisfaction may be higher amongst women with mixed risk of complications receiving midwifery-led continuity of care compared to other models of care.

2.5.1.1.3 Variation in parity

First time mothers receiving midwifery-led continuity of care versus first time mothers receiving other models of care:

- Moderate quality evidence from 1 RCTs with2006 participants showed no difference in use of regional analgesia (epidural / spinal).
- Moderate quality evidence from 1 RCT with 1610 participants showed lower caesarean birth with midwifery-led continuity of care yet this effect did not reach minimum important difference.
- High quality evidence from 1 RCT with 1611 participants showed no difference in instrumental vaginal birth using forceps or vacuum.
- Moderate quality evidence from 1 RCT with 1610 participants showed there may be higher spontaneous vaginal birth with midwifery-led continuity of care.
- Low quality evidence from 1 RCT with 396 participants showed there may be no difference in augmentation / artificial oxytocin during labour and induction of labour.

Mothers who have previously given birth receiving midwifery-led continuity of care versus mothers who have previously given birth receiving other models of care:

- Moderate quality evidence from 2 RCTs with 1115 participants showed lower use of regional analgesia with midwifery-led continuity of care.
- Low quality evidence from 1 RCT with 697 participants showed lower caesarean birth with midwifery-led continuity of care although a clinically important reduction, or increase, cannot be excluded.
- Low quality evidence from 1 RCT with 697 participants showed no difference in instrumental vaginal birth using forceps or vacuum although a clinically important reduction, or increase, cannot be excluded.
- High quality evidence from 1 RCT with 697 participants showed no difference in spontaneous vaginal birth.
- Low quality evidence from 1 RCT with 418 participants showed there may be no difference in augmentation / artificial oxytocin during labour women.
- Low quality evidence from1RCT with 418 participants showed that induction of labour may be lower in women who have previously given birth receiving midwifery-led continuity of care and women who have previously given birth receiving other models care.

2.5.2 Health economic evidence statements

Seven studies were included in the economic review. All studies were within-trial cost analyses that compared costs over the perinatal period. The most recent study from Ireland found that midwifery-led continuity of care model was cost saving. Four studies from Australia found that midwifery-led care was cost saving. One study from Scotland, found that midwifery-led care was more expensive in the postnatal period and the same cost as shared care in the antenatal and intrapartum periods. One study from England found that midwifery-led care was 20% to 25% less costly than usual care.

2.6 Evidence to recommendations

	Committee discussions
Relative value of different outcomes	The committee noted the importance of considering outcomes for both mother and baby when considering recommendations. The committee identified maternal satisfaction as a critical outcome for the mother as the committee noted this is an indicator of the quality and continuity of care received and places importance on maternal psychological and emotional wellbeing throughout pregnancy and birth. Mode of birth was considered critical and it includes three outcomes: caesarean birth, instrumental vaginal birth and spontaneous vaginal birth. For critical outcomes in relation to the baby, the committee discussed the importance of perinatal mortality as a marker of good quality of care received throughout pregnancy and valued

	Committee discussions
	overall fetal loss and neonatal death as a critical outcome for decision making. It was noted that the provision of education and awareness of breastfeeding throughout pregnancy and the initiation of breastfeeding after birth is important promoting bonding and for the baby's wellbeing. For this reason, breastfeeding on hospital discharge was identified as a critical outcome. The committee discussed preterm birth and that the majority of preterm birth (< 37 weeks) occurs in women at high risk of complications who are not covered by this review question. However, it was noted that preterm birth also occurs in women at low and mixed risk of complications and that it may be challenging to identify risk status of a pregnancy. Therefore, the committee considered preterm birth (< 37 weeks) as an important outcome to consider when considering recommendations.
Quality of evidence	Evidence was available for the majority of the outcomes identified in the review protocol. No evidence was available for the outcomes 'transfer to physician led care' and 'breastfeeding on hospital discharge'. An indirect outcome, 'breastfeeding initiation' was included for 'breastfeeding on hospital discharge' as this was reported by the studies and downgraded for serious indirectness. The quality of the evidence available ranged from very low to high quality, with the majority of evidence being low or moderate quality. The main reasons for downgrading evidence were concerns of risk of bias in the studies (including lack of adequate randomisation), indirectness and imprecision. It was noted that there is lack of clarity of the randomisation process in the studies and it may be the woman's choice to receive either midwifery-led continuity or care or other models of care. The committee noted that many of the included studies were not recent (only 3 were published in the last six years) and may not necessarily reflect the current practice of midwifery-led continuity of care for healthy women in the UK. In addition, the comparators were largely models of care that are rarely available in the UK now. The committee noted that 10 RCTs were conducted in settings outside of the UK and therefore may not be applicable to the UK due to differences in how maternity services are organised and structured in those countries. In particular, the committee noted that midwifery-led care in non-UK countries may involve a physician / obstetrician directly in the provision or responsibility of care, and this is not reflective of UK practice. The committee accepted that healthy women who are at low risk of complications receive midwifery-led care, with varying degrees of continuity in which midwife they see. It was also noted that these healthy women will not routinely see an obstetrician during antenatal care, intrapartum care or the postnatal period, unless the woman and midwife decide such care is needed when a woman is no longer at low risk of complications. When this happens, a woman may subsequently return to being at low risk of complications and no longer need medical care. It was noted that in the trials included, midwifery-led care was delivered in an obstetric unit and women may have received other models of care including obstetrician-led or physician-led care. However, the committee noted that there is a grey area where a woman receiving midwifery-led care is examined by or her labour is in some way reviewed by an obstetrician but no medical intervention is advised and accepted and it is unclear if the woman remains in midwifery-led care or obstetrician-led care. The committee noted that physician-led, obstetrician-led or shared care is more applicable to a population of women at high risk of complications. The committee agreed that the definition included in Sandall 2016, which states that "some antenatal and/or intrapartum and/or postpartum care may be provided in consultation with medical staff as appropriate" is not applicable to a population of healthy pregnant women within the UK.

	Committee discussions
	Of the 8 studies included in Sandall 2016 which included low risk women, the committee noted that 4 (Hicks 2003, Turnbull 1996 and Waldenstrom 2001) used midwifery-led continuity of care. There were concerns regarding the applicability of the intervention in Flint 1989, MacVicar 1993, Begley 2011, Harvey 1996 and McLachlan 2012. This is because women saw obstetricians at various time points, including at booking and at 36 weeks, while this may not be applicable to midwifery-led continuity of care. It was noted that the comparison available in Tracy 2013 is the closest to midwifery-led continuity of care compared to standard UK practice. However, this study population included women at low and at high risk of complications and the intervention included some level of involvement from an obstetrician. The committee considered that it would have been ideal to compare midwifery-led continuity of care to standard care (midwifery-led care) for women at low risk in the UK rather than all other models of care. However, no evidence was found for this comparison so the committee drafted a research recommendation to answer this question. Generally, the committee noted that this guideline addresses intrapartum care for women at low risks of complications and concerns were raised regarding applicability of the studies where women at high risk of complications were included. However, the committee discussed that women may be at low risk of complications during the antenatal period but move to high risk because of complications during the intrapartum period The committee discussed if it is appropriate to include this population in this guideline or in the guideline on intrapartum care for women at high risk.
Trade-off between benefits and harms	Overall the evidence showed either no difference or a benefit (though not clinically significant) in favour of midwifery-led continuity of care. When examining subgroup analysis, the committee noted there was no evidence of an increase in harms associated with the use of midwifery-led continuity of care in any of the subgroups. In this connection, the committee also discussed the original recommendation that recommends against team midwifery. The committee noted that this recommendation was mostly based on evidence in 2007 that indicated an increased rate of perinatal mortality for the team midwifery model, which was not found in this evidence review. In this update the committee noted that the risk of fetal loss before and after 24 weeks plus neonatal death is slightly lower when using midwifery-led continuity care compared to other models of care. The committee noted that this may be explained by the support offered by midwifery-led continuity of care throughout pregnancy and birth as the relationship between a woman and her midwife or group of midwives can reduce stress and help improve social support through attendance at antenatal classes. The committee noted this support from a midwife or group of midwives may be particularly beneficial in women who have complex needs, mental health issues or are socially isolated, although this guideline covers women at low risk of complications. The committee considered that this outcome could include miscarriages before 24 weeks and terminations. The committee acknowledged that fetal loss from 24 weeks onwards plus neonatal death would be more appropriate and consistent with the outcome behind the 2007 negative recommendation on team midwifery. When data for this post-hoc analysis was discussed, it was agreed that there was evidence to show no difference between midwifery-led continuity of care and other models of care for this outcome.

	Committee discussions
	The committee noted that removal of recommendation 1.7.3 in CG190 intrapartum care will allow commissioners to reconsider commissioning either caseload or team model of midwifery-led continuity of care. Therefore, the committee agreed to stand down recommendation 1.7.3 which recommended against the use of team midwifery. The committee noted that the removal of recommendation 1.7.3 will allow greater access to either caseload or team midwifery and this was viewed positively. The committee agreed that the nature of the interventions reviewed is complex and that there is little consistency in the literature in regards to defining midwifery-led continuity of care. Additionally, it was discussed that number of midwives in caseload and team midwifery varies nationally, but studies included in this evidence review used teams of up to 8 midwives and the committee noted this was consistent with their experience. The committee agreed that midwifery-led care in the UK is the default model of care for women at low risk of complications and that this involves a midwife or midwives in the provision of care and support and does not involve routine care from physicians or obstetricians. However, it was noted that in some models of midwifery-led continuity of care, for example in Australia, include an aspect of involvement of a physician or obstetrician which may impact on the findings of this review. Additionally, the committee agreed that the limited information presented on the interventions and comparators was insufficient to judge the applicability of the studies to the review question. Further concerns were raised about the usefulness of the findings as none of the outcomes showed a clear benefit using the default criteria to define a minimal important difference. The committee discussed at length the possibility of making a new recommendation in favour of midwifery-led continuity of care. Due to the limited evidence and applicability concerns raised, the committee as a whole agreed not to formulate a recommendation. A cross-reference to NICE CG138 “Patient experience in adult NHS services” recommendation 1.4.1 on continuity of care is included. The committee agreed that there is a lack of recent, UK evidence investigating midwifery-led care and the optimum model of care (caseload or team) for improved clinical outcomes. The committee reviewed the research recommendations made in the original 2007 guideline (research recommendation number 8 in CG190 full guideline) and decided it is appropriate to use it as a basis for formulating a new research recommendation. This new research recommendation addresses both the clinical and cost effectiveness of midwifery-led continuity of care (both continuity of care and relational continuity) compared to standard care during the antenatal, intrapartum and postnatal period. The committee noted that inclusion of maternal satisfaction should be included as a core outcome in the research recommendation and this can be measured by a reliable and validated tool. Additionally, the committee noted the value of including the outcome breastfeeding at 3 and 6 months as an indicator of the effectiveness of midwifery-led continuity of care. The committee also noted that the number of midwives in a caseload or team model varies across maternity services and wish for this to be examined as a part of the research recommendation formulated.
Trade-off between net health benefits and resource use	The committee accepted the costs presented in the HE economic review and noted that for the majority of included studies midwifery-led care was cost-saving compared to other models of care. Because the evidence review did not show that midwifery-led continuity of care was less effective or more harmful than the comparators economic modelling could not be conducted because a difference in effectiveness needs to be demonstrated first.

	Committee discussions
	The committee noted that most of the studies were conducted outside of the UK and discussed that the applicability of studies from other countries may be limited because these healthcare systems are significantly different. The committee noted that costs may vary by outcome. For example, caesarean sections may have a consultant or registrar and assisted by a nurse. Despite these limitations, the committee generally agreed that midwifery-led continuity of care were likely to be cost saving compared to the other models of care reviewed
Other considerations	Two aspects of midwifery-led continuity of care were discussed: • Midwifery-led care refers to receiving care from a midwife or midwives during pregnancy and birth from booking to sign-off and it is standard for this to be midwife-led, i.e a midwife is the lead professional in planning and being responsible for care at all points. This is standard practice in the UK for healthy pregnant women. • Relational continuity refers to receiving care from a known midwife (or midwives) throughout pregnancy, birth and postnatal period. The committee noted that for women at high risk of complications, midwifery-led continuity of care may not be applicable as they may require care from a physician or an obstetrician. They also agreed that for the purposes of this evidence review, midwifery-led continuity of care occurs when a midwife or group of midwives is/are the lead and managing professional at all points of care. This can be delivered by caseload midwifery or team midwifery and relational continuity is maintained. The committee noted that relational continuity is more feasible in caseload midwifery as women have a greater chance of receiving care from the same midwife. Equalities issues It was noted that midwifery-led continuity of care can help women to feel supported and comfortable during pregnancy and birth and this likely optimises physical, emotional and mental well-being. The committee noted that this may be particularly beneficial in overcoming potential language barriers in women who, for example, do not speak English as a first language. The topic experts noted that maternity services across the UK are generally overworked and suggested that this is particularly the case in large urban cities which may result in a lack of continuity of care.

2.7 Recommendations

2. **For guidance on ensuring continuity of care, see recommendation 1.4.1 in the NICE guideline on patient experience in adult NHS services. [new 2016]**

2.8 Research recommendations

1. **What are the clinical and cost effectiveness of midwifery-led continuity of care compared with standard care in the UK for healthy pregnant women, their babies and healthcare professionals throughout the antenatal, intrapartum and postnatal periods?**

2.9 Why is this important?

2.10 Midwifery-led continuity of care encompasses both continuity of care and relational continuity. Relational continuity involves the woman being cared for by a known midwife (or midwives) during pregnancy and birth. Standard care for healthy pregnant women in the UK is midwifery-led care in which the woman is cared for by a midwife or midwives during pregnancy and birth, from the booking appointment to sign-off. This includes varying degrees of continuity of care and relational continuity. A study comparing midwifery-led continuity of care with standard UK practice will determine the clinical and cost effectiveness of midwifery-led continuity of care. This will allow recommendations on this topic to be included in future updates of this guideline.

2.11 Table 5: Criteria for selecting high-priority research recommendations

PICO	**Population:** Healthy pregnant women at low risk of pregnancy complications. **Intervention:** Midwifery-led continuity of care: the midwife or midwives is/are the lead professional/s in the planning, organisation and delivery of care offered to a woman from initial booking to the postnatal period. This usually involves two aspects, continuity of care and relational continuity: • Midwifery-led care refers to receiving care from a midwife or midwives during pregnancy and birth from booking to sign-off. This is standard practice in the UK for healthy pregnant women • Relational continuity involves receiving care from a known midwife (or midwives) during pregnancy and birth throughout pregnancy and birth. Midwifery-led continuity of care can be provided in either caseload or team models: Caseload midwifery: a model of care where one midwife known to the woman (sometimes referred to as the 'named midwife') is responsible, and provides the majority of the care throughout the antenatal, intrapartum and postnatal period for a group of women backed up by a few associate midwives to form a group of four or less. Team midwifery: a model of care where a group of midwives (usually five or more) providing care and take shared responsibility for a group of women from the antenatal, intrapartum and postnatal period. **Comparison:** - Standard UK practice: receiving care from a midwife or midwives during pregnancy and birth from booking to sign-off. **Outcomes:** Maternal satisfaction which can be measured by a reliable and validated tool.

	Regional analgesia (epidural/spinal) Caesarean birth Instrumental vaginal birth (forceps/vacuum) Spontaneous vaginal birth (as defined by trial authors) Intact perineum Preterm birth (less than 37 weeks) Overall fetal loss and neonatal death Perinatal mortality fetal loss at or after 24 weeks and up to seven days after birth Augmentation of labour Induction of labour Breastfeeding at 3 and 6 months Transfer to physician-led care
Current evidence base	There are no studies examining of effectiveness of midwifery-led continuity of care over usual standard care in the UK (midwifery-led care) in healthy women.
Study design	• Randomised control trials including cluster randomised • Qualitative or mixed method design studies
Other comments	The committee are interested in identifying the appropriate number of midwives to maintain sustainable midwifery-led continuity of care and identifying the components that impact on care. Additional outcomes in relation to mental health and wellbeing of women can be considered. Researchers should note why caseload or team are selected for the study, size of caseload and team midwifery, number of whole time equivalent (WTE) and part-time midwives, midwifery turn-over and reasons for turnover and women's views about the model of care.

3 References

Evidence review

Sandall J, Soltani H, Gates S, et al (2016). Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5.

4 Glossary and abbreviations

Please refer to the NICE glossary.

Additional terms used in this document are listed below.

Antenatal care: the care a woman receives during pregnancy.

Intrapartum care: care of healthy women and their babies during childbirth.

Postnatal care: the care a woman and her baby receive in the first 6-8 weeks after birth.

Caseload midwifery: a model of care where one midwife known to the woman (sometimes referred to as the 'named midwife') is responsible, and provides the majority of the care throughout the antenatal, intrapartum and postnatal period for a group of women backed up by a few associate midwives to form a group of four or less.

Continuity of care: Care delivered by the same healthcare professional or team throughout the single episode of care

Midwifery-led continuity model of care: a midwife or midwives is/are the lead professional/s in the planning, organisation and delivery of care given to a woman from initial booking to the postnatal period.

Midwifery-led unit: A unit for giving birth where care is provided by midwives. The unit can be next to a hospital obstetric unit (called 'alongside') or in a different place (called 'freestanding') and is run by midwives. They do not have the same medical facilities as a hospital obstetric unit, but have medical equipment to deal with an emergency

Obstetric unit: A unit for giving birth often called a 'delivery suite' or 'labour ward' where care is provided by a team of obstetricians, midwifes and other healthcare professionals. It is led by an obstetrician and is the only birth setting where obstetricians are available.

Perinatal mortality: Fetal loss at or after 24 weeks and neonatal death.

Team midwifery: a model of care where a group of midwives (usually five or more) providing care and take shared responsibility for a group of women throughout the antenatal, intrapartum and postnatal period.

5 Acknowledgement

We thank Cochrane Pregnancy and Childbirth for their assistance with the evidence review for this update, in particular Frances Kellie and Nancy Medley, and for use of the characteristics of included studies table.

Appendices

Appendix A: Standing Committee members and NICE teams

A.1 Core members

Name	Role
Tessa Lewis (Chair for part of the update)	GP, Medical Advisor in Therapeutics
Sophie Wilne (Chair for part of the update)	Paediatric Oncologist, Nottingham Children's Hospital
John Cape	Director of Psychological Therapies Programme, University College London
Alison Eastwood	Professor, Centre for Reviews and Dissemination, University of York
Sarah Fishburn	Lay Member
Victoria Hetherington	Senior Nurse Practitioner, Clinical Lead, Derbyshire Health United
Imran Jawaid	Sessional GP, West Kent CCG area
Catriona McDaid	Senior Research Fellow Department of Health Sciences, University of York
Nick Screaton	Radiologist, Papworth Hospital NHS Foundation Trust

A.2 Topic expert Committee members

Name	Role
Tracey Cooper	Consultant Midwife, Lancashire Teaching Hospitals Trust
Sarah Noble	Consultant Midwife, Birmingham Women's Hospital
Stephanie Oliver-Beech	Lay member
Helen Scholefield	Consultant Obstetrician, Liverpool Women's NHS Foundation Trust
Catherine Williams	Lay member

A.3 NICE project team

Name	Role
Mark Baker	NICE Clinical Adviser
Christine Carson	NICE Guideline Lead
Emma Chambers	NICE PIP Lead
Helen Dickinson	NICE Guideline Coordinator
Caroline Kier	NICE Programme Manager
Lyn Knott	NICE Technical Editor
Ross Maconachie	NICE Health Economist

A.4 Clinical guidelines update team

Name	Role
Omnia Abdulrazeg	Technical Analyst
Philip Alderson	Clinical Advisor
Emma Banks	Coordinator
Lee Berry	Project Manager (until July 2016)
Paul Crosland	Health Economist
Nicole Elliott	Associate Director
Kathryn Hopkins	Technical Analyst (until March 2016)
Hugh McGuire	Technical Advisor
Susannah Moon	Programme Manger
Sadia Mughal	Information Specialist
Rebecca Parsons	Project Manager
Charlotte Purves	Administrator
Lorraine Taylor	Associate Director (until June 2016)

Appendix B: Declarations of interest

The standing committee and topic experts interests have been declared and collated and are available here.

Appendix C: Review protocol

Review Protocol	
Components	**Details**
Review question	What is the effectiveness of midwife-led continuity models versus other models of care for childbearing women?
Background/objectives	The NICE surveillance team was alerted to new evidence that might contradict existing recommendations. An initial assessment of this led to the decision to commission an update. The aim of the review is to compare the effectiveness of midwife-led continuity models of care with other care models for the care of women in pregnancy and childbirth.
Types of study to be included	Randomised trials including trials using individual- or cluster-randomisation methods. Quasi-randomised trials, where allocation may not have been truly random (e.g. where allocation was alternate or not clear).
Language	No language restrictions
Status	All study reports containing sufficient detail to adequately assess study quality.
Population	Pregnant women with low risk status. Studies which included women with mixed risk statuses will also be considered, and the evidence considered for the degree to which it is applicable to the population specified by the guideline.
Intervention	Midwife-led continuity models of care: defined as care models where a midwife is the lead professional in the antepartum and intrapartum periods.
Comparator	Other models of care, including: a) where the physician/obstetrician is the lead professional, and midwives and/or nurses provide intrapartum care and in-hospital postpartum care under medical supervision b) shared care, where the lead professional changes depending on whether the woman is pregnant, in labour or has given birth, and on whether the care is given in the hospital, birth centre (free standing or integrated) or in community setting(s); and c) where the majority of care is provided by physicians or obstetricians.
Outcomes	Regional analgesia (epidural/spinal) Caesarean birth Instrumental vaginal birth (forceps/vacuum) Spontaneous vaginal birth (as defined by trial authors) Intact perineum Preterm birth (less than 37 weeks) Overall fetal loss and neonatal death Maternal satisfaction Augmentation of labour Induction of labour Breast feeding on hospital discharge Transfer to physician led care

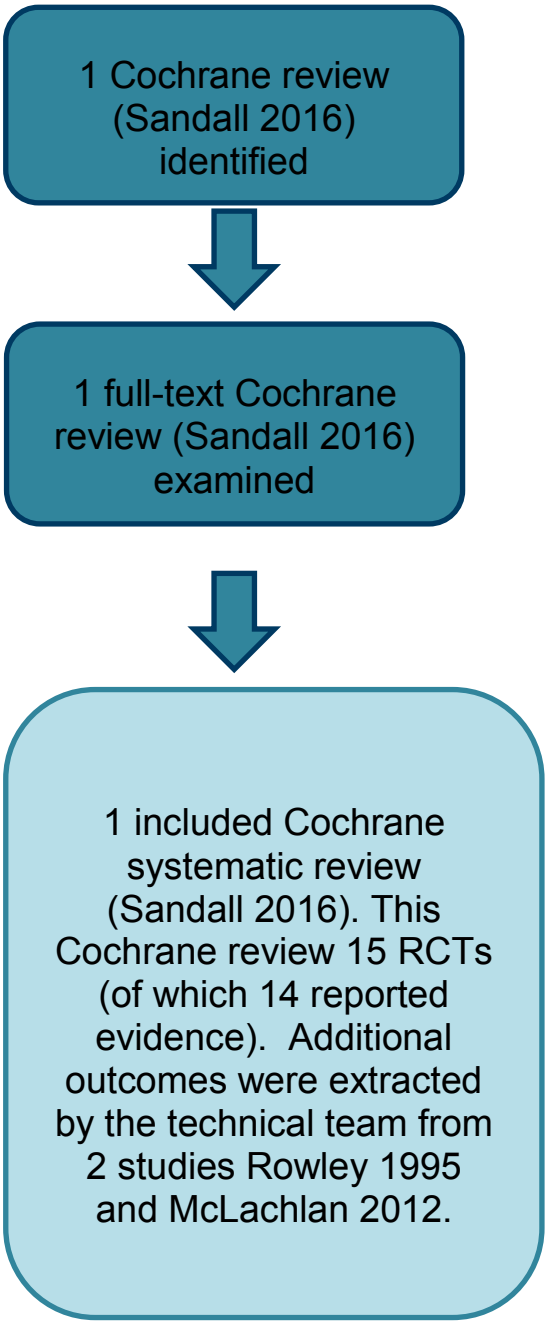
Review Protocol	
Any other information or criteria for inclusion/exclusion	Selection of papers: i) Selection based on titles and abstracts Two Cochrane review authors independently assessed all the potential studies identified as a result of the search strategy for inclusion. Disagreement resolved through discussion or by consulting the third review author if required. The committee will be sent the list of included and excluded studies prior to the committee meeting, and requested to cross check whether any studies have been excluded inappropriately, or whether there are any relevant studies they have known of which have not been identified by the searches.
Analysis of subgroups or subsets	Different midwife-led continuity models (e.g. team midwifery (5 or more midwives), caseload midwifery (up to 4 midwives)) Studies on low-risk women vs mixed risk women First time mothers vs previously given birth Hospital vs community care
Data extraction and quality assessment	Data extracted using a form designed by the review authors. Two review authors extracted the data using the agreed form and discrepancies resolved through discussion or, if required, with consultation with the third review author. Data was entered into Review Manager software (RevMan 2014) and checked for accuracy. Quality assessment Two review authors independently assessed risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). Any disagreement was resolved by discussion or by involving a third assessor. Outcome data will be assessed using the approach described by the GRADE working group. The risk of bias ratings carried out by the Cochrane review authors will be used to inform the 'risk of bias' assessment required by GRADE. Indirectness will be assessed by considering the applicability of population, intervention and outcomes to the review question. When meta-analysis is conducted, inconsistency will be assessed by considering the degree of unexplained heterogeneity across studies (I2 and tau2 and chi2 statistics will be calculated). Imprecision will be assessed using whether the confidence intervals around point estimates cross the minimally important differences for each outcome. Reliability of quality assessment: Quality assurance mechanisms will include: Internal QA by CGUT technical adviser on the quality assessment that is being conducted. The Committee will be sent the evidence synthesis prior to the committee meeting and the Committee will be requested to comment on the quality assessment, which will serve as another QA function.
Strategy for data synthesis	Data for each outcome from different studies synthesised using pairwise meta-analysis where possible. The COMET database, published literature and previous NICE guidance will be checked for appropriate minimal important differences (MID) for each outcome. If none are available GRADE default MIDs will be used. The topic experts will be consulted on

Review Protocol	
	the approach to determining MIDs to ensure that they are appropriate. Review Manager 5 will be used for meta-analysis and the results will be presented, when available, in GRADE profile, forest plot and summary evidence statement formats. Random effects models will be used for consistency with the analysis already conducted by the Cochrane authors, because of clinical heterogeneity in the included studies. Where synthesis by meta-analysis is not possible, data presented for individual studies on a per outcome basis.
Searches	Search of the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (January 2016). The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from: monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL); weekly searches of MEDLINE (Ovid); weekly searches of Embase (Ovid); monthly searches of CINAHL (EBSCO); handsearches of 30 journals and the proceedings of major conferences; weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts. Details of the search strategies for CENTRAL, MEDLINE, Embase and CINAHL, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group. Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords. Reference list of the studies identified examined for further studies. No language or date restrictions.

Appendix D: Search strategy

The Cochrane search strategies were reviewed in line with the normal quality assurance process. In addition, the Trial Search Co-ordinator was contacted to provide further information about the search methods. The Cochrane Specialised Register strategies have been developed over a long period of time to complement each other which is why they are not all direct translations of a single strategy. It was noted that the thesaurus term 'midwifery' is not used in the Medline strategy, however, 'pregnancy' is a checktag in Medline and it is highly unlikely that a trial that contains the term midwife (in MeSH or free text) would not be indexed with the pregnancy checktag. In order to mitigate the risks of this, the Cochrane team conducted a search of the specialised register to retrieve all studies with the term midwif$ (truncated search term to capture the variations 'midwife' or 'midwifery') that were not coded to the Cochrane review. An additional 474 references were retrieved which were then sifted by the NICE technical analyst and no additional references were included from this in the evidence review.

Appendix E: Review flowchart



Appendix F:Excluded studies

No studies were excluded from this evidence review. For further details of the excluded studies in the Cochrane review, please see Sandall 2016 page 28.

Appendix G: Evidence tables

Bibliographic reference	**Sandall J, Soltani H, Gates S, et al (2016). Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5.** **For full details, please see full Cochrane review here.**
Study type	Systematic review of RCTs
Aim	To compare the effects of midwife-led continuity models of care with other models of care for childbearing women and their infants.
Patient characteristics	Inclusion criteria - RCT using individual or cluster randomisation methods - Quasi RCT, where allocation may not have been truly random (e.g. where allocation was alternative or not clear) - Pregnant women. Exclusion criteria None reported. Search strategy: - Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (25 January 2016). - Register contains trials identified from: - monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL); - weekly searches of MEDLINE (Ovid); - weekly searches of Embase (Ovid); - monthly searches of CINAHL (EBSCO); - 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. - Planned analysis: Dichotomous data were presented as summary risk ratio (RR) with 95% confidence intervals.

Bibliographic reference	**Sandall J, Soltani H, Gates S, et al (2016). Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5.** **For full details, please see full Cochrane review here.**
	Dealing with missing data: for all outcomes, analyses were carried out, as far as possible, on an intention-to-treat basis (attempted to include all participants randomised to each group in the analyses). The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing. Meta-analysis: A random effects meta-analysis was used to produce an overall summary.
Number of Patients	In this Cochrane review: 17674 randomised women in total from 15 trials.
Intervention	Midwife-led continuity of care "The midwife led continuity model of care is based on the premise that pregnancy and birth are normal life events. The midwife-led continuity model of care includes: continuity of care; monitoring the physical, psychological, spiritual and social well-being of the woman and family throughout the childbearing cycle; providing the woman with individualised education, counselling and antenatal care; attendance during labour, birth and the immediate postpartum period by a known midwife; ongoing support during the postnatal period; minimising unnecessary technological interventions; and identifying, referring and co-ordinating care for women who require obstetric or other specialist attention." Includes: continuity of care; monitoring the physical, psychological, spiritual and social wellbeing of the woman and family throughout the childbearing cycle; providing the woman with individualised education, counselling and antenatal care; attendance during labour, birth and the immediate postpartum period by a known midwife; ongoing support during the postnatal period; minimising unnecessary technological interventions; and identifying, referring and co-ordinating care for women who require obstetric or other specialist attention.
Comparison	Other models of care: - Obstetrician-provided care, where obstetricians are the primary providers of antenatal care for most childbearing women. - Family doctor-provided care, with referral to specialist obstetric care is needed. - Shared models of care, w here responsibility for the organisation and delivery of care, throughout initial booking to the postnatal period, is shared between different health professionals.
Length of follow up	Not specified.
Location	Systematic review of studies from different locations.
Outcomes measures and effect size	Search results:

Bibliographic reference	**Sandall J, Soltani H, Gates S, et al (2016). Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5.** **For full details, please see full Cochrane review here.**
	Our search strategy identified 88 citations relating to 38 studies in total. The updated search in May 2015 identified 11 new reports. The updated search in January 2016 identified three new reports relating to three already included studies in the review. 15 trials in total were included. Parity* **Midwife-led continuity of care versus shared care** First time mothers Regional analgesia (epidural/spinal): Midwife-led continuity of care: 50/194 Shared care: 48/202 Augmentation/artificial oxytocin during labour: Midwife-led continuity of care: 72/194 Shared care: 65/202 Induction of labour: Midwife-led continuity of care: 37/194 Shared care: 32/202 Previously given birth Regional analgesia (epidural/spinal): Midwife-led continuity of care: 19/211 Shared care: 25/207 Augmentation/artificial oxytocin during labour: Midwife-led continuity of care: 46/211 Shared care: 39/207

Bibliographic reference	**Sandall J, Soltani H, Gates S, et al (2016). Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5.** **For full details, please see full Cochrane review here.**
	Induction of labour: Midwife-led continuity of care: 21/211 Shared care: 36/207 **Midwife-led continuity of care versus Other mixed models of care** <u>First time mothers</u> Regional analgesia (epidural/spinal): Midwife-led continuity of care: 290/804 Shared care: 325/806 Caesarean birth: Midwife-led continuity of care: 200/804 Shared care: 257/806 Instrumental vaginal birth (forceps/vacuum): Midwife-led continuity of care: 187/804 Shared care: 207/807 Spontaneous vaginal birth (as defined by trial authors): Midwife-led continuity of care: 415/804 Shared care: 329/806 <u>Previously given birth</u> Regional analgesia (epidural/spinal): Midwife-led continuity of care: 36/346 Shared care: 33/351 Caesarean birth:

Bibliographic reference	**Sandall J, Soltani H, Gates S, et al (2016). Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5.** **For full details, please see full Cochrane review here.**
	Midwife-led continuity of care: 15/346 Shared care: 28/351 Instrumental vaginal birth (forceps/vacuum): Midwife-led continuity of care: 207/807 Shared care: 15/351 Spontaneous vaginal birth (as defined by trial authors): Midwife-led continuity of care: 304/346 Shared care: 308/351
Source of funding	Supported by the National Institute for Health Research, via Cochrane Infrastructure funding to Cochrane Pregnancy and Childbirth.
Comments	Quality assessment: The quality of this Cochrane systematic review was assessed using the AMSTAR (Assessing the Methodological Quality of Systematic Reviews) checklist. The AMSTAR checklist assesses: study selection and data extraction, literature search used, status of publication, availability of included and excluded studies table, assessment of quality of the studies included, publication bias and conflict of interest. This Cochrane review received an AMSTAR score of 11/11. *Data on subgroup of parity was extracted by the CGUT technical analyst.

Appendix H: Sandall 2016 summary of included studies

Begley 2011

Methods	**Study design:** RCT. **Duration of study:** 2004-2007.
Participants	**Setting:** Health Service Executive, Dublin North-East, Republic of Ireland. **Inclusion criteria:** women were eligible for trial entry if they were: (a) healthy with an absence of risk factors for complications for labour and delivery as identified in the *'Midwifery-led Unit (Integrated) Guidelines for Practitioners'* (at http://www.nehb.ie/midu/guidelines.htm); (b) aged between 16 and 40 years of age; and (c) within 24 completed weeks of pregnancy. **Exclusion criteria:** women with risk factors. **Participants randomised:** 1101 midwife-led care, 552 to CLC.
Interventions	**Experimental:** women randomised to midwife-led care (MLU) received antenatal care from midwives and, if desired, from their GPs for some visits. Where complications arose, women were transferred to CLU based on agreed criteria. Intrapartum care was provided by midwives in a MLU with transfer to CLU if necessary. Postnatal care was by midwives in the MLU for up to 2 days, with transfer of women or neonates to CLU if necessary (and back, as appropriate). On discharge, MLU midwives visited at home, and/or provided telephone support, up to the seventh postpartum day. **Control:** women randomised to consultant-led care (CLU) received standard care: antenatal care provided by obstetricians supported by the midwifery and medical team; intrapartum and postpartum care (2 to 3 days in hospital) provided by midwives, overseen by consultants. Women were discharged into the care of Public Health Nurses.

Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antenatal hospitalisation Antepartum haemorrhage Augmentation/artificial oxytocin during labour Breastfeeding initiation Caesarean birth Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Low birthweight (< 2500 g) Mean labour length Mean length of neonatal hospital stay (days)

	Neonatal convulsions (as defined by trial authors) No intrapartum analgesia/anaesthesia Opiate analgesia Fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) PPH (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors) Cost
Notes	Women were randomised to MLU or CLU in a 2:1 ratio. Kenny 2015 reports an economic analysis - a comparison of the cost of care of the 2 types of services. We have described these results above - data added 2016 update.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'Random integers were obtained using a random number generator…'

Allocation concealment (selection bias)	Low risk	'…an independent telephone randomisation service.'
Blinding of participants and personnel (performance bias) All outcomes	High risk	'...lack of blinding of participants and carers...'
Blinding of outcome assessment (detection bias) All outcomes	High risk	'Assessors for certain outcomes, such as laboratory tests, were blinded to study group.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 5 midwife-led care, 3 CLC.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in results.
Other bias	Low risk	No other bias identified.

Biro 2000

Methods	**Study design:** RCT. **Duration of study:** 1996-1998.
Participants	**Setting:** public tertiary hospital, Monash Medical Centre, Melbourne, Australia. **Inclusion criteria:** participants included women at low and high risk of complications. **Exclusion criteria:** women who requested shared obstetric care, needed care in the maternal-fetal medicine unit, were > 24 weeks' gestation, did not speak English. **Participants randomised:** 502 team midwifery, 498 to standard care.

Interventions	**Experimental:** team of 7 full-time midwives who provided antenatal, intrapartum, and some postnatal care in hospital in consultation with medical staff. Doctors and team midwife jointly saw women at 12-16, 28, 36, 41 weeks. Women at high risk of complications had individual care plans. **Control:** various options of care including shared care between GPs in the community and hospital obstetric staff, shared care between midwives in a community health centre and hospital obstetric staff, care by hospital obstetric staff only, and less commonly, care by hospital midwives in collaboration with obstetric staff. Women within these options experienced a variable level of continuity of care during their pregnancy, from seeing the same midwife or doctor at most visits to seeing several doctors and midwives.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Intact perineum Instrumental vaginal birth (forceps/vacuum) Mean length of neonatal hospital stay (days)

	No intrapartum analgesia/anaesthesia Fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)	
Notes	2 groups similar at baseline. 80% of experimental group and 0.3% of standard group had previously met midwife attending labour.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'Allocations were computer generated...'
Allocation concealment (selection bias)	Low risk	'...the research team member telephoned the medical records staff and asked them to select an envelope with the randomized treatment allocation.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 14 team care, 18 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.
Other bias	Low risk	No other bias identified.

Flint 1989

Methods	**Study design:** RCT, Zelen design. **Duration of study:** 1983-1985.
Participants	**Setting:** tertiary hospital and community settings, St George's Hospital, London, UK. **Inclusion criteria:** low risk of complications who booked at the study hospital and were likely to receive all their antenatal care at that hospital. **Exclusion criteria:** under 5 feet tall, serious medical problems, previous uterine surgery, past obstetric history of > 2 miscarriages/TOP/SB/NND, Rh antibodies. **Participants randomised:** 503 team-midwifery, 498 to standard care (shared care).
Interventions	**Experimental:** team of 4 midwives who provided antenatal, intrapartum and postnatal care in hospital, and postnatal care in the community for women in predefined geographic area. Obstetrician seen at 36 and 41 weeks as appropriate. **Control:** standard antenatal, intrapartum and postpartum care provided by assortment of midwives and obstetricians.

Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antenatal hospitalisation Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks High perceptions of control during labour and childbirth Induction of labour Intact perineum Instrumental vaginal birth (forceps/vacuum) Low birthweight (< 2500 g) No intrapartum analgesia/anaesthesia Opiate analgesia Fetal loss and neonatal death PPH (as defined by trial authors)

	Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)	
Notes	At baseline, more Asian women in control group (18% vs 10%) and more smokers in experimental group (30% vs 22%). Sub-analysis of case notes found that 98% of experimental group and 20% of standard group had previously met midwife attending labour. Discrepancy in instrumental birth data. Date taken from report and not published paper.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not stated.
Allocation concealment (selection bias)	Unclear risk	'...randomised into two groups by pinning sealed envelopes on their notes containing either the motto KNOW YOUR MIDWIFE or CONTROL GROUP' (Does not state if envelopes were number consecutively.).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 15 team care, 19 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.
Other bias	Low risk	No other bias identified.

Harvey 1996

Methods	**Study design:** RCT. **Duration of study:** 1992-1994.
Participants	**Setting:** range of city hospitals and community settings in Alberta, Canada. **Inclusion criteria:** women at low risk of complications who requested and qualified for nurse-midwife-led care. **Exclusion criteria:** past history of caesarean section, primigravidas < 17 or > 37, > 24 weeks' gestation at time of entry to study. **Participants randomised:** 109 team-midwife-led care, 109 to standard care (Physician care).
Interventions	**Experimental:** team of 7 nurse-midwives who provided antenatal and intrapartum care in the hospital and postnatal care in the community. Obstetrician seen at booking and at 36 weeks. **Control:** physician care (family practice or obstetrician) which women chose from a range of city hospitals following usual process.

Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Opiate analgesia Fetal loss and neonatal death PPH (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial author)

Notes	At baseline, more women in experimental group had longer period in education (16 years vs 15.23 years). Level of continuity not reported.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...computer-generated random allocation.'
Allocation concealment (selection bias)	Low risk	'...using a series of consecutively numbered, sealed, opaque envelopes...'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 4 team care and 12 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.

Other bias	Low risk	No other bias identified.

Hicks 2003

Methods	**Study design:** RCT. **Duration of study:** not stated.
Participants	**Setting:** tertiary hospital and community, city not stated but UK. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** not stated. **Participants randomised:** 100 team-midwife-led care, 100 to standard care (shared care).
Interventions	**Experimental:** team of 8 midwives who provided antenatal, intrapartum and postnatal care 24 hours a day, 7 days a week in both hospital and community. The team was attached to a GP practice. Referral to obstetrician as necessary. **Control:** shared care between community and hospital midwives and GPs and obstetricians when necessary. Women delivered by hospital midwife or community midwife if under domino scheme (1 midwife provides care for a woman throughout pregnancy, accompanies her into hospital for birth and returns home with her and baby a few hours after the birth, and care in postnatal period).
Outcomes	Outcomes considered in the review and reported in or extracted from the study: Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Opiate analgesia Fetal loss and neonatal death

	PPH (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)	
Notes	71% of experimental group and 14% of standard group had previously met midwife attending labour.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Envelopes '...had been shuffled previously by an individual not involved in the recruitment process, and then numbered consecutively'.
Allocation concealment (selection bias)	Low risk	'Allocation was undertaken by giving each woman a sealed envelope containing one of the care options.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.

Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 19 team care and 8 standard. Due to non-response to questionnaires.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.
Other bias	Low risk	No other bias identified.

Homer 2001

Methods	**Study design:** RCT, Zelen method. **Duration of study:** 1997-1998.
Participants	**Setting:** public tertiary hospital and community, Sydney, Australia. **Inclusion criteria:** women at low and high risk of complications. **Exclusion criteria:** women more than 24 weeks' gestation at their first visit to the hospital, women with an obstetric history of 2 previous caesareans or a previous classical caesarean and medical history of significant maternal disease. **Participants randomised:** 640 team-midwife-led care, 643 to standard care (shared care).
Interventions	**Experimental:** 2 teams of 6 midwives sharing a caseload of 300 women a year/team. Antenatal care in outreach community-based clinics. Intrapartum and postpartum hospital and community care. Obstetrician or obstetric registrar did not see women routinely, but acted as a consultant and reviewed women only as necessary. Women who developed complications during their pregnancy continued to receive care from the same group of carers. **Control:** standard care provided by hospital midwives and doctors in hospital-based antenatal clinic, delivery suite and postnatal ward. Woman at high risk of complications were seen by obstetrician or registrar. Low-risk women were seen by midwives and shared care with GPs in a shared model of care.

Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Antenatal hospitalisation Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Opiate analgesia Fetal loss and neonatal death PPH (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)

Notes	63% of experimental group and 21% of standard group had previously met midwife attending labour.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...computer-generated random numbers...'
Allocation concealment (selection bias)	Low risk	'...group allocation was not revealed until the woman's details were recorded by the administrative assistant.'
Blinding of participants and personnel (performance bias) All outcomes	High risk	No (states 'unblinded').
Blinding of outcome assessment (detection bias) All outcomes	High risk	No (states 'unblinded').
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: team care 46, standard care 42.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.

Other bias	Low risk	No other bias identified.

Kenny 1994

Methods	**Study design:** RCT. **Duration of study:** 1992-199.
Participants	**Setting:** Westmead public hospital, NSW, Australia. **Inclusion criteria:** women at low and high risk of complications. **Exclusion criteria:** women requiring use of the 'Drug use in pregnancy service' or booked after 16' weeks' gestation. **Participants randomised:** 213 team-midwife-led care, 233 to standard care (shared care).
Interventions	**Experimental:** team of 6.8 WTE midwives sharing a caseload. Provided antenatal and intrapartum care in hospital and postnatal care in hospital and community. Obstetrician saw all women at first visit and 32 weeks, and after 40 weeks, and as appropriate. Team midwife was on call for out-of-hours care. **Control:** low-risk women seen in midwives' hospital antenatal clinics, and all other women seen by medical staff. Women received intrapartum care from delivery suite midwives, and postnatal care from midwives on postnatal ward and community postnatal care.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antenatal hospitalisation Attendance at birth by known midwife

	Augmentation/artificial oxytocin during labour
	Breastfeeding initiation
	Caesarean birth
	Episiotomy
	Fetal loss/neonatal death equal to/after 24 weeks
	Induction of labour
	Instrumental vaginal birth (forceps/vacuum)
	Intact perineum
	Mean labour length
	Mean number of antenatal visits
	No intrapartum analgesia/anaesthesia
	Opiate analgesia
	Fetal loss and neonatal death
	Perineal laceration requiring suturing
	PPH (as defined by trial authors)
	Regional analgesia (epidural/spinal)
	Spontaneous vaginal birth (as defined by trial authors)

Notes	96% of experimental group and 13% of standard group had previously met midwife attending labour. Randomisation before consent to participate.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'...allocated a numbered randomisation envelope (the number was recorded by the booking-in midwife on a list of women booked in the session).'
Allocation concealment (selection bias)	Low risk	'Allocated a numbered randomisation envelope (the number was recorded by the booking-in midwife on a list of women booked in the session). When each woman returned for her first visit to the doctor at the antenatal clinic she was approached in the waiting room by a program midwife, reminded about the research and asked to sign a consent form. If the woman agreed to join the study, the randomisation envelope was opened and the woman informed of the type of care she was to receive and the appropriate future appointments made.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 19 team care and 22 standard who either moved or had a miscarriage.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.
Other bias	Low risk	No other bias identified.

MacVicar 1993

Methods	**Study design:** RCT, Zelen method. **Duration of study:** 1989-1991.
Participants	**Setting:** tertiary hospital and community in Leicester, UK. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** women who had a previous caesarean section or difficult vaginal delivery, a complicating general medical condition, a previous stillbirth or neonatal death, or a previous small-for-gestational-age baby, multiple pregnancy, Rhesus antibodies, and a raised level of serum alpha-feto protein. **Participants randomised:** 2304 team midwifery, 1206 to standard care (shared care).
Interventions	**Experimental:** team of 2 midwifery sisters assisted by 8 staff midwives provided hospital-based antenatal, intrapartum (in hospital-based 3 room home-from-home unit (no EFM or epidural) and hospital postnatal care only. All the staff were volunteers. Antenatal midwife-led hospital clinic with scheduled visits at 26, 36 and 41 weeks' gestation. Intervening care shared with GPs and community midwives. Referral to obstetrician as appropriate. At 41 weeks mandatory referral to consultant. Postnatal care in community provided by

	community midwife and GP. **Control group:** shared antenatal care with GP and midwife. Intrapartum care provided by hospital staff.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: Admission to special care nursery/NICU Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Intact perineum Instrumental vaginal birth (forceps/vacuum) Low birthweight (< 2500 g) No intrapartum analgesia/anaesthesia Opiate analgesia Fetal loss and neonatal death Perineal laceration requiring suturing PPH (as defined by trial authors)

	Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)	
Notes	2:1 randomisation ratio in favour of midwife-led care. 189/2304 (8%) women opted out of team-midwife care post-randomisation. Analysis by intention-to-treat analysis. Level of continuity not reported.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...by a random sequence...'
Allocation concealment (selection bias)	Low risk	'...sealed envelope...cards could not be read through the envelopes. Each envelope was numbered, and unused envelopes were not reallocated...'
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated re participants but not possible to have achieved. Clinical staff were unaware whether a particular woman was in the control group or was not in the study. No information given re blinding of women in intervention arm.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information given on losses to follow-up.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.
Other bias	Low risk	No other bias identified.

McLachlan 2012

Methods	**Study design:** RCT. **Duration of study:** 2007-2010.
Participants	**Setting:** Royal Women's Hospital (RWH), Melbourne, Australia. **Inclusion criteria:** low-risk pregnant women; fewer than 24 completed weeks' gestation; a singleton pregnancy; and considered low obstetric risk at recruitment including an uncomplicated obstetric history. **Exclusion criteria:** previous caesarean section, history of stillbirth or neonatal death, 3 or more consecutive miscarriages, previous fetal death in utero, previous preterm birth (< 32 weeks), previous midtrimester loss/cervical incompetence/cone biopsy/known uterine anomaly, previous early onset of pre-eclampsia (< 32 weeks' gestation), or rhesus iso-immunisation; complications during the current pregnancy (such as multiple pregnancy or fetal abnormality); medical conditions (such as cardiac disease, essential hypertension, renal disease, pre-existing diabetes, previous gestational diabetes, epilepsy, severe asthma, substance use, significant psychiatric disorders and obesity [BMI > 35] or significantly underweight [BMI < 17]). **Participants randomised:** 1156 caseload, 1158 standard care.

Interventions	**Experimental:** majority of care from a 'primary' caseload midwife at the hospital. The primary midwife collaborated with obstetricians and other health professionals and continued to provide caseload care if complications arose. Women saw an obstetrician at booking, at 36 weeks' gestation and postdates if required, and usually had 1 or 2 visits with a 'back-up' midwife. Intrapartum care was provided in the hospital birthing suite. Where possible, primary midwife was on call for the woman's labour and birth. The primary midwife (or a back-up) attended the hospital on most days to provide some postnatal care and provided domiciliary care following discharge from hospital. Fulltime midwives had a caseload of 45 women per annum. During the trial there were 7.5 (at commencement) to 12 full-time equivalent midwives employed in caseload care, equating to 10–14 midwives. **Control:** options included midwifery-led care with varying levels of continuity, obstetric trainee care and community-based care 'shared' between a general medical practitioner (GP) and the hospital, where the GP provided the majority of antenatal care. In the midwife and GP-led models women saw an obstetrician at booking, 36 weeks' gestation and postdates if required, with other referral or consultation as necessary. In all standard-care options, women were cared for by whichever midwives and doctors were rostered for duty when they came into the hospital for labour, birth and postnatal care.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Caesarean birth Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum)

	Low birthweight (< 2500 g) Fetal loss and neonatal death Preterm birth (< 37 weeks) PPH (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors) Maternal satisfaction	
Notes	'Around 90% of the women had a known carer in labour'. McLachlan 2015 reports the results of a postal survey of women's experiences of childbirth. Data for several relevant outcome domains are displayed in our additionalTable 2 - data added in 2016 update.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...using stratified permuted blocks of varying size.'
Allocation concealment (selection bias)	Low risk	'Randomisation was undertaken using an interactive voice response system activated by telephone...'

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Obstetric and medical outcome data (including type of birth) were obtained directly from the electronic obstetric database, blinded to treatment allocation. Data not available this way (e.g. continuity of carer) were manually abstracted (unblinded) from the medical record.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 6 caseload and 1 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results.
Other bias	Low risk	No other bias identified.

North Stafford 2000

Methods	**Study design:** RCT, cluster randomisation. **Duration of study:** not stated.
Participants	**Setting:** tertiary hospital and community, UK. **Inclusion criteria:** 'all-risks'. **Exclusion criteria:** not stated. **Participants randomised:** 770 midwife-led caseload care, 735 standard care (shared care).

Interventions	**Experimental:** caseload midwife-led care. 3 geographic areas with 21 WTE midwives working in 3 practices offering a caseload model of care. Each midwife was attached to 2-3 GP practices and cared for 35-40 women. Midwives worked in pairs/threesomes. Caseload midwives were existing community midwives, plus new midwives recruited from community and hospital resulting in a mix of senior and junior staff. Monthly antenatal care in the community, intrapartum and postnatal care in hospital and postnatal care in the community provided. **Control:** shared care in the community between GPs, community midwives and obstetricians. Each community midwife cared for 100/150 women each.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Low birthweight (< 2500 g) Fetal loss and neonatal death

	Perineal laceration requiring suturing Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal)	
Notes	95% of experimental group and 7% of standard group had previously met midwife attending labour.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'Randomisation was undertaken by one of the principal investigators...who had no prior knowledge of the area or medical and midwifery staff involved.... three pairs, one of each...randomised to receive caseload care and the other to traditional care.'
Allocation concealment (selection bias)	High risk	No information given about allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	'It was not possible to mask allocation and both women and professionals were aware of the allocated type of midwifery care.'
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.

Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: not reported but appears complete.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in results.
Other bias	Low risk	No other bias identified.

Rowley 1995

Methods	**Study design:** RCT. **Duration of study:** 1991-1992.
Participants	**Setting:** John Hunter hospital, Newcastle, NSW, Australia. **Inclusion criteria:** women booked for delivery at hospital of low and high risk. **Exclusion criteria:** women who had chosen shared antenatal care with their GP or had a substance abuse problem. **Participants randomised:** 405 team care, 409 standard care (shared care).
Interventions	**Experimental:** team of 6 experienced and newly graduated midwives provided antenatal care, intrapartum care, and postnatal care in hospital. Women at low risk had scheduled consultations with an obstetrician at 12-16, 36, 41 weeks and additional consultations as needed. Women at high risk had consultations with an obstetrician at a frequency determined according to their needs. **Control:** antenatal care from hospital physicians and intrapartum and postnatal care from midwives and doctors working in the delivery suite, and the postnatal ward. Women were usually seen by a doctor at each visit. Control-group midwives were also a mix of experienced and newly qualified midwives.
Outcomes	Outcomes considered in the review and reported in or extracted from the study:

5-minute Apgar score below or equal to 7

Admission to special care nursery/NICU

Antenatal hospitalisation

Augmentation/artificial oxytocin during labour

Caesarean birth

Episiotomy

Fetal loss/neonatal death before 24 weeks

Fetal loss/neonatal death equal to/after 24 weeks

Induction of labour

Instrumental vaginal birth (forceps/vacuum)

Low birthweight (< 2500 g)

Opiate analgesia

Fetal loss and neonatal death

Perineal laceration requiring suturing

Preterm birth (< 37 weeks)

Regional analgesia(epidural/spinal)

Spontaneous vaginal birth (as defined by trial authors)

Notes	Degree of continuity not reported.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'Allocation to either team care or routine care was done by computer-generated random assignments.'
Allocation concealment (selection bias)	Unclear risk	'The women were allocated at random to team care or routine care....'
Blinding of participants and personnel (performance bias) All outcomes	High risk	'...the unblinded nature of the study could have led to differences in practice and measurement of outcomes...'
Blinding of outcome assessment (detection bias) All outcomes	High risk	'...the unblinded nature of the study could have led to differences in practice and measurement of outcomes...'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up not reported (appears minimal).
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in result.

Other bias	Low risk	No other bias identified.

Tracy 2013

Methods	Study took place in 2 Australian centres (site 1: Royal Hospital for Women, Randwick; and site 2: Mater Mother's Hospital, Brisbane). The randomised trial compared caseload midwifery with standard care. Women were recruited to the study from site 1 between December 2008 and May 2011, and from site 2 between June 2010 and May 2011.
Participants	Women were included if they were less than 24 weeks pregnant at the booking visit, and aged 18 years and older. Women were excluded if they had planned to have an elective caesarean section, had a multiple pregnancy, or were planning to book with another care provider (e.g. a GP, caseload midwife, or private obstetrician).
Interventions	Intervention: caseload midwifery care (receiving care through antenatal, intrapartum and postpartum, in hospital and in the community) from a named caseload midwife working in a small group of midwives known as a midwifery group practice (4 full-time MWs). Each midwife provides care to 40 women a year as named midwife. The named midwife was on call for labour and birth. The caseload midwives were backed up when necessary by other caseload colleagues and by hospital staff during women's stay in the postnatal ward. Community postnatal care was provided for up to 6 weeks. An obstetrician was allocated to each midwifery practice for consultation and referral using national guidelines. Total number randomised to intervention: 871. Comparison: standard care, which involved shared antenatal care from a GP and hospital midwives, labour and birth and postnatal hospital care from hospital midwives. It was unclear whether community postnatal care was provided in standard care. Total number randomised to standard care: 877. Data were collected at recruitment, at 36 weeks' gestation and at 6 weeks and 6 months postpartum.
Outcomes	Primary outcomes:

	Caesarean section (main PO), instrumental vaginal birth, unassisted vaginal birth, epidural analgesia, Apgar scores ≤ 7 at 5 minutes, admission to SCBU, preterm birth (GA < 37 weeks) Secondary outcomes: Antenatal admission to hospital; induction or augmentation of labour; perineal status after birth; blood loss after birth; GAs and birthweights of the infants; breastfeeding at hospital discharge, 6 weeks and 6 months postnatally; and perinatal and maternal mortality, hospital cost by mode of birth (cost of birth per woman)
Notes	Forti 2015, additional report of Tracy 2013 identified from 2016 update. This reports on a subset of publicly funded women randomised in the M@ngo trial (n = 420); women receiving caseload midwifery care saw fewer midwives and health professionals during their intrapartum care than did women in standard care. No additional data provided. 1. Denominator = total randomised minus loss to follow-up, but including fetal loss before 20 weeks. Intervention = 871 - 31 + 11 = 951; standard care = 877 - 50 + 14 = 841. 2. 19 (2%) women crossed over from caseload to standard care and 65 (7%) crossed over from standard to caseload care. 3. 70%of participants were first time mothers. 4. The 2 groups were statistically different in terms of their BMI, which was judged as clinically not significant by authors. 5. An interesting observation was an overall reduction in caesarean sections for both groups from the pre-trial from 29% (at site 1) to 22% in the study population. This decrease could be seen as a limitation of the trial and the result of the Hawthorn effect. 6. Participants' satisfaction data and long-term cost analysis will be reported elsewhere. 7. Cost calculation: the per-woman cost of care calculated includes both direct and indirect costs for each full episode of maternity care, taking account of the length of hospital stay for each woman. These were calculated for midwifery and obstetric clinical time; use of operating theatres, laboratory tests, imaging, wards, allied health, pharmacy; capital

depreciation; and clinical overheads. Further comprehensive cost analyses, including neonatal costs, will be reported elsewhere, as will the results of a survey to assess the participants' experiences and satisfaction with the different models of care.

8. For the outcome of PPH, we have added together women who had between 500 and 1000 mL blood loss with those who had > 1000 mL.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women were randomly assigned by a telephone-based computer randomisation service provided by ANHMRC clinical trials randomisation centre to each group.
Allocation concealment (selection bias)	Low risk	As above, centralised allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the study it is not possible to blind participants or clinicians.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Due to the nature of the study it is not possible to blind participants or clinicians.

Incomplete outcome data (attrition bias) All outcomes	Low risk	Withdrawls and losses outlined in a trial profile in Tracy 2013. 20/871 lost or withdrew from caseload care; 36 lost or withdrew from standard care. Pregnancies lost before 20 weeks and terminations of pregnancy have been added back in (see Notes above).
Selective reporting (reporting bias)	Unclear risk	Authors were emailed for length of neonatal stay and antepartum haemorrhage; these were mentioned in the protocol and were not included in publications. Answer expected 9.3.15. Authors emailed for GA of the 2 terminations of pregnancy for lethal abnormalities. Authors asked to clarify if length of stay outcome is for infants or women.
Other bias	Unclear risk	19 (2%) women crossed over from caseload to standard care and 65 (7%) crossed over from standard to caseload care.

Turnbull 1996

Methods	**Study design:** RCT. **Duration of study:** 1993-1994.
Participants	**Setting:** Glasgow Royal Maternity Hospital, Scotland, United Kingdom. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** women booking after 16 weeks of pregnancy, not living in catchment area or with medical/obstetric complications. **Participants randomised:** 648 caseload, 651 standard care (shared care).

Interventions	**Experimental:** caseload midwifery provided by 20 midwives who volunteered to join the MDU. Each pregnant woman had a named midwife whom she met at her first booking visit who aimed to provide the majority of care. When the named midwife was not available, care was provided by up to 3 associate midwives. Women were not seen by medical staff at booking. Antenatal care was provided at home, community-based clinics or hospital clinics. Intrapartum care was in hospital (MDU - 3 rooms with fewer monitors and homely surroundings) or main labour suite. Postnatal care was provided in designated 8-bed MDU ward and community. A medical visit was scheduled where there was a deviation from normal. **Control:** all women seen by medical staff at booking. Shared antenatal care with from midwives, hospital doctors and GPs/family doctors. Intrapartum care from labour ward midwife on labour suite. Postnatal care on postnatal ward and community by community midwife.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Antepartum haemorrhage Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum

	Low birthweight (< 2500 g) Mean labour length Neonatal convulsions (as defined by trial authors) No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum depression PPH (as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	Women in the intervention group saw 7 fewer care providers across antenatal, labour and postnatal periods and 2 fewer providers during labour.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Low risk	'...random number tables...'
Allocation concealment (selection bias)	Low risk	'The research team telephoned a clerical officer in a separate office for care allocation for each woman.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Participants:** not stated. **Personnel:** clinical staff were unaware whether a particular woman was in the control group or was not in the study. No information given for women in intervention arm.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	'Clinical data were gathered through a retrospective review of records by the research team who were not involved in providing care.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: 5 team care and 16 shared care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in result.
Other bias	Low risk	No other bias identified.

Waldenstrom 2001

Methods	**Study design:** RCT. **Duration of study:** 1996-1997.

Participants	**Setting:** Royal Women's Hospital, Melbourne, Australia. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** non-English speaking women, women > 25 weeks' gestation at booking, women with high-risk criteria including previous obstetric complications, preterm delivery, IUGR, PET, previous fetal loss, significant medical disease, > 3 abortions, substance addiction, infertility > 5 years. **Participants randomised:** 495 team-midwife care, 505 standard care (combination of different models of care).
Interventions	**Experimental:** team-midwife care provided by team of 8 midwives who provided hospital-based antenatal, intrapartum (delivery suite or family birth centre) and some postnatal care in collaboration with medical staff. **Control:** standard care included different options of care being provided mostly by doctors, care mainly by midwives in collaboration with doctors (midwives clinics), birth centres and shared care between GPs and hospital doctors.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Antenatal hospitalisation Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Duration of postnatal hospital stay(days)

	Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Mean length of neonatal hospital stay (days) Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing PPH (as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	65% and 9% of experimental (team) and control (standard) group participants had previously met midwife attending labour.
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information given.
Allocation concealment (selection bias)	Low risk	'The research midwife rang a clerk at the hospital's information desk who opened an opaque, numbered envelope that contained information about the allocated group.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up: 11 team care and 9 standard-care group.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in result.
Other bias	Low risk	No other bias identified.

Abbreviations:

BMI: body mass index

CLC: consultant-led care

CLU: consultant-led unit

EFM: electronic fetal monitoring

GA: gestational age

GP: general practitioner

IUGR: intrauterine growth restriction

MDU: midwifery development unit

MLU: midwife-led unit

NICU: neonatal intensive care unit

PET: positron emissions tomography

PPH: postpartum haemorrhage

RCT: randomised controlled trial

SCBU: special care baby unit

vs: versus

WTE: whole time equivalent

Appendix I: GRADE profiles

I.1 Midwifery-led continuity of care versus other models of care

Table 6: Midwifery-led continuity of care versus other models of care and variation in caseload and team midwifery

Quality assessment							No of patients		Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care	Relative (95% CI)	Absolute	Quality
Regional analgesia (epidural/spinal)											
14[1]	randomised trials	serious[2]	serious[3]	no serious indirectness[4]	no serious imprecision[5]	none	2178/9667 (22.5%)	2161/8007 (27%)	RR 0.85 (0.78 to 0.92)	40 fewer per 1000 (from 22 fewer to 59 fewer)	LOW
Regional analgesia (epidural/spinal) - Caseload model (4 or fewer midwives)											
5[6]	randomised trials	serious[7]	very serious[8]	no serious indirectness[4]	no serious imprecision[5]	none	1002/3917 (25.6%)	1113/3866 (28.8%)	RR 0.85 (0.72 to 1)	43 fewer per 1000 (from 81 fewer to 0 more)	VERY LOW
Regional analgesia (epidural/spinal) - Team model (5 to 8 midwives)											
9[9]	randomised trials	serious[10]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	1176/5750 (20.5%)	1048/4141 (25.3%)	RR 0.84 (0.78 to 0.91)	40 fewer per 1000 (from 23 fewer to 56 fewer)	MODERATE

Quality assessment							No of patients		Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care	Relative (95% CI)	Absolute	Quality
Caesarean birth											
14[1]	randomised trials	serious[2]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	1281/9655 (13.3%)	1242/8003 (15.5%)	RR 0.92 (0.84 to 1)	12 fewer per 1000 (from 25 fewer to 0 more)	MODERATE
Caesarean birth - Caseload model (4 or fewer midwives)											
5[6]	randomised trials	serious[7]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	657/3917 (16.8%)	723/3866 (18.7%)	RR 0.92 (0.8 to 1.05)	15 fewer per 1000 (from 37 fewer to 9 more)	MODERATE
Caesarean birth - Team model (5 to 8 midwives)											
9[9]	randomised trials	serious[10]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	624/5738 (10.9%)	519/4137 (12.5%)	RR 0.93 (0.82 to 1.05)	9 fewer per 1000 (from 23 fewer to 6 more)	MODERATE
Instrumental vaginal birth (forceps/vacuum)											
13[12]	randomised trials	serious[2]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	1230/9824 (12.5%)	1182/8141 (14.5%)	RR 0.9 (0.84 to 0.97)	15 fewer per 1000 (from 4 fewer to 23 fewer)	MODERATE
Instrumental vaginal birth (forceps/vacuum) - Caseload model (4 or fewer midwives)											
5[6]	randomised trials	serious[7]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	587/3917 (15%)	629/3866 (16.3%)	RR 0.93 (0.84 to 1.03)	11 fewer per 1000 (from 26 fewer to 5 more)	MODERATE
Instrumental vaginal birth (forceps/vacuum) - Team model (5 to 8 midwives)											
8[13]	randomised trials	serious[10]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	643/5907 (10.9%)	553/4275 (12.9%)	RR 0.88 (0.78 to 0.99)	16 fewer per 1000 (from 1 fewer to 28 fewer)	MODERATE
Spontaneous vaginal birth (as defined by trial authors)											
12[14]	randomised trials	serious[2]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	6485/9181 (70.6%)	4937/7506 (65.8%)	RR 1.05 (1.03 to 1.07)	33 more per 1000 (from 20 more to 46 more)	MODERATE
Spontaneous vaginal birth (as defined by trial authors) - Caseload model (4 or fewer midwives)											
5[6]	randomised trials	serious[7]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	2584/3917 (66%)	2412/3866 (62.4%)	RR 1.05 (1 to 1.1)	31 more per 1000 (from 0 more to 62 more)	MODERATE
Spontaneous vaginal birth (as defined by trial authors) - Team model (5 to 8 midwives)											
7[15]	randomised trials	serious[10]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	3901/5264 (74.1%)	2525/3640 (69.4%)	RR 1.05 (1.02 to 1.08)	35 more per 1000 (from 14 more to 55 more)	MODERATE
Intact perineum											
10[16]	randomised trials	serious[17]	serious[3]	no serious indirectness[4]	no serious imprecision[5]	none	2159/7438 (29%)	1544/5748 (26.9%)	RR 1.04 (0.95 to 1.13)	11 more per 1000 (from 13 fewer to 35 more)	LOW
Intact perineum - Caseload model (4 or fewer midwives)											

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care	Relative (95% CI)	Absolute	
4[18]	randomised trials	serious[7]	serious[3]	no serious indirectness[4]	no serious imprecision[5]	none	727/2767 (26.3%)	669/2709 (24.7%)	RR 1.07 (0.93 to 1.24)	17 more per 1000 (from 17 fewer to 59 more)	LOW
Intact perineum - Team model (5 to 8 midwives)											
6[19]	randomised trials	serious[7]	serious[3]	no serious indirectness[4]	no serious imprecision[5]	none	1432/4671 (30.7%)	875/3039 (28.8%)	RR 1.01 (0.89 to 1.14)	3 more per 1000 (from 32 fewer to 40 more)	LOW
Preterm birth (< 37 weeks)											
8[20]	randomised trials	serious[17]	no serious inconsistency[11]	no serious indirectness[4]	serious[21]	none	360/7440 (4.8%)	367/5798 (6.3%)	RR 0.76 (0.64 to 0.91)	15 fewer per 1000 (from 6 fewer to 23 fewer)	LOW
Preterm birth (< 37 weeks) - Caseload model (4 or fewer midwives)											
3[22]	randomised trials	serious[23]	no serious inconsistency[11]	no serious indirectness[4]	serious[21]	none	98/2644 (3.7%)	141/2633 (5.4%)	RR 0.69 (0.54 to 0.89)	17 fewer per 1000 (from 6 fewer to 25 fewer)	LOW
Preterm birth (< 37 weeks) - Team model (5 to 8 midwives)											
5[24]	randomised trials	serious[10]	serious[3]	no serious indirectness[4]	serious[21]	none	262/4796 (5.5%)	226/3165 (7.1%)	RR 0.81 (0.62 to 1.07)	14 fewer per 1000 (from 27 fewer to 5 more)	VERY LOW
All fetal loss before and after 24 weeks plus neonatal death											
13[12]	randomised trials	no serious risk of bias[2]	no serious inconsistency[11]	no serious indirectness[4]	serious[21]	none	257/9596 (2.7%)	273/7931 (3.4%)	RR 0.84 (0.71 to 0.99)	6 fewer per 1000 (from 0 fewer to 10 fewer)	MODERATE
All fetal loss before and after 24 weeks plus neonatal death - Caseload model (4 or fewer midwives)											
5[6]	randomised trials	serious[7]	no serious inconsistency[11]	no serious indirectness[4]	serious[21]	none	67/3902 (1.7%)	82/3847 (2.1%)	RR 0.81 (0.58 to 1.12)	4 fewer per 1000 (from 9 fewer to 3 more)	LOW
All fetal loss before and after 24 weeks plus neonatal death - Team model (5 to 8 midwives)											
8[25]	randomised trials	serious[10]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	190/5694 (3.3%)	191/4084 (4.7%)	RR 0.85 (0.7 to 1.04)	7 fewer per 1000 (from 14 fewer to 2 more)	MODERATE
Fetal loss equal to/after 24 weeks and neonatal death											
12[26]	randomised trials	serious[27]	no serious inconsistency[11]	no serious indirectness[4]	very serious[28]	none	61/9506 (0.64%)	51/7853 (0.65%)	RR 1.00 (0.67 to 1.49)	0 fewer per 1000 (from 2 fewer to 3 more)	VERY LOW
Fetal loss equal to/after 24 weeks and neonatal death - Caseload model											
5[6]	randomised trials	serious[7]	no serious inconsistency[11]	no serious indirectness[4]	very serious[28]	none	24/3917 (0.61%)	30/3866 (0.78%)	RR 0.79 (0.45 to 1.37)	2 fewer per 1000 (from 4 fewer to 3 more)	VERY LOW
Fetal loss equal to/after 24 weeks and neonatal death - Team model (5 to 8 midwives)											

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care	Relative (95% CI)	Absolute	
7[25]	randomised trials	serious[29]	no serious inconsistency[11]	no serious indirectness[4]	serious[28]	none	37/5589 (0.66%)	21/3987 (0.53%)	RR 1.29 (0.73 to 2.27)	2 more per 1000 (from 1 fewer to 7 more)	LOW
Augmentation/artificial oxytocin during labour											
12[30]	randomised trials	serious[2]	very serious[8]	no serious indirectness[4]	no serious imprecision[5]	none	2008/8436 (23.8%)	1977/6758 (29.3%)	RR 0.88 (0.78 to 0.99)	35 fewer per 1000 (from 3 fewer to 64 fewer)	VERY LOW
Augmentation/artificial oxytocin during labour - Caseload model (4 or fewer midwives)											
4[18]	randomised trials	serious[7]	very serious[8]	no serious indirectness[4]	serious[21]	none	910/2767 (32.9%)	1018/2709 (37.6%)	RR 0.86 (0.71 to 1.02)	53 fewer per 1000 (from 109 fewer to 8 more)	VERY LOW
Augmentation/artificial oxytocin during labour - Team model (5 to 8 midwives)											
8[13]	randomised trials	serious[10]	very serious[8]	no serious indirectness[4]	no serious imprecision[5]	none	1098/5669 (19.4%)	959/4049 (23.7%)	RR 0.9 (0.76 to 1.06)	24 fewer per 1000 (from 57 fewer to 14 more)	VERY LOW
Induction of labour											
12[31]	randomised trials	serious[2]	serious[3]	no serious indirectness[4]	no serious imprecision[5]	none	1602/8490 (18.9%)	1601/7366 (21.7%)	RR 0.93 (0.85 to 1.03)	15 fewer per 1000 (from 33 fewer to 7 more)	LOW
Induction of labour - Caseload model (4 or fewer midwives)											
5[6]	randomised trials	serious[7]	serious[3]	no serious indirectness[4]	no serious imprecision[5]	none	861/3917 (22%)	968/3866 (25%)	RR 0.87 (0.77 to 0.99)	33 fewer per 1000 (from 3 fewer to 58 fewer)	LOW
Induction of labour - Team model (5 to 8 midwives)											
7[32]	randomised trials	serious[7]	no serious inconsistency[11]	no serious indirectness[4]	no serious imprecision[5]	none	741/4573 (16.2%)	633/3500 (18.1%)	RR 1.01 (0.9 to 1.14)	2 more per 1000 (from 18 fewer to 25 more)	MODERATE
Breastfeeding initiation											
2[33]	randomised trials	serious[34]	very serious[8]	serious[35]	serious[21]	none	694/1290 (53.8%)	380/760 (50%)	RR 1.12 (0.81 to 1.53)	60 more per 1000 (from 95 fewer to 265 more)	VERY LOW
Breastfeeding initiation - Team model (5 to 8 midwives)											
2[33]	randomised trials	serious[34]	very serious[8]	serious[35]	serious[21]	none	694/1290 (53.8%)	380/760 (50%)	RR 1.12 (0.81 to 1.53)	60 more per 1000 (from 95 fewer to 265 more)	VERY LOW
Maternal satisfaction											
1[36]	randomised trials	no serious risk of bias[37]	no serious inconsistency[38]	no serious indirectness[4]	serious[21]	none	215/341 (63%)	134/282 (47.5%)	RR 1.33 (1.15 to 1.54)	157 more per 1000 (from 71 more to 257 more)	MODERATE
Maternal satisfaction - Team model (5 to 8 midwives)											

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care	Relative (95% CI)	Absolute	
1[36]	randomised trials	no serious risk of bias[37]	no serious inconsistency[38]	no serious indirectness[4]	serious[21]	none	215/341 (63%)	47.5%	RR 1.33 (1.15 to 1.54)	157 more per 1000 (from 71 more to 256 more)	MODERATE

1 Biro 2000, Begley 2011, Flint 1999, Hicks 2003, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, McLachlan 2012, North Stafford 2000, Rowley 1995, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.
2 Evidence was downgraded by 1 due to serious risk of bias concerns in 7 studies.
3 Evidence was downgraded by 1 due to serious inconsistency as I squared ≥ 50%.
4 No indirectness as population, intervention, comparison and outcomes are direct to the review protocol.
5 No imprecision as 95% CIs do not cross MIDs.
6 Flint 1999, McLachlan 2012, North Stafford 2000, Tracy 2013 and Turnbull 1996
7 Evidence was downgraded by 1 due to serious risk of bias concerns in 3 studies.
8 Evidence was downgraded by 2 due to very serious heterogeneity (I squared > 75%).
9 Begley 2011, Biro 2000, Hicks 2003, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, Rowley 1995 and Waldenstrom 2001.
10 Evidence was downgraded by 1 due to serious risk of bias concerns in 4 studies.
11 No inconsistency (heterogeneity) as I squared is < 50.
12 Biro 2000, Begley 2011, Flint 1999, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, McLachlan 2012, North Stafford 2000, Rowley 1995, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.
13 Begley 2011, Biro 2000, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, Rowley 1995 and Waldenstrom 2001.
14 Biro 2000, Begley 2011, Flint 1999, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, McLachlan 2012, North Stafford 2000, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.
15 Begley 2011, Biro 2000, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993 and Waldenstrom 2001.
16 Biro 2000, Begley 2011, Flint 1999, Harvey 1996, Kenny 1994, MacVicar 1993, North Stafford 2000, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.
17 Evidence was downgraded by 1 due to serious risk of bias concerns in 5 studies.
18 Flint 1999, North Stafford 2000, Tracy 2013 and Turnbull 1996
19 Begley 2011, Biro 2000, Harvey 1996, Kenny 1994, MacVicar 1993 and Waldenstrom 2001.
20 Biro 2000, Begley 2011, MacVicar 1993, North Stafford 2000, Rowley 1995, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.
21 Evidence was downgraded by 1 due to serious imprecision as 95% CIs crossed one default MID.
22 McLachlan 2012, Tracy 2013 and Turnbull 1996
23 Evidence was downgraded by 1 due to serious risk of bias concerns in 2 studies.
24 Begley 2011, Biro 2000, MacVicar 1993, Rowley 1995 and Waldenstrom 2001.
25 Biro 2000, Begley 2011, Homer 2001, Kenny 1994, MacVicar 1993, Rowley 1995, Waldenstrom 2001.
26 Biro 2000, Begley 2011, Flint 1999, Homer 2001, Kenny 1994, MacVicar 1993, McLachlan 2012, North Stafford 2000, Rowley 1995, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.
27 Evidence was downgraded by 1 due to serious risk of bias concerns in 8 studies.
28 Evidence was downgraded by 2 due to serious imprecision as 95% CIs crossed two default MID.
29 Evidence was downgraded by 1 due to serious risk of bias concerns in 6 studies.
30 Biro 2000, Begley 2011, Flint 1999, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, North Stafford 2000, Rowley 1995, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.

31 Biro 2000, Flint 1999, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, McLachlan 2012, North Stafford 2000, Rowley 1995, Tracy 2013, Turnbull 1996 and Waldenstrom 2001.
32 Biro 2000, Harvey 1996, Homer 2001, Kenny 1994, MacVicar 1993, Rowley 1995, Tracy 2013 and Waldenstrom 2001.
33 Begley 2011 and Kenny 1994.
34 Evidence was downgraded by 1 due to serious risk of bias concerns in 1 study.
35 Evidence was downgraded by 1 as outcome is indirect for the outcome 'breastfeeding on hospital discharge'.
36 Biro 2000.
37 No serious risk of bias concerns.
38 Inconsistency not applicable as evidence is from a single study and not analysed in a meta-analysis.

Table 7: Midwifery-led care versus other models of care: variation in risk status

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care: variation in risk status (low / mixed)	Relative (95% CI)	Absolute	
Regional analgesia (epidural/spinal) - Low risk											
8[1]	randomised trials	serious[2]	serious[3]	no serious indirectness[4]	serious[5]	none	1406/6366 (22.1%)	1309/4730 (27.7%)	RR 0.82 (0.73 to 0.92)	50 fewer per 1000 (from 22 fewer to 75 fewer)	VERY LOW
Regional analgesia (epidural/spinal) - Mixed risk											
6[6]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	772/3301 (23.4%)	852/3277 (26%)	RR 0.88 (0.78 to 1)	31 fewer per 1000 (from 57 fewer to 0 more)	MODERATE
Caesarean birth - Low risk											
8[1]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	712/6366 (11.2%)	637/4730 (13.5%)	RR 0.91 (0.79 to 1.06)	12 fewer per 1000 (from 28 fewer to 8 more)	MODERATE
Caesarean birth - Mixed risk											
6[6]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	569/3301 (17.2%)	605/3277 (18.5%)	RR 0.93 (0.84 to 1.03)	13 fewer per 1000 (from 30 fewer to 6 more)	MODERATE
Instrumental vaginal birth (forceps/vacuum) - Low risk											
7[9]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	751/6285 (11.9%)	663/4638 (14.3%)	RR 0.89 (0.81 to 0.99)	16 fewer per 1000 (from 1 fewer to 27 fewer)	MODERATE
Instrumental vaginal birth (forceps/vacuum) - Mixed risk											
6[6]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	serious[5]	none	425/3301 (12.9%)	470/3277 (14.3%)	RR 0.87 (0.73 to 1.04)	19 fewer per 1000 (from 39 fewer to 6 more)	LOW
Spontaneous vaginal birth (as defined by trial authors) - Low risk											

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care: variation in risk status (low / mixed)	Relative (95% CI)	Absolute	
7[9]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	4614/6285 (73.4%)	3183/4638 (68.6%)	RR 1.05 (1.02 to 1.08)	34 more per 1000 (from 14 more to 55 more)	MODERATE
Spontaneous vaginal birth (as defined by trial authors) - Mixed risk											
5[10]	randomised trials	serious[11]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	1871/2896 (64.6%)	1754/2868 (61.2%)	RR 1.06 (1.02 to 1.1)	37 more per 1000 (from 12 more to 61 more)	MODERATE
Intact perineum - Low risk											
6[12]	randomised trials	serious[11]	serious[3]	no serious indirectness	no serious imprecision[8]	none	1535/5135 (29.9%)	922/3481 (26.5%)	RR 1.06 (0.93 to 1.21)	16 more per 1000 (from 19 fewer to 56 more)	LOW
Intact perineum - Mixed risk											
4[13]	randomised trials	serious[11]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	624/2303 (27.1%)	622/2267 (27.4%)	RR 0.99 (0.91 to 1.08)	3 fewer per 1000 (from 25 fewer to 22 more)	MODERATE
Preterm birth (< 37 weeks) - Low risk											
5[14]	randomised trials	serious[11]	no serious inconsistency[7]	no serious indirectness[4]	serious[5]	none	233/5679 (4.1%)	220/4047 (5.4%)	RR 0.71 (0.54 to 0.92)	16 fewer per 1000 (from 4 fewer to 25 fewer)	LOW
Preterm birth (< 37 weeks) - Mixed risk											
3[15]	randomised trials	serious[16]	no serious inconsistency[7]	no serious indirectness[4]	serious[5]	none	127/1761 (7.2%)	147/1751 (8.4%)	RR 0.87 (0.69 to 1.09)	11 fewer per 1000 (from 26 fewer to 8 more)	LOW
All fetal loss before and after 24 weeks plus neonatal death - Low risk											
7[9]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	serious[5]	none	138/6272 (2.2%)	117/4623 (2.5%)	RR 0.94 (0.73 to 1.2)	2 fewer per 1000 (from 7 fewer to 5 more)	LOW
All fetal loss before and after 24 weeks plus neonatal death - Mixed risk											
6[6]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	serious[5]	none	119/3324 (3.6%)	156/3308 (4.7%)	RR 0.76 (0.61 to 0.96)	11 fewer per 1000 (from 2 fewer to 18 fewer)	LOW
Fetal loss equal to/after 24 weeks and neonatal death - low risk											
6[17]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	very serious[18]	none	38/6182 (0.61%)	28/4545 (0.62%)	RR 1.02 (0.58 to 1.8)	0 more per 1000 (from 3 fewer to 5 more)	VERY LOW
Fetal loss equal to/after 24 weeks and neonatal death - mixed risk											

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care: variation in risk status (low / mixed)	Relative (95% CI)	Absolute	
6[6]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	very serious[18]	none	23/3324 (0.69%)	23/3308 (0.7%)	RR 0.96 (0.53 to 1.74)	0 fewer per 1000 (from 3 fewer to 5 more)	VERY LOW
Augmentation/artificial oxytocin during labour - Low risk											
6[17]	randomised trials	serious[2]	very serious[19]	no serious indirectness[4]	serious[5]	none	958/5135 (18.7%)	837/3481 (24%)	RR 0.82 (0.68 to 1)	43 fewer per 1000 (from 77 fewer to 0 more)	VERY LOW
Augmentation/artificial oxytocin during labour - Mixed risk											
6[6]	randomised trials	serious[2]	very serious[19]	no serious indirectness[4]	no serious imprecision[8]	none	1050/3301 (31.8%)	1140/3277 (34.8%)	RR 0.93 (0.8 to 1.09)	24 fewer per 1000 (from 70 fewer to 31 more)	VERY LOW
Induction of labour - Low risk											
7[9]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	1149/6285 (18.3%)	1024/4638 (22.1%)	RR 0.89 (0.8 to 0.99)	24 fewer per 1000 (from 2 fewer to 44 fewer)	MODERATE
Induction of labour - Mixed risk											
6[6]	randomised trials	serious[2]	no serious inconsistency[7]	no serious indirectness[4]	no serious imprecision[8]	none	701/3301 (21.2%)	715/3277 (21.8%)	RR 0.99 (0.86 to 1.13)	2 fewer per 1000 (from 31 fewer to 28 more)	MODERATE
Breastfeeding initiation - Low risk											
1[20]	randomised trials	serious[21]	no serious inconsistency[22]	serious[23]	no serious imprecision[8]	none	616/1096 (56.2%)	317/549 (57.7%)	RR 0.97 (0.89 to 1.06)	17 fewer per 1000 (from 64 fewer to 35 more)	LOW
Breastfeeding initiation - Mixed risk											
1[24]	randomised trials	serious[21]	no serious inconsistency[22]	serious[23]	serious[5]	none	78/194 (40.2%)	63/211 (29.9%)	RR 1.35 (1.03 to 1.76)	105 more per 1000 (from 9 more to 227 more)	VERY LOW
Maternal satisfaction - Mixed risk											
1[25]	randomised trials	no serious risk of bias[26]	no serious inconsistency[22]	no serious indirectness[4]	serious[5]	none	215/341 (63%)	134/282 (47.5%)	RR 1.33 (1.15 to 1.54)	157 more per 1000 (from 71 more to 257 more)	MODERATE

1 Begley 2011, Flint 1989, Harvey 1996, Hicks 2003, MacVicar 1993, McLachlan 2012, Turnbull 1996 and Waldenstrom 2001.
2 Evidence was downgraded due to serious risk of bias concerns in 4 studies.
3 Evidence was downgraded by 1 due to very serious inconsistency as I squared > 50%.
4 No indirectness as population, intervention, comparison and outcomes are direct to the review protocol.

5 Evidence was downgraded by 1 due to serious imprecision as 95% CIs crossed one default MID.
6 Biro 2000, Homer 2001, Kenny 199, North Stafford 2000, Rowley 1995 and Tracy 2013.
7 No inconsistency (heterogeneity) as I squared is < 50.
8 No imprecision as 95% CIs do not cross default MIDs.
9 Begley 2011, Flint 1989, Harvey 1996, MacVicar 1993, McLachlan 2012, Turnbull 1996 and Waldenstrom 2001.
10 Biro 2000, Homer 2001, Kenny 199, North Stafford 2000 and Tracy 2013.
11 Evidence was downgraded by 1 due to serious risk of bias concerns in 3 studies.
12 Begley 2011, Flint 1989, Harvey 1996, MacVicar 1993, Turnbull 1996 and Waldenstrom 2001.
13 Biro 2000, Kenny 199, North Stafford 2000 and Tracy 2013.
14 Begley 2011, McLachlan 2012, MacVicar 1993, Turnbull 1996 and Waldenstrom 2001.
15 Biro 2000, Rowley 1995 and Tracy 2013.
16 Evidence was downgraded due to serious risk of bias concerns in 2 studies.
17 Begley 2011, Flint 1989, MacVicar 1993, McLachlan 2012,Turnbull 1996 and Waldenstrom 2001.
18 Evidence was downgraded by 2 due to serious imprecision as 95% CIs crossed two default MID.
19 Evidence was downgraded by 2 due to very serious inconsistency as I squared > 75%.
20 Begley 2011
21 Evidence was downgraded due to serious risk of bias concerns in 1 study.
22 Inconsistency not applicable as evidence is from a single study and not analysed in a meta-analysis.
23 Evidence was downgraded by 1 as outcome is indirect for the outcome 'breastfeeding on hospital discharge'.
24 Kenny 1994
25 Biro 2000
26 No serious risk of bias concerns.

Table 8: Midwifery-led care versus other models of care: variation in parity

Quality assessment							No of patients		Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care: variation in parity	Relative (95% CI)	Absolute	Quality
Regional analgesia (epidural/spinal) - First time mothers											
2[1]	randomised trials	serious[2]	no serious inconsistency[3]	no serious indirectness[4]	no serious imprecision[5]	none	340/998 (34.1%)	373/1008 (37%)	RR 0.92 (0.81 to 1.05)	30 fewer per 1000 (from 70 fewer to 19 more)	MODERATE
Regional analgesia (epidural/spinal) - Previously given birth											
2[1]	randomised trials	serious[2]	no serious inconsistency[3]	no serious indirectness[4]	very serious[6]	none	55/557 (9.9%)	58/558 (10.4%)	RR 0.94 (0.65 to 1.38)	6 fewer per 1000 (from 36 fewer to 39 more)	VERY LOW
Caesarean birth - First time mothers											

Quality assessment							No of patients		Effect		Quality
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care: variation in parity	Relative (95% CI)	Absolute	
1[7]	randomised trials	no serious risk of bias[8]	no serious inconsistency[9]	no serious indirectness[4]	serious[10]	none	200/804 (24.9%)	257/806 (31.9%)	RR 0.78 (0.67 to 0.91)	70 fewer per 1000 (from 29 fewer to 105 fewer)	MODERATE
Caesarean birth - Previously given birth											
1[7]	randomised trials	no serious risk of bias[8]	no serious inconsistency[9]	no serious indirectness[4]	very serious[6]	none	21/346 (6.1%)	28/351 (8%)	RR 0.76 (0.44 to 1.31)	19 fewer per 1000 (from 45 fewer to 25 more)	LOW
Instrumental vaginal birth (forceps/vacuum) - First time mothers											
1[7]	randomised trials	no serious risk of bias[8]	no serious inconsistency[9]	no serious indirectness[4]	no serious imprecision[5]	none	187/804 (23.3%)	207/807 (25.7%)	RR 0.91 (0.76 to 1.08)	23 fewer per 1000 (from 62 fewer to 21 more)	HIGH
Instrumental vaginal birth (forceps/vacuum) - Previously given birth											
1[7]	randomised trials	no serious risk of bias[8]	no serious inconsistency[9]	no serious indirectness[4]	very serious[6]	none	15/346 (4.3%)	15/351 (4.3%)	RR 1.01 (0.5 to 2.04)	0 more per 1000 (from 21 fewer to 44 more)	LOW
Spontaneous vaginal birth (as defined by trial authors) - First time mothers											
1[7]	randomised trials	no serious risk of bias[8]	no serious inconsistency[9]	no serious indirectness[4]	serious[10]	none	415/804 (51.6%)	329/806 (40.8%)	RR 1.26 (1.14 to 1.41)	106 more per 1000 (from 57 more to 167 more)	MODERATE
Spontaneous vaginal birth (as defined by trial authors) - Previously given birth											
1[7]	randomised trials	no serious risk of bias[8]	no serious inconsistency[9]	no serious indirectness[4]	no serious imprecision[5]	none	304/346 (87.9%)	308/351 (87.7%)	RR 1 (0.95 to 1.06)	0 fewer per 1000 (from 44 fewer to 53 more)	HIGH
Augmentation/artificial oxytocin during labour - First time mothers											
1[11]	randomised trials	serious[2]	no serious inconsistency[9]	no serious indirectness[4]	serious[10]	none	72/194 (37.1%)	65/202 (32.2%)	RR 1.15 (0.88 to 1.51)	48 more per 1000 (from 39 fewer to 164 more)	LOW
Augmentation/artificial oxytocin during labour - Previously given birth											
1[11]	randomised trials	serious[2]	no serious inconsistency[9]	no serious indirectness[4]	serious[10]	none	46/211 (21.8%)	39/207 (18.8%)	RR 1.16 (0.79 to 1.69)	30 more per 1000 (from 40 fewer to 130 more)	LOW
Induction of labour - First time mothers											
1[11]	randomised trials	serious[2]	no serious inconsistency[9]	no serious indirectness[4]	serious[10]	none	37/194 (19.1%)	32/202 (15.8%)	RR 1.2 (0.78 to 1.85)	32 more per 1000 (from 35 fewer to 135 more)	LOW

Quality assessment							No of patients		Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Midwifery-led continuity of care	Other models of care: variation in parity	Relative (95% CI)	Absolute	Quality
Induction of labour - Previously given birth											
1[11]	randomised trials	serious[2]	no serious inconsistency[9]	no serious indirectness[4]	serious[10]	none	21/211 (10%)	36/207 (17.4%)	RR 0.57 (0.35 to 0.95)	75 fewer per 1000 (from 9 fewer to 113 fewer)	LOW

1 McLachlan 2012 and Rowley 1995
2 Evidence downgraded by 1 due to serious risk of bias concerns in one study.
3 No inconsistency as I squared < 50%.
4 No indirectness as population, intervention, comparison and outcomes are direct to the review protocol.
5 No imprecision as 95% CIs do not cross default MIDs.
6 Evidence was downgraded by 2 due to serious imprecision as 95% CIs crossed two default MID.
7 McLachlan 2012
8 No serious risk of bias concerns.
9 Inconsistency not applicable as evidence is from a single study and not analysed in a meta-analysis.
10 Evidence was downgraded by 1 due to serious imprecision as 95% CIs crossed one default MID.
11 Rowley 1995

Appendix J: Forest plots

J.1 Midwifery-led continuity of care versus other models of care

J.1.1 Midwifery-led continuity of care versus other models of care and variation in caseload and team midwifery

Figure 1: Regional analgesia

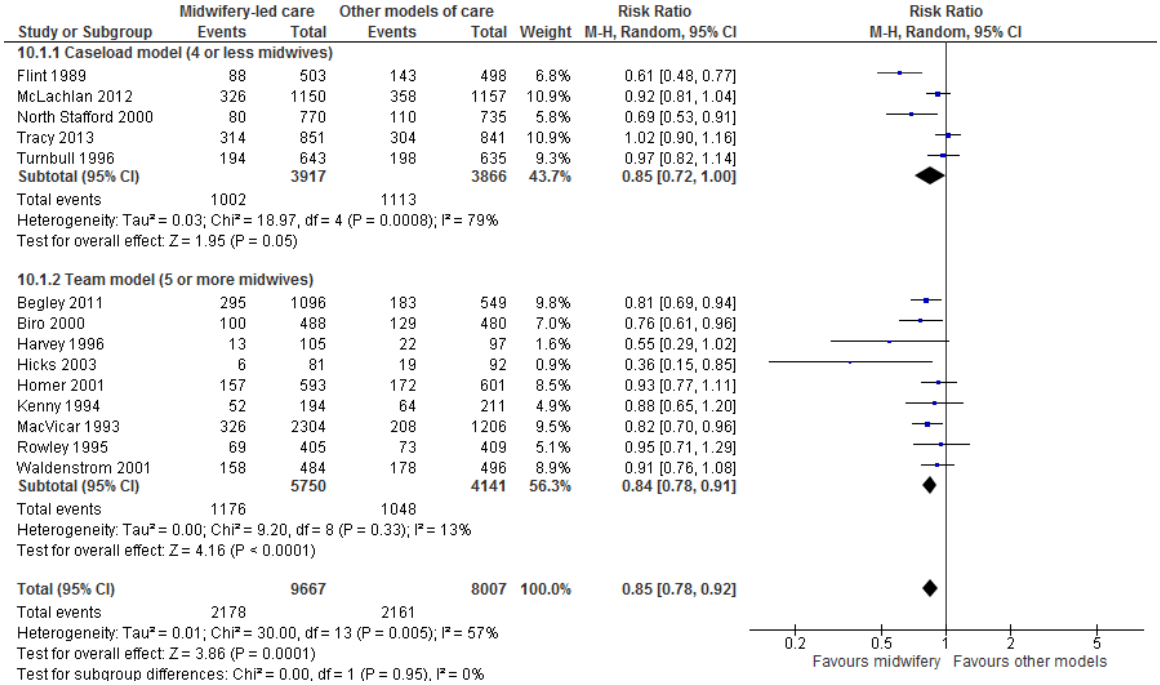


Figure 2: Caesarean birth

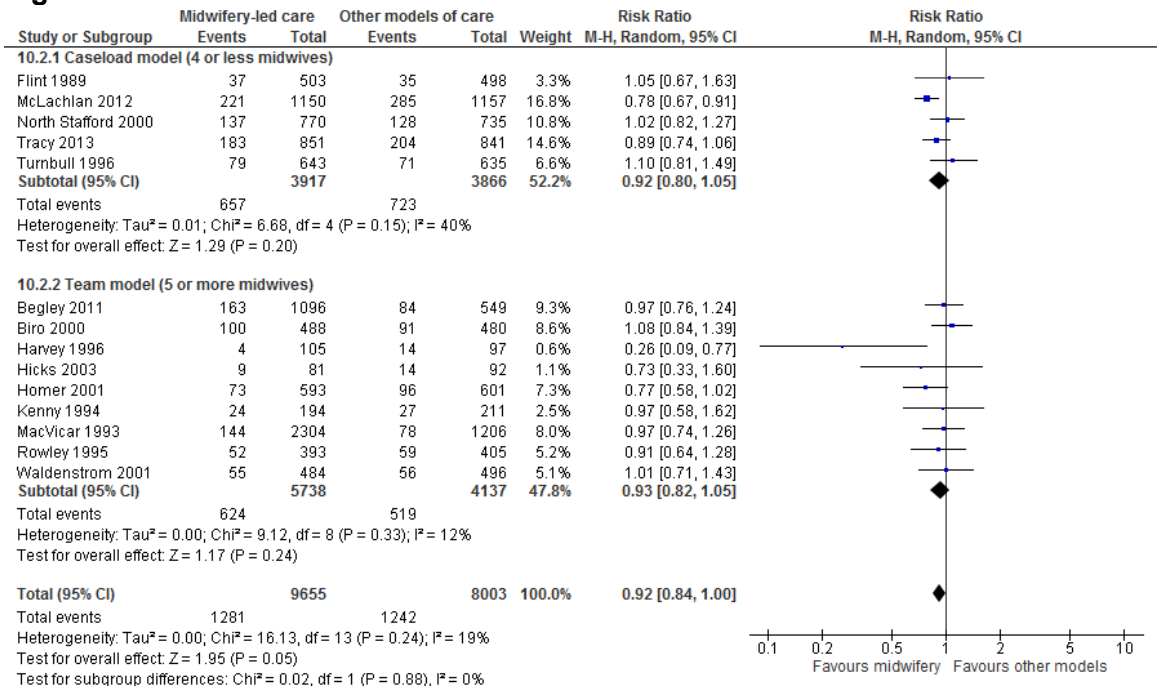


Figure 3: Instrumental vaginal birth (forceps / vacuum)

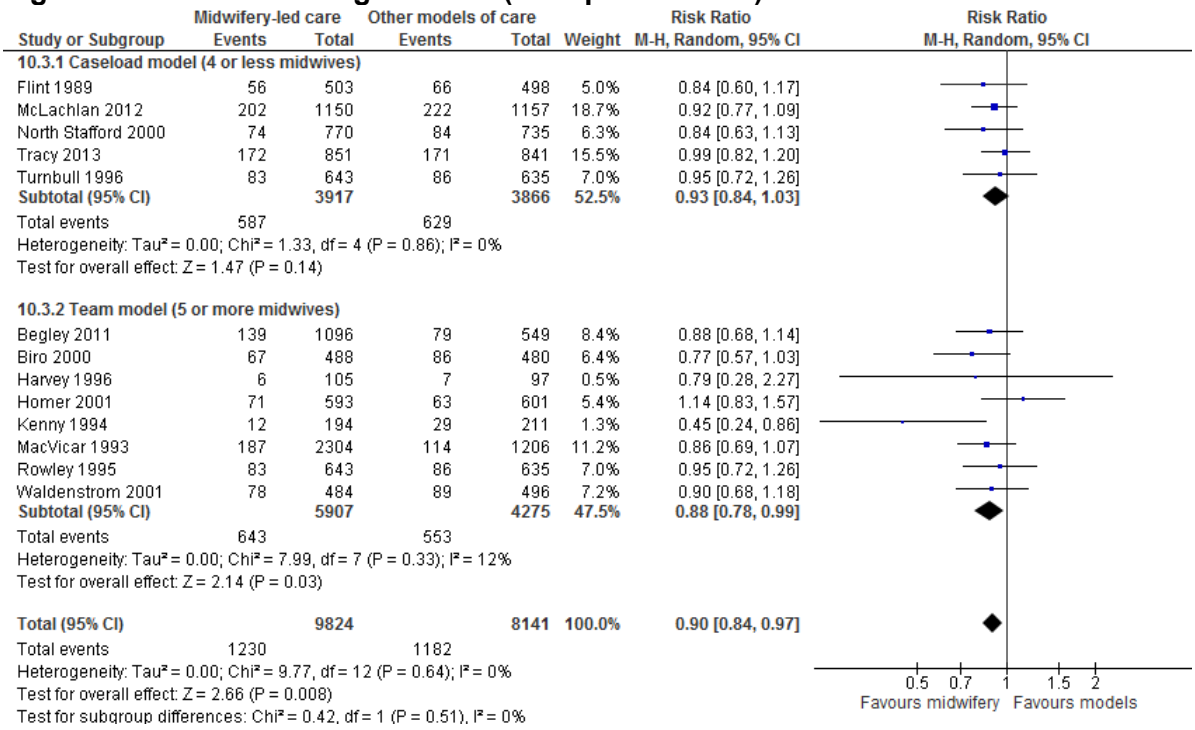


Figure 4: Spontaneous vaginal birth

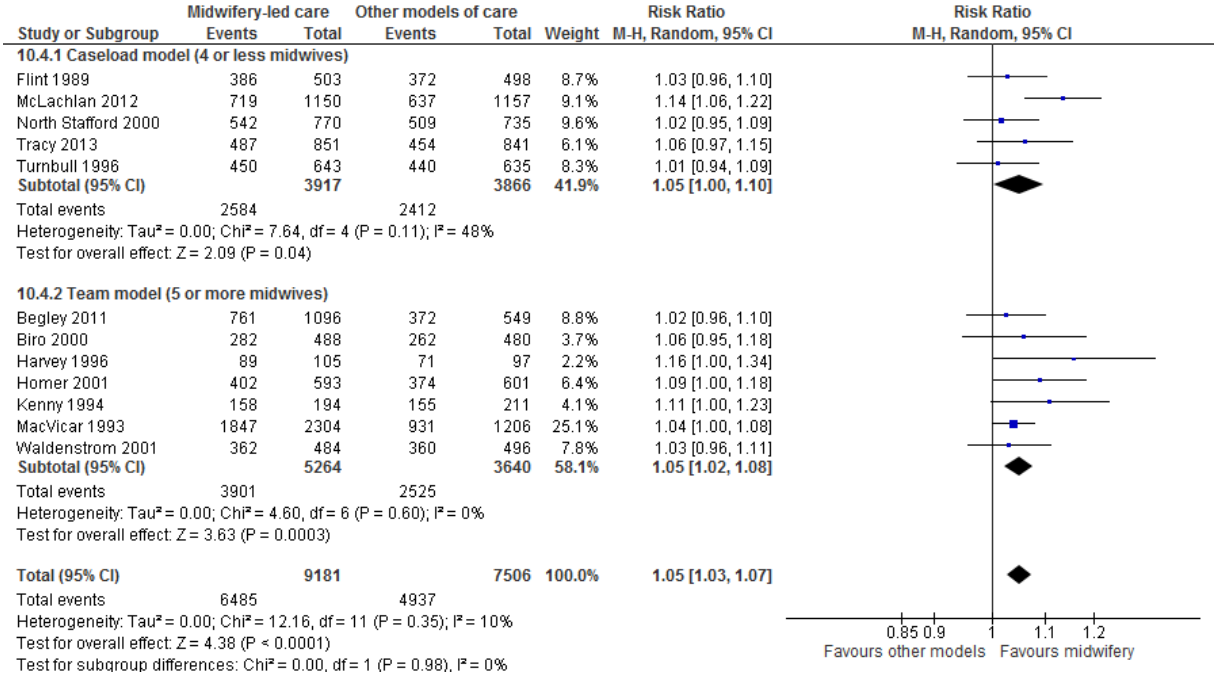


Figure 5: Intact perineum

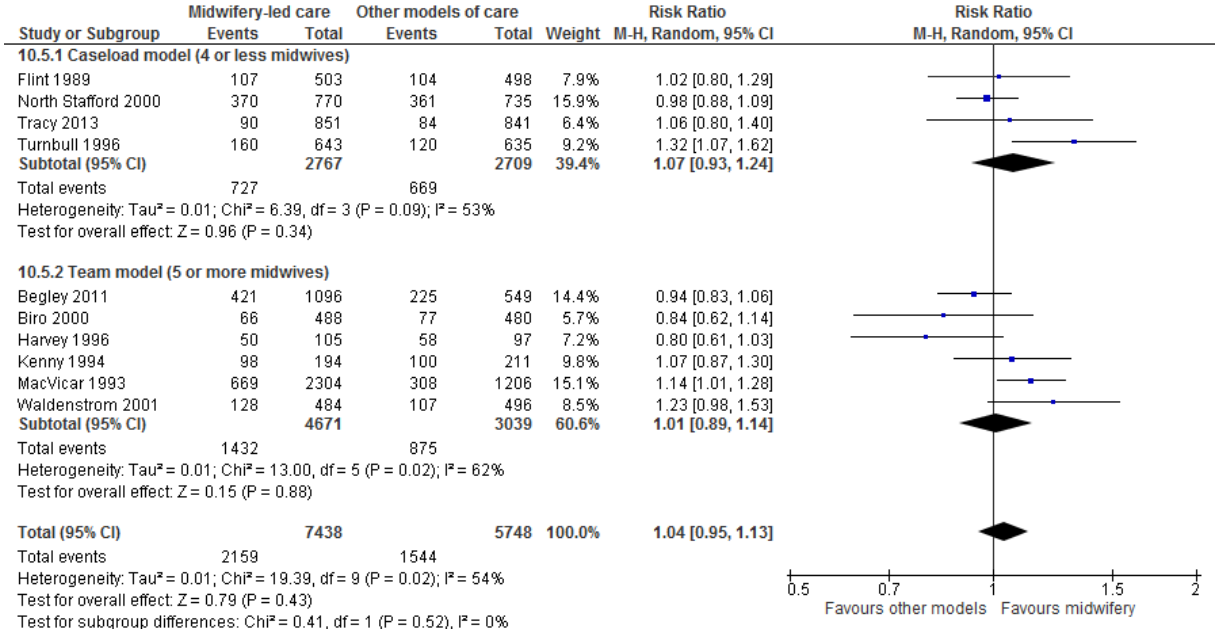


Figure 6: Preterm birth (< 37 weeks)

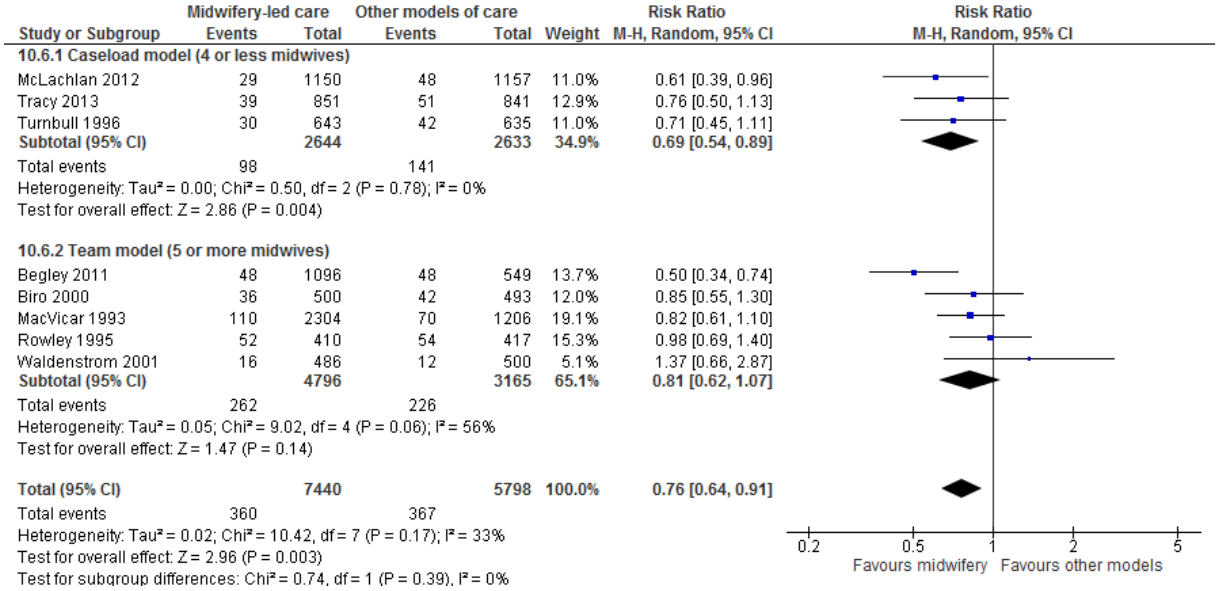


Figure 7: All fetal loss before and after 24 weeks plus neonatal death

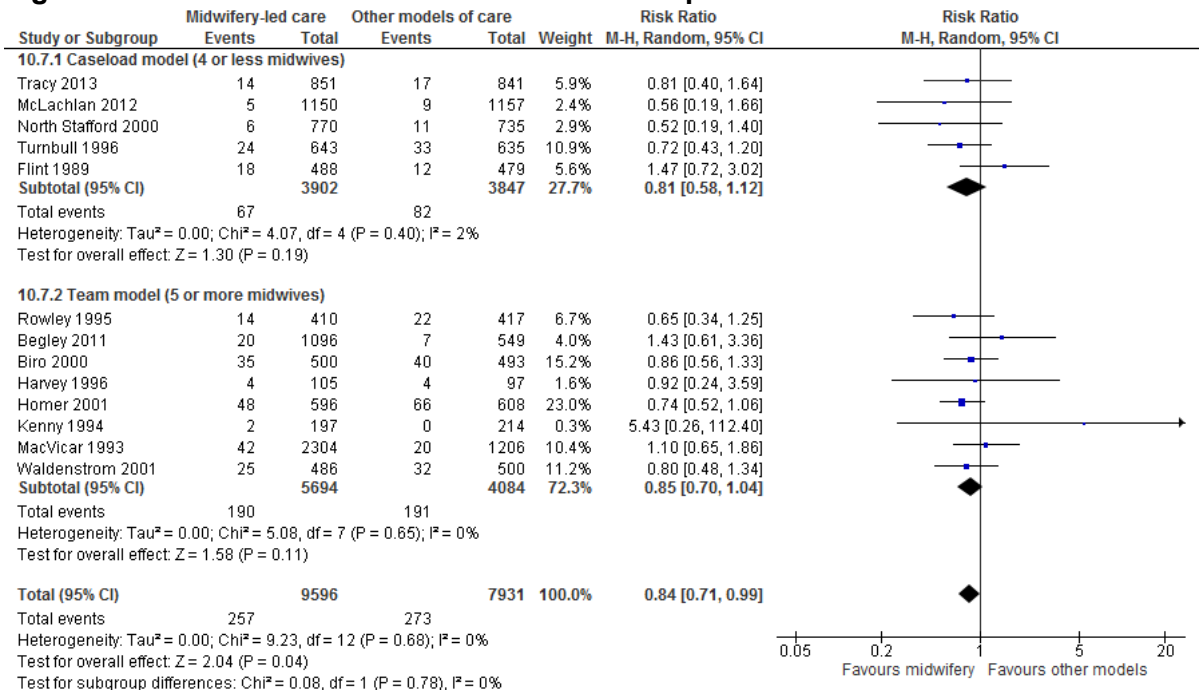


Figure 8: Fetal loss equal to/after 24 weeks and neonatal death

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
10.8.2 Caseload						
Flint 1989	7	503	4	498	10.5%	1.73 [0.51, 5.88]
McLachlan 2012	4	1150	3	1157	7.0%	1.34 [0.30, 5.98]
North Stafford 2000	6	770	11	735	16.0%	0.52 [0.19, 1.40]
Tracy 2013	3	851	3	841	6.2%	0.99 [0.20, 4.88]
Turnbull 1996	4	643	9	635	11.4%	0.44 [0.14, 1.42]
Subtotal (95% CI)		**3917**		**3866**	**51.2%**	**0.79 [0.45, 1.37]**
Total events	24		30			
Heterogeneity: Tau² = 0.00; Chi² = 3.79, df = 4 (P = 0.44); I² = 0%						
Test for overall effect: Z = 0.84 (P = 0.40)						
10.8.3 Team model						
Begley 2011	3	1096	2	549	4.9%	0.75 [0.13, 4.48]
Biro 2000	3	500	4	493	7.1%	0.74 [0.17, 3.29]
Homer 2001	4	596	2	608	5.5%	2.04 [0.38, 11.10]
Kenny 1994	2	197	0	214	1.7%	5.43 [0.26, 112.40]
MacVicar 1993	18	2304	5	1206	16.1%	1.88 [0.70, 5.06]
Rowley 1995	5	410	3	417	7.7%	1.70 [0.41, 7.05]
Waldenstrom 2001	2	486	5	500	5.9%	0.41 [0.08, 2.11]
Subtotal (95% CI)		**5589**		**3987**	**48.8%**	**1.29 [0.73, 2.27]**
Total events	37		21			
Heterogeneity: Tau² = 0.00; Chi² = 4.62, df = 6 (P = 0.59); I² = 0%						
Test for overall effect: Z = 0.87 (P = 0.38)						
Total (95% CI)		**9506**		**7853**	**100.0%**	**1.00 [0.67, 1.49]**
Total events	61		51			
Heterogeneity: Tau² = 0.00; Chi² = 9.87, df = 11 (P = 0.54); I² = 0%						
Test for overall effect: Z = 0.01 (P = 0.99)						
Test for subgroup differences: Chi² = 1.46, df = 1 (P = 0.23), I² = 31.5%						

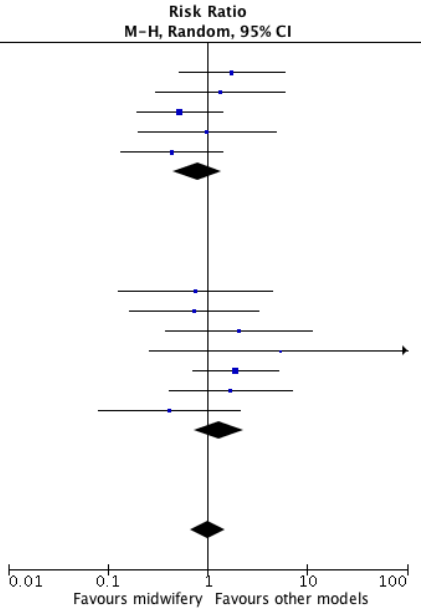


Figure 9: Augmentation / artificial oxytocin during labour

Study or Subgroup	Midwifery-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
10.9.1 Caseload model (4 or less midwives)						
Flint 1989	80	503	114	498	7.5%	0.69 [0.54, 0.90]
North Stafford 2000	351	770	387	735	11.1%	0.87 [0.78, 0.96]
Tracy 2013	215	851	280	841	10.1%	0.76 [0.65, 0.88]
Turnbull 1996	264	643	237	635	10.4%	1.10 [0.96, 1.26]
Subtotal (95% CI)		**2767**		**2709**	**39.2%**	**0.86 [0.71, 1.02]**
Total events	910		1018			
Heterogeneity: Tau² = 0.03; Chi² = 17.38, df = 3 (P = 0.0006); I² = 83%						
Test for overall effect: Z = 1.71 (P = 0.09)						
10.9.2 Team model (5 or more midwives)						
Begley 2011	208	1096	145	549	9.2%	0.72 [0.60, 0.87]
Biro 2000	109	488	139	480	8.5%	0.77 [0.62, 0.96]
Harvey 1996	14	105	19	97	2.6%	0.68 [0.36, 1.28]
Homer 2001	227	593	200	601	10.0%	1.15 [0.99, 1.34]
Kenny 1994	30	194	30	211	4.0%	1.09 [0.68, 1.73]
MacVicar 1993	270	2304	192	1206	9.6%	0.74 [0.62, 0.87]
Rowley 1995	118	405	104	409	8.3%	1.15 [0.91, 1.43]
Waldenstrom 2001	122	484	130	496	8.6%	0.96 [0.78, 1.19]
Subtotal (95% CI)		**5669**		**4049**	**60.8%**	**0.90 [0.76, 1.06]**
Total events	1098		959			
Heterogeneity: Tau² = 0.04; Chi² = 29.11, df = 7 (P = 0.0001); I² = 76%						
Test for overall effect: Z = 1.30 (P = 0.19)						
Total (95% CI)		**8436**		**6758**	**100.0%**	**0.88 [0.78, 0.99]**
Total events	2008		1977			
Heterogeneity: Tau² = 0.03; Chi² = 46.64, df = 11 (P < 0.00001); I² = 76%						
Test for overall effect: Z = 2.19 (P = 0.03)						
Test for subgroup differences: Chi² = 0.14, df = 1 (P = 0.71), I² = 0%						

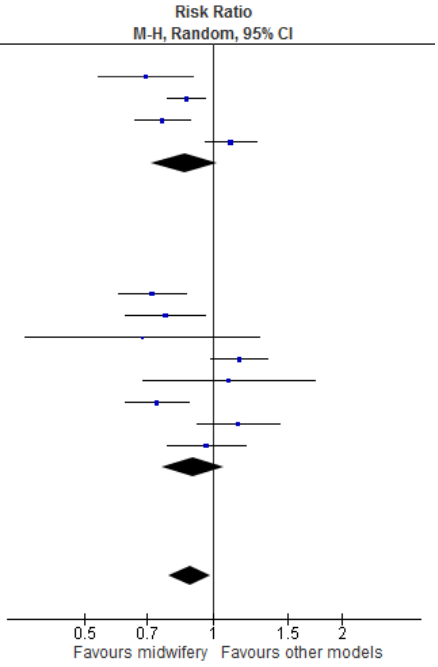


Figure 10: Induction of labour

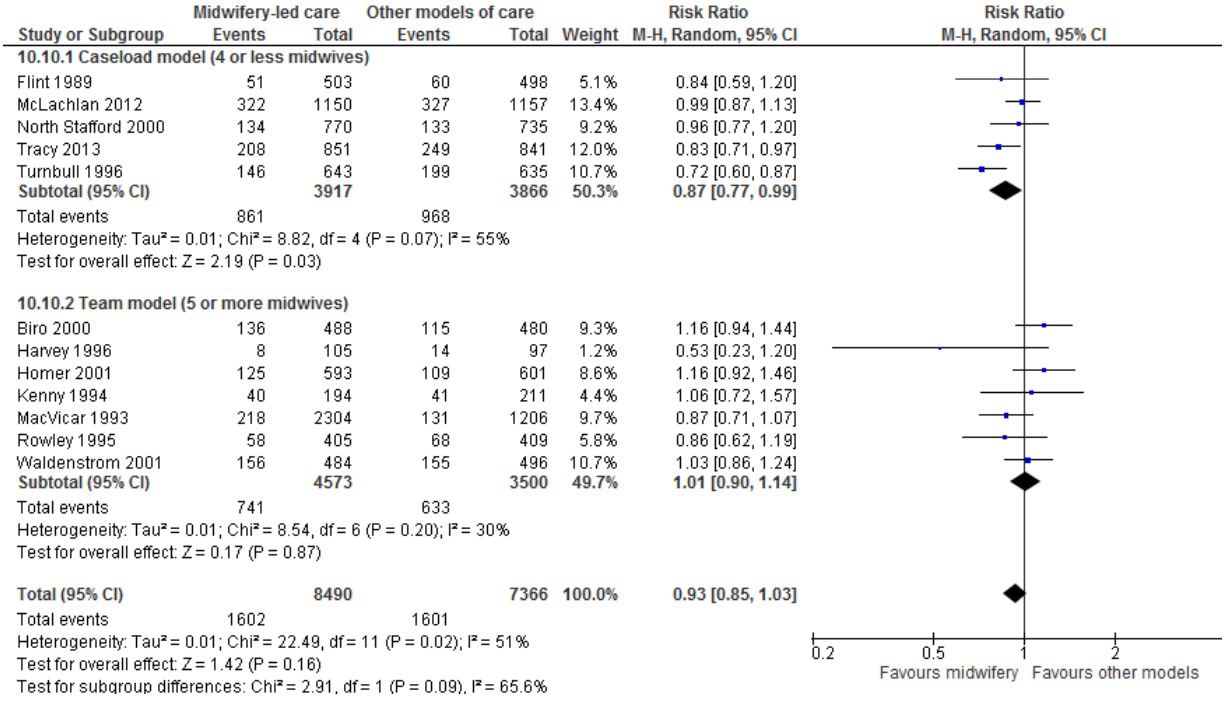
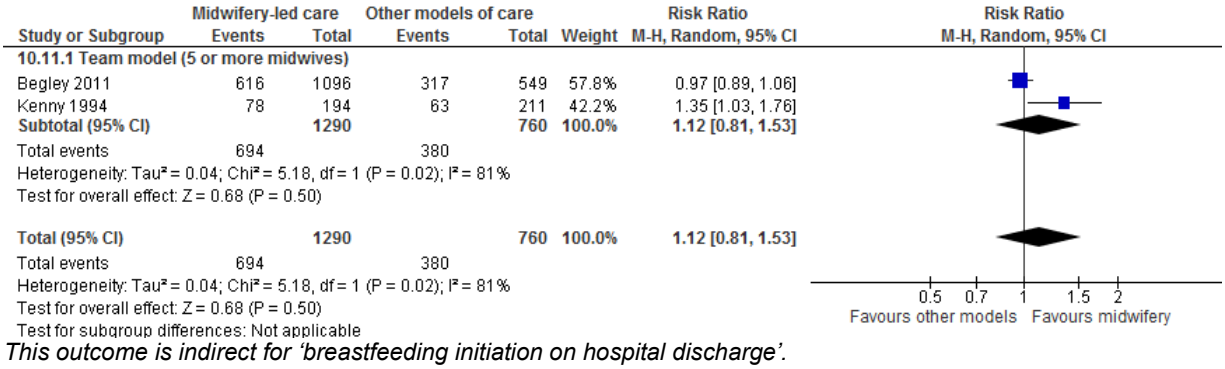
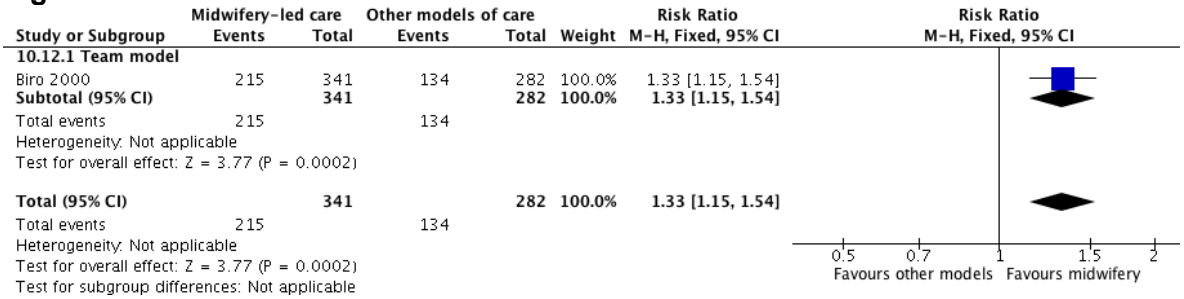


Figure 11: Breastfeeding initiation



This outcome is indirect for 'breastfeeding initiation on hospital discharge'.

Figure 12: Maternal satisfaction



J.1.2 Variation in risk status (low risk / mixed (low and high) risk)

Figure 13: Regional analgesia

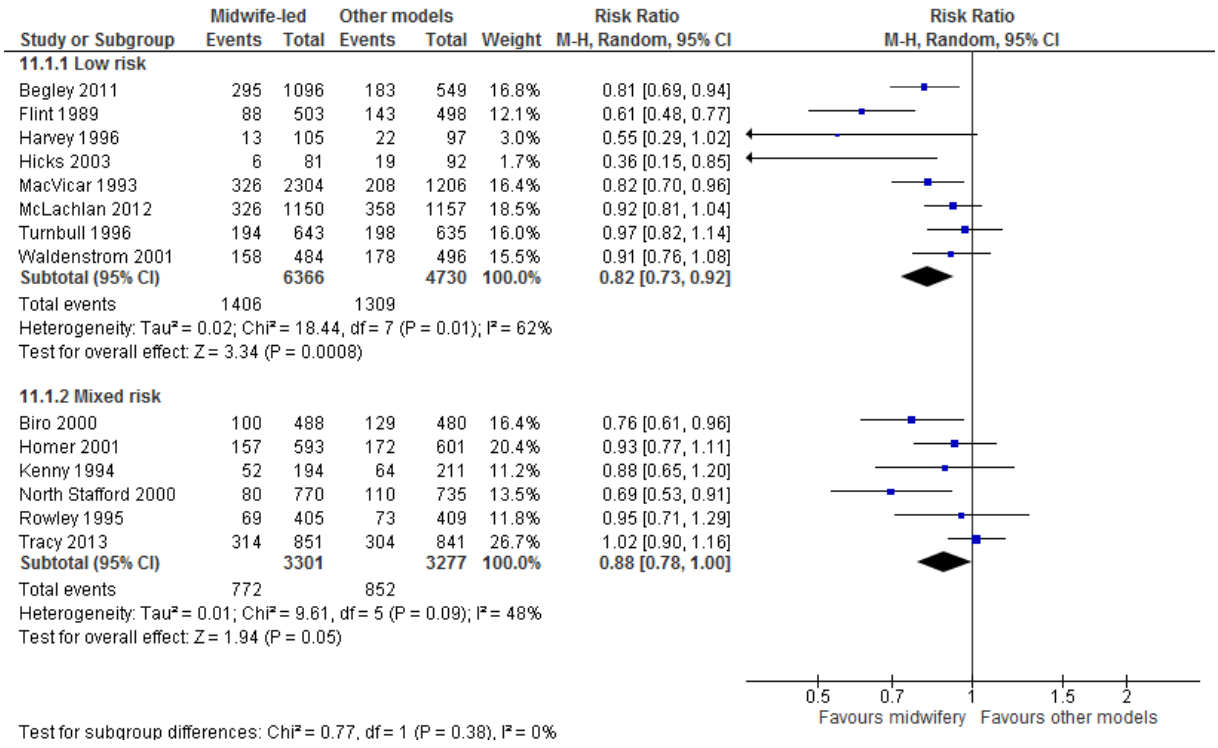


Figure 14: Caesarean birth

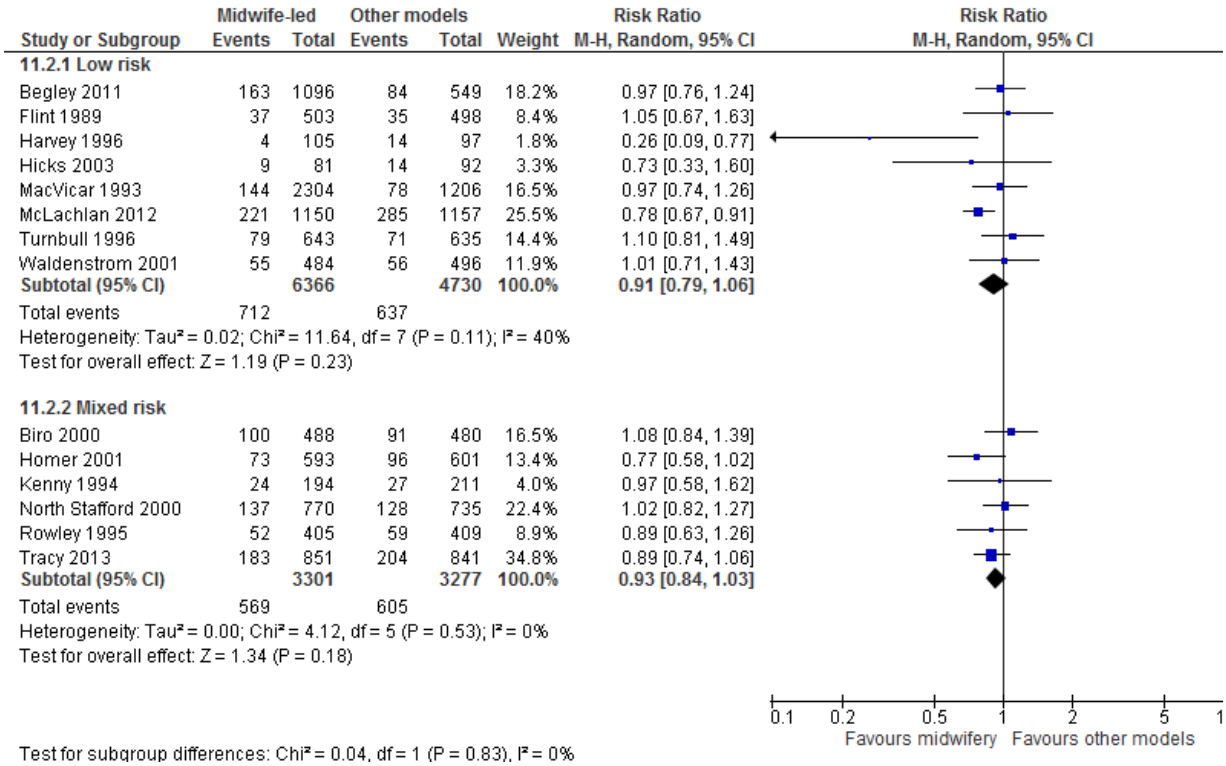


Figure 15: Instrumental vaginal birth (forceps / vacuum)

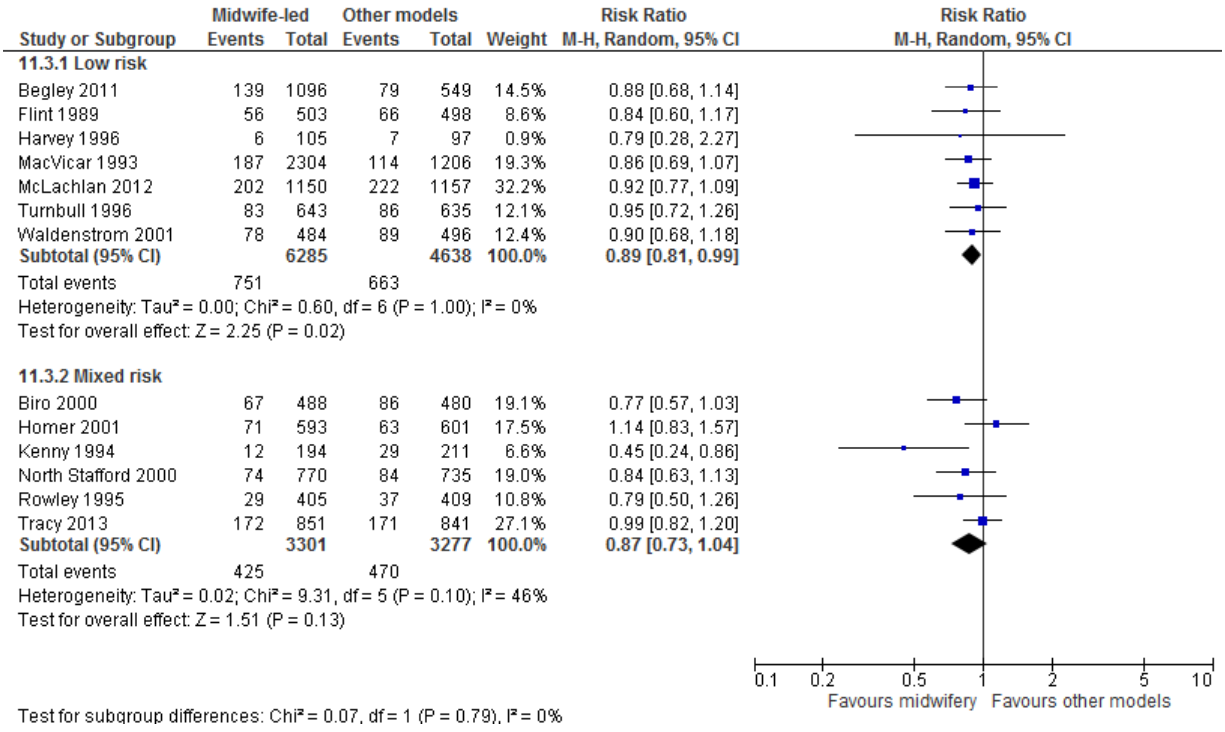


Figure 16: Spontaneous vaginal birth

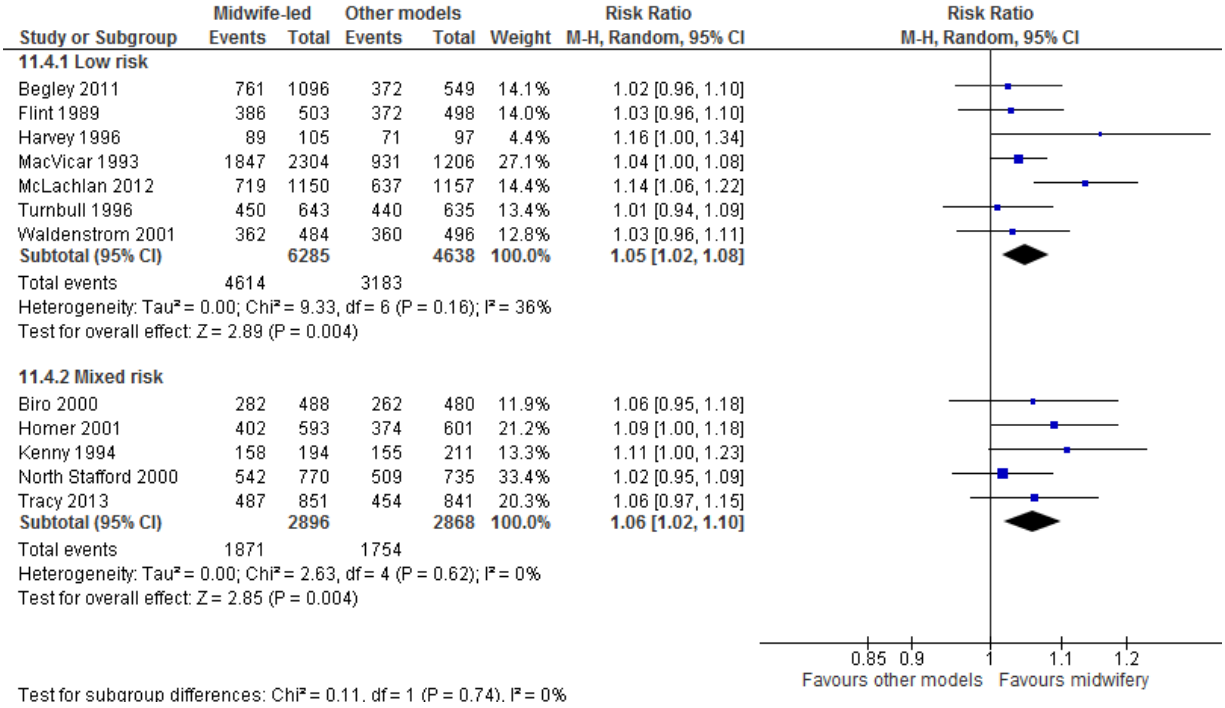


Figure 17: Intact perineum

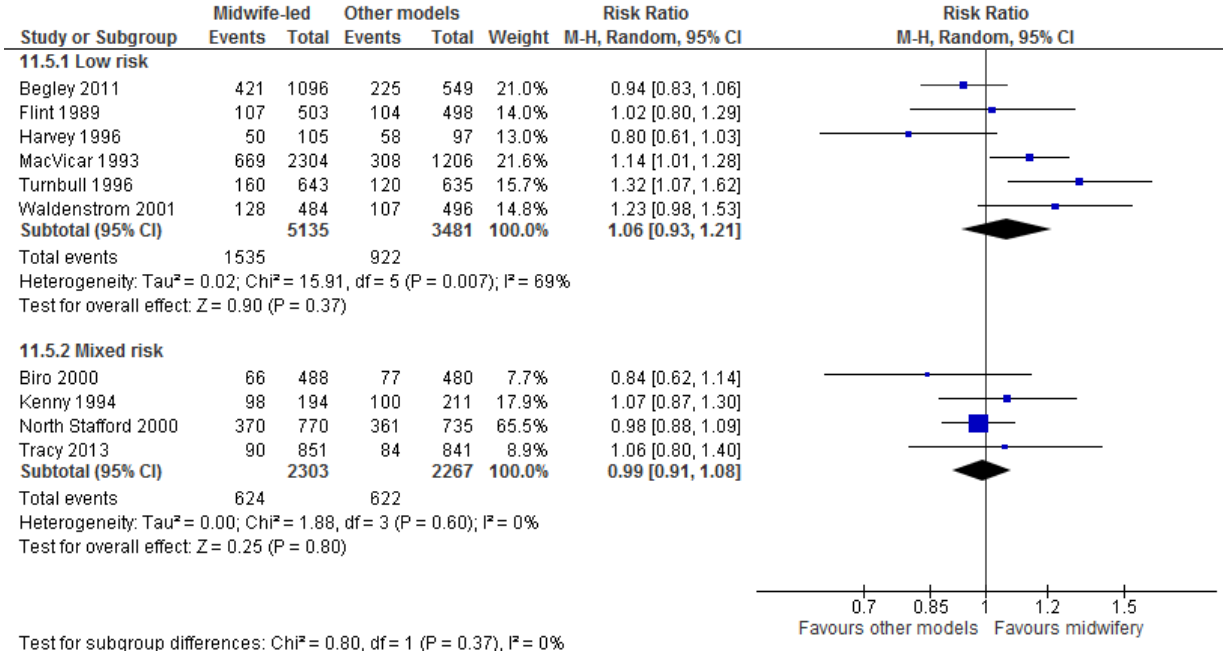


Figure 18: Preterm birth (< 37 weeks)

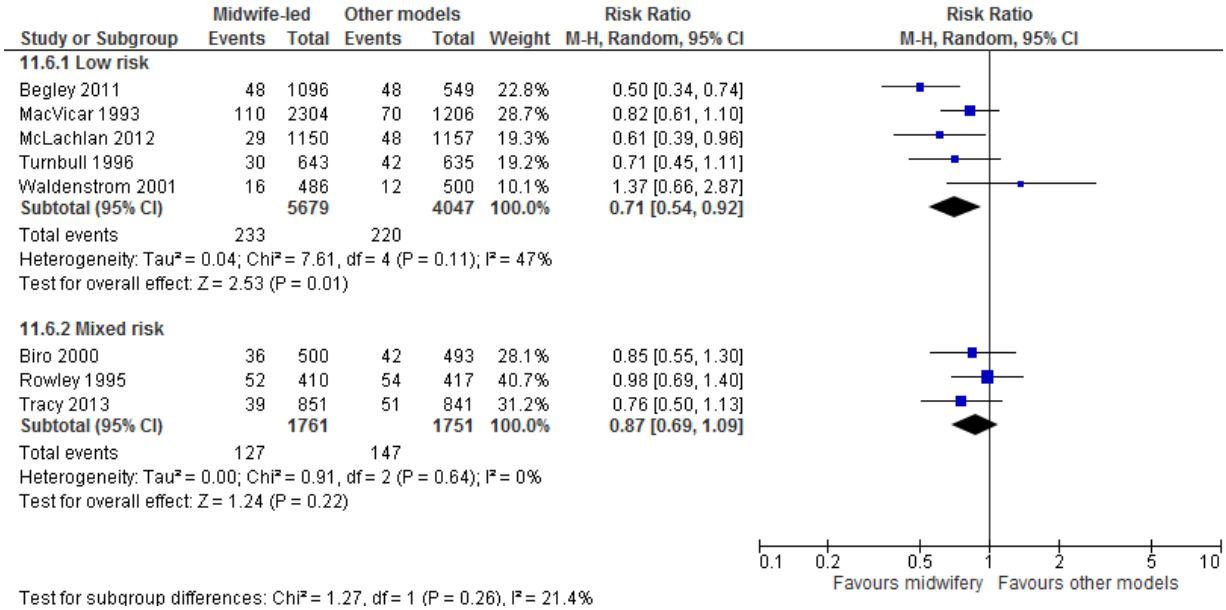
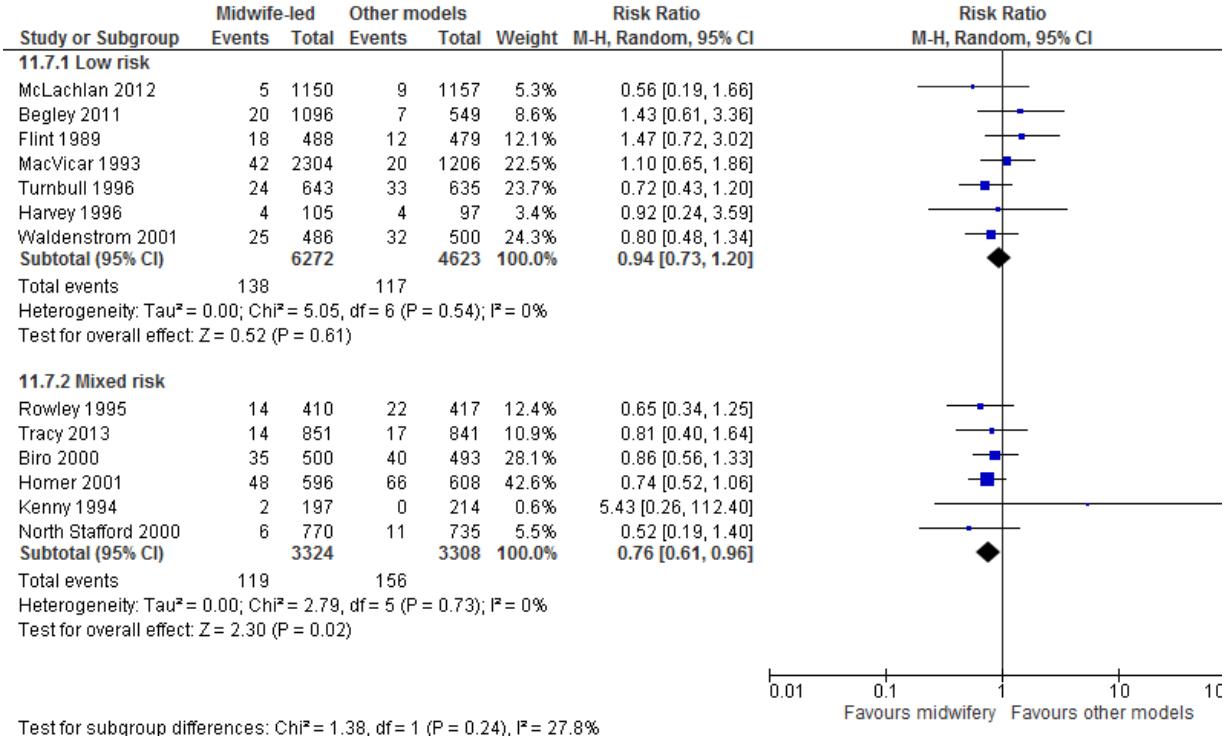
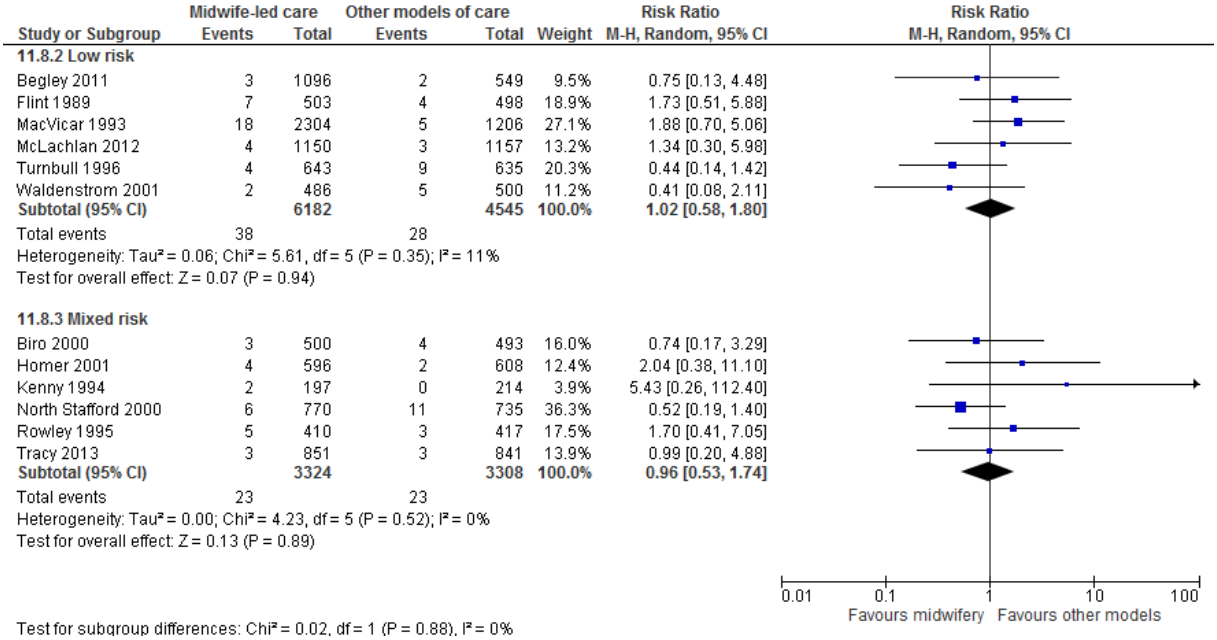


Figure 19: All fetal loss before and after 24 weeks plus neonatal death



Test for subgroup differences: Chi² = 1.38, df = 1 (P = 0.24), I² = 27.8%

Figure 20: Fetal loss equal to/after 24 weeks plus neonatal death



Test for subgroup differences: Chi² = 0.02, df = 1 (P = 0.88), I² = 0%

Figure 21: Augmentation / artificial oxytocin during labour

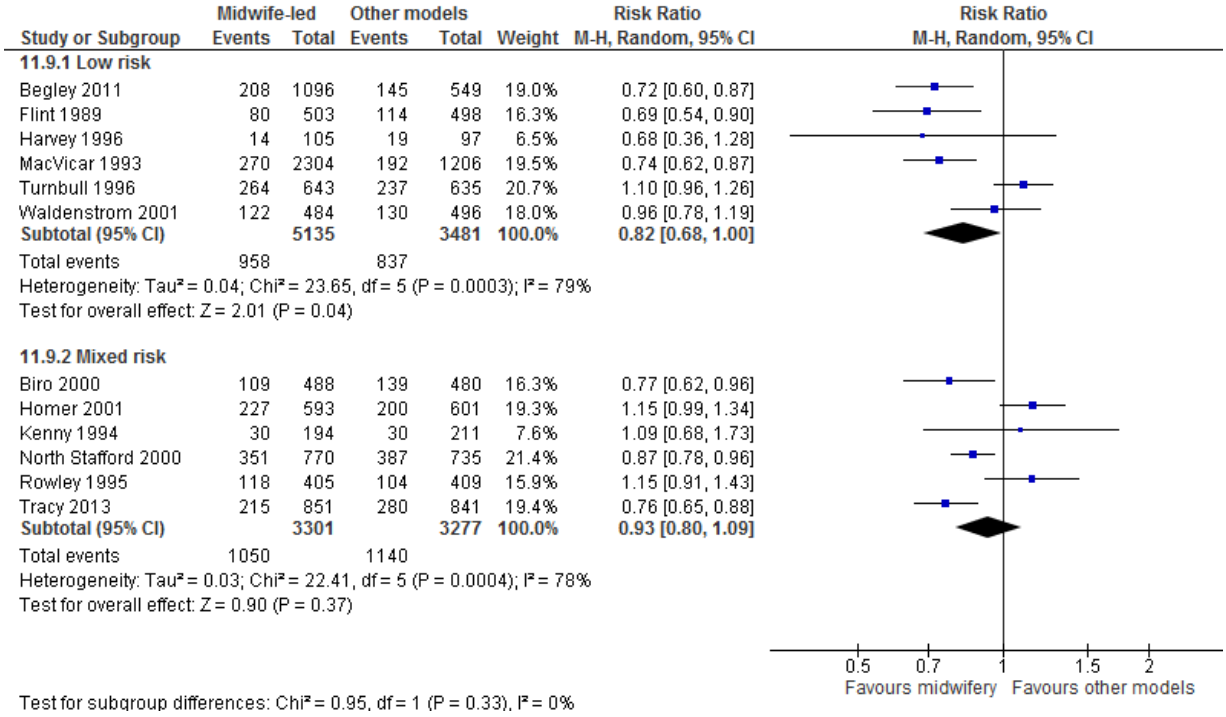


Figure 22: Induction of labour

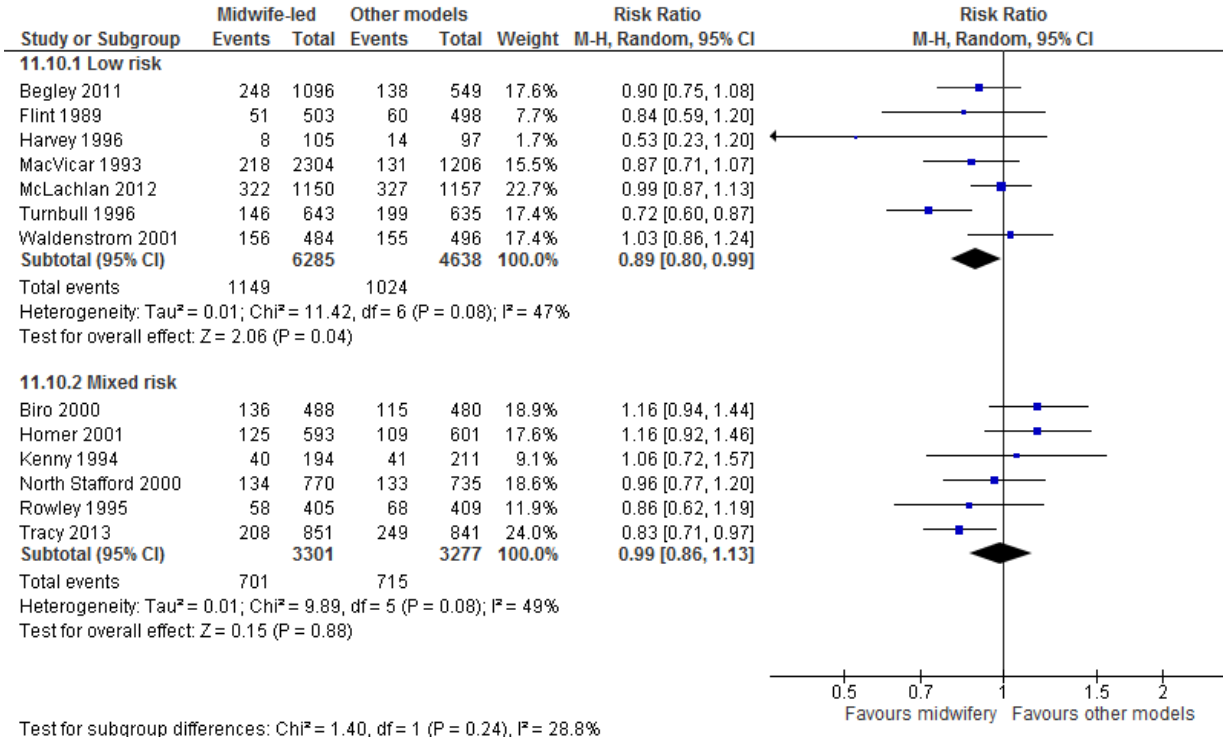
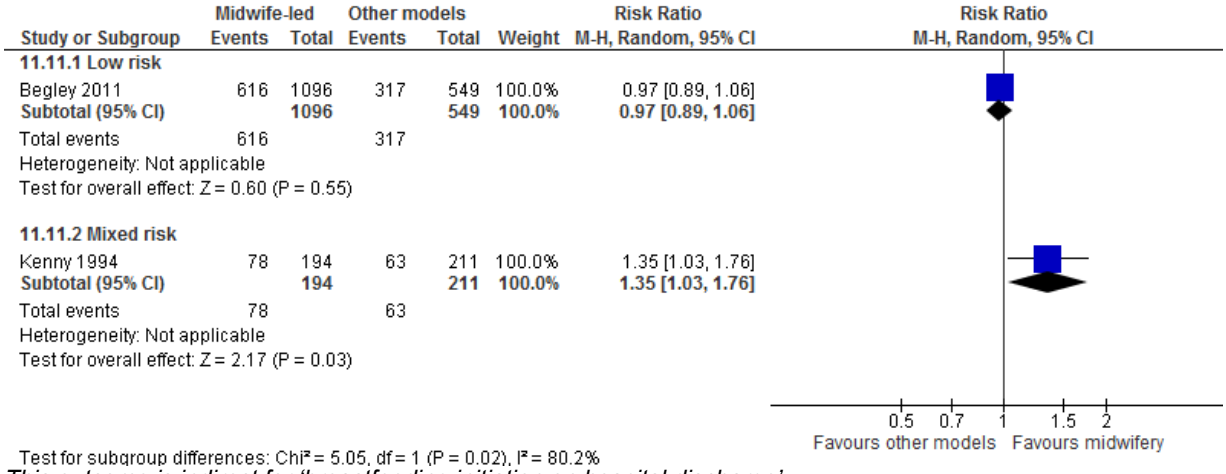
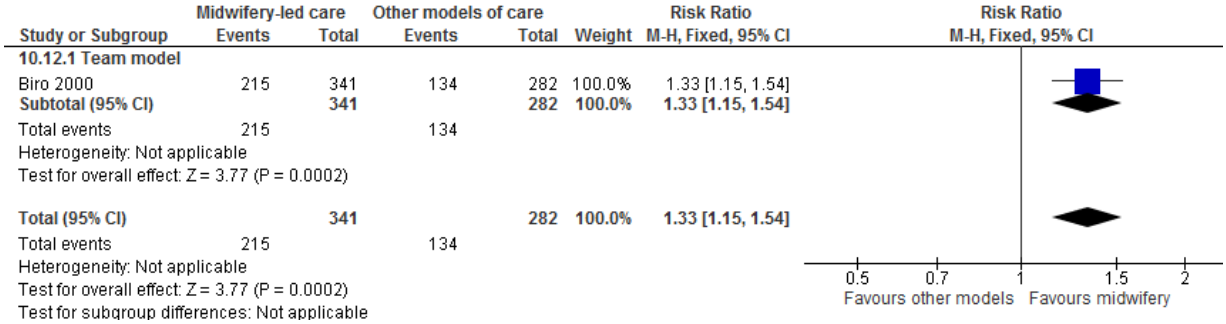


Figure 23: Breastfeeding initiation



This outcome is indirect for 'breastfeeding initiation on hospital discharge'.

Figure 24: Maternal satisfaction



J.1.3 Variation in parity

Figure 25: Regional analgesia

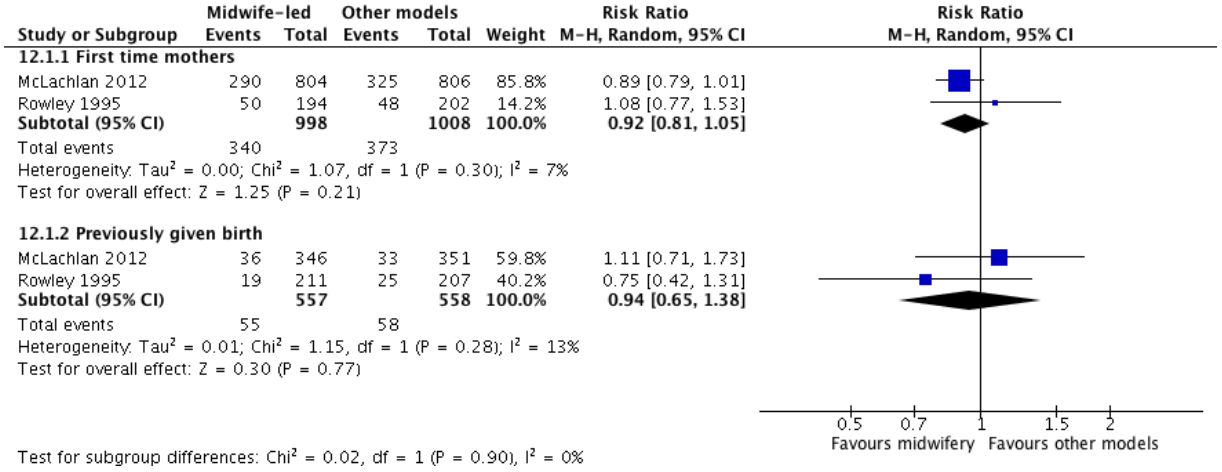


Figure 26: Caesarean birth

Study or Subgroup	Midwife-led Events	Total	Other models Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
12.2.2 First time mothers						
McLachlan 2012	200	804	257	806	100.0%	0.78 [0.67, 0.91]
Subtotal (95% CI)		**804**		**806**	**100.0%**	**0.78 [0.67, 0.91]**
Total events	200		257			
Heterogeneity: Not applicable						
Test for overall effect: Z = 3.10 (P = 0.002)						
12.2.3 Previously given birth						
McLachlan 2012	21	346	28	351	100.0%	0.76 [0.44, 1.31]
Subtotal (95% CI)		**346**		**351**	**100.0%**	**0.76 [0.44, 1.31]**
Total events	21		28			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.98 (P = 0.33)						

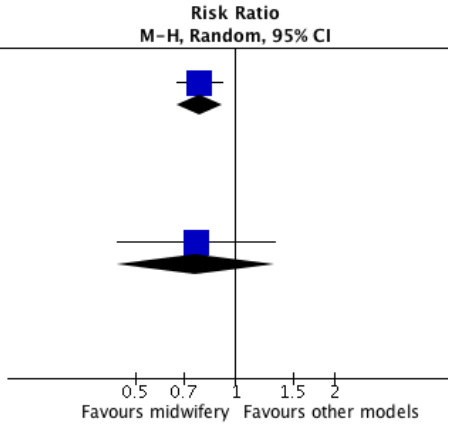


Figure 27: Instrumental vaginal birth

Study or Subgroup	Midwife-led Events	Total	Other models Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
12.3.2 First time mothers						
McLachlan 2012	187	804	207	807	100.0%	0.91 [0.76, 1.08]
Subtotal (95% CI)		**804**		**807**	**100.0%**	**0.91 [0.76, 1.08]**
Total events	187		207			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.12 (P = 0.26)						
12.3.3 Previously given birth						
McLachlan 2012	15	346	15	351	100.0%	1.01 [0.50, 2.04]
Subtotal (95% CI)		**346**		**351**	**100.0%**	**1.01 [0.50, 2.04]**
Total events	15		15			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.04 (P = 0.97)						

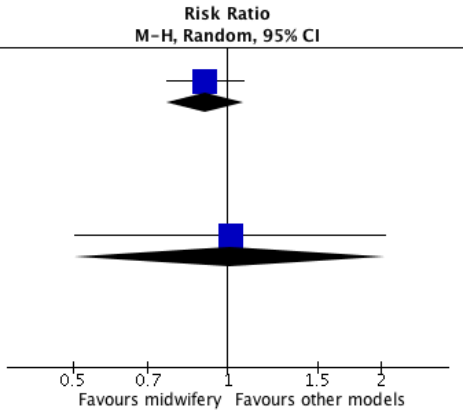


Figure 28: Spontaneous vaginal birth

Study or Subgroup	Midwife-led Events	Total	Other models Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
12.4.2 First time mothers						
McLachlan 2012	415	804	329	806	100.0%	1.26 [1.14, 1.41]
Subtotal (95% CI)		**804**		**806**	**100.0%**	**1.26 [1.14, 1.41]**
Total events	415		329			
Heterogeneity: Not applicable						
Test for overall effect: Z = 4.31 (P < 0.0001)						
12.4.3 Previously given birth						
McLachlan 2012	304	346	308	351	100.0%	1.00 [0.95, 1.06]
Subtotal (95% CI)		**346**		**351**	**100.0%**	**1.00 [0.95, 1.06]**
Total events	304		308			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.05 (P = 0.96)						

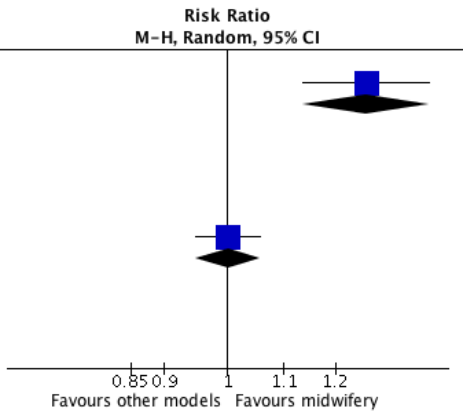


Figure 29: Augmentation / artificial oxytocin during labour

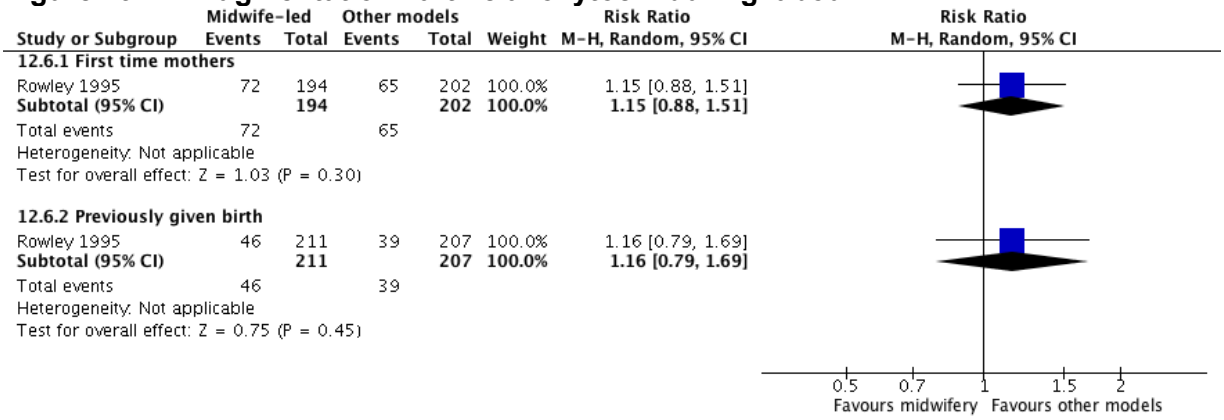
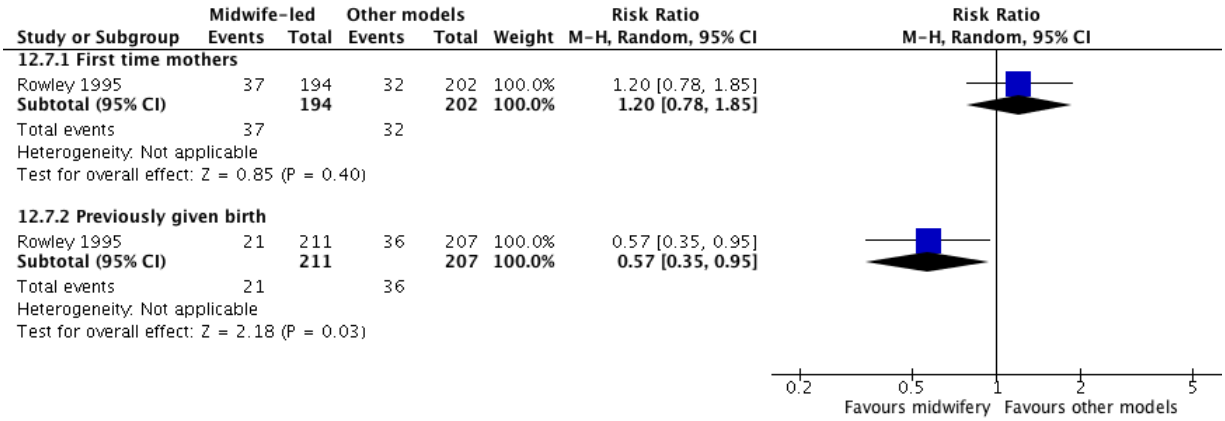


Figure 30: Induction of labour



Appendix K: Economic search strategy

The search was conducted by the Cochrane group. Seven studies were included in the Cochrane review. Data were extracted from these 7 studies by the NICE clinical guidelines update team for this update.

Appendix L:Economic review flowchart

The search was conducted by the Cochrane group. Seven studies were included in the Cochrane review. Data were extracted from these 7 studies by the NICE clinical guidelines update team for this update.

Appendix M: Economic excluded studies

The search was conducted by the Cochrane group. Seven studies were included in the Cochrane review. Data were extracted from these 7 studies by the NICE clinical guidelines update team for this update.

Appendix N: Full economic evidence tables

These are the full evidence tables for all included economic studies.

Table 9: Full economic evidence tables

Bibliographic reference	**Kenny C, Devane D, Normand C et al. (2015) A cost-comparison of midwife-led compared with consultant-led maternity care in Ireland (the MidU study). *Midwifery* 31(11): 1032-8**
Evaluation design	

Interventions	Midwife-led continuity of care (alongside units) Appears to be team midwifery although this is not explicitly stated
Comparators	Consultant-led
Type of Analysis	Within-trial cost analysis
Structure	Not applicable
Cycle length	Not applicable
Time horizon	Perinatal period
Perspective	Public healthcare service
Country	Ireland
Currency unit	€
Cost year	2009
Discounting	Not applicable
Other comments	Nil

Results

Comparison	Midwife-led continuity of care vs. consultant-led care
Incremental cost	-€181.94 (95% CI -33 to -330) (midwife-led cost saving)
Incremental effects	Assumed equivalent effectiveness
Incremental cost effectiveness ratio	Not applicable
Conclusion	“Care in these two midwife-led units costs less than care provided by the consultant-led units.” “The differences in cost stem from the shorter hospital stays for women randomised to the [midwife-led] arm and the lower level of some tests and interventions.”

Bibliographic reference	**Kenny C, Devane D, Normand C et al. (2015) A cost-comparison of midwife-led compared with consultant-led maternity care in Ireland (the MidU study). *Midwifery* 31(11): 1032-8**
	Comments: Capital costs of opening the midwife-led units (not included in cost comparison) range from €39.79 to €53.56 equivalent annual cost per birth
Uncertainty	**One-way sensitivity analysis**: 1 additional midwife visit to mothers in the midwife-led arm: mean cost saving reduced to €170 (95% CI 20-331) **Probabilistic sensitivity analysis**: Distribution of costs taken into account in the confidence interval around the mean difference
Applicability	**Partially Applicable** • Costs in the Irish healthcare system may differ to those in England • Models of care in the Irish healthcare system may differ to those in England
Limitations	**Potentially Serious Limitations** • Time horizon is the perinatal period only and does not capture the cost and health consequences over an extended period of time
Conflicts	None of the authors have any conflict of interest.

Bibliographic reference	**Tracy SK, Hartz DL, Tracy MB et al. (2013) Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial. *Lancet* 382: 1723-32**
Evaluation design	**Interventions**: Named caseload midwife continuity of care **Comparators**: Standard care (shared care with rostered midwives in discrete wards or clinics) **Type of Analysis**: Within-trial cost analysis **Structure**: Not applicable **Cycle length**: Not applicable **Time horizon**: Perinatal period

Bibliographic reference	**Tracy SK, Hartz DL, Tracy MB et al. (2013) Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial. *Lancet* 382: 1723-32**

	Perspective	Healthcare provider
	Country	Australia
	Currency unit	Australian dollars
	Cost year	Not stated
	Discounting	Not applicable
	Other comments	Caseload midwives match their workload to need up to 152 hours over 4 weeks. Each midwife cares for 40 women per year and provides backup care for an additional 40. The key difference between caseload midwifery and the control was that the standard care group did not receive substantial continuity of midwifery carer.
Results		
	Comparison	Caseload midwife-led continuity of care vs. shared care with rostered midwives
	Incremental cost	-AUD$566.74 (95% CI -106.17 to -1,027) (caseload midwifery cost saving)
	Incremental effects	Equivalent effectiveness assumed
	Incremental cost effectiveness ratio	Not applicable
	Conclusion	“Total cost of care per woman was less for caseload midwifery than for standard maternity care.” “Higher proportions of women with spontaneous onset of labour, less use of pharmacological analgesia for labour and fewer women having a postpartum blood loss greater than 500 mL, combined with one fewer antenatal visit and a significant reduction in median length of stay in the postnatal ward by roughly 8 hours for women in the caseload group are the most likely differences to have led to the AUD$566.74 reduction in cost per woman for caseload midwifery.”
Uncertainty		
	One-way sensitivity analysis	Not conducted
	Probabilistic sensitivity analysis	Distribution of costs taken into account in the confidence interval around the mean difference

Bibliographic reference	**Tracy SK, Hartz DL, Tracy MB et al. (2013) Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial. *Lancet* 382: 1723-32**
Applicability	**Partially Applicable** • Costs in the Australian healthcare system may not be generalisable • Models of care in the Australian healthcare system may be different to the UK
Limitations	**Potentially Serious Limitations** • The perinatal time horizon may not sufficiently capture all important health and cost consequences.
Conflicts	The authors had no conflicts of interest.

Bibliographic reference	**Homer CS, Matha DV, Jordan LG, Wills J, Davis GK (2001) Community-based continuity of midwifery care versus standard hospital care: a cost analysis. *Australian Health Review* 24(1): 85-93**
Evaluation design	

Interventions	Community-based midwife-led care (team midwifery with 6 per team)
Comparators	Standard care (hospital-based shared care)
Type of Analysis	Within-trial cost analysis
Structure	Not applicable
Cycle length	Not applicable
Time horizon	Perinatal period
Perspective	Healthcare provider
Country	Australia
Currency unit	Australian dollars
Cost year	Not stated
Discounting	Not applicable
Other comments	25 births per month per midwife team

<table>
<tr><td>Bibliographic reference</td><td>Homer CS, Matha DV, Jordan LG, Wills J, Davis GK (2001) Community-based continuity of midwifery care versus standard hospital care: a cost analysis. Australian Health Review 24(1): 85-93</td></tr>
<tr><td>Results</td><td>
<table>
<tr><td>Comparison</td><td>Continuity of midwife-led care (team) vs. hospital-based shared care</td></tr>
<tr><td>Incremental cost</td><td>AUD$904 per woman (confidence interval not provided)</td></tr>
<tr><td>Incremental effects</td><td>Equivalent effectiveness assumed</td></tr>
<tr><td>Incremental cost effectiveness ratio</td><td>Not applicable</td></tr>
<tr><td>Conclusion</td><td>“Results indicate that the STOMP model resulted in a cost saving.”</td></tr>
<tr><td>Comments</td><td>Initial setup costs of AUD$9,130 for the midwife-led clinics not included in the cost comparison.</td></tr>
</table>
</td></tr>
<tr><td>Uncertainty</td><td>
<table>
<tr><td>One-way sensitivity analysis</td><td>• Excluding costs associated with neonate special care nursery: reduced savings to AUD$139
• Excluding costs associated with neonate special care nursery and reducing the number of women seen in the midwife-led clinical to 10 per week from 60: midwife-led model cost more than the shared-care model
• Excluding the costs associated with neonate special care nursery and increasing the caesarean section rate in the midwife-led model to 20% while maintaining the rate of caesarean section at 17% for the shared-care model: models have similar cost</td></tr>
<tr><td>Probabilistic sensitivity analysis</td><td>Not conducted</td></tr>
</table>
</td></tr>
<tr><td>Applicability</td><td>Partially Applicable

• Costs in the Australian healthcare system may not be generalisable
• Models of care in the Australian healthcare system may be different to the UK</td></tr>
<tr><td>Limitations</td><td>Potentially Serious Limitations

• The perinatal time horizon may not sufficiently capture all important health and cost consequences</td></tr>
<tr><td>Conflicts</td><td>Research grants provided by government departments</td></tr>
</table>

Bibliographic reference	**Young D, Lees A, Twaddle S (1997) The costs to the NHS of maternity care: midwife-managed vs. shared. *British Journal of Midwifery*, 5(8): 465-472**

Evaluation design

Interventions	Midwife-led continuity care (caseload with named midwife)
Comparators	Shared care
Type of Analysis	Within-trial cost analysis
Structure	Not applicable
Cycle length	Not applicable
Time horizon	Perinatal period
Perspective	NHS
Country	Scotland
Currency unit	£
Cost year	Not stated
Discounting	Not applicable
Other comments	Caseload of 29 women per midwife as base case

Results

Comparison	Caseload midwife-led continuity of care vs. shared care
Incremental cost	Antenatal: no significant difference Intrapartum: no significant difference Postpartum: +£118.81 (p<0.001) (midwife-led care more expensive)
Incremental effects	Not included
Incremental cost effectiveness ratio	Not applicable
Conclusion	"In the postnatal period, service providers would ultimately need to consider whether the increased costs of midwife-managed care were worth the enhanced levels of women's satisfaction measured in the randomised controlled trials."

Uncertainty

One-way sensitivity analysis	• Caseload increased to 39 women per midwife: ○ Antenatal: -£20.97 (midwife-led cost saving) ○ Intrapartum: no difference ○ Postpartum: +£52.14 (midwife-led care more expensive)

Bibliographic reference	**Young D, Lees A, Twaddle S (1997) The costs to the NHS of maternity care: midwife-managed vs. shared. *British Journal of Midwifery*, 5(8): 465-472**
	Probabilistic sensitivity analysis: Not conducted
Applicability	**Partially Applicable** • Costs in the Scottish healthcare system may not be generalisable • Models of care in the Scottish healthcare system may be different to the UK
Limitations	**Potentially Serious Limitations** • The perinatal time horizon may not sufficiently capture all important health and cost consequences
Conflicts	Research grants provided by government departments No declarations provided

Bibliographic reference	**Rowley MJ, Hensley MJ, Brinsmead MW, Wlodarczyk JH (1995) Continuity of care by a midwife team versus routine care during pregnancy and birth: a randomised trial. *The Medical Journal of Australia*, 163:289-293**
Evaluation design	

Interventions	Team midwife-led continuity of care
Comparators	Shared care
Type of Analysis	Within-trial cost analysis
Structure	Not applicable
Cycle length	Not applicable
Time horizon	Perinatal period
Perspective	Healthcare provider
Country	Australia
Currency unit	Australian dollars
Cost year	Not stated
Discounting	Not applicable

Bibliographic reference	**Rowley MJ, Hensley MJ, Brinsmead MW, Wlodarczyk JH (1995) Continuity of care by a midwife team versus routine care during pregnancy and birth: a randomised trial. *The Medical Journal of Australia*, 163:289-293**
	Other comments |
Results	

Comparison	Team midwife-led care vs. shared care
Incremental cost	-AUD$151 (midwife-led cost saving)
Incremental effects	Equivalent effectiveness assumed
Incremental cost effectiveness ratio	Not applicable
Conclusion	"The team approach (which provided continuity of midwifery care) is as effective as routine care and was associated with improved satisfaction and a reduction in costs per woman."

Uncertainty

One-way sensitivity analysis	Not conducted
Probabilistic sensitivity analysis	Not conducted

Applicability

Partially Applicable

- Costs in the Australian healthcare system may not be generalisable
- Models of care in the Australian healthcare system may be different to the UK

Limitations

Potentially Serious Limitations

- The perinatal time horizon may not sufficiently capture all important health and cost consequences

Conflicts

No declaration, government grants provided

Bibliographic reference	**Kenny P, Brodie P, Eckermann S, Hall J (1994) *Final report, Westmead Hospital Team Midwifery Project Evaluation*. Centre for Health Economics Research and Evaluation**

Evaluation design

Interventions	Team midwifery
Comparators	Usual care
Type of Analysis	Within-trial cost analysis
Structure	Not applicable
Cycle length	Not applicable
Time horizon	Perinatal period
Perspective	Healthcare provider
Country	Australia
Currency unit	Australian dollars
Cost year	Not stated
Discounting	Not applicable
Other comments	Nil

Results

Comparison	Team midwifery vs. shared care
Incremental cost	-AUD$98
Incremental effects	Equivalent effectiveness
Incremental cost effectiveness ratio	Not applicable
Conclusion	“Antenatal costs are similar for both forms of care. [Team midwifery] clients had a lower rate of manipulative delivery and slightly lower cost of intrapartal care overall. The costs of postnatal care were slightly less for the team midwifery group.”

Uncertainty

One-way sensitivity analysis	Not conducted
Probabilistic sensitivity analysis	Not conducted

Bibliographic reference	**Kenny P, Brodie P, Eckermann S, Hall J (1994) *Final report, Westmead Hospital Team Midwifery Project Evaluation*. Centre for Health Economics Research and Evaluation**
Applicability	**Partially Applicable** • Costs in the Australian healthcare system may not be generalisable • Models of care in the Australian healthcare system may be different to the UK
Limitations	**Potentially Serious Limitations** • The perinatal time horizon may not sufficiently capture all important health and cost consequences
Conflicts	No declaration, government grants provided

Could not obtain Flint & Poulengeris 1987, The 'Know Your Midwife' Report. Narrative summary taken from Cochrane review and provided in section 2.4.2.

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