NCC-WCH

Version 1

Diabetes in Pregnancy (update) Appendices – Set 1

Document Sub Title

Clinical Guideline <…>

Appendices set 1

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Draft for Consultation

Commissioned 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/or their guardian or carer.

Funding
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Contents

Appendices

Appendix A: Scope

A.1 Guideline title

Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period

A.1.1 Short title

Diabetes in pregnancy

A.2 The remit

This is an update of Diabetes in pregnancy (NICE clinical guideline 63). See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation. This update is being undertaken as part of the guideline review cycle.

This is the scope for 1 of 4 NICE clinical guidelines being developed that address diabetes care. Included below is a summary of the content for each guideline and of the NICE steering committee.

Guideline 1 – Diabetes in children and young people (developed by the National Collaborating Centre for Women's and Children's Health)

This guideline will update Type 1 diabetes in children, young people and adults (NICE clinical guideline 15) It will cover the diagnosis and management of type 1 and type 2 diabetes in children and young people (younger than 18 years). It will include: structured education programmes, behavioural interventions to improve adherence, glucose monitoring strategies, ketone monitoring, insulin regimens for type 1 diabetes and metformin monotherapy for type 2 diabetes.

Guideline 2 – Diabetes in pregnancy (developed by the National Collaborating Centre for Women's and Children's Health)

This guideline will update Diabetes in pregnancy (NICE clinical guideline 63). It will cover women of reproductive age who have pre-existing diabetes or who develop diabetes during pregnancy and it will also cover their newborn babies. It will include: target glucose ranges in the preconception period and during pregnancy, glucose monitoring strategies during pregnancy, screening, diagnosis and treatment of gestational diabetes, and postnatal testing for type 2 diabetes.

Guideline 3 – Type 1 diabetes in adults (developed by the National Clinical Guideline Centre)

This guideline will update Type 1 diabetes in children, young people and adults (NICE clinical guideline 15). It will cover adults (18 years or older) with type 1 diabetes. It will include: tests to differentiate type 1 diabetes from type 2 diabetes, structured education programmes, clinical monitoring of glucose control, insulin regimens, ketone monitoring, dietary advice on carbohydrate counting and glycaemic index, and treatment and monitoring of specific complications.

Guideline 4 –Type 2 diabetes in adults (developed by the Internal Clinical Guidelines Programme, Centre for Clinical Practice, NICE)

This guideline will update Type 2 diabetes (NICE clinical guideline 66) and Type 2 diabetes: newer agents (NICE clinical guideline 87). It will cover adults (18 years or older) with type 2 diabetes. It will include: pharmacological management of blood glucose levels, target values for blood glucose control, self-monitoring of blood glucose levels for blood glucose control, antithrombotic therapy and drug therapy for erectile dysfunction.

NICE steering committee

NICE has set up a steering committee to oversee the production of these clinical guidelines. The group, which includes the Guideline Groups' chairs, together with staff from the 3 guidance-producing centres and NICE, will identify and act on any gaps or overlaps across the different guidance topics to ensure that the final guidelines are complementary and consistent. It is intended that the guidance-producing centres will share systematic reviews and cross-refer to recommendations in the other guidelines where appropriate. This update is being undertaken as part of the guideline review cycle.

A.3 Clinical need for the guideline

A.3.1 Epidemiology

a) Diabetes is a disorder of carbohydrate metabolism that requires immediate changes in lifestyle. People who have diabetes for many years can develop long-term microvascular complications, including retinopathy, nephropathy and neuropathy as well as macrovascular complications of cardiovascular disease.

b) Diabetes that complicates pregnancy is becoming more common worldwide. Up to 5% of the approximately 700,000 women who give birth in England and Wales each year have pre-existing or gestational diabetes.

c) Less than 1% of pregnant women have pre-existing diabetes. Within this 1%, around 75% have type 1 diabetes, 25% have type 2 diabetes and a small number have secondary diabetes (for example, cystic fibrosis-related or monogenic diabetes). The proportion of women with type 1 or type 2 diabetes varies depending on the ethnic origins of the population. The duration of diabetes before conception also varies but is increasing because the average age of onset of type 1 diabetes is declining and more women are developing type 2 diabetes at an earlier age. This is important because duration of diabetes is one of the strongest factors associated with microvascular complications and it is, therefore, more likely that women with diabetes will enter pregnancy with established retinopathy, nephropathy and neuropathy.

d) In the UK, at least 4% of women have gestational diabetes but this figure will vary greatly depending on the local population. The incidence of gestational diabetes is increasing due to higher rates of obesity in the general population and more pregnancies in older women. Most of the risks of gestational diabetes occur in the second half of pregnancy because the majority of women affected are normoglycaemic at the time of conception.

e) Gestational diabetes is defined as any degree of glucose intolerance that is detected for the first time during pregnancy. This includes women whose glucose intolerance resolves after pregnancy and up to 20% whose glucose intolerance persists, including women who had undiagnosed pre-existing type 2 diabetes (or in small numbers, type 1 diabetes) before pregnancy. Women with gestational diabetes are at increased risk of developing type 2 diabetes in the future.

f) Maternal risks of pre-existing diabetes include recurrent hypoglycaemia, progression of retinopathy, nephropathy, increased incidence of pre-eclampsia (especially in women with microvascular disease) and operative delivery.

g) Fetal risks of pre-existing maternal diabetes include structural congenital abnormality, pathological fetal growth (macrosomia) and 'unexplained' fetal death. Neonatal complications include premature delivery, respiratory distress syndrome, transient tachypnoea, birth trauma, hypoglycaemia, hypomagnesaemia, hypocalcaemia, polycythaemia and neonatal death.

A.3.2 Current practice

a) The additional care of women with diabetes in pregnancy, as set out in Diabetes in pregnancy (NICE clinical guideline 63), can be considered according to the stage of the pregnancy.

b) Preconception care aims to enable women with established diabetes to have a positive experience of pregnancy and childbirth and to minimise the risk of structural abnormalities in the baby. It includes information-giving and education, and emphasises the importance of planning pregnancy; offering assessment for, and management of, diabetes complications; improving blood glucose control; high-dose folic acid supplementation and changing potentially teratogenic medications are also important components of this stage of care.

c) Identification of gestational diabetes is a routine element of antenatal care for all women, as set out in Antenatal care (NICE clinical guideline 62). A risk factor based screening approach is recommended to identify women with gestational diabetes in a healthy population.

d) Antenatal care of women with diabetes follows a multidisciplinary approach characterised by an increased schedule of appointments. Care includes:

- regular blood glucose testing (fasting or preprandial, and 1-hour postprandial)
- treating diabetes with diet, insulin and/or oral hypoglycaemic drugs to maintain blood glucose profiles in the normal range
- use of concentrated glucose solutions or glucagon to treat hypoglycaemic episodes
- vigilance for diabetic ketoacidosis
- regular ophthalmic review and, if necessary, specialist referral
- review of renal function and, if necessary, specialist referral
- vigilance for pre-eclampsia.

e) Antenatal care for the baby includes offering screening for fetal abnormality and monitoring fetal growth and wellbeing. In special cases, monitoring may need to be individualised.

f) Care during labour includes offering elective birth after 38 completed weeks of pregnancy, maintaining blood glucose levels in the normal range and continuous electronic fetal heart rate monitoring.

g) Postnatal care for women with diabetes includes:

- resuming pre-pregnancy diabetes treatment in women with pre-existing diabetes
- stopping all diabetic treatment initiated during pregnancy in women with gestational diabetes and monitoring their blood glucose levels to confirm euglycaemia
- monitoring women with gestational diabetes who have persistently high blood glucose levels after birth to detect type 2 diabetes
- offering advice about the importance of contraception.

h) Additional postnatal and neonatal care for women and their babies includes encouraging breastfeeding and vigilance to prevent neonatal hypoglycaemia.

i) Since the publication of Diabetes in pregnancy (NICE clinical guideline 63), new evidence has been published on levels of hyperglycaemia in pregnancy. The blood glucose level at which intervention becomes cost effective and the importance that should be given to different outcomes remain issues for debate.

j) Consideration is also being given to early screening in pregnancy to identify and treat women with gestational diabetes who may have undiagnosed pre-existing diabetes and be unaware of the risks associated with diabetes in pregnancy.

k) New evidence has also been identified that may alter recommendations on:

- target ranges for preconception care
- continuous glucose monitoring
- the appropriate test to undertake at the postnatal check-up to diagnose type 2 diabetes in women who had gestational diabetes in pregnancy but who are euglycaemic on discharge to community care.

A.4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

A.4.1 Population

A.4.1.1 Groups that will be covered

For the topic of screening for gestational diabetes:

a) All pregnant women who do not have previously diagnosed non-gestational diabetes (new 2012).

For all other topics:

b) Women of reproductive age who have pre-existing diabetes or who develop diabetes during pregnancy, and their newborn babies.

c) Where the evidence supports it, the following subgroups will be given special consideration:

- Women of reproductive age with type 1 or type 2 diabetes.
- Women with gestational diabetes or a history of gestational diabetes.
- Young women of reproductive age with diabetes whose care has not yet transferred from paediatric to adult services
- Women with an ethnicity associated with a high prevalence of diabetes.

A.4.1.2 Groups that will not be covered

For the topic of screening for gestational diabetes:

a) Women of reproductive age who are not pregnant (new 2012).

b) Women who have previously diagnosed type 1 or type 2 diabetes (new 2012).

For all other topics:

c) Women of reproductive age who do not have diabetes.

A.4.2 Healthcare setting

a) All healthcare settings in which NHS care is received or commissioned.

A.4.3 Clinical management

A.4.3.1 Key clinical issues that will be covered

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

Areas from the original guideline that will be updated

a) Target ranges for haemoglobin A_{1c} (HbA_{1c}) and blood glucose for women with type 1 or type 2 diabetes who are planning pregnancy and for women with type 1, type 2 or gestational diabetes during pregnancy.

b) The effectiveness of blood ketone monitoring when compared with urine ketone monitoring in women with type 1 or type 2 diabetes who are planning pregnancy and in women with type 1, type 2 or gestational diabetes during pregnancy.

c) The effectiveness of the following screening procedures to detect gestational diabetes between 24–28 weeks:

- risk factor based screening
- urine testing for glycosuria
- random blood glucose test
- 50 g oral glucose challenge test
- fasting blood glucose test
- HbA_{1c} test.

d) The criteria that should be used to diagnose gestational diabetes using the 75 g oral glucose tolerance test (OGTT). There are two options:

- World Health Organization (WHO)
- International Association of Diabetes and Pregnancy Study Groups (IADPSG).

e) The effectiveness of the following interventions (alone or in combination) in women with gestational diabetes:

- non-pharmacological interventions (diet and/or exercise)
- pharmacological interventions (metformin, glibenclamide and insulin).

g) The effectiveness of specialist teams for pregnant women with diabetes.

h) The gestational age specific risk of intrauterine death in pregnancies with type 1, type 2 or gestational diabetes and the optimal timing of birth.

i) The effectiveness of the following tests in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care):

- fasting plasma glucose test
- HbA_{1c} test
- 75 g OGTT.

j) The optimal timing of postnatal testing for the detection of glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care).

Areas not in the original guideline that will be included in the update

k) The effectiveness of oral hormonal contraceptives in women with diabetes compared with women without diabetes.

l) The effectiveness of the following screening procedures to detect glucose intolerance in the first trimester:

- risk factor based screening
- urine test for glycosuria
- random blood glucose test
- 50 g oral glucose challenge test
- fasting blood glucose test
- HbA_{1c} test.

A.4.3.2 Clinical issues that will not be covered

Areas from the original guideline that will not be updated

The following areas addressed in Diabetes in pregnancy (NICE clinical guideline 63) will not be updated (the existing recommendations will remain as current guidance):

a) All aspects of preconception care, gestational diabetes, antenatal care, intrapartum care, postnatal care that are not listed in section 4.3.1.

b) Neonatal care.

Areas not covered by the original guideline or the update

c) Aspects of routine antenatal, intrapartum and postnatal care that apply equally to women with or without diabetes.

d) Aspects of routine care for women with diabetes that do not change during the preconception, antenatal, intrapartum and postnatal periods.

e) Investigation, management and treatment of comorbidities, for example fertility problems or pre-eclampsia.

f) Management of morbidity in newborn babies of women with diabetes beyond initial assessment and diagnosis.

A.4.4 Main outcomes

Outcomes will vary by the type of clinical question and systematic review undertaken. No more than seven outcomes will normally be prioritised for each topic.

a) Diagnostic accuracy:

- sensitivity and specificity.

b) Quality of life:

- health-related quality of life (validated questionnaire) – for example, diabetes-specific health-related quality of life.

c) Neonatal outcomes:

- admission to a neonatal intensive care unit, special care baby unit, or transitional care unit
- miscarriage, stillbirth (fetal death), neonatal or infant death
- macrosomia, large for gestational age, small for gestational age and intrauterine growth restriction
- neonatal hypoglycaemia requiring active management
- respiratory distress
- shoulder dystocia and birth trauma (bone fracture or nerve palsy)
- other neonatal complications (jaundice, polycythaemia, sepsis, hypocalcaemia or hypoxic ischaemic encephalopathy)
- congenital abnormality.

d) Maternal outcomes:

- maternal death
- perineal trauma
- preterm birth
- mode of birth (spontaneous vaginal, instrumental, or caesarean section)
- mode of infant feeding
- diabetic complications (hypoglycaemia, diabetic ketoacidosis, retinopathy, nephropathy, or macrovascular disease)
- antenatal and intrapartum complications in the unborn baby
- development of type 2 diabetes
- obstetric complications (haemorrhage, infection, thrombosis, admission to critical care, or incontinence)
- diabetes control (HbA_{1c}, fructosamine or mean glucose)
- postnatal mental health
- maternal satisfaction.

A.5 Review questions

These are draft review questions and the final questions will be agreed by the Guideline Development Group during development.

A.5.1 Preconception care

What is the effectiveness of oral oestrogen-containing contraceptives in women with diabetes compared with women without diabetes?

What is the effectiveness of oral progestogen-containing contraceptives in women with diabetes compared with women without diabetes?

What is the target value for HbA_{1c} in women with type 1 or type 2 diabetes who are planning pregnancy?

What are the target ranges for blood glucose in women with type 1 or type 2 diabetes who are planning pregnancy?

What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1 or type 2 diabetes who are planning pregnancy?

A.5.2 Gestational diabetes

What is the effectiveness of the following procedures in detecting glucose intolerance in the first trimester:

- risk factor based screening
- urine test for glycosuria
- random blood glucose test
- 50 g oral glucose challenge test
- fasting blood glucose test
- HbA_{1c} test?

What is the effectiveness of the following procedures in detecting glucose intolerance in the second trimester:

- risk factor based screening
- urine test for glycosuria
- random blood glucose test
- 50 g oral glucose challenge test
- fasting blood glucose test
- HbA_{1c} test?

Which criteria should be used to diagnose gestational diabetes using the 75 g OGTT:

- WHO or
- IADPSG?

What is the effectiveness of the following interventions (alone or in combination) in women with gestational diabetes:

- non-pharmacological interventions (diet and/or exercise)
- pharmacological interventions (metformin, glibenclamide and insulin)?

A.5.3 Antenatal care

What is the effectiveness of HbA_{1c} monitoring in predicting adverse outcomes in women with type 1 or type 2 diabetes during pregnancy?

What is the effectiveness of blood glucose monitoring in predicting adverse outcomes in women with type 1 or type 2 diabetes during pregnancy?

What is the target value for HbA_{1c} in women with type 1, type 2 or gestational diabetes during pregnancy?

What are the target ranges for blood glucose in women with type 1, type 2 or gestational diabetes during pregnancy?

What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1, type 2 or gestational diabetes during pregnancy?

What is the effectiveness of continuous glucose monitoring in pregnant women with diabetes compared with intermittent capillary blood glucose monitoring?

What is the effectiveness of specialist teams for pregnant women with diabetes?

A.5.4 Intrapartum care

What is the gestational age-specific risk of intrauterine death in pregnancies with type 1, type 2 or gestational diabetes, and the optimal timing of birth?

A.5.5 Postnatal care

What is the effectiveness of the following tests in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care):

- fasting plasma glucose test
- HbA_{1c} test
- 75 g OGTT?

What is the optimal timing of postnatal testing in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care)?

A.6 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

A.7 Status

A.7.1 Scope

This is the final scope.

A.7.2 Timing

The development of the guideline recommendations is expected to begin in October 2012.

A.8 Related NICE guidance

A.8.1 Published guidance

A.8.2 NICE guidance to be updated

Depending on the evidence, this guideline might update and replace parts of the following NICE guidance (in relation to gestational diabetes only):

Antenatal care. NICE clinical guideline 62 (2008).

A.8.3 Related NICE guidance

Preventing type 2 diabetes – risk identification and interventions for individuals at high risk. NICE public health guidance 38 (2012).

Patient experience in adult NHS services. NICE clinical guideline 138 (2012).

Caesarean section. NICE clinical guideline 132 (2011).

Multiple pregnancy. NICE clinical guideline 129 (2011).

Diabetic foot problems. NICE clinical guideline 119 (2011).

Preventing type 2 diabetes: population and community-level interventions in high-risk groups and the general population. NICE public health guidance 35 (2011).

Hypertension in pregnancy. NICE clinical guideline 107 (2010).

Dietary interventions and physical activity interventions for weight management before, during and after pregnancy. NICE public health guidance 27 (2010).

Type 2 diabetes: newer agents. NICE clinical guideline 87 (2009).

Induction of labour. NICE clinical guideline 70 (2008).

Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE technology appraisal guidance 151 (2008).

Intrapartum care. NICE clinical guideline 55 (2007).

Antenatal and postnatal mental health. NICE clinical guideline 45 (2007).

Routine postnatal care of women and their babies. NICE clinical guideline 37 (2006).

Smoking cessation services. NICE public health guidance 10 (2008).

Obesity. NICE clinical guideline 43 (2006).

Nutrition support in adults. NICE clinical guideline 32 (2006).

Four commonly used methods to increase physical activity. NICE public health guidance 2 (2006).

Type 1 diabetes. NICE clinical guideline 15 (2004).

Type 2 diabetes: prevention and management of foot problems. NICE clinical guideline 10 (2004).

A.9 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

Type 1 diabetes (update). NICE clinical guideline. Publication expected 2014.

Type 2 diabetes (update). NICE clinical guideline. Publication expected 2014.

Diabetes in children and young people (update). NICE clinical guideline. Publication expected 2014.

A.10 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

‘How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS’

‘The guidelines manual'.

Information on the progress of the guideline will also be available from the NICE website.

Appendix B: Declarations of interests

B.1 Declarations of interest from GDG for original (2008 guideline)

Table 1: 2008 GDG members' declarations of interest

GDG member	Interest
Dominique Acolet	No interests declared
Lynne Carney	Personal non-pecuniary interests: Speaker at Welsh CEMACH conference Non-current interests – planned: T eacher on specialist antenatal course for women with diabetes
Anne Dornhorst	Personal pecuniary interests – specific: Consultancy for GlaxoSmithKline, Novo Nordisk and Takeda; UK principal investigator for PREDICTIVE post-marketing surveillance study for treatment of type 1 and type 2 diabetes using insulin detemir and insulin aspart funded by Novo Nordisk; conference expenses and/or lecture fees from Aventis, GlaxoSmithKline, Merck Sharp & Dohme Limited, Novo Nordisk and Servier Personal non-pecuniary interests: Officer of the Royal College of Physicians; Member of the Working Lives intercollegiate committee Non-personal pecuniary interests – specific: Hospital department receives funding from Novo Nordisk in connection with the PREDICTIVE study and insulin detemir in pregnancy study
Robert Fraser	No interests declared
Roger Gadsby	Personal pecuniary interests – specific: Adviser to Bristol-Myers Squibb, Colgate-Palmolive, Merck Pharma, Merck Sharp & Dohme Limited, Novo Nordisk, Osaki, Pfizer, Sanofi Aventis and Takeda Personal non-pecuniary interests: Medical adviser to Warwick Diabetes Care, University of Warwick; Chairman of Trustees of Pregnancy Sickness Support, Nuneaton, Warwickshire; Honorary Treasurer of the Primary Care Diabetes Society Non-personal pecuniary interests – specific: Warwick Diabetes Care receives sponsorship for educational programmes from the British In Vitro Diagnostics Association (BIVDA), Eli Lilly, GlaxoSmithKline, Lifescan, Novo Nordisk, Pfizer, Sanofi Aventis and Servier; the Primary Care Diabetes Society receives sponsorship for educational programmes from Eli Lilly,

GDG member	Interest
	GlaxoSmithKline, Merck Pharma, Novo Nordisk, Roche Diagnostics, Sanofi Aventis, Servier and Takeda Non-current interests – previous: Consultancy, conference expenses and/or lecture fees from Bristol-Myers Squibb, GlaxoSmithKline, Merck, Novartis, Novo Nordisk, Roche, Roche Diagnostics, Sanofi Aventis, Servier and Takeda; Warwick Diabetes Care received start-up sponsorship from Aventis, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Lifescan, Novo Nordisk, Owen Mumford, Pfizer and Takeda
Jane Hawdon	Personal non-pecuniary interests: Chair of neonatal working group for the CEMACH Diabetes in Pregnancy Enquiry; adviser and speaker for Baby Friendly Initiative, BLISS and CEMACH
Richard Holt	Personal pecuniary interests – specific: Investigator for insulin aspart and insulin detemir in pregnancy studies funded by Novo Nordisk; conference expenses and/or lecture fees from Eli Lilly and GlaxoSmithKline Personal pecuniary interests – non-specific: Consultancy, lecture fees and educational grants from Astra-Zeneca, Eli Lilly, GlaxoSmithKline, Merck Sharp & Dohme Limited, Novo Nordisk, Roche and Takeda Non-personal pecuniary interests – specific: Investigator for Softsense blood glucose meter in pregnancy study funded by Abbott Laboratories and insulin aspart and insulin detemir in pregnancy studies funded by Novo Nordisk; research funding from GlaxoSmithKline to examine the role of insulin resistance in gestational diabetes Personal non-pecuniary interests: Chair of the Professional Advisory Council of Diabetes UK
Anne Parker	No interests declared
Nickey Tomkins	No interests declared
Stephen Walkinshaw	No interests declared
Jackie Webb	Personal pecuniary interests – specific: Conference/meeting expenses and/or lecture fees from Abbot Diabetes Care, Bayer, Becton and Dickenson, Eli Lilly, GlaxoSmithKline, Lifescan, Menarini, Novartis, Novo Nordisk, Roche Diagnostics, Sanofi Aventis and the Centre for Pharmacy Postgraduate Education, University of Manchester; funded by Novo Nordisk to work on an out-of-hours helpline and to attend related update meetings Personal non-pecuniary interests: Member of Diabetes UK and Royal College of Nursing; participation in CEMACH meetings; attended a meeting of the Management of Diabetes for Excellence (MODEL) group

GDG member	Interest
	Non-personal pecuniary interests – specific: Adviser on patient education literature for Eli Lilly; adviser on GlucoGel for British BioCell; Department Trust fund receives funding to support attendance at conferences, courses, study days, meetings and patient-support events and meetings from Abbot Diabetes Care, Bayer, Becton and Dickenson, Diabetes UK, Eli Lilly, GlaxoSmithKline, Lifescan, Menarini, Novo Nordisk, Roche Diagnostics and Sanofi Aventis; insulin detemir study funded by Novo Nordisk
Saiyyidah Zaidi	No interests declared

B.2 Declarations of interest from GDG for updated (2014) guideline

All GDG members' interests were recorded on declaration forms provided by NICE. The form covered consultancies, fee-paid work, shareholdings, fellowships and support from the healthcare industry. GDG members' interests are listed in this section. Where conflicts were identified, GDG members were asked not to participate in the relevant discussions. Details are available from the GDG minutes available on the NICE website.

This appendix includes all interests declared on or before 1 July 2014

Table 2: 2014 GDG members' declarations of interest

GDG member	Interest
Rudolf Bilous	Personal pecuniary: Speaker fees from Boehringer Ingelheim, Novo Nordisk and Roche diagnostics (no ongoing links with any of these companies in terms of topics covered by the guideline update); consultancy for Roche diagnostics and Roche Pharma (to advise on a peroxisome proliferator-activated receptor (PPAR) alpha and gamma agonists for type 2 diabetes and renal disease); meeting expenses from Animas (insulin pumps), Boehringer Ingelheim, Johnson and Johnson (insulin pumps); invited to act as Principal Investigator on a study of a new insulin pump being developed by Roche, honorarium and meeting expenses from the Cordelier Research Center (Paris). Personal non-pecuniary: Member of the Medicines and Healthcare products Regulatory Agency (MHRA) Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group (CDDRAEG) of the Commission on Human Medicines and the MHRA Insulin Use group; GDG member for the National Kidney Foundation guideline on chronic

GDG member	Interest
	kidney disease and diabetic kidney disease; published research on diabetes and pregnancy based on the Northern Regional Diabetes Database of the Regional Maternity Survey Office (RMSO); member of data monitoring safety boards of the Adolescent type 1 Diabetes cardio-renal Intervention Trial (AdDIT) and the atrasentan trial (not related to diabetes in pregnancy) Non-personal pecuniary: Department receives funding from Diabetes UK; department participates in a clinical trial on diabetes and hypertension through the Comprehensive Clinical Research Network (CCRN)
Jacqueline Berry	Personal pecuniary: £100 towards Diabetes UK Conference fees for one day admission to the conference from Novo Nordisk. Personal non-pecuniary: Member of the Royal College of Nursing; seconded to King's College London; speaker at a Diabetes UK meeting (sensor-augmented pump therapy in diabetes in pregnancy); Spoke at SETDiG (South East London Diabetes Specialist Nurses about practical management of diabetes in pregnancy). Did not receive payment or expenses.
Anne Dornhorst	Personal pecuniary: Meeting expenses from Reata Pharmaceuticals (clinical trial of bardoxolone methyl; the meetings were also funded by Eli Lilly) and from European Association for the Study of Diabetes (EASD). Personal non-pecuniary: Seeking funding from Boehringer Ingelheim and Eli Lilly for a randomised controlled trial (RCT) of asymptomatic hypoglycaemia in people with type 2 diabetes and chronic kidney disease using glicazide (a sulfonylurea) and linagliptin (a dipeptidyl peptidase-4 (DPP4) inhibitor); honoraria for speaking about diabetic renal guidelines at North West Thames consultants and general practitioners (GPs) meetings funded by Boehringer Ingelheim and Eli Lilly; honorarium and expenses for speaking about diabetes in pregnancy at a diabetes symposium in Bristol funded by NovoNordisk Personal family: Husband is employed by Quintiles, which undertakes clinical trials for pharmaceutical companies (involves contact with scientific advisors at various companies) Non-personal pecuniary:

GDG member	Interest
	Co-applicant for funding from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme for research relating to hyperglycaemia in pregnancy Personal non-pecuniary: board member of the NovoNordisk Foundation and the International Association of Diabetes and Pregnancy Study Groups (IADPSG).
Stacia Smales Hill	No interest declared
Aderonke Kuti	No interest declared
Michael Maresh	Personal pecuniary: Speaker expenses from Diabetes UK; expenses to attend annual steering group re HAPO follow up study funded by NIH (US) Non-personal pecuniary: Department is funded by Diabetes UK to develop a test for fetal wellbeing in pregnancies complicated by type1 diabetes (the test will not available before 2014); department funded by Bridges for an RCT using a DVD for women with gestational diabetes; department funded by the National Institutes of Health (NIH), USA for a follow-up of women and children from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study; co-applicant for funding from the NIHR HTA programme for research relating to hyperglycaemia in pregnancy Personal non-pecuniary: Spoke about non-applicability of the World Health Organization diagnostic criteria for gestational diabetes, advantages of centralisation of care for type 1 diabetes, individualisation of decision making for timing and mode of birth, and results of the HAPO study. Paper accepted for publication on "Stillbirth rates in pre-gestational diabetic women" in Diabetic Medicine; Papers published on Timing of delivery and stillbirth rate in type 1 & 2 diabetes and Post natal follow up of GDM – full GTT or fasting glucose; is submitting a paper on Perinatal outcomes and Glycaemic control in pregnancy
Judy Shakespeare	No interest declared
Katharine Stanley	Personal pecuniary: Honorarium and meeting expenses from Diabetes UK Non-personal pecuniary: Department received a midwifery research grant from NovoNordisk
Elizabeth Stenhouse	Personal pecuniary: Received payment for a manuscript in Practical Diabetes.

GDG member	Interest
Diane Todd	Personal non-pecuniary: member of the Diabetes UK conference organising committee, the NHS Diabetes Pregnancy Audit Group and Diabetes in Pregnancy Network Steering Group Personal pecuniary: Novonordisk paid registration fee for Diabetes UK annual professional conference 5-7 March 2014

B.3 Declarations of interest from expert advisors

Table 3: Expert advisors' declarations of interest

Expert	Interest
Rhona Hughes	Personal non-pecuniary: Published research on comparison of American Diabetes Association and the American College of Obstetricians and Gynecologists Guidelines With the U.K. National Institute for Health and clinical excellence guidelines; Published research on the cost-effectiveness of different screening strategies for gestational diabetes
William Lamb	Volunteer for Diabetes UK, JDRF, charity fund-raising Professional member of Diabetes UK Member British Society of Endocrinology and Diabetes Member of International Society for Paediatric and Adolescent Diabetes Member of Association Of Children's Diabetes Clinicians Associate editor Clinical Diabetes Attended a variety of diabetes and paediatric related meetings which have attracted varying amounts of sponsorship from a very wide variety of sources
Chris Patterson	Spouse holds stock in GlaxoSmithKline (GSK) Plc

B.4 Declarations of Interest from NCC-WCH staff

Table 4: NCC-WCH staff's declarations of interest

NCC-WCH staff member	Interest
Sarah Bailey	No interest declared
Frauke Becker	No interest declared
Shona Burman-Roy	No interest declared
Anne Carty	No interest declared
Ella Fields	No interest declared
Paul Jacklin	Personal non-pecuniary: Published research on comparison of American Diabetes Association and the American College of Obstetricians and Gynecologists Guidelines With the U.K. National Institute for Health and clinical excellence guidelines; Published research on the cost-effectiveness of different screening strategies for gestational diabetes
David James	No interest declared
Juliet Kenny	No interest declared
Rosalind Lai	No interest declared
Hugh McGuire	No interest declared
Paul Mitchell	No interest declared
Moira Mugglestone	Non-personal pecuniary: Co-applicant for funding from the NIHR HTA programme for research relating to hyperglycaemia in pregnancy
Nitara Prasannan	No interest declared
Cristina Visintin	No interest declared

Appendix C: List of review questions

Preconception care

1. What is the effectiveness of oral oestrogen-containing contraceptives in women with diabetes compared with women without diabetes?

2. What is the effectiveness of oral progestogen-containing contraceptives in women with diabetes compared with women without diabetes?

3. What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1 or type 2 diabetes who are planning pregnancy?

4. What are the target ranges for blood glucose in women with type 1 or type 2 diabetes who are planning pregnancy?

5. What is the target value for haemoglobin A1c (HbA1c) in women with type 1 or type 2 diabetes who are planning pregnancy?

Gestational diabetes

6. What is the effectiveness of the following procedures in detecting glucose intolerance in the first trimester diagnosed using a 75g OGTT:

   - risk factor based screening
   - urine test for glycosuria
   - random blood glucose test
   - 50 g oral glucose challenge test
   - fasting blood glucose test
   - HbA1c test?

7. What is the effectiveness of the following procedures in detecting glucose intolerance in the second trimester diagnosed using a 75g OGTT:

   - risk factor based screening
   - urine test for glycosuria
   - random blood glucose test
   - 50 g oral glucose challenge test
   - fasting blood glucose test
   - HbA1c test?

8. Which criteria should be used to diagnose gestational diabetes using the 75 g oral glucose tolerance test (OGTT):

   - World Health Organization (WHO) or

- International Association of Diabetes and Pregnancy Study Groups (IADPSG)?

9. What is the effectiveness of the following interventions (alone or in combination) in women with gestational diabetes:

- non-pharmacological interventions (diet and/or exercise)
- pharmacological interventions (metformin, glibenclamide and insulin)?

Antenatal care

10. What is the effectiveness of blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?

11. What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1, type 2 or gestational diabetes during pregnancy?

12. What are the target ranges for blood glucose in women with type 1, type 2 or gestational diabetes during pregnancy?

13. What is the effectiveness of HbA1c monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?

14. What is the target value for HbA1c in women with type 1, type 2 or gestational diabetes during pregnancy?

15. What is the effectiveness of continuous glucose monitoring in pregnant women with diabetes compared with intermittent capillary blood glucose monitoring?

16. What is the effectiveness of specialist teams for pregnant women with diabetes?

Intrapartum care

17. What is the gestational age-specific risk of intrauterine death in pregnancies with type 1, type 2 or gestational diabetes, and the optimal timing of birth?

Postnatal care

18. What is the effectiveness of the following tests in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care):

- fasting plasma glucose test
- HbA1c test
- 75 g OGTT?

19. What is the optimal timing of postnatal testing in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care)?

Appendix D: Review Protocols

D.1 Oral Contraceptives containing oestrogen and/or progestogen

Questions 1 and 2		
Existing recommendation(s) in 2008 guideline	Women with diabetes who are planning to become pregnant should be advised: that the risks associated with pregnancies complicated by diabetes increase with the duration of diabetes to use contraception until good glycaemic control (assessed by HbA_{1c})† has been established that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy that additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers. † Diabetes Control and Complications Trial (DCCT)-aligned haemoglobin A_{1c} (HbA_{1c}) test.	
Review questions for update	What is the effectiveness of oral oestrogen-containing contraceptives in women with diabetes compared with women without diabetes? What is the effectiveness of oral progestogen-containing contraceptives in women with diabetes compared with women without diabetes?	NCC-WCH technical team to note alternative spelling of progestogen is progestogen – NICE style is to use progestogen, and this spelling should be used in all documents, even if source articles use the spelling progestogen (the only exception is the full guideline reference list where the titles of cited articles should match the wording in the source publications).
Objectives	To determine whether the use of oral contraceptives containing oestrogen and/or progestogen is associated with any risks in women with pre-existing (type 1 or type 2) diabetes, especially those with vascular complications of diabetes. Risks of interest	There is existing NICE guidance on the topic of long-acting reversible contraception (Clinical Guideline 30),

Questions 1 and 2		
	include the risk of pregnancy despite contraceptive use, and the risk of adverse effects in the woman as a result of using the contraceptives. Since all oral oestrogen-containing contraceptives also contain progestogen, the review questions can be interpreted as follows. What is the effectiveness of oral combined oestrogen and progestogen contraceptives in women with diabetes compared with women without diabetes? What is the effectiveness of oral progestogen-only contraceptives in women with diabetes compared with women without diabetes? The GDG agreed that the evidence identified in the searches for the above questions should also be used to evaluate the risk of adverse effects of using oral contraceptives in women with diabetes compared with women with diabetes using other forms of contraception, or compared with women with diabetes using no contraception. Where the evidence allows it, the systematic review will include comparison of effectiveness according to: whether the woman has type 1 diabetes or type 2 diabetes whether the woman does or does not have diabetes-related complications the dosage of oestrogen and/or progestogen.	which includes recommendations about certain forms of contraception not being contraindicated in women with diabetes The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2009, available at http://www.fsrh.org/pdfs/UKMEC2009.pdf) also provides guidance that may assist the GDG in formulating recommendations.
Language	English	
Study design	Systematic reviews Randomised controlled trials Comparative observational studies (cohort and case-control studies)	
Status	Published articles (no limitation on year of publication)	The topic of whether oral contraceptives containing oestrogen and/or progestogen are effective in women with diabetes was not addressed in the 2008 guideline, and so the search should not be restricted by year of publication. However, studies relating to use of a 50 microgram dose of ethinyloestradiol should be excluded because this dose is not currently used in contraceptive practice.

Questions 1 and 2		
Population	Women with and without type 1 or type 2 diabetes wishing to use contraception	The population should be interpreted as being broad enough to include young women wishing to use contraception (there is no age limit on this search).
Intervention or index test	Oral contraceptives containing oestrogen and progestogen Oral contraceptives containing progestogen only	Systematic search to include the terms: ethinyloestradiol, mestranol and oestradiol (oestrogens) estradiol as a synonym for oestradiol dienogest, desogestrel, etynodiol, gestodene, levonorgestrel, norethisterone, norgestimate and progesterone (progestogens) progestagen as a synonym for progestogen (see notes above)
Comparator or reference standard	Main comparisons will be between: women with diabetes using oral contraceptives and women without diabetes using oral contraceptives women with diabetes using oral contraceptives and women with diabetes not using oral contraceptives Consider subgroup analyses by: type of diabetes (type 1 or type 2) presence of vascular disease (micro- and macrovascular) dosage of oestrogen and/or progestogen age body mass index smoking	
Clinical outcomes	For the comparison of women with diabetes using oral contraceptives and women without diabetes using oral contraceptives (to document the risk of pregnancy): Pregnancy rate (preferably using the Pearl Index)	The GDG selected up to 7 outcomes for presentation in GRADE, plus mortality in the woman or baby if relevant.

Questions 1 and 2		
	For the comparison of women with diabetes using oral contraceptives and women with diabetes not using oral contraceptives (to document the risk of adverse effects): Worsening of retinopathy and/or nephropathy (as indicators of severity of diabetic microvascular disease) Change in HbA_{1c} (as an indicator of glycaemic control) Incidence of dyslipidaemia (also an indicator of glycaemic control) Venous thromboembolic disease Arterial thromboembolic disease (as an indicator of macrovascular disease) Hypertension Mortality	For this question, mortality in the woman was prioritised as an important adverse event to consider. The NICE long-acting reversible contraception guideline (clinical guideline 30) includes evidence for pregnancy rate based on the Pearl Index The GDG noted that neuropathy would be difficult to evaluate in studies with short-term follow-up, and so it was not prioritised as an outcome. The GDG also noted that hypoglycaemia is unlikely to occur as a result of using oral hormonal contraceptives because the homeones would tend to exacerbate hyperglycaemia, and so it was not prioritised as an outcome.
Health economic outcomes	These questions were not prioritised for health economic analysis	
Other criteria for inclusion/ exclusion of studies	Exclude results relating to use of a 50 microgram dose of ethinyloestradiol (see note above) Exclude parenteral (including 'depot') administration of progestogen (medroxyprogesterone, norethisterone and etonogestrel) Exclude intra-uterine devices for administration of progestogen (levonorgestrel)	NCC-WCH to outline for the GDG what is identified in the search results to inform completion of the review. NCC-WCH to note that subgroup analysis for the age group 14-24 years would be useful if the evidence identified for inclusion allows this.
Search strategies	See separate document	
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012)	

Questions 1 and 2		
	A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.2 Ketone monitoring in the preconception and antenatal periods

Questions 3 and 11		
Existing recommendations in 2008 guideline	Women with type 1 diabetes who are planning to become pregnant should be offered ketone testing strips and advised to test for ketonuria or ketonaemia if they become hyperglycaemic or unwell. Women with type 1 diabetes who are pregnant should be offered ketone testing strips and advised to test for ketonuria or ketonaemia if they become hyperglycaemic or unwell.	
Review questions for update	What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1 or type 2 diabetes who are planning pregnancy? What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1, type 2 or gestational diabetes during pregnancy?	There are two separate review questions but the difference between them relates only to the timing at which monitoring is performed, and they will probably be addressed via a single search for evidence.

Questions 3 and 11		
		These questions are solely about self-monitoring of ketones (not monitoring of ketones by healthcare professionals during clinic visits).
Objectives	To determine the effectiveness of ketone monitoring in: women with pre-existing diabetes who are planning pregnancy women with pre-existing diabetes or gestational diabetes during pregnancy The aim of ketone monitoring is early detection of impending or actual diabetic ketoacidosis, which is associated with poor maternal and fetal or neonatal outcomes. Both reviews should consider: frequency of monitoring maternal and fetal or neonatal outcomes associated with specific ketone targets or concentrations Urine ketone monitoring is the historical comparator, and is recommended in the 2008 guideline as an alternative to blood ketone monitoring	
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs)	Although RCTs are unlikely, there may be observational studies comparing outcomes of different

Questions 3 and 11		
	Comparative observational studies (cohort and case-control studies)	monitoring strategies (although there may be very little evidence at all).
Status	Articles indexed after the searches for the 2008 guideline were completed	This is an update of a review conducted for the 2008 guideline, although no evidence was identified for inclusion in the 2008 guideline (see the questions 'How should blood glucose and ketones be monitored in the preconception period?' and 'How should blood glucose and ketones be monitored during pregnancy?' in the 2008 guideline).
Population	Women with type 1 or type 2 diabetes who are planning pregnancy Pregnant women with type 1 diabetes, type 2 diabetes or gestational diabetes	The populations differ according to the timing of monitoring (before or during pregnancy) in the two questions.
Intervention or index test	Blood ketone monitoring	Ketoacidosis, ketosis and pregnancy may be useful as search terms.
Comparator or reference standard	Urine ketone monitoring	
Outcomes	Maternal Preterm birth (birth before 37 + 0 weeks' gestation; take dichotomous or continuous data) Non-routine hospital contact or assessment for ketosis (ketonaemia or ketonuria, however defined), including phone contact	The GDG selected up to 7 outcomes for presentation in GRADE, plus mortality in the woman or baby if relevant.

Questions 3 and 11		
	Hospital admission for diabetic ketoacidosis Maternal satisfaction Fetal/Neonatal Mortality - perinatal and neonatal death Neonatal intensive care unit length of stay greater than 24 hours	For these questions, maternal mortality in association with diabetic ketoacidosis was recognised as a possibility but maternal mortality is unlikely to occur often, and so it was not prioritised. Even if these questions were prioritised for health economic analysis, the risk of perinatal or neonatal death with diabetic ketoacidosis would be more likely to influence the cost effectiveness of monitoring than would the risk of maternal mortality, and so the omission of maternal mortality is unlikely to present problems during any health economic analysis Also, shoulder dystocia was recognised as being an important outcome, but because it might be defined differently in different studies it was not prioritised as an outcome. If shoulder dystocia is needed for health economic analysis it may be necessary to extrapolate from large-for-gestational-age (for example, using data from CEMACH).

Questions 3 and 11		
		Non-routine hospital contact or assessment for ketosis is specified as an outcome because pregnant women with diabetes will be tested routinely for ketones.
Health economic outcomes	These questions were not selected as priorities for health economic analysis	
Other criteria for inclusion/ exclusion of studies	None	
Search strategies	See separate document	It is likely that a single search will be conducted to cover both review questions.
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.3 Blood glucose target values in the preconception and antenatal periods

Questions 4 and 12		
Existing recommendations in 2008 guideline	Women with diabetes who are planning to become pregnant should be advised: • that the risks associated with pregnancies complicated by diabetes increase with the duration of diabetes • to use contraception until good glycaemic control (assessed by HbA_{1c})† has been established • that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy • that additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers. Individualised targets for self-monitoring of blood glucose should be agreed with women with diabetes in pregnancy, taking into account the risk of hypoglycaemia. Recommendations for target ranges for blood glucose during pregnancy If it is safely achievable, women with diabetes should aim to keep fasting blood glucose between 3.5 and 5.9 mmol/litre and 1 hour postprandial blood glucose below 7.8 mmol/litre during pregnancy. † Diabetes Control and Complications Trial (DCCT)-aligned haemoglobin A_{1c} (HbA_{1c}) test.	HbA_{1c} is haemoglobin A
Review questions for update	What are the target ranges for blood glucose in women with type 1 or type 2 diabetes who are planning pregnancy? What are the target ranges for blood glucose in women with type 1, type 2 or gestational diabetes during pregnancy?	Note that there are six inter-related review questions about the effectiveness of monitoring HbA_{1c} and blood glucose during pregnancy, and target values or ranges for HbA_{1c} and blood glucose before and during

Questions 4 and 12		
		pregnancy (questions 3, 4, 10, 11, 12 and 13). The six questions will probably be addressed via a single search for evidence. The two questions addressed in this protocol differ only in the timing at which targets apply (before or during pregnancy).
Objectives	To define clinically important and achievable blood glucose target ranges in: women with type 1 or type 2 diabetes who are planning pregnancy pregnant women with type 1, type 2 or gestational diabetes To consider whether target ranges in the preconception period and/or during pregnancy should be aligned with target ranges that apply outside pregnancy (as defined in the NICE guidelines for type 1 diabetes in adults, type 2 diabetes in adults, and type 1 and type 2 diabetes in children and young people) The review relating to the target range for blood glucose in women planning pregnancy should include consideration of pregnancy outcomes (especially congenital abnormality rates) associated with particular blood glucose values in and around the preconception period Both reviews should consider: the trade-off between the increased risk of hypoglycaemia with tighter glycaemic control and the benefits of improved pregnancy outcomes setting individualised targets setting different targets for type 1, type 2 and gestational diabetes to reflect different risks associated with the different types of diabetes	Liaison with the GDGs and/or technical teams for the NICE guidelines on type 1 diabetes in adults, type 2 diabetes in adults, and type 1 and type 2 diabetes in children and young people will be important for aligning prepregnancy target values and ranges for HbA_{1c} and blood glucose, or justifying the need for different targets in the different guidelines.
Language	English	

Questions 4 and 12		
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational studies (cohort and case-control studies) Non-comparative studies	Although RCTs evaluating different degrees of control are unlikely, there may be observational studies relating different degrees of control to clinical outcomes, preferably through predictive accuracy measures. Other relevant comparative study designs would be those which report associations between blood glucose values and pregnancy outcomes, such as the Hyperglycemia and Pregnancy Outcome (HAPO) study. Non-comparative studies will be considered for inclusion only if no comparative studies are identified for inclusion.
Status	Articles indexed after the searches for the 2008 guideline were completed	This is an update of two reviews conducted for the 2008 guideline. Studies included in the 2008 guideline will need to be considered against the current protocol and data will be extracted for presentation in evidence profiles where relevant (see the questions 'What are the target ranges for blood glucose in the preconception period?' and 'What are the target ranges for blood glucose during pregnancy?' in the 2008 guideline).
Population	Women with type 1 or type 2 diabetes who are planning pregnancy Pregnant women with type 1 diabetes, type 2 diabetes or gestational diabetes	The populations differ according to the timing at which targets apply (before or during pregnancy) in the two questions.
Intervention or index test	Specified target ranges for blood glucose or blood glucose values achieved (recorded) in women planning pregnancy	It may be difficult to disentangle effects (or associations) with blood glucose targets for the preconception period and

Questions 4 and 12		
	Specified target values for blood glucose or blood glucose values achieved (recorded) in women with type 1 diabetes, type 2 diabetes or gestational diabetes during pregnancy	during pregnancy. In RCTs look for intention-to-treat analysis based on targets set (rather than post hoc analysis based on values achieved) and downgrade retrospective analyses based on what was achieved in groups randomised to treatment. Include highest quality evidence available for each type of diabetes when considered separately, and extend to lower levels for any types of diabetes for which the highest-quality evidence is not available. NCC-WCH to refine approach to inclusion/exclusion in consultation with GDG when the results of search are available.
Comparator or reference standard	Comparisons to be made between outcomes according to target ranges for blood glucose and/or blood glucose values achieved (recorded)	
Clinical outcomes	For the question relating to targets when planning pregnancy Maternal outcomes: HbA_{1c} values in the first trimester Hypoglycaemic episodes before pregnancy or in the first trimester Spontaneous miscarriage Acceptability of targets (covers concordance and implications of hypoglycaemia) Neonatal outcomes: Any congenital abnormality, regardless of gestational age *Mortality For the question relating to targets during pregnancy	The GDG selected up to 7 outcomes plus mortality (where relevant) for each review question Evidence tables should document: the types of congenital abnormality and how many resulted in planned termination of pregnancy in the question relating to targets when planning pregnancy the indication for mode of birth (if reported) in the question relating to targets during pregnancy any treatment administered in response to monitoring in the question relating to targets during pregnancy

Questions 4 and 12		
	Maternal outcomes: **Mode of birth (spontaneous vaginal, operative vaginal, caesarean section (elective or emergency)) Pre-eclampsia HbA_{1C} values at any time during pregnancy Hypoglycaemic episodes at any time during pregnancy Neonatal outcomes: Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) Neonatal intensive care unit length of stay greater than 24 hours Shoulder dystocia (as a specific example of birth trauma) *Mortality *The definition of mortality includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth) **If neither of these outcomes is available, onset of labour (spontaneous, induced, or no labour) should be considered and the GDG advised about available evidence	the definition of maternal hypoglycaemic episodes The GDG noted that: presence of pre-eclampsia was of interest for the question on targets during pregnancy, and the studies should provide data on this there would be some overlap between neonatal intensive care unit length of stay greater than 24 hours and presence of neonatal hypoglycaemia neonatal hypoglycaemia was less important than the other outcomes selected for the question relating to targets during pregnancy, although it may be important in defining future research priorities presence of congenital abnormality was not a priority for the question relating to targets during pregnancy because such abnormalities arise very early in pregnancy
Health economic outcomes	These questions were not prioritised for health economic analysis	This question will not be a priority for health economic analysis even if the effectiveness of blood glucose monitoring is prioritised
Other criteria for inclusion/ exclusion of studies	None	
Search strategies	See separate document	NCC-WCH technical team to consider whether one search across the two questions addressed in this protocol, or even across all six questions relating to

Questions 4 and 12		
		target values and ranges and monitoring during pregnancy, would be appropriate
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.4 HbA_{1c} target values in the preconception and antenatal periods

Questions 5 and 14		
Existing recommendations in 2008 guideline	Women with diabetes who are planning to become pregnant should be advised: • that the risks associated with pregnancies complicated by diabetes increase with the duration of diabetes • to use contraception until good glycaemic control (assessed by HbA_{1c})† has been established • that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy • that additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers. If it is safely achievable, women with diabetes who are planning to become pregnant should aim to maintain their HbA_{1c} below 6.1%. Women should be reassured that any reduction in HbA_{1c} towards the target of 6.1% is likely to reduce the risk of congenital malformations. Women with diabetes whose HbA_{1c} is above 10% should be strongly advised to avoid pregnancy. Recommendations for target ranges for blood glucose during pregnancy HbA_{1c} should not be used routinely for assessing glycaemic control in the second and third trimesters of pregnancy. † Diabetes Control and Complications Trial (DCCT)-aligned haemoglobin A_{1c} (HbA_{1c}) test.	HbA_{1c} is haemoglobin A_{1c}. The 2008 guideline did not include targets for HbA_{1c} during pregnancy because the guideline recommended that HbA_{1c} should not be used routinely for assessing glycaemic control in the second and third trimesters (note that there were no recommendations that explicitly recommended what to do in terms of HbA_{1c} monitoring in the first trimester). The reasons for reconsidering targets for HbA_{1c} in the update include a need to re-evaluate the effectiveness of HbA_{1c} monitoring during pregnancy, which is being addressed by a separate review question (question 10). Setting targets for HbA_{1c} during pregnancy will only become relevant if the GDG concludes that monitoring HbA_{1c} during pregnancy is effective – the GDG may, however, need to consider the evidence identified for inclusion in this question to reach a conclusion (for example, if no evidence is identified for the effectiveness of pre-specified monitoring strategies, there may still be evidence relating pregnancy outcomes to HbA_{1c} values achieved or recorded during pregnancy that would support setting targets and, therefore, specifying a monitoring strategy)
Review questions for update	What is the target value for HbA_{1c} in women with type 1 or type 2 diabetes who are planning pregnancy? What is the target value for HbA_{1c} in women with type 1, type 2 or gestational diabetes during pregnancy?	Note that there are six inter-related review questions about the effectiveness of monitoring HbA_{1c} and blood glucose during pregnancy, and target values or ranges for HbA_{1c} and

Questions 5 and 14		
		blood glucose before and during pregnancy (questions 3, 4, 10, 11, 12 and 13). The six questions will probably be addressed via a single search for evidence. The two questions addressed in this protocol differ only in the timing at which targets apply (before or during pregnancy).
Objectives	To define clinically important and achievable HbA_{1C} target values in: women with type 1 or type 2 diabetes who are planning pregnancy pregnant women with type 1, type 2 or gestational diabetes To consider whether target values in the preconception period and/or during pregnancy should be aligned with target values that apply outside pregnancy (as defined in the NICE guidelines for type 1 diabetes in adults, type 2 diabetes in adults, and type 1 and type 2 diabetes in children and young people) The review relating to the target value for HbA_{1c} in women planning pregnancy should include consideration of pregnancy outcomes (especially congenital abnormality rates) associated with particular HbA_{1c} values in and around the preconception period The review relating to the target value for HbA_{1c} during pregnancy should include consideration of the rate of reduction of HbA_{1c} (towards a target value) in women who enter pregnancy with very high values (for example, HbA_{1c} above 10%) Both reviews should consider:* the trade-off between the increased risk of hypoglycaemia with tighter glycaemic control and the benefits of improved pregnancy outcomes setting individualised targets	Liaison with the GDGs and/or technical teams for the NICE guidelines on type 1 diabetes in adults, type 2 diabetes in adults, and type 1 and type 2 diabetes in children and young people will be important for aligning prepregnancy target values and ranges for HbA_{1c} and blood glucose, or justifying the need for different targets in the different guidelines. * Targets for HbA_{1c} should take account of physiological changes (reductions and sometimes later increases) in HbA_{1c} during pregnancy, regardless of diabetes (document in evidence tables whether or not included studies have adapted normal ranges to take account of pregnancy, for example, specific to a particular trimester).

Questions 5 and 14		
	setting different targets for type 1, type 2 and gestational diabetes to reflect different risks associated with the different types of diabetes	
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational studies (cohort and case-control studies) Non-comparative studies	Although RCTs evaluating different degrees of control are unlikely, there may be observational studies relating different degrees of control to clinical outcomes, preferably through predictive accuracy measures. Other relevant comparative study designs would be those which report associations between blood glucose values and pregnancy outcomes, such as the Hyperglycemia and Pregnancy Outcome (HAPO) study. Non-comparative studies will be considered for inclusion only if no comparative studies are identified for inclusion. Include highest quality evidence available for each type of diabetes when considered separately, and extend to lower levels for any types of diabetes for which the highest-quality evidence is not available. NCC-WCH to refine approach to inclusion/exclusion in consultation with GDG when the results of search are available.
Status	Articles indexed after the searches for the 2008 guideline were completed	This is an update of two reviews conducted for the 2008 guideline. Studies included in the 2008 guideline will need to be considered against the current protocol and data will be

Questions 5 and 14		
		extracted for presentation in evidence profiles where relevant (see the questions 'What are the target ranges for blood glucose in the preconception period?' and 'What are the target ranges for blood glucose during pregnancy?' in the 2008 guideline; these questions were broad enough to cover targets for HbA_{1c}).
Population	Women with type 1 or type 2 diabetes who are planning pregnancy Pregnant women with type 1 diabetes, type 2 diabetes or gestational diabetes	The populations differ according to the timing at which targets apply (before or during pregnancy) in the two questions.
Intervention or index test	Specified target values for HbA_{1C} or HbA_{1c} values achieved (recorded) in women planning pregnancy Specified target values for HbA_{1C} or HbA_{1c} values achieved (recorded) in women with type 1 diabetes, type 2 diabetes or gestational diabetes during pregnancy	It may be difficult to disentangle effects (or associations) with HbA_{1c} targets for the preconception period and during pregnancy.
Comparator or reference standard	Comparisons to be made between outcomes according to target values for HbA_{1c} and/or HbA_{1c} values achieved (recorded)	
Clinical outcomes	For the question relating to targets when planning pregnancy Maternal outcomes: Hypoglycaemic episodes before pregnancy or in the first trimester Spontaneous miscarriage Acceptability of targets (covers concordance and implications of hypoglycaemia) Neonatal outcomes: Any congenital abnormality, regardless of gestational age *Mortality For the question relating to targets during pregnancy Maternal outcomes:	The GDG selected up to 7 outcomes plus mortality (where relevant) for each review question Evidence tables should document: the types of congenital abnormality and how many resulted in planned termination of pregnancy in the question relating to targets when planning pregnancy the indication for mode of birth (if reported) in the question relating to targets during pregnancy any treatment administered in response to monitoring in the question relating to targets during pregnancy

Questions 5 and 14		
	**Mode of birth (spontaneous vaginal, operative vaginal, caesarean section (elective or emergency)) Pre-eclampsia Hypoglycaemic episodes at any time during pregnancy Neonatal outcomes: Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) Neonatal intensive care unit length of stay greater than 24 hours Shoulder dystocia (as a specific example of birth trauma) Neonatal hypoglycaemia (however defined) *Mortality *The definition of mortality includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth) **If neither of these outcomes is available, onset of labour (spontaneous, induced, or no labour) should be considered and the GDG advised about available evidence	the definition of maternal hypoglycaemic episodes. The GDG noted that: presence of pre-eclampsia was of interest for the question on targets during pregnancy, and there should be data on this there would be some overlap between neonatal intensive care unit length of stay greater than 24 hours and presence of neonatal hypoglycaemia neonatal hypoglycaemia was more important for the question relating to targets during pregnancy than the presence of neonatal hyperinsulinaemia or hyper C-peptide-aemia, although the latter may be important in defining future research priorities presence of congenital abnormality was not a priority for the question relating to targets during pregnancy because such abnormalities arise very early in pregnancy.
Health economic outcomes	These questions were not prioritised for health economic analysis	
Other criteria for inclusion/ exclusion of studies	None	
Search strategies	See separate document	NCC-WCH technical team to consider whether one search across the two questions addressed in this protocol, or even across all six questions relating to target values and ranges and monitoring during pregnancy, would be appropriate.

Questions 5 and 14		
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.5 Screening for gestational diabetes in the first trimester

Question 6		
	Screening for gestational diabetes using fasting plasma glucose, random blood glucose, glucose challenge test and urinalysis for glucose should not be undertaken. The 2 hour 75 g oral glucose tolerance test (OGTT) should be used to test for gestational diabetes and diagnosis made using the criteria defined by the World Health Organization. Women who have had gestational diabetes in a previous pregnancy should be offered early self-monitoring of blood glucose or OGTT at 16–18 weeks, and a further OGTT at 28 weeks if the results are normal. Women with any of the other risk factors for gestational diabetes should be offered an OGTT at 24–28 weeks.	OGTT is oral glucose tolerance test The recommendations listed are from the NICE 2008 routine antenatal care guideline. This guideline update covers first and second-trimester screening for gestational diabetes, and the routine antenatal care guideline will be updated in accordance with any changes to the recommendations listed
Review question for update	What is the effectiveness of the following procedures in detecting glucose intolerance in the first trimester diagnosed using a 75g OGTT: risk factor based screening urine test for glycosuria random blood glucose test 50 g oral glucose challenge test	The term glucose intolerance covers: impaired fasting glucose (IFG) impaired glucose tolerance (IGT) and diabetes.

Question 6		
	fasting blood glucose test HbA_{1c} test	
Objectives	To examine if a 'test' or combination of 'tests' in the first trimester identifies women with gestational diabetes Whether this identification improves the outcome	A 'test' is shorthand for 'screening procedure' as defined above. First trimester is defined as up to and including 13 weeks + 6 days
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational cohort studies (of more than one of these tests in same population would be ideal) Observational cohort studies (of tests in different populations only to be considered if no comparative data available	
Status	Published articles (no limitation on year of publication)	
Population	Pregnant women in the first trimester who do not have a pre-existing diagnosis of diabetes	Ideally the whole population should have a 75g OGTT to determine the predictive accuracy of the individual screening tests for an abnormal OGTT but that is unlikely to be done.
Intervention or index test	Risk factor based screening (which could be either risk factor screening alone to predict gestational diabetes, or risk factor plus a subsequent biochemical test to predict gestational diabetes) Urine test for glycosuria Random blood glucose test 50 g oral glucose challenge test Fasting blood glucose test HbA_{1c} test	The risk factors detailed in the 2008 diabetes in pregnancy guideline are : body mass index (BMI) above 30 kg/m2 previous macrosomic baby weighing 4.5 kg or above previous gestational diabetes) family history of diabetes (first-degree relative with diabetes) family origin with a high prevalence of diabetes: South Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh), black Caribbean, Middle Eastern (specifically women whose country of family origin is

Question 6		
		Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt).
Comparator or reference standard	75g OGTT	Interpreted using the World Health Organization (WHO) 1999 or International Association of Diabetes and Pregnancy Study Groups (IADPSG) diagnostic criteria, or diagnostic criteria with thresholds equivalent to WHO 1999.
Clinical outcomes	Incidence of gestational diabetes Comparative incidence of diagnosis of gestational diabetes in the first and second trimesters Diagnostic test accuracy Sensitivity, specificity and likelihood ratios for diagnosis of gestational diabetes Maternal outcomes Mode of birth: spontaneous vaginal , operative vaginal, caesarean section (elective/emergency) Treatment such as diet, oral hypoglycaemic agents and/or insulin Acceptability/take-up of testing regimen Neonatal outcomes Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) All mortality - includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth) Neonatal intensive care unit length of stay (greater than 24 hours) Shoulder dystocia (no permanent damage, neurological injury (brachial plexus and cerebral palsy)	
Health economic outcomes	Prevalence of gestational diabetes in the first trimester	

Question 6		
	Diagnostic test accuracy Sensitivity, specificity Neonatal outcomes Stillbirth, shoulder dystocia, perinatal death, birth trauma ('serious perinatal complications') Maternal outcomes From the clinical outcomes above, although these predominantly affect 'downstream costs' rather than health-related quality of life Health-related quality of life EQ5D, SF36	
Other criteria for inclusion/ exclusion of studies	Exclusions Studies comparing incidence of gestational diabetes by applying different diagnostic criteria without presenting relevant diagnostic data or outcomes data Studies where the screening test (e.g. glucose challenge test) is examined for prediction of maternal/neonatal outcomes	
Search strategies	See separate document	A single search will be conducted for the questions relating to first- and second-trimester screening.
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	Note that the QUADAS methodology checklist for diagnostic test accuracy studies (NICE guidelines manual January 2009) has been used for this question for consistency with the question relating to diagnosis of gestational diabetes. All other aspects of the review are consistent with the 2012 edition of the manual.
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.6 Screening for gestational diabetes in the second trimester

Question 7		
Existing recommendation(s) in 2008 guideline	Screening for gestational diabetes using fasting plasma glucose, random blood glucose, glucose challenge test and urinalysis for glucose should not be undertaken. The 2 hour 75 g oral glucose tolerance test (OGTT) should be used to test for gestational diabetes and diagnosis made using the criteria defined by the World Health Organization. Women who have had gestational diabetes in a previous pregnancy should be offered early self-monitoring of blood glucose or OGTT at 16‑18 weeks, and a further OGTT at 28 weeks if the results are normal. Women with any of the other risk factors for gestational diabetes should be offered an OGTT at 24‑28 weeks.	OGTT is oral glucose tolerance test The recommendations listed are from the NICE 2008 routine antenatal care guideline. This guideline update covers first and second-trimester screening for gestational diabetes, and the routine antenatal care guideline will be updated in accordance with any changes to the recommendations listed Screening in the first trimester was not recommended in the 2008 antenatal care guideline, but the recommendations listed may change depending on outcome of this review
Review question for update	What is the effectiveness of the following procedures in detecting glucose intolerance in the second trimester diagnosed using a 75g OGTT: risk factor based screening urine test for glycosuria random blood glucose test 50 g oral glucose challenge test fasting blood glucose test HbA_{1c} test	The term glucose intolerance covers: impaired fasting glucose (IFG) impaired glucose tolerance (IGT) and diabetes.
Objectives	To examine if a ‘test’ or combination of ‘tests’ in the second trimester identifies women with gestational diabetes Whether this identification improves the outcome	A ‘test’ is shorthand for ‘screening procedure’ as defined above.

Question 7		
		Second trimester is the period between 14 weeks + 0 days and 28 weeks + 6 days.
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational cohort studies (of more than one of these tests in same population would be ideal) Observational cohort studies (of tests in different populations if comparative studies unavailable – only to be considered if no comparative data)	
Status	Published articles (no limitation on year of publication)	
Population	Pregnant women in the second trimester who do not have a pre-existing diagnosis of diabetes	Ideally the whole population should have a 75g OGTT to determine the predictive accuracy of the individual screening tests for an abnormal OGTT.
Intervention or index test	Risk factor based screening (which could be either risk factor screening alone to predict gestational diabetes, or risk factor plus a subsequent biochemical test to predict gestational diabetes) Urine test for glycosuria Random blood glucose test 50 g oral glucose challenge test Fasting blood glucose test HbA_{1c} test	The risk factors detailed in the 2008 diabetes in pregnancy guideline are : body mass index (BMI) above 30 kg/m2 previous macrosomic baby weighing 4.5 kg or above previous gestational diabetes) family history of diabetes (first-degree relative with diabetes) family origin with a high prevalence of diabetes: South Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh), black Caribbean, Middle Eastern (specifically women whose country of family origin is Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt).

Question 7		
Comparator or reference standard	75g OGTT	Interpreted using the World Health Organization (WHO) 1999 or International Association of Diabetes and Pregnancy Study Groups (IADPSG) diagnostic criteria, or diagnostic criteria with thresholds equivalent to WHO 1999.
Clinical outcomes	Incidence of gestational diabetes Comparative incidence of diagnosis of gestational diabetes in the first and second trimesters Diagnostic test accuracy Sensitivity, specificity and likelihood ratios for diagnosis of gestational diabetes Maternal outcomes Mode of birth: spontaneous vaginal , operative vaginal, caesarean section (elective/emergency) Treatment such as diet, oral hypoglycaemic agents and/or insulin Acceptability/take-up of testing regimen Neonatal outcomes Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) All mortality - includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth Neonatal intensive care unit length of stay (greater than 24 hours) Shoulder dystocia (no permanent damage, neurological injury (brachial plexus and cerebral palsy)	
Health economic outcomes	Prevalence of gestational diabetes in the second trimester Diagnostic test accuracy	

Question 7		
	Sensitivity, specificity Neonatal outcomes Stillbirth, shoulder dystocia, perinatal death, birth trauma ('serious perinatal complications') Maternal outcomes From the clinical outcomes above, although these predominantly affect 'downstream costs' rather than health-related quality of life Health-related quality of life EQ5D, SF36	
Other criteria for inclusion/ exclusion of studies	Studies that overlap 28 weeks + 6 into the third trimester, or screen later than 28 weeks + 6 will be excluded Studies that do not use IADPSG or WHO 1999 (or equivalent) diagnostic criteria will be excluded Studies where the screening test (eg GCT) is examined for prediction of maternal/neonatal outcomes will be excluded	
Search strategies	See separate document	A single search will be conducted for the questions relating to first- and second-trimester screening.
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	Note that the QUADAS methodology checklist for diagnostic test accuracy studies (NICE guidelines manual January 2009) has been used for this question for consistency with the question relating to diagnosis of gestational diabetes. All other aspects of the review are consistent with the 2012 edition of the manual.
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.7 Diagnostic criteria for gestational diabetes

Question 8		
Existing recommendation(s) in 2008 guideline	The 2 hour 75 g oral glucose tolerance test (OGTT) should be used to test for gestational diabetes and diagnosis made using the criteria defined by the World Health Organization.* Women who have had gestational diabetes in a previous pregnancy should be offered early self-monitoring of blood glucose or OGTT at 16–18 weeks, and a further OGTT at 28 weeks if the results are normal. Women with any of the other risk factors for gestational diabetes should be offered an OGTT at 24–28 weeks. * Fasting plasma venous glucose concentration greater than or equal to 7.0 mmol/litre or 2 hour plasma venous glucose concentration greater than or equal to 7.8 mmol/litre. World Health Organization Department of Non communicable Disease Surveillance (1999) Definition, diagnosis and classification of diabetes mellitus and its complications. Report of a WHO consultation. Part 1: diagnosis and classification of diabetes mellitus. Geneva: World Health Organization.	OGTT is oral glucose tolerance test
Review question for update	Which criteria should be used to diagnose gestational diabetes using the 75 g OGTT: World Health Organization (WHO) (1999) or International Association of Diabetes and Pregnancy Study Groups (IADPSG)?	This is a new topic for the update to investigate use of the new (IADPSG) criteria against WHO 1999 as recommended in the 2008 guideline.
Objectives	To investigate whether using IADPSG criteria rather than WHO (1999) criteria would improve: clinical diagnostic effectiveness and cost effectiveness of diagnosis for women who are diagnosed with gestational diabetes. The evaluation of cost effectiveness should take account of any increase in the number of women who would be diagnosed with gestational diabetes using the IADPSG criteria rather than the WHO criteria.	During the course of the development of the Guideline in 2014, WHO updated their criteria for diagnosing gestational diabetes. So these critieria were considered alongside the IADPSG and WHO (1999) criteria.
Language	English	
Study design	Comparison of the two sets of criteria using: systematic reviews	

Question 8		
	randomised controlled trials (RCTs) cohort studies	
Status	Published articles (no limitation on year of publication)	Although no limitation on year of publication will be applied in the search, the relevant evidence is expected to have been published since the 2008 guideline because the IADPSG criteria were published after that guideline.
Population	Pregnant women who do not have pre-existing diabetes	
Intervention or index test	A 75 g OGTT interpreted using the IADPSG diagnostic criteria (based on an odds ratio (OR) for adverse outcomes of 1.5, 1.75 or 2.0) in the first or second trimester	Health economic analysis might incorporate interpretation at different thresholds (ORs for adverse outcomes).
Comparator or reference standard	A 75 g OGTT interpreted using the WHO 1999 diagnostic criteria in the first or second trimester	
Clinical outcomes	Incidence of gestational diabetes Comparative incidence of diagnosis of diabetes with the two sets of criteria Diagnostic test accuracy Sensitivity, specificity and likelihood ratios for positive and negative test results in the diagnosis of gestational diabetes using and comparing the IADPSG and WHO 1999 criteria Maternal and neonatal outcomes Prioritised maternal outcomes: *Mode of birth (spontaneous vaginal, operative vaginal, caesarean section (elective or emergency)) *Preterm birth (birth before 37 + 0 weeks' gestation; take dichotomous or continuous data) Need for treatment for gestational diabetes, such as diet, oral hypoglycaemic agents or insulin	

Question 8		
	Prioritised neonatal outcomes: Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) Neonatal intensive care unit length of stay greater than 24 hours Shoulder dystocia Neonatal hyperinsulinaemia or hyper C-peptide-aemia (raised neonatal blood concentrations of insulin or C-peptide) **Mortality *If neither of these outcomes is available, onset of labour (spontaneous, induced, or no labour) should be considered and the GDG advised about available evidence **The definition of mortality includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth)	
Health economic outcomes	Prevalence of gestational diabetes Estimated prevalence of gestational diabetes using the IADPSG and WHO criteria Diagnostic test accuracy Sensitivity and specificity for diagnosis of gestational diabetes using the IADPSG and WHO criteria Maternal and neonatal outcomes Mortality (defined as above; maternal mortality will not be considered)	
Other criteria for inclusion/ exclusion of studies	Include studies that report test and outcome results from a single population of women (and their babies) according to a diagnosis of gestational diabetes made by applying the IADPSG and WHO 1999 criteria Include studies that do not report IADPSG valuesfor 1 hour in the OGTT results, but downgrade such evidence in the evidence profiles Exclude studies that do not use the WHO 1999 criteria as defined above (for example, studies that use only 2-hour plasma glucose concentrations and not fasting plasma glucose (FPG) concentrations, or that apply different threshold values to WHO 1999 criteria)	
Search strategies	See separate document	

Question 8		
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	Note that the QUADAS methodology checklist for diagnostic test accuracy studies (NICE guidelines manual January 2009) has been used for this question because the majority of the systematic reviewing was undertaken when the 2009 edition of the manual was still in use. All other aspects of the review are consistent with the 2012 edition of the manual.
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.8 Interventions for gestational diabetes

Question 9		
Existing recommendation(s) in 2008 guideline	Women with gestational diabetes should be offered information covering: · the role of diet, body weight and exercise · the increased risk of having a baby who is large for gestational age, which increases the likelihood of birth trauma, induction of labour and caesarean section · the importance of maternal glycaemic control during labour and birth and early feeding of the baby in order to reduce the risk of neonatal hypoglycaemia · the possibility of transient morbidity in the baby during the neonatal period, which may require admission to the neonatal unit · the risk of the baby developing obesity and/or diabetes in later life.	.

Question 9		
	Women with gestational diabetes should be advised to choose, where possible, carbohydrates from low glycaemic index sources, lean proteins including oily fish and a balance of polyunsaturated fats and monounsaturated fats. Women with gestational diabetes whose pre-pregnancy body mass index was above 27 kg/m2 should be advised to restrict calorie intake (to 25 kcal/kg/day or less) and to take moderate exercise (of at least 30 minutes daily). Hypoglycaemic therapy should be considered for women with gestational diabetes if diet and exercise fail to maintain blood glucose targets during a period of 1–2 weeks. Hypoglycaemic therapy should be considered for women with gestational diabetes if ultrasound investigation suggests incipient fetal macrosomia (abdominal circumference above the 70th percentile) at diagnosis. Hypoglycaemic therapy for women with gestational diabetes (which may include regular insulin, rapid-acting insulin analogues [aspart and lispro] and/or hypoglycaemic agents [metformin and glibenclamide] should be tailored to the glycaemic profile of, and acceptability to, the individual woman.	
Review question for update	What is the effectiveness of the following interventions (alone or in combination) in women with gestational diabetes: non-pharmacological interventions (diet and/or exercise) pharmacological interventions (metformin, glibenclamide and insulin)?	
Objectives	To examine the effectiveness of Diet strategies Exercise regimens Different pharmacological interventions (metformin, glibenclamide and insulin) as first line pharmacological treatment in the management of gestational diabetes in the second and third trimesters	
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs)	It is anticipated that there will be a large number of RCTs and studies of other

Question 9		
		designs will, therefore, not be considered.
Status	Published articles	
Population	Pregnant women with gestational diabetes (however the study defines gestational diabetes), but who are presumed to not have pre-existing diabetes	
Intervention or index test	Diet strategy/advice (including strategies to increase intake of vitamins, minerals and micronutrients), with or without insulin use Exercise regimen with or without diet strategy/advice 3a) Metformin 3b) Glibenclamide 3c) Metformin	Non-pharmacological comparisons a) Diet strategy/advice vs standard care or no diet strategy/advice b) Insulin + Diet strategy/advice vs Diet strategy/advice c) Exercise regimen + Diet strategy/advice vs Exercise regimen d) Diet A vs Diet B e) Exercise regimen vs standard care or no exercise regimen f) Exercise regimen + Diet strategy/advice vs Diet strategy/advice g) Intense exercise regimen vs exercise regimen h) Exercise regimen A vs Exercise regime B. Consider cultural dietary practices including food types and dietary observances. Pharmacological comparisons i)Metformin vs Insulin j)Glibenclamide vs Insulin k)Metformin vs Glibenclamide.

Question 9		
		Note that glibenclamide is usually referred to as ‘glyburide’ in US studies.
Comparator or reference standard	Standard care, Diet strategy /advice, Exercise regimen Standard care, Exercise regimen, Diet strategy/advice 3a) Insulin 3b) Insulin 3c) Glibenclamide	
Clinical outcomes	Maternal outcomes Mode of birth: spontaneous vaginal , operative vaginal, caesarean section (elective/emergency) Treatment such as diet, oral hypoglycaemic agents and/or insulin Acceptability/take-up of treatment (including hypoglycaemic episodes where insulin is used, if reported) Neonatal outcomes Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) Neonatal intensive care unit length of stay (greater than 24 hours) Shoulder dystocia (no permanent damage, neurological injury (brachial plexus and cerebral palsy) Neonatal hyperinsulinaemia/ hyper C-peptide-aemia* All mortality - includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth *Neonatal hypoglycaemia (which can be further subdivided by (biochemical or symptomatic) diagnosis alone, extra complementary formula milk, oral glucose (extra feeds), need for intravenous glucose) is to be used when there is no data on neonatal hyperinsulinaemia/hyper C-peptide aemia available	
Health economic outcomes	Neonatal outcomes Stillbirth, shoulder dystocia, perinatal death, neonatal death, birth trauma (thus focussing on ‘serious perinatal complications’)	

Question 9		
	Maternal outcomes From the clinical outcomes above, although these predominantly affect 'downstream costs' rather than health-related quality of life Health-related quality of life EQ5D, SF36	
Other criteria for inclusion/ exclusion of studies	Non-randomised comparative studies will be excluded No limitation on year of publication	
Search strategies	See separate document	
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

HbA1c moni

D.9 Antenatal blood glucose monitoring

Question 10		
Existing recommendations in 2008 guideline	Women with diabetes who are planning to become pregnant should be advised: • that the risks associated with pregnancies complicated by diabetes increase with the duration of diabetes • to use contraception until good glycaemic control (assessed by HbA_{1c})† has been established • that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy • that additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers. Women with diabetes who are planning to become pregnant should be offered a meter for self-monitoring of blood glucose. Women with diabetes who are planning to become pregnant and who require intensification of hypoglycaemic therapy should be advised to increase the frequency of self-monitoring of blood glucose to include fasting and a mixture of pre- and postprandial levels. Women with diabetes should be advised to test fasting blood glucose levels and blood glucose levels 1 hour after every meal during pregnancy. Women with insulin-treated diabetes should be advised to test blood glucose levels before going to bed at night during pregnancy. † Diabetes Control and Complications Trial (DCCT)-aligned haemoglobin A_{1c} (HbA_{1c}) test.	HbA_{1c} is haemoglobin A_{1c} The recommendations in the 2008 guideline relating to monitoring blood glucose in women who are planning pregnancy are not being updated, but are included here for context
Review question for update	What is the effectiveness of blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?	Note that there are six inter-related review questions about the effectiveness of monitoring HbA_{1c} and blood glucose during pregnancy, and target values or ranges for HbA_{1c} and

Question 10		
		blood glucose before and during pregnancy (questions 3, 4, 10, 11, 12 and 13). The six questions will probably be addressed via a single search for evidence.
Objectives	To evaluate the effectiveness of monitoring blood glucose in pregnant women with type 1, type 2 or gestational diabetes This review question relates specifically to intermittent capillary blood glucose self-monitoring (continuous glucose monitoring during pregnancy is addressed in a separate question). The review should specifically focus on the frequency of monitoring blood glucose and timing relative to meals (for example, to include testing blood glucose before meals and adjusting insulin accordingly), since this is likely to reflect practice outside pregnancy The effectiveness of monitoring blood glucose in women with type 1 or type 2 diabetes who are planning pregnancy has already been established and the corresponding section of the 2008 guideline is not being updated	Liaison with the GDGs and/or technical teams for the NICE guidelines on type 1 diabetes in adults, type 2 diabetes in adults, and type 1 and type 2 diabetes in children and young people will be important for aligning monitoring strategies for HbA_{1c} and blood glucose, or justifying the need for different strategies in the different guidelines. However, alignment of recommendations during pregnancy with other guidelines for non-pregnant individuals is unlikely to be as important as in the preconception period.
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational studies (cohort and case-control studies)	RCTs evaluating monitoring strategies may be limited in number (a few RCTs comparing different monitoring strategies were included in the 2008 guideline, but no RCTs compared monitoring with no monitoring). There may, however, be more evidence from observational studies relating different strategies to clinical outcomes.
Status	Articles indexed after the searches for the 2008 guideline were completed	This is an update of a review conducted for the 2008 guideline. Studies included in the 2008 guideline will need to be considered against the current protocol

Question 10		
		and data will be extracted for presentation in evidence profiles where relevant (see the question 'How should blood glucose and ketones be monitored during pregnancy?' in the 2008 guideline).
Population	Pregnant women with type 1 diabetes, type 2 diabetes or gestational diabetes	
Intervention or index test	Specified monitoring strategies for blood glucose	The way in which blood glucose was monitored, including the frequency and timing of monitoring, should be documented for each included study. Studies that report outcomes associated with different levels of blood glucose but without documenting a particular monitoring strategy are not eligible for inclusion in this question – they should instead be considered for the corresponding questions on blood glucose target ranges.
Comparator or reference standard	Comparisons to be made between outcomes according to monitoring strategies used	The ideal study would be one which allowed a direct comparison between two or more monitoring strategies (including before-and-after comparisons in the same cohort of women).
Clinical outcomes	Maternal outcomes: *Mode of birth (spontaneous vaginal, operative vaginal, caesarean section (elective or emergency)) HbA_{1c} % (as a measure of glycaemic control during pregnancy) Hypoglycaemic episodes during pregnancy (another measure of glycaemic control during pregnancy) Neonatal outcomes:	The GDG selected up to 7 outcomes plus mortality (where relevant); maternal mortality was not considered to be a priority for blood glucose monitoring during pregnancy Evidence tables should document: the indication for mode of birth (if reported)

Question 10		
	Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) Neonatal intensive care unit length of stay greater than 24 hours Shoulder dystocia (as a specific example of birth trauma) Neonatal hypoglycaemia (however defined) **Mortality *If neither of these outcomes is available, onset of labour (spontaneous, induced, or no labour) should be considered and the GDG advised about available evidence **The definition of mortality includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth)	any treatment administered in response to monitoring the definition of maternal and/or neonatal hypoglycaemic episodes (results for neonatal hypoglycaemia may be difficult to compare between studies because of different definitions). The GDG noted that: presence of pre-eclampsia was of interest for this question, but was less of a priority than the other outcomes selected maternal hypoglycaemia was an important outcome that would not be covered by HbA_{1c} there would be some overlap between neonatal intensive care unit length of stay greater than 24 hours and presence of neonatal hypoglycaemia respiratory distress would be covered by admission to neonatal intensive care neonatal hypoglycaemia was more important than the presence of neonatal hyperinsulinaemia or hyper C-peptide-aemia, although the latter may be important in defining future research priorities presence of a congenital abnormality is not relevant during pregnancy.
Health economic outcomes	This question was not prioritised for health economic analysis	Availability of testing strips for blood glucose monitoring might be a cost issue and reviewing health economic priorities if time allows (and if relevant evidence is identified) and considering

Question 10		
		differences between planning pregnancy, during pregnancy and women with pre-existing diabetes who are not planning pregnancy (for example, type 2 diabetes in adults guideline update) might be undertaken.
Other criteria for inclusion/ exclusion of studies	None	
Search strategies	See separate document	NCC-WCH technical team to consider whether one search across all six questions relating to target values and ranges and monitoring during pregnancy would be appropriate.
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.10 Antenatal HbA_{1c} monitoring

Question 13		
Existing recommendations in 2008 guideline	Women with diabetes who are planning to become pregnant should be advised: • that the risks associated with pregnancies complicated by diabetes increase with the duration of diabetes	HbA_{1c} is haemoglobin A_{1c}

Question 13		
	• to use contraception until good glycaemic control (assessed by HbA_{1c})† has been established • that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy • that additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers. Women with diabetes who are planning to become pregnant should be offered monthly measurement of HbA_{1c}. HbA_{1c} should not be used routinely for assessing glycaemic control in the second and third trimesters of pregnancy. † Diabetes Control and Complications Trial (DCCT)-aligned haemoglobin A_{1c} (HbA_{1c}) test.	The 2008 guideline is not explicit about whether or not to monitor HbA_{1c} in the first trimester, although this is implicitly acceptable. The GDG may want to address this as part of the update The recommendation in the 2008 guideline relating to monitoring HbA_{1c} in women who are planning pregnancy is not being updated, but is included here for context. Note that 'routinely' does not rule out monitoring if clinically indicated
Review question for update	What is the effectiveness of HbA_{1c} monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?	Note that there are six inter-related review questions about the effectiveness of monitoring HbA_{1c} and blood glucose during pregnancy, and target values or ranges for HbA_{1c} and blood glucose before and during pregnancy (questions 3, 4, 10, 11, 12 and 13).

Question 13		
		The six questions will probably be addressed via a single search for evidence.
Objectives	To evaluate the effectiveness of monitoring HbA_{1c} in pregnant women with type 1, type 2 or gestational diabetes, specifically in the context of whether the 2008 guideline recommendation not to monitor HbA_{1c} routinely in the second and third trimesters of pregnancy should be changed The review should include consideration of: the frequency of monitoring HbA_{1c} whether monitoring HbA_{1c} is more effective that monitoring blood glucose alone whether different monitoring strategies are appropriate in women with type 1, type 2 and gestational diabetes The effectiveness of monitoring HbA_{1c} in women with type 1 or type 2 diabetes who are planning pregnancy has already been established and the corresponding section of the 2008 guideline is not being updated	Liaison with the GDGs and/or technical teams for the NICE guidelines on type 1 diabetes in adults, type 2 diabetes in adults, and type 1 and type 2 diabetes in children and young people will be important for aligning monitoring strategies for HbA_{1c} and blood glucose, or justifying the need for different strategies in the different guidelines. However, alignment of recommendations during pregnancy with other guidelines for non-pregnant individuals is unlikely to be as important as in the preconception period. Include evidence based on HbA_{1c} monitoring in any trimester.
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational studies (cohort and case-control studies)	RCTs evaluating monitoring strategies may be limited in number (a few RCTs comparing different monitoring strategies were included in the 2008 guideline, but no RCTs compared monitoring with no monitoring). There may, however, be more evidence from observational studies relating different strategies to clinical outcomes.
Status	Articles indexed after the searches for the 2008 guideline were completed	This is an update of a review conducted for the 2008 guideline. Studies included in the 2008 guideline will need to be considered against the current protocol and data will be extracted for

Question 13		
		presentation in evidence profiles where relevant (see the question 'How should blood glucose and ketones be monitored during pregnancy?' in the 2008 guideline; this question was broad enough to cover monitoring HbA_{1c}).
Population	Pregnant women with type 1 diabetes, type 2 diabetes or gestational diabetes	
Intervention or index test	Specified monitoring strategies for HbA_{1c} (with or without monitoring of blood glucose)	The way in which HbA_{1c} (and blood glucose if relevant) was monitored, including the frequency of monitoring, should be documented for each included study, as should the gestational age or trimester at which HbA_{1c} monitoring was performed. Studies that report outcomes associated with different levels of HbA_{1c} but without documenting a particular monitoring strategy are not eligible for inclusion in this question – they should instead be considered for the corresponding questions on HbA_{1c} target values.
Comparator or reference standard	Comparisons to be made between outcomes according to monitoring strategies used Comparison with monitoring based on blood glucose alone	The ideal study would be one which allowed a direct comparison between two or more monitoring strategies (including before-and-after comparisons in the same cohort of women). The GDG noted that there may be evidence relating to comparison between HbA_{1c} monitoring and monitoring based on blood glucose alone for women with gestational diabetes.

Question 13		
Clinical outcomes	Maternal outcomes: *Mode of birth (spontaneous vaginal, operative vaginal, caesarean section (elective or emergency)) Pre-eclampsia (HbA_{1c} may predict this) Neonatal outcomes: Large for gestational age (however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) Neonatal intensive care unit length of stay greater than 24 hours Shoulder dystocia (as a specific example of birth trauma) Neonatal hypoglycaemia (however defined) Any congenital abnormality, regardless of gestational age **Mortality *If neither of these outcomes is available, onset of labour (spontaneous, induced, or no labour) should be considered and the GDG advised about available evidence **The definition of mortality includes perinatal mortality (stillbirth and neonatal death up to 7 days after birth) and neonatal mortality (neonatal death up to 28 days after birth)	The GDG selected up to 7 outcomes plus mortality (where relevant); maternal mortality was not considered to be a priority for HbA_{1c} monitoring during pregnancy. Evidence tables should document: the indication for mode of birth (if reported) any treatment administered in response to monitoring the definition of neonatal hypoglycaemic episodes (results for neonatal hypoglycaemia may be difficult to compare between studies because of different definitions) the types of congenital abnormality and how many resulted in planned termination of pregnancy. The GDG noted that: preterm birth was not selected as a priority for this question because the presence of a congenital abnormality was considered a greater priority there would be some overlap between neonatal intensive care unit length of stay greater than 24 hours and presence of neonatal hypoglycaemia neonatal hypoglycaemia was more important than the presence of neonatal hyperinsulinaemia or hyper C-peptide-aemia, although the latter may be important in defining future research priorities

Question 13		
		presence of a congenital abnormality is relevant during pregnancy because although such abnormalities arise very early in pregnancy, HbA_{1c} represents a retrospective average measure of glycaemic control and this (especially first-trimester HbA_{1c}) could be useful (for example, for counselling, fetal monitoring during pregnancy and evaluating the likelihood of needing neonatal intensive care).
Health economic outcomes	This question was not prioritised for health economic analysis	Availability of testing strips for blood glucose monitoring might be a costissue and reviewing health economic priorities if time allows (and if relevant evidence is identified) and considering differences between planning pregnancy, during pregnancy and women with pre-existing diabetes who are not planning pregnancy (for example, type 2 diabetes in adults guideline update) might be undertaken.
Other criteria for inclusion/ exclusion of studies	None	
Search strategies	See separate document	NCC-WCH technical team to consider whether one search across all six questions relating to target values and ranges and monitoring during pregnancy would be appropriate.
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	

Question 13		
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.11 Antenatal continuous glucose monitoring

Question 15		
Existing recommendations in 2008 guideline	Women with diabetes should be advised to test fasting blood glucose levels and blood glucose levels 1 hour after every meal during pregnancy. Women with insulin-treated diabetes should be advised to test blood glucose levels before going to bed at night during pregnancy.	When the 2008 guideline was developed, there was insufficient evidence to evaluate the effectiveness of continuous blood glucose monitoring. The 2008 guideline did, however, include a research recommendation to evaluate the effectiveness of (ambulatory) continuous blood glucose monitoring in pregnancies complicated by diabetes
Review question for update	What is the effectiveness of continuous glucose monitoring in pregnant women with diabetes compared with intermittent capillary blood glucose monitoring?	
Objectives	To assess whether continuous glucose monitoring during pregnancy is more effective than intermittent capillary blood glucose monitoring for improving: glycaemic control maternal and fetal/neonatal outcomes	
Language	English	

Question 15		
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational studies if RCTs not available	Details of discussions about including Cochrane reviews are included in the 'Email repository' folder on the V drive. In summary, two Cochrane review protocols were published when reviewing started in May 2013, but the full reviews were unlikely to be published in the near future, and so the protocols were excluded from the current review.
Status	Articles indexed after the searches for the 2008 guideline were completed	The searches for the 2008 guideline included up to 21st March 2007. The first run of the searches for the updated guideline started from October 2007. Therefore, the rerun searches need to include March 2007 to October 2007 (this has been agreed with RL). This is an update of a review conducted for the 2008 guideline. Three studies involving continuous glucose monitoring during pregnancy were included in the 2008 guideline. These studies will need to be considered against the current protocol and data will be extracted for presentation in evidence profiles where relevant (see the question 'How should blood glucose and ketones be monitored during pregnancy?' in the 2008 guideline). Published systematic reviews on continuous glucose monitoring in general (not specifically during pregnancy) may be good sources of

Question 15		
		studies to consider for the update. One such study is a published meta-analysis of RCTs using individual patient data (Pickup JC, BMJ 2011, 343, d3805; see http://www.bmj.com/content/343/bmj.d3805)
Population	Pregnant women with type 1 diabetes, type 2 diabetes or gestational diabetes	Continuous glucose monitoring is sometimes use by women with type 2 diabetes or gestational diabetes, but its main use is in women with type 1 diabetes
Intervention or index test	Continuous glucose monitoring	Some (older) articles might use the term ambulatory continuous glucose monitoring. Duration of the use of continuous monitoring may vary from study to study – document in evidence tables.
Comparator or reference standard	Intermittent capillary blood glucose monitoring	Other relevant terms and abbreviations for intermittent capillary blood glucose monitoring might include: capillary glucose series ICGM ICBGM 'testing' instead of 'monitoring' spot testing home glucose monitoring or testing self-monitoring or self-testing
Clinical outcomes	Maternal Mode of birth: spontaneous vaginal delivery, , instrumental vaginal delivery, caesarean section Preterm birth (birth before 37 + 0 weeks' gestation; take dichotomous or continuous data) Glycaemic control in the pregnancy measured by HbA_{1C}	The GDG selected up to 7 outcomes for presentation in GRADE, plus mortality in the woman or baby if relevant. For this question, mortality in the woman was not prioritised. Also,

Question 15		
	Severe hypoglycaemic episodes Maternal satisfaction Fetal/Neonatal Mortality - perinatal and neonatal death Large for gestational age (or however defined in the study, for example, using a customised measure based on gestational age and population norms; dichotomous data preferred) Neonatal intensive care unit length of stay greater than 24 hours	shoulder dystocia was recognised as being an important outcome, but because it might be defined differently in different studies it was not prioritised as an outcome. If shoulder dystocia is needed for health economic analysis it may be necessary to extrapolate from large-for-gestational-age (for example, using data from CEMACH). Similarly, although the GDG expected that neonatal hypoglycaemia might be reported in some studies considered for this question, admission to a neonatal intensive care unit would be a more important outcome, and so neonatal hypoglycaemia was not prioritised. A severe hypoglycaemic episode is an episode of hypoglycaemia requiring third-party assistance.
Health economic outcomes	This question was selected as a priority for health economic analysis	
Other criteria for inclusion/ exclusion of studies	None	
Search strategies	See separate document	
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.12 Antenatal specialist teams

Question 16		
Existing recommendation(s) in 2008 guideline	Women with diabetes who are pregnant should be offered immediate contact with a joint diabetes and antenatal clinic.	
Review question for update	What is the effectiveness of specialist teams for pregnant women with diabetes?	
Objectives	Women with diabetes sometimes have appointments with different teams on different sites. The aim of this question is to assess the benefits of concentrating care in one place for delivery by an integrated team. The term 'specialist team' is to be interpreted in this question to include specialist centres and centralisation of care, for example, offering women with type 1 diabetes access to insulin pumps. The question should consider: adverse outcome rates associated with specialist care maternal satisfaction (including ease of access to care, for example, in terms of travelling to or between diabetes and antenatal clinics) models of care for women with gestational diabetes, for example, including community midwifery equality of access to, for example, insulin pumps for all groups (especially ethnic minority women)	Separate analyses to be considered for type 1 diabetes, type 2 diabetes and gestational diabetes. The GDG may wish to refer to the National Service Framework (NSF) for diabetes. Note that the emphasis in this question is on integration of care.
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational studies (cohort and case-control studies)	Although RCTs are unlikely, there may be observational studies comparing

Question 16		
	Qualitative studies	outcomes of care delivered under different team structures.
Status	Published articles (no limitation on year of publication)	This is an update of a review conducted for the 2008 guideline. However, no specific searches were undertaken for the relevant section of the 2008 guideline and so the search for the update will not be limited by date.
Population	Pregnant women with type 1, type 2 or gestational diabetes	
Intervention or index test	Integrated care in one location, offering access to all relevant members of a multidisciplinary team (this should be the norm already but it may not yet be available everywhere) Centralised regional care for women with pregnancy complicated by diabetes	The NSF for diabetes recommends that antenatal care for women with diabetes should be delivered by a multidisciplinary team consisting of an obstetrician, a diabetes physician, a diabetes specialist nurse, a midwife and a dietitian. In this question, interest focuses on whether centralised care is important for women with pre-existing diabetes rather than gestational diabetes (even specialist care may be unnecessary for women with gestational diabetes, that is, community based care may be appropriate for women with gestational diabetes). Consistency and continuity of advice/care may be more important for the woman than the geographical location in which care is delivered. Westminster City Council, the London Borough of Hammersmith & Fulham and the Royal Borough of Kensington and Chelsea are undertaking a tri-borough

Question 16		
		pilot of combined public services that might have some useful data (see, for example, http://www.lbhf.gov.uk/combinedservices). However, the pilot is not specific to healthcare for women with diabetes in pregnancy.
Comparator or reference standard	Divided care, possibly in more than one location (relevant comparator for both integrated care and centralised regional care) Integrated care between centres (comparator for centralised regional care only)	
Clinical outcomes	Maternal Mode of birth: spontaneous vaginal, instrumental vaginal delivery, caesarean section, Preterm birth (birth before 37 + 0 weeks' gestation; using dichotomous or continuous data) Glycaemic control in the pregnancy measured using HbA_{1C} Maternal satisfaction Fetal/Neonatal Mortality - perinatal and/or neonatal death Large for gestational age (however defined in the study, dichotomous data preferred) Neonatal intensive care unit length of stay greater than 24 hours Initiation of breastfeeding (when started and exclusivity)	The GDG selected up to 7 outcomes for presentation in GRADE, plus mortality in the woman or baby if relevant and reported. For this question, mortality in the woman was not prioritised. Also, shoulder dystocia was recognised as being an important outcome, but because it might be defined differently in different studies it was not prioritised as an outcome. If shoulder dystocia is needed for health economic analysis it may be necessary to extrapolate from large-for-gestational-age (for example, using data from CEMACH). Exclusivity of breastfeeding means whether the baby was fed using breast milk only.
Health economic outcomes	This question was selected as a priority for health economic analysis	
Other criteria for inclusion/	Nested case-control studies that have not adjusted for confounding variables will be excluded	

Question 16		
exclusion of studies		
Search strategies	See separate document	
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.13 Timing of birth

Question 17		
Existing recommendation(s) in 2008 guideline	Pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labour, or by elective caesarean section if indicated, after 38 completed weeks.	
Review question for update	What is the gestational age-specific risk of intrauterine death in pregnancies with type 1, type 2 or gestational diabetes, and the optimal timing of birth?	For the purposes of this review question, intrauterine death (stillbirth) is defined as fetal death from 24 weeks' gestation. Whilst the timing of stillbirth can be used as the main pregnancy outcome others should be included to inform the GDG. In summary: Consequences of elective delivery (37-39 weeks has been suggested in the literature) are – neonatal problems

Question 17		
		especially respiratory disorders, admission to NNICU. Consequences of an expectant approach to care are – stillbirth, shoulder dystocia, increased CS rates, macrosomia.
Objectives	To determine the optimal timing of birth in women with pregnancies complicated by the three forms of diabetes (type 1, type 2 and gestational diabetes). The optimal timing of birth will be determined by the nadir (minimum) in perinatal mortality and morbidity rates in diabetic pregnancies. This may vary between the different types of diabetes The question should consider stratifying risk and associated interventions (such as elective birth) according to: gestational age type of diabetes (type 1, type 2 or gestational diabetes, with the further possibility of defining a continuum of risk within one or more of these types) HbA_{1c} as an individualised measure of glycaemic control. The question should also consider: pregnancy complications (other than those already covered by NICE guidelines for routine maternity care, for example, pre-eclampsia) diabetes complications (for example, accelerated retinopathy) potential confounders, such as age, parity, smoking, and body mass index (BMI) Possible subquestions for the GDG to consider are as follows. What is the intrauterine death rate in spontaneous or uncomplicated deliveries in women with diabetes in pregnancy (type 1 diabetes, type 2 diabetes or gestational diabetes)? What is the effectiveness of elective birth in women with diabetes in pregnancy (type 1 diabetes, type 2 diabetes or gestational diabetes)?	The main focus of interest in terms of comparing types of diabetes, and making recommendations relating to timing of birth, is whether the evidence supports separate recommendaitons for gestational diabetes versus pre-existing diabetes (type 1 or type 2 diabetes).
Language	English	
Study design	Systematic reviews Randomised controlled trials (RCTs) Comparative observational studies (cohort and case-control studies)	Although RCTs are unlikely, there may be observational studies comparing elective birth at a particular gestational

Question 17		
		age with expectant management (allowing pregnancy to continue).
Status	Articles indexed after the searches for the 2008 guideline were completed	This is an update of a review conducted for the 2008 guideline. Included studies from the 2008 guideline will need to be considered against the current protocol and data will be extracted for presentation in evidence profiles where relevant (see the question 'Does intervening in the timing and mode of birth improve outcomes for women with diabetes and their babies?' in the 2008 guideline).
Population	Pregnant women with type 1, type 2 or gestational diabetes	Ideally it would be useful to know about any clinical confounders (maternal comorbidities) in the study population, such as hypertension or obesity.
Intervention or index test	Descriptive studies of intrauterine death rates according to gestational age Elective birth at a particular gestational age (intervention studies)	Studies eligible for inclusion are those in which: pregnancies complicated by diabetes have been allowed to go into spontaneous labour, or intervention relating to timing of birth is performed at or before 41 weeks' gestation. Studies in which intervention relating to timing of birth occurs after 41 weeks' gestation will, therefore, be excluded. Document mode of birth in each included study

Question 17		
Comparator or reference standard	Intrauterine death rates at different gestational ages Expectant management (intervention studies)	
Clinical outcomes	For studies evaluating intrauterine death rates by gestational age, gestational age-specific risk of intrauterine death is the only relevant outcome For intervention studies comparing elective birth and expectant management the following outcomes were prioritised. Maternal - Mode of birth (spontaneous vaginal, operative vaginal, caesarean section (elective or emergency)) - Maternal complications of delivery (including wound infection, urinary infection, postpartum haemorrhage, psychological outcomes and other complications developing over a longer period) - Maternal satisfaction/experiences Foetal/Neonatal - Mortality - still birth and neonatal death (and other mortality outcomes if reported) - Admission to NICU (to include respiratory disease - respiratory distress syndrome and transient tachypnoea of the newborn- and neonatal hypoglycaemia where reported) - NICU stay >24 hours - Macrosomia - Shoulder dystocia (with and without consequences for the baby such as trauma, neuromuscular injury)	
Health economic outcomes	This question was selected as a priority for health economic analysis	
Other criteria for inclusion/	Exclude: multiple pregnancies	'Hypertension in pregnancy' (NICE clinical guideline 107) includes recommendations on timing of birth for

Question 17		
exclusion of studies	pregnancies with known potentially lethal congenital abnormalities pregnancies with any complications not exclusively associated with diabetes that would lead to elective preterm birth	women with chronic hypertension, gestational hypertension and pre-eclampsia, but that guideline does not cover women with diabetes who have co-existent hypertension(such women fall within the scope of the diabetes in pregnancy guideline).
Search strategies	See separate document	
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.14 Diagnostic accuracy of postnatal testing

Question 18		
Existing recommendation(s) in 2008 guideline	Women who were diagnosed with gestational diabetes should be offered lifestyle advice (including weight control, diet and exercise) and offered a fasting plasma glucose measurement (but not an OGTT) at the 6 week postnatal check and annually thereafter.	OGTT stands for 'oral glucose tolerance test'
Review question for update	What is the effectiveness of the following tests in the detection of glucose intolerance after pregnancy in women who have had gestational diabetes (but are euglycaemic before they are transferred to community care): fasting plasma glucose (FPG) test HbA_{1c} test 75 g OGTT?	The term glucose intolerance covers: impaired fasting glucose (IFG) impaired glucose tolerance (IGT) and diabetes. Alternative terminology for type 1 diabetes for NCC-WCH technical team to be aware of: type 1 diabetes mellitus;

Question 18		
		type I diabetes mellitus; insulin-dependent diabetes. Alternative terminology for type 2 diabetes for NCC-WCH technical team to be aware of: type 2 diabetes mellitus; type II diabetes mellitus; non-insulin-dependent diabetes.
Objectives	The two review questions (18 & 19) relating to postnatal testing have the combined aims of: identifying which test should be used in the postnatal period identifying the optimal timing for testing	The need to update this topic in the guideline was partly prompted by concerns that the recommendation in the 2008 guideline was based on a single study, conducted using a small sample (122 OGTTs) in a single hospital. Although the review question and objectives refer to postnatal testing, it was agreed that the question should be interpreted more broadly than the standard 6-8 week postnatal period to allow consideration of studies that evaluate testing at 12 weeks or later. The guideline scope is broad enough to allow the GDG to consider recommending testing annually after pregnancy, as in the 2008 guideline.
Language	English	
Study design	Randomised controlled trials (RCTs) Comparative observational studies	
Status	Published articles (no limitation on year of publication)	The original intention was to search for articles published after the searches for the 2008 guideline were completed, but such a search identified a systematic review that included relevant articles published before the cut-off date for the 2008 guideline that were not included in

Question 18		
		the 2008 guideline and so a search was executed without any limitation on year of publication.
Population	Women who have had gestational diabetes	It will be important to record whether included studies document a return to euglycaemia in the immediate days following the birth and before discharge to community care. It is, however, recognised that many studies may not provide this information. The criteria used to define gestational diabetes should be documented if resported (there are many variations of this).
Intervention or index test	Postnatal FPG test Postnatal HbA_{1c} test	In the first instance, include studies only if the WHO 1999 criteria (or equivalents) are used for diagnosing diabetes after delivery (GDG to consider relaxing this restriction if there is not enough evidence to allow a recommendation to be made) Note that glucose challenge tests (GCTs), random glucose measurements and urinalysis are not to be included. The type of OGTT used and where it is done (primary or secondary care) should be documented in the evidence tables.
Comparator or reference standard	Postnatal OGTT	
Clinical outcomes	Incidence of IFG, IGT and diabetes in women at different time intervals in the postnatal period Accuracy in detecting IFG, IGT or diabetes	The definitions of glucose intolerance should be documented in the evidence tables to allow consideration of different thresholds used

Question 18		
Health economic outcomes	This question was selected as a priority for health economic analysis (a combined analysis for the questions on accuracy and timing of postnatal testing for diabetes may be undertaken)	
Other criteria for inclusion/ exclusion of studies	Exclude results for diagnosis based on WHO 1985 criteria (because the 2008 guideline recommends diagnosis of gestational diabetes using WHO 1999 criteria)	
Search strategies	A single search will be conducted to cover both review questions relating to postnatal testing - see separate document for further details	
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	Note that the QUADAS methodology checklist for diagnostic test accuracy studies (NICE guidelines manual January 2009) has been used for this question because the majority of the systematic reviewing was undertaken when the 2009 edition of the manual was still in use. All other aspects of the review are consistent with the 2012 edition of the manual.
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

D.15 Timing of postnatal testing

Question 19		
Existing recommendation(s) in 2008 guideline	Women who were diagnosed with gestational diabetes should be offered lifestyle advice (including weight control, diet and exercise) and offered a fasting plasma glucose measurement (but not an OGTT) at the 6 week postnatal check and annually thereafter.	OGTT stands for 'oral glucose tolerance test' The recommendation to offer a test coinciding with the postnatal check at 6 weeks appears to have been based on:

Question 19		
		an existing National Service Framework (NSF) obstetric and gynaecology specialist recommendations
Review question for update	What is the optimal timing of postnatal testing for the detection of glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care)?	The term glucose intolerance covers: impaired fasting glucose (IFG) impaired glucose tolerance (IGT) and diabetes. The gold-standard reference test is a fasting plasma glucose (FPG) measurement and 2-hour OGTT using the diagnostic criteria defined by WHO 1999 for IFG, IGT and diabetes. A positive test result from either the FPG or the OGTT components is sufficient to diagnose 'impairedness' or diabetes Many different criteria are used to specify thresholds for diagnosis. Some require only one test to be performed (for example, ADA 1997) while others require two tests (for example, WHO 1999) Studies report outcomes for impairedness as IFG alone, IGT alone, or IFG and IGT together.
Objectives	The two review questions (18 & 19) relating to postnatal testing have the combined aims of: identifying which test should be used in the postnatal period identifying the optimal timing for testing	Although the review question and objectives refer to postnatal testing, it was agreed that the question should be interpreted more broadly than the standard 6-8 week postnatal period to allow consideration of studies that evaluate testing at 12 weeks or later. The guideline scope is broad enough to allow the GDG to consider recommending testing

Question 19		
		annually after pregnancy, as in the 2008 guideline.
Language	English	
Study design	Observational studies	
Status	Published articles (no limitation on year of publication)	The original intention was to search for articles published after the searches for the 2008 guideline were completed, but such a search identified a systematic review that included relevant articles published before the cut-off date for the 2008 guideline that were not included in the 2008 guideline and so a search was executed without any limitation on year of publication.
Population	Women who have had gestational diabetes	
Intervention	Postnatal FPG Postnatal HbA_{1c} Postnatal OGTT	In the first instance, include studies only if the WHO 1999 criteria (or equivalents) are used for the diagnosis of diabetes after delivery (GDG to consider relaxing this restriction if there is not enough evidence to allow a recommendation to be made).
Comparator or reference standard	NA	
Clinical outcomes	Incidence of IFG, IGT and diabetes in women at different time intervals in the postnatal period	
Health economic outcomes	This question was selected as a priority for health economic analysis (a combined analysis for the questions on accuracy and timing of postnatal testing for diabetes may be undertaken)	
Other criteria for inclusion/ exclusion of studies	Exclude results for diagnosis based on WHO 1985 criteria (because the 2008 guideline recommends diagnosis of gestational diabetes using WHO 1999 criteria)	

Question 19		
Search strategies	A single search will be conducted to cover both review questions relating to postnatal testing - see separate document for further details	
Review strategies	Evidence will be assessed for quality according to the process described in the NICE guidelines manual (November 2012) A list of excluded studies will be provided following weeding Evidence tables and an evidence profile will be used to summarise the evidence	Note that the QUADAS methodology checklist for diagnostic test accuracy studies (NICE guidelines manual January 2009) has been used for this question because the majority of the systematic reviewing was undertaken when the 2009 edition of the manual was still in use. All other aspects of the review are consistent with the 2012 edition of the manual.
Equality	Equalities issues with be assessed according to processes described in NICE guidelines manual (November 2012)	

Appendix E: Search strategies

E.1 Search 1: Oral contraceptives containing oestrogen and/or progestogen

A single search was conducted for 2 review questions

Review Question 1: What is the effectiveness of oral oestrogen-containing contraceptives in women with diabetes compared with women without diabetes?

Review Question 2: What is the effectiveness of oral progestogen-containing contraceptives in women with diabetes compared with women without diabetes?

Database(s): Ovid MEDLINE(R) 1946 to March Week 2 2014
Search Strategy: **DiP_update_combined_oral_contraceptive_RERUN1_medline_200314**

#	Searches
1	exp DIABETES MELLITUS/
2	(T1DM or T2DM).ti,ab.
3	IDDM.ti,ab.
4	diabet$.ti.
5	PREDIABETIC STATE/
6	prediabet$.ti,ab.
7	impaired glucose tolerance.ti,ab.
8	IGT.ti,ab.
9	Impaired fasting glucose.ti,ab.
10	IFG.ti,ab.
11	Impaired glucose regulation.ti,ab.
12	IGR.ti,ab.
13	GLUCOSE INTOLERANCE/
14	or/1-13
15	CONTRACEPTIVES, ORAL/ or CONTRACEPTIVES, ORAL, COMBINED/ or CONTRACEPTIVES, ORAL, HORMONAL/ or CONTRACEPTIVES, ORAL, SEQUENTIAL/ or CONTRACEPTIVES, ORAL, SYNTHETIC/ or exp CONTRACEPTIVES, POSTCOITAL/
16	ETHINYL ESTRADIOL/ or ETHINYL ESTRADIOL-NORGESTREL COMBINATION/ or MESTRANOL/
17	ESTRADIOL/
18	ESTROGENS/ or ESTROGENS, NON-STEROIDAL/
19	PROGESTINS/
20	DESOGESTREL/
21	DRSP.ti,ab.
22	exp NORPREGNENES/
23	gestodene.ti,ab.
24	drospirenone.ti,ab.

#	Searches
25	levonorgestrel.ti,ab.
26	(norethisterone or norgestimate).ti,ab.
27	NANDROLONE/
28	dienogest.ti,ab.
29	etynodiol.ti,ab.
30	"combined oral contracepti$".ti,ab.
31	COCP.ti,ab.
32	mini?pill.ti,ab.
33	progest#gen$.ti,ab.
34	(Gedarel or Mercilon or Femodette or Millinette or Sunya or Loestrin or Marvelon or Yasmin or Katya or Levest or Microgynon, or Ovranette, or Rigevidon or Cilest or Brevinor or Ovysmen or Norimin or Norinyl or Femodene or Triadene or Logynon or Triregol or Binovum or Synphase or Trinovum or Qlaira).ti,ab.
35	(combined adj oral adj3 contracept$).ti,ab.
36	or/15-35
37	and/14,36
38	randomized controlled trial.pt.
39	controlled clinical trial.pt.
40	DOUBLE BLIND METHOD/
41	SINGLE BLIND METHOD/
42	RANDOM ALLOCATION/
43	or/38-42
44	((single or double or triple or treble) adj5 (blind$ or mask$)).tw,sh.
45	clinical trial.pt.
46	exp CLINICAL TRIAL/
47	exp CLINICAL TRIALS AS TOPIC/
48	(clinic$ adj5 trial$).tw,sh.
49	PLACEBOS/
50	placebo$.tw,sh.
51	random$.tw,sh.
52	or/44-51
53	or/43,52
54	META ANALYSIS/
55	META ANALYSIS AS TOPIC/
56	meta analysis.pt.
57	(metaanaly$ or meta-analy$ or (meta adj analy$)).tw,sh.
58	(systematic$ adj5 (review$ or overview$)).tw,sh.
59	(methodologic$ adj5 (review$ or overview$)).tw,sh.
60	or/54-59
61	review$.pt.
62	(medline or medlars or embase or cinahl or cochrane or psycinfo or psychinfo or psychlit or psyclit or "web of science" or "science citation" or scisearch).tw.
63	((hand or manual$) adj2 search$).tw.
64	(electronic database$ or bibliographic database$ or computeri?ed database$ or online database$).tw,sh.
65	(pooling or pooled or mantel haenszel).tw,sh.

#	Searches
66	(peto or dersimonian or der simonian or fixed effect).tw,sh.
67	or/62-66
68	and/61,67
69	exp CASE-CONTROL STUDIES/
70	(case$ adj2 control$).tw.
71	exp COHORT STUDIES/
72	cohort$.tw.
73	or/69-72
74	comparative study.pt.
75	or/73-74
76	or/53,60,68,75
77	letter.pt.
78	comment.pt.
79	editorial.pt.
80	historical article.pt.
81	or/77-80
82	76 not 81
83	and/37,82
84	limit 83 to english language
85	limit 84 to animals
86	limit 84 to (animals and humans)
87	85 not 86
88	84 not 87
89	limit 88 to yr="2012 -Current"

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations March 19, 2014
Search Strategy: **DiP_update_combined_oral_contraceptive_RERUN1_mip_200314**

#	Searches
1	diabet$.ti,ab.
2	(T1DM or T2DM).ti,ab.
3	IDDM.ti,ab.
4	pre?diabet$.ti,ab.
5	((impaired or fasting) adj3 glucose).ti,ab.
6	IGT.ti,ab.
7	IFG.ti,ab.
8	Impaired glucose regulation.ti,ab.
9	IGR.ti,ab.
10	(glucose adj intoleran$).ti,ab.
11	or/1-10
12	((oral or combined or hormonal) adj3 (contracept$ or pill$)).ti,ab.
13	(estradiol or oestradiol or estrogen? or oestrogen?).ti,ab.
14	progestin?.ti,ab.
15	desogestrel.ti,ab.

#	Searches
16	DRSP.ti,ab.
17	norpregnenes.ti,ab.
18	gestodene.ti,ab.
19	drospirenone.ti,ab.
20	levonorgestrel.ti,ab.
21	(norethisterone or norgestimate).ti,ab.
22	nandrolone.ti,ab.
23	dienogest.ti,ab.
24	etynodiol.ti,ab.
25	(hormonal adj3 contracept$).ti,ab.
26	"combined oral contracepti$".ti,ab.
27	COCP.ti,ab.
28	mini?pill.ti,ab.
29	progest#gen$.ti,ab.
30	(Gedarel or Mercilon or Femodette or Millinette or Sunya or Loestrin or Marvelon or Yasmin or Katya or Levest or Microgynon, or Ovranette, or Rigevidon or Cilest or Brevinor or Ovysmen or Norimin or Norinyl or Femodene or Triadene or Logynon or Triregol or Binovum or Synphase or Trinovum or Logynon or Qlaira).ti,ab.
31	(combined adj oral adj3 contracept$).ti,ab.
32	or/12-31
33	and/11,32
34	limit 33 to yr="2012 -Current"

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials January 2014
Search Strategy: **DiP_update_combined_oral_contraceptive_RERUN1_cctr_200314**

#	Searches
1	exp DIABETES MELLITUS/
2	(T1DM or T2DM).ti,ab.
3	IDDM.ti,ab.
4	diabet$.ti.
5	PREDIABETIC STATE/
6	prediabet$.ti,ab.
7	impaired glucose tolerance.ti,ab.
8	IGT.ti,ab.
9	Impaired fasting glucose.ti,ab.
10	IFG.ti,ab.
11	Impaired glucose regulation.ti,ab.
12	IGR.ti,ab.
13	GLUCOSE INTOLERANCE/
14	or/1-13
15	CONTRACEPTIVES, ORAL/ or CONTRACEPTIVES, ORAL, COMBINED/ or CONTRACEPTIVES, ORAL, HORMONAL/ or CONTRACEPTIVES, ORAL, SEQUENTIAL/ or CONTRACEPTIVES, ORAL, SYNTHETIC/ or exp CONTRACEPTIVES, POSTCOITAL/

#	Searches
16	ETHINYL ESTRADIOL/ or ETHINYL ESTRADIOL-NORGESTREL COMBINATION/ or MESTRANOL/
17	ESTRADIOL/
18	ESTROGENS/ or ESTROGENS, NON-STEROIDAL/
19	PROGESTINS/
20	DESOGESTREL/
21	DRSP.ti,ab.
22	exp NORPREGNENES/
23	gestodene.ti,ab.
24	drospirenone.ti,ab.
25	levonorgestrel.ti,ab.
26	(norethisterone or norgestimate).ti,ab.
27	NANDROLONE/
28	dienogest.ti,ab.
29	etynodiol.ti,ab.
30	"combined oral contracepti$".ti,ab.
31	COCP.ti,ab.
32	mini?pill.ti,ab.
33	progest#gen$.ti,ab.
34	(Gedarel or Mercilon or Femodette or Millinette or Sunya or Loestrin or Marvelon or Yasmin or Katya or Levest or Microgynon, or Ovranette, or Rigevidon or Cilest or Brevinor or Ovysmen or Norimin or Norinyl or Femodene or Triadene or Logynon or Triregol or Binovum or Synphase or Trinovum or Qlaira).ti,ab.
35	(combined adj oral adj3 contracept$).ti,ab.
36	or/15-35
37	and/14,36
38	limit 37 to yr="2012 -Current"

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to February 2014, EBM Reviews - Database of Abstracts of Reviews of Effects 1st Quarter 2014
Search Strategy: **DiP_update_combined_oral_contraceptive_RERUN1_cdsrdare_200314**

#	Searches
1	DIABETES MELLITUS.kw.
2	(T1DM or T2DM).tw,tx.
3	IDDM.tw,tx.
4	diabet$.ti.
5	PREDIABETIC STATE.kw.
6	prediabet$.tw,tx.
7	impaired glucose tolerance.tw,tx.
8	IGT.tw,tx.
9	Impaired fasting glucose.tw,tx.
10	IFG.tw,tx.
11	Impaired glucose regulation.tw,tx.
12	IGR.tw,tx.

#	Searches
13	GLUCOSE INTOLERANCE.kw.
14	or/1-13
15	(CONTRACEPTIVES, ORAL or CONTRACEPTIVES, ORAL, COMBINED or CONTRACEPTIVES, ORAL, HORMONAL or CONTRACEPTIVES, ORAL, SEQUENTIAL or CONTRACEPTIVES, ORAL, SYNTHETIC or CONTRACEPTIVES, POSTCOITAL).kw.
16	(ETHINYL ESTRADIOL or ETHINYL ESTRADIOL-NORGESTREL COMBINATION or MESTRANOL).kw.
17	ESTRADIOL.kw.
18	(ESTROGENS or ESTROGENS, NON-STEROIDAL).kw.
19	PROGESTINS.kw.
20	DESOGESTREL.kw.
21	DRSP.tw,tx.
22	NORPREGNENES.kw.
23	gestodene.tw,tx.
24	drospirenone.tw,tx.
25	levonorgestrel.tw,tx.
26	(norethisterone or norgestimate).tw,tx.
27	NANDROLONE.kw.
28	dienogest.tw,tx.
29	etynodiol.tw,tx.
30	(hormonal adj3 contracept$).tw,tx.
31	"combined oral contracepti$".tw,tx.
32	COCP.tw,tx.
33	mini?pill.tw,tx.
34	progest#gen$.tw,tx.
35	(Gedarel or Mercilon or Femodette or Millinette or Sunya or Loestrin or Marvelon or Yasmin or Katya or Levest or Microgynon, or Ovranette, or Rigevidon or Cilest or Brevinor or Ovysmen or Norimin or Norinyl or Femodene or Triadene or Logynon or Triregol or Binovum or Synphase or Trinovum or Qlaira).tw,tx.
36	(combined adj oral adj3 contracept$).tw,tx.
37	or/15-36
38	and/14,37
39	("2012" or "2013" or "2014").dp.
40	and/38-39

Database(s): EBM Reviews - Health Technology Assessment 1st Quarter 2014
Search Strategy: **DiP_update_combined_oral_contraceptive_RERUN1_hta_200314**

#	*Searches*
1	*exp DIABETES MELLITUS/*
2	*(T1DM or T2DM).tw.*
3	*IDDM.tw.*
4	*diabet$.tw.*
5	*PREDIABETIC STATE/*
6	*prediabet$.tw.*

#	Searches
7	*impaired glucose tolerance.tw.*
8	*IGT.tw.*
9	*Impaired fasting glucose.tw.*
10	*IFG.tw.*
11	*Impaired glucose regulation.tw.*
12	*IGR.tw.*
13	*GLUCOSE INTOLERANCE/*
14	*or/1-13*
15	*CONTRACEPTIVES, ORAL/ or CONTRACEPTIVES, ORAL, COMBINED/ or CONTRACEPTIVES, ORAL, HORMONAL/ or CONTRACEPTIVES, ORAL, SEQUENTIAL/ or CONTRACEPTIVES, ORAL, SYNTHETIC/ or exp CONTRACEPTIVES, POSTCOITAL/*
16	*ETHINYL ESTRADIOL/ or ETHINYL ESTRADIOL-NORGESTREL COMBINATION/ or MESTRANOL/*
17	*ESTRADIOL/*
18	*ESTROGENS/ or ESTROGENS, NON-STEROIDAL/*
19	*PROGESTINS/*
20	*DESOGESTREL/*
21	*DRSP.tw.*
22	*exp NORPREGNENES/*
23	*gestodene.tw.*
24	*drospirenone.tw.*
25	*levonorgestrel.tw.*
26	*(norethisterone or norgestimate).tw.*
27	*NANDROLONE/*
28	*dienogest.tw.*
29	*etynodiol.tw.*
30	*"combined oral contracepti$".tw.*
31	*COCP.tw.*
32	*mini?pill.tw.*
33	*progest#gen$.tw.*
34	*(Gedarel or Mercilon or Femodette or Millinette or Sunya or Loestrin or Marvelon or Yasmin or Katya or Levest or Microgynon, or Ovranette, or Rigevidon or Cilest or Brevinor or Ovysmen or Norimin or Norinyl or Femodene or Triadene or Logynon or Triregol or Binovum or Synphase or Trinovum or Qlaira).tw.*
35	*(combined adj oral adj3 contracept$).tw.*
36	*or/15-35*
37	*and/14,36*
38	*limit 37 to yr="2012 -Current"*

Database(s): Embase 1974 to 2014 March 19
Search Strategy: DiP**_update_combined_oral_contraceptive_RERUN1_embase_200314**

#	Searches
1	DIABETES MELLITUS/ or IMPAIRED GLUCOSE TOLERANCE/ or INSULIN DEPENDENT DIABETES MELLITUS/ or JUVENILE DIABETES MELLITUS/ or NON INSULIN DEPENDENT DIABETES MELLITUS/

#	Searches
2	(T1DM or T2DM).ti,ab.
3	(IDDM or NIDDM).ti,ab.
4	diabet$.ti.
5	pre?diabet$.ti,ab.
6	impaired fasting glucose.ti,ab.
7	(IGT or IFG).ti,ab.
8	IGR.ti,ab.
9	GLUCOSE INTOLERANCE/
10	or/1-9
11	exp ORAL CONTRACEPTIVE AGENT/
12	DIENOGEST PLUS ESTRADIOL VALERATE/
13	ESTRADIOL/
14	*ESTROGEN/
15	*GESTAGEN/
16	progestin?.ti,ab.
17	progest#gen$.ti,ab.
18	(hormonal adj3 contracept$).ti,ab.
19	"combined oral contracepti$".ti,ab.
20	COCP.ti,ab.
21	mini?pill.ti,ab.
22	(Gedarel or Mercilon or Femodette or Millinette or Sunya or Loestrin or Marvelon or Yasmin or Katya or Levest or Microgynon, or Ovranette, or Rigevidon or Cilest or Brevinor or Ovysmen or Norimin or Norinyl or Femodene or Triadene or Logynon or Triregol or Binovum or Synphase or Trinovum or Qlaira).ti,ab.
23	(combined adj oral adj3 contracept$).ti,ab.
24	or/11-23
25	and/10,24
26	CLINICAL TRIAL/ or "CLINICAL TRIAL (TOPIC)"/
27	(clinic$ adj5 trial$).tw,sh.
28	SINGLE BLIND PROCEDURE/
29	DOUBLE BLIND PROCEDURE/
30	RANDOM ALLOCATION/
31	CROSSOVER PROCEDURE/
32	PLACEBO/
33	placebo$.tw,sh.
34	random$.tw,sh.
35	RANDOMIZED CONTROLLED TRIAL/ or "RANDOMIZED CONTROLLED TRIAL (TOPIC)"/
36	((single or double or triple or treble) adj (blind$ or mask$)).tw,sh.
37	randomi?ed control$ trial$.tw.
38	or/26-37
39	META ANALYSIS/
40	((meta adj analy$) or metaanalys$ or meta-analy$).tw,sh.
41	(systematic$ adj5 (review$ or overview$)).tw,sh.
42	(methodologic$ adj5 (review$ or overview$)).tw,sh.
43	or/39-42
44	review.pt.

#	Searches
45	(medline or medlars or embase).ab.
46	(scisearch or science citation index).ab.
47	(psychlit or psyclit or psychinfo or psycinfo or cinahl or cochrane).ab.
48	((hand or manual$) adj2 search$).tw.
49	(electronic database$ or bibliographic database$ or computeri?ed database$ or online database$).tw.
50	(pooling or pooled or mantel haenszel).tw.
51	(peto or dersimonian or "der simonian" or fixed effect).tw.
52	or/45-51
53	and/44,52
54	exp CASE CONTROL STUDY/
55	RETROSPECTIVE STUDY/
56	(case$ adj2 control$).tw.
57	COHORT ANALYSIS/
58	LONGITUDINAL STUDY/
59	FOLLOW UP/
60	PROSPECTIVE STUDY/
61	cohort$.tw.
62	or/54-61
63	or/38,43,53,62
64	(book or conference paper or editorial or letter or note or proceeding or short survey).pt.
65	63 not 64
66	COMPARATIVE STUDY/ or COMPARATIVE EFFECTIVENESS/ or DOSAGE SCHEDULE COMPARISON/ or exp DRUG COMPARISON/ or DRUG DOSAGE FORM COMPARISON/ or DRUG DOSE COMPARISON/ or INTERMETHOD COMPARISON/
67	and/25,65
68	and/25,66
69	or/67-68
70	limit 69 to english language
71	exp HORMONE SUBSTITUTION/
72	((hormone or oestrogen or estrogen) adj replacement therap?).ti,ab.
73	(HRT or EBHT).ti,ab.
74	or/71-73
75	70 not 74
76	limit 75 to yr="2012 -Current"

E.2 **Search 2:** Ketone monitoring in the preconception and antenatal periods

A single search was conducted for 2 review questions

Review question 3: What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1 or type 2 diabetes who are planning pregnancy?

Review question 11: What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1, type 2 or gestational diabetes during pregnancy?

Database(s): Ovid MEDLINE(R) 1946 to February Week 2 2014
Search Strategy: **DiP_update_ketone_monitoring_RERUN1_medline_260214**

#	Searches
1	randomized controlled trial.pt.
2	controlled clinical trial.pt.
3	DOUBLE BLIND METHOD/
4	SINGLE BLIND METHOD/
5	RANDOM ALLOCATION/
6	or/1-5
7	((single or double or triple or treble) adj5 (blind$ or mask$)).tw,sh.
8	clinical trial.pt.
9	exp CLINICAL TRIAL/
10	exp CLINICAL TRIALS AS TOPIC/
11	(clinic$ adj5 trial$).tw,sh.
12	PLACEBOS/
13	placebo$.tw,sh.
14	random$.tw,sh.
15	or/7-14
16	or/6,15
17	META ANALYSIS/
18	META ANALYSIS AS TOPIC/
19	meta analysis.pt.
20	(metaanaly$ or meta-analy$ or (meta adj analy$)).tw,sh.
21	(systematic$ adj5 (review$ or overview$)).tw,sh.
22	(methodologic$ adj5 (review$ or overview$)).tw,sh.
23	or/17-22
24	review$.pt.
25	(medline or medlars or embase or cinahl or cochrane or psycinfo or psychinfo or psychlit or psyclit or "web of science" or "science citation" or scisearch).tw.
26	((hand or manual$) adj2 search$).tw.
27	(electronic database$ or bibliographic database$ or computeri?ed database$ or online database$).tw,sh.
28	(pooling or pooled or mantel haenszel).tw,sh.
29	(peto or dersimonian or der simonian or fixed effect).tw,sh.
30	or/25-29
31	and/24,30
32	exp CASE-CONTROL STUDIES/
33	(case$ adj2 control$).tw.
34	exp COHORT STUDIES/
35	cohort$.tw.
36	or/32-35
37	or/16,23,31,36
38	exp PREGNANCY IN DIABETICS/

#	Searches
39	DIABETES, GESTATIONAL/
40	(diabet$ adj3 (gestat$ or pregnan$ or gravid$)).ti,ab.
41	GDM.ti,ab.
42	or/38-41
43	exp DIABETES MELLITUS/
44	exp DIABETES INSIPIDUS/
45	(T?1DM or T?2DM or IDDM or NIDDM).ti,ab.
46	diabet$.ti.
47	PREDIABETIC STATE/
48	(prediabet$ or pre diabet$).ti,ab.
49	impaired glucose tolerance.ti,ab.
50	IGT.ti,ab.
51	(impaired fasting glucose or impaired fasting glyc?emi$).ti,ab.
52	IFG.ti,ab.
53	Impaired glucose regulation.ti,ab.
54	IGR.ti,ab.
55	(Non diabetic hyperglyc?emi# or nondiabetic hyperglyc?emi#).ti,ab.
56	NDH.ti,ab.
57	GLUCOSE INTOLERANCE/
58	(glucose adj2 intoleran$).ti,ab.
59	or/43-58
60	PREGNANCY/
61	(pregnan$ or gestat$ or gravid$).ti,ab.
62	PREGNANT WOMEN/
63	or/60-62
64	and/59,63
65	or/42,64
66	KETONES/ or KETONE BODIES/
67	3-HYDROXYBUTYRIC ACID/
68	(keton?e$ or hyperketon?e$ or ketonuria or hyperketonuria).ti,ab.
69	(ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB).ti,ab,nm.
70	exp KETOSIS/
71	(diabet$ adj3 (ketogenesis or ketosis or ketoacido$)).ti,ab.
72	DKA.ti,ab.
73	or/66-72
74	MONITORING, PHYSIOLOGIC/ or BLOOD GLUCOSE SELF-MONITORING/ or exp FETAL MONITORING/ or SELF CARE/
75	(self monitor$ or monitor$ or meter$ or measur$ or test$ or screen$ or determin$ or assess$ or surveillance or check$).ti,ab.
76	or/74-75
77	and/73,76
78	((capillar$ or blood$ or plasma or serum or urine or urinary) adj5 (ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB)).ti,ab.

#	Searches
79	or/77-78
80	and/65,79
81	and/37,80
82	LETTER/
83	EDITORIAL/
84	NEWS/
85	exp HISTORICAL ARTICLE/
86	ANECDOTES AS TOPIC/
87	COMMENT/
88	CASE REPORT/
89	(letter or comment* or abstracts).ti.
90	or/82-89
91	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
92	90 not 91
93	ANIMALS/ not HUMANS/
94	exp ANIMALS, LABORATORY/
95	exp ANIMAL EXPERIMENTATION/
96	exp MODELS, ANIMAL/
97	exp RODENTIA/
98	(rat or rats or mouse or mice).ti.
99	or/92-98
100	81 not 99
101	limit 100 to english language
102	limit 101 to yr="2013 -Current"

Database(s): **Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations** March 22, 2013

Search Strategy: DiP_update_ketone_monitoring_mip_250313

#	Searches
1	(diabet$ adj3 (gestat$ or pregnan$ or gravid$)).ti,ab.
2	GDM.ti,ab.
3	or/1-2
4	(T?1DM or T?2DM or IDDM or NIDDM).ti,ab.
5	diabet$.ti.
6	(prediabet$ or pre diabet$).ti,ab.
7	impaired glucose tolerance.ti,ab.
8	IGT.ti,ab.
9	(impaired fasting glucose or impaired fasting glyc?emi$).ti,ab.
10	IFG.ti,ab.
11	Impaired glucose regulation.ti,ab.
12	IGR.ti,ab.

#	Searches
13	(Non diabetic hyperglyc?emi# or nondiabetic hyperglyc?emi#).ti,ab.
14	NDH.ti,ab.
15	(glucose adj2 intoleran$).ti,ab.
16	or/4-15
17	(pregnan$ or gestat$ or gravid$).ti,ab.
18	and/16-17
19	or/3,18
20	(keton?e$ or hyperketon?e$ or ketonuria or hyperketonuria).ti,ab.
21	(ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB).ti,ab.
22	(diabet$ adj3 (ketogenesis or ketosis or ketoacido$)).ti,ab.
23	DKA.ti,ab.
24	or/20-23
25	(self monitor$ or monitor$ or meter$ or measur$ or test$ or screen$ or determin$ or assess$ or surveillance or check$).ti,ab.
26	and/24-25
27	((capillar$ or blood$ or plasma or serum or urine or urinary) adj5 (ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB)).ti,ab.
28	or/26-27
29	and/19,28

Database(s): **EBM Reviews - Cochrane Central Register of Controlled Trials** February 2013

Search Strategy: DiP_update_ketone_monitoring_cctr_250313

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(diabet$ adj3 (gestat$ or pregnan$ or gravid$)).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T?1DM or T?2DM or IDDM or NIDDM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	(prediabet$ or pre diabet$).ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	(impaired fasting glucose or impaired fasting glyc?emi$).ti,ab.
15	IFG.ti,ab.

#	Searches
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	(Non diabetic hyperglyc?emi# or nondiabetic hyperglyc?emi#).ti,ab.
19	NDH.ti,ab.
20	GLUCOSE INTOLERANCE/
21	(glucose adj2 intoleran$).ti,ab.
22	or/6-21
23	PREGNANCY/
24	(pregnan$ or gestat$ or gravid$).ti,ab.
25	PREGNANT WOMEN/
26	or/23-25
27	and/22,26
28	or/5,27
29	KETONES/ or KETONE BODIES/
30	3-HYDROXYBUTYRIC ACID/
31	(keton?e$ or hyperketon?e$ or ketonuria or hyperketonuria).ti,ab.
32	(ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB).ti,ab.
33	exp KETOSIS/
34	(diabet$ adj3 (ketogenesis or ketosis or ketoacido$)).ti,ab.
35	DKA.ti,ab.
36	or/29-35
37	MONITORING, PHYSIOLOGIC/ or BLOOD GLUCOSE SELF-MONITORING/ or exp FETAL MONITORING/ or SELF CARE/
38	(self monitor$ or monitor$ or meter$ or measur$ or test$ or screen$ or determin$ or assess$ or surveillance or check$).ti,ab.
39	or/37-38
40	and/36,39
41	((capillar$ or blood$ or plasma or serum or urine or urinary) adj5 (ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB)).ti,ab.
42	or/40-41
43	and/28,42
44	limit 43 to yr="2007 -Current"

Database(s): **EBM Reviews - Health Technology Assessment** 1st Quarter 2013
Search Strategy: DiP_update_ketone_monitoring_hta_250313

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(diabet$ adj3 (gestat$ or pregnan$ or gravid$)).tw.

#	Searches
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T?1DM or T?2DM or IDDM or NIDDM).tw.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	(prediabet$ or pre diabet$).tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	(impaired fasting glucose or impaired fasting glyc?emi$).tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	(Non diabetic hyperglyc?emi# or nondiabetic hyperglyc?emi#).tw.
19	NDH.tw.
20	GLUCOSE INTOLERANCE/
21	(glucose adj2 intoleran$).tw.
22	or/6-21
23	PREGNANCY/
24	(pregnan$ or gestat$ or gravid$).tw.
25	PREGNANT WOMEN/
26	or/23-25
27	and/22,26
28	or/5,27
29	KETONES/ or KETONE BODIES/
30	3-HYDROXYBUTYRIC ACID/
31	(keton?e$ or hyperketon?e$ or ketonuria or hyperketonuria).tw.
32	(ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB).tw.
33	exp KETOSIS/
34	(diabet$ adj3 (ketogenesis or ketosis or ketoacido$)).tw.
35	DKA.tw.
36	or/29-35
37	MONITORING, PHYSIOLOGIC/ or BLOOD GLUCOSE SELF-MONITORING/ or exp FETAL MONITORING/ or SELF CARE/
38	(self monitor$ or monitor$ or meter$ or measur$ or test$ or screen$ or determin$ or assess$ or surveillance or check$).tw.
39	or/37-38
40	and/36,39
41	((capillar$ or blood$ or plasma or serum or urine or urinary) adj5 (ketone? or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or "3-hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or B OHB or BOHB or "3 OHB" or "3-OHB" or 3OHB or "3 HB" or "3-HB" or 3HB)).tw.
42	or/40-41
43	and/28,42

#	Searches
44	limit 43 to yr="2007 -Current"

Database(s): Embase 1974 to 2014 February 25
Search Strategy: **DiP_update_ketone_monitoring_RERUN1_embase_260214**

#	Searches
1	CLINICAL TRIALS/ or "CLINICAL TRIAL (TOPIC)"/
2	(clinic$ adj5 trial$).tw,sh.
3	SINGLE BLIND PROCEDURE/
4	DOUBLE BLIND PROCEDURE/
5	RANDOM ALLOCATION/
6	CROSSOVER PROCEDURE/
7	PLACEBO/
8	placebo$.tw,sh.
9	random$.tw,sh.
10	RANDOMIZED CONTROLLED TRIALS/
11	((single or double or triple or treble) adj (blind$ or mask$)).tw,sh.
12	randomi?ed control$ trial$.tw.
13	or/1-12
14	META ANALYSIS/
15	((meta adj analy$) or metaanalys$ or meta-analy$).tw,sh.
16	(systematic$ adj5 (review$ or overview$)).tw,sh.
17	(methodologic$ adj5 (review$ or overview$)).tw,sh.
18	or/14-17
19	review.pt.
20	(medline or medlars or embase).ab.
21	(scisearch or science citation index).ab.
22	(psychlit or psyclit or psychinfo or psycinfo or cinahl or cochrane).ab.
23	((hand or manual$) adj2 search$).tw.
24	(electronic database$ or bibliographic database$ or computeri?ed database$ or online database$).tw.
25	(pooling or pooled or mantel haenszel).tw.
26	(peto or dersimonian or "der simonian" or fixed effect).tw.
27	or/20-26
28	19 and 27
29	COMPARATIVE STUDY/
30	(compar$ adj5 stud$).tw.
31	CASE-CONTROL STUDY/
32	RETROSPECTIVE STUDY/
33	PROSPECTIVE STUDY/
34	COHORT STUDY/
35	(case$ adj2 control$).tw.
36	or/29-35
37	or/13,18,28,36

#	Searches
38	abstract report.tw,sh.
39	note.tw,sh.
40	short survey.tw,sh.
41	letter.tw,sh.
42	editorial.tw,sh.
43	or/38-42
44	37 not 43
45	exp PREGNANCY DIABETES MELLITUS/
46	(diabet$ adj3 (gestation$ or pregnan$ or gravid$)).ti,ab.
47	GDM.ti,ab.
48	or/45-47
49	exp DIABETES MELLITUS/
50	exp DIABETES INSIPIDUS/
51	diabet$.ti.
52	(T?1DM or T?2DM).ti,ab.
53	(IDDM or NIDDM).ti,ab.
54	(prediabet$ or pre diabet$).ti,ab.
55	IMPAIRED GLUCOSE TOLERANCE/
56	IGT.ti,ab.
57	(impaired fasting glucose or impaired fasting glyc?emi$).ti,ab.
58	IFG.ti,ab.
59	impaired glucose regulat$.ti,ab.
60	IGR.ti,ab.
61	(Non diabetic hyperglyc?emi# or nondiabetic hyperglyc?emi#).ti,ab.
62	NDH.ti,ab.
63	GLUCOSE INTOLERANCE/
64	(glucose adj2 intoleran$).ti,ab.
65	or/49-62
66	PREGNANCY/ or FIRST TRIMESTER PREGNANCY/ or PREGNANT WOMAN/ or SECOND TRIMESTER PREGNANCY/ or THIRD TRIMESTER PREGNANCY/
67	(pregnan$ or gestation$ or gravid$).ti,ab.
68	or/66-67
69	and/65,68
70	or/48,69
71	KETOGENESIS/
72	KETONE/
73	KETONE BODY/
74	KETONURIA/
75	3 HYDROXYBUTYRIC ACID/
76	DIABETIC KETOACIDOSIS/
77	(keton?e$ or hyperketon?e$ or keton?ur$ or hyperketon?e$).ti,ab.
78	(hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or "B OHB" or 3OHB or "3 OHB" or BHB? or 3HB or "3 HB").ti,ab.
79	(diabet$ adj3 (ketogenesis or ketosis or ketoacido$)).ti,ab.
80	DKA.ti,ab.

#	Searches
81	or/71-80
82	PATIENT MONITORING/
83	FETUS MONITORING/
84	BLOOD GLUCOSE MONITORING/
85	SELF CARE/
86	(self monitor$ or monitor$ or meter$ or measure$ or test$ or assess$ or screen$ or determin$ or surveillance or check$).ti,ab.
87	or/82-86
88	and/81,87
89	((capillar$ or blood$ or plasma or serum or urine or urinary) adj5 (keton$ or hydroxy butyr$ or hydroxybutyr$ or beta hydroxybutyr$ or betahydroxybutyr$ or "3 hydroxybutyr$" or 3hydroxybutyr$ or OHB or beta OHB or betaOHB or "B OHB" or 3OHB or "3 OHB" or BHB? or 3HB or "3 HB")).ti,ab.
90	or/88-89
91	and/70,90
92	and/44,91
93	conference abstract.pt.
94	letter.pt. or LETTER/
95	note.pt.
96	editorial.pt.
97	CASE REPORT/ or CASE STUDY/
98	(letter or comment* or abstracts).ti.
99	or/93-98
100	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
101	99 not 100
102	ANIMAL/ not HUMAN/
103	NONHUMAN/
104	exp ANIMAL EXPERIMENT/
105	exp EXPERIMENTAL ANIMAL/
106	ANIMAL MODEL/
107	exp RODENT/
108	(rat or rats or mouse or mice).ti.
109	or/101-108
110	92 not 109
111	limit 110 to english language
112	limit 111 to yr="2013 -Current"

E.3 Search 3: Blood glucose and HbA1c target values in the preconception period and antenatal monitoring and target values

A single search was conducted for six review questions:

Review question 4: What are the target ranges for blood glucose in women with type 1 or type 2 diabetes who are planning pregnancy?

Review question 5: What is the target value for HbA1c in women with type 1 or type 2 diabetes who are planning pregnancy?

Review question 10: What is the effectiveness of blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?

Review question 12: What are the target ranges for blood glucose in women with type 1, type 2 or gestational diabetes during pregnancy?

Review question 13: What is the effectiveness of HbA1c monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?

Review question 14: What is the target value for HbA1c in women with type 1, type 2 or gestational diabetes during pregnancy?

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials March 2013
Search Strategy: DiP_update_HbA1c_blood_glucose_HbA1c_monitor_values_cctr_260413

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	GLUCOSE INTOLERANCE/
19	HYPERGLYCEMIA/
20	hyperglyc?emi?.ti,ab.
21	or/6-20
22	PREGNANCY/
23	(pregnan$ or gestation$).ti,ab.
24	PREGNANT WOMEN/
25	PRECONCEPTION CARE/
26	PRENATAL CARE/
27	pre?conception.ti,ab.
28	(pre adj conception).ti,ab.
29	pre?pregnancy.ti,ab.
30	(pre adj pregnancy).ti,ab.

#	Searches
31	(pre?natal$ or pre?conception or ante?natal$).ti,ab.
32	(pre adj natal$).ti,ab.
33	(pre adj conception).ti,ab.
34	(ante adj natal$).ti,ab.
35	or/22-34
36	and/21,35
37	or/5,36
38	BLOOD GLUCOSE/
39	(blood adj3 (glucose or sugar?)).ti,ab.
40	BLOOD GLUCOSE SELF-MONITORING/
41	BGSM.ti,ab.
42	(home glucose adj (test$ or monitor$)).ti,ab.
43	(self adj (test$ or monitor$)).ti,ab.
44	GLUCOSE TOLERANCE TEST/
45	OGTT.ti,ab.
46	(glucose adj (toleran$ or test$ or load$)).ti,ab.
47	(fasting adj plasma adj glucose).ti,ab.
48	FPG.ti,ab.
49	HEMOGLOBIN A, GLYCOSYLATED/
50	HbA1c.ti,ab.
51	(h?emoglobin? adj3 glycosylat$).ti,ab.
52	(glycated adj3 h?emoglobin?).ti,ab.
53	or/38-52
54	and/37,53
55	limit 54 to yr="2008 -Current"

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to March 2013, EBM Reviews - Database of Abstracts of Reviews of Effects 1st Quarter 2013
Search Strategy: DiP_update_HbA1c_blood_glucose_HbA1c_monitor_values_cdsrdare_260413

#	Searches
1	PREGNANCY IN DIABETICS.kw.
2	DIABETES, GESTATIONAL.kw.
3	(gestation$ adj3 diabet$).tw,tx.
4	GDM.tw,tx.
5	or/1-4
6	DIABETES MELLITUS.kw.
7	DIABETES INSIPIDUS.kw.
8	(T1DM or T2DM).tw,tx.
9	diabet$.tw,tx.
10	PREDIABETIC STATE.kw.
11	prediabet$.tw,tx.
12	impaired glucose tolerance.tw,tx.
13	IGT.tw,tx.
14	Impaired fasting glucose.tw,tx.

#	Searches
15	IFG.tw,tx.
16	Impaired glucose regulation.tw,tx.
17	IGR.tw,tx.
18	GLUCOSE INTOLERANCE.kw.
19	HYPERGLYCEMIA.kw.
20	hyperglyc?emi?.tw,tx.
21	or/6-20
22	PREGNANCY.kw.
23	(pregnan$ or gestation$).tw,tx.
24	PREGNANT WOMEN.kw.
25	PRECONCEPTION CARE.kw.
26	PRENATAL CARE.kw.
27	pre?conception.tw,tx.
28	(pre adj conception).tw,tx.
29	pre?pregnancy.tw,tx.
30	(pre adj pregnancy).tw,tx.
31	(pre?natal$ or pre?conception or ante?natal$).tw,tx.
32	(pre adj natal$).tw,tx.
33	(pre adj conception).tw,tx.
34	(ante adj natal$).tw,tx.
35	or/22-34
36	and/21,35
37	or/5,36
38	BLOOD GLUCOSE.kw.
39	(blood adj3 (glucose or sugar?)).tw,tx.
40	BLOOD GLUCOSE SELF-MONITORING.kw.
41	BGSM.tw,tx.
42	(home glucose adj (test$ or monitor$)).tw,tx.
43	(self adj (test$ or monitor$)).tw,tx.
44	GLUCOSE TOLERANCE TEST.kw.
45	OGTT.tw,tx.
46	(glucose adj (toleran$ or test$ or load$)).tw,tx.
47	(fasting adj plasma adj glucose).tw,tx.
48	FPG.tw,tx.
49	HEMOGLOBIN A, GLYCOSYLATED.kw.
50	HbA1c.tw,tx.
51	(h?emoglobin? adj3 glycosylat$).tw,tx.
52	(glycated adj3 h?emoglobin?).tw,tx.
53	or/38-52
54	and/37,53

Database(s): Embase 1974 to 2013 April 25
Search Strategy: DiP_update_HbA1c_blood_glucose_HbA1c_monitor_values_embase_250413

#	Searches
1	PREGNANCY DIABETES MELLITUS/ or MATERNAL DIABETES MELLITUS/
2	(gestation$ adj3 diabet$).ti,ab.
3	or/1-2
4	DIABETES MELLITUS/ or IMPAIRED GLUCOSE TOLERANCE/ or INSULIN DEPENDENT DIABETES MELLITUS/ or JUVENILE DIABETES MELLITUS/ or NON INSULIN DEPENDENT DIABETES MELLITUS/
5	(T1DM or T2DM).ti,ab.
6	(IDDM or NIDDM).ti,ab.
7	diabet$.ti.
8	pre?diabet$.ti,ab.
9	impaired fasting glucose.ti,ab.
10	(IGT or IFG).ti,ab.
11	IGR.ti,ab.
12	GLUCOSE INTOLERANCE/
13	HYPERGLYCEMIA/
14	hyperglyc?emi?.ti,ab.
15	or/4-14
16	PREGNANCY/ or PREGNANT WOMAN/
17	(pregnan$ or gestation$).ti,ab.
18	MATERNAL CARE/
19	pre?conception.ti,ab.
20	(pre adj conception).ti,ab.
21	pre?pregnancy.ti,ab.
22	(pre adj pregnancy).ti,ab.
23	PRENATAL CARE/
24	(pre?natal$ or ante?natal$).ti,ab.
25	(pre adj natal$).ti,ab.
26	(ante adj natal$).ti,ab.
27	or/16-26
28	and/15,27
29	or/3,28
30	BLOOD GLUCOSE MONITORING/
31	(blood adj3 (glucose or sugar?)).ti,ab.
32	BGSM.ti,ab.
33	GLUCOSE BLOOD LEVEL/
34	(home glucose adj (test$ or monitor$)).ti,ab.
35	(self adj (test$ or monitor$)).ti,ab.
36	GLUCOSE TOLERANCE TEST/ or GLUCOSE CLAMP TECHNIQUE/ or INTRAVENOUS GLUCOSE TOLERANCE TEST/ or ORAL GLUCOSE TOLERANCE TEST/
37	(glucose adj (test$ or toleran$ or load?)).ti,ab.
38	(fasting adj plasma adj glucose).ti,ab.
39	FPG.ti,ab.
40	HEMOGLOBIN A1c/
41	HbA1c.ti,ab.
42	(h?emoglobin? adj3 glycosylat$).ti,ab.
43	(glycated adj3 h?emoglobin?).ti,ab.

#	Searches
44	or/30-43
45	and/29,44
46	conference abstract.pt.
47	letter.pt. or LETTER/
48	note.pt.
49	editorial.pt.
50	CASE REPORT/ or CASE STUDY/
51	(letter or comment* or abstracts).ti.
52	or/46-51
53	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
54	52 not 53
55	ANIMAL/ not HUMAN/
56	NONHUMAN/
57	exp ANIMAL EXPERIMENT/
58	exp EXPERIMENTAL ANIMAL/
59	ANIMAL MODEL/
60	exp RODENT/
61	(rat or rats or mouse or mice).ti.
62	or/54-61
63	45 not 62
64	limit 63 to english language
65	limit 64 to yr="2008 -Current"

Database(s): EBM Reviews - Health Technology Assessment 1st Quarter 2013
Search Strategy: DiP_update_HbA1c_blood_glucose_HbA1c_monitor_values_hta_260413

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.tw.
10	PREDIABETIC STATE/
11	prediabet$.tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	GLUCOSE INTOLERANCE/

#	Searches
19	HYPERGLYCEMIA/
20	hyperglyc?em?.tw.
21	or/6-20
22	PREGNANCY/
23	(pregnan$ or gestation$).tw.
24	PREGNANT WOMEN/
25	PRECONCEPTION CARE/
26	PRENATAL CARE/
27	pre?conception.tw.
28	(pre adj conception).tw.
29	pre?pregnancy.tw.
30	(pre adj pregnancy).tw.
31	(pre?natal$ or pre?conception or ante?natal).tw.
32	(pre adj natal$).tw.
33	(pre adj conception).tw.
34	(ante adj natal$).tw.
35	or/22-34
36	and/21,35
37	or/5,36
38	BLOOD GLUCOSE/
39	(blood adj3 (glucose or sugar?)).tw.
40	BLOOD GLUCOSE SELF-MONITORING/
41	BGSM.tw.
42	(home glucose adj (test$ or monitor$)).tw.
43	(self adj (test$ or monitor$)).tw.
44	GLUCOSE TOLERANCE TEST/
45	OGTT.tw.
46	(glucose adj (toleran$ or test$ or load$)).tw.
47	(fasting adj plasma adj glucose).tw.
48	FPG.tw.
49	HEMOGLOBIN A, GLYCOSYLATED/
50	HbA1c.tw.
51	(h?emoglobin? adj3 glycosylat$).tw.
52	(glycated adj3 h?emoglobin?).tw.
53	or/38-52
54	and/37,53

Database(s): Ovid MEDLINE(R) 1946 to April Week 3 2013
Search Strategy: DiP_update_HbA1c_blood_glucose_HbA1c_monitor_values_medline_260413

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.

#	Searches
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	GLUCOSE INTOLERANCE/
19	HYPERGLYCEMIA/
20	hyperglyc?emi?.ti,ab.
21	or/6-20
22	PREGNANCY/
23	(pregnan$ or gestation$).ti,ab.
24	PREGNANT WOMEN/
25	PRECONCEPTION CARE/
26	PRENATAL CARE/
27	pre?conception.ti,ab.
28	(pre adj conception).ti,ab.
29	pre?pregnancy.ti,ab.
30	(pre adj pregnancy).ti,ab.
31	(pre?natal$ or pre?conception or ante?natal$).ti,ab.
32	(pre adj natal$).ti,ab.
33	(pre adj conception).ti,ab.
34	(ante adj natal$).ti,ab.
35	or/22-34
36	and/21,35
37	or/5,36
38	BLOOD GLUCOSE/
39	(blood adj3 (glucose or sugar?)).ti,ab.
40	BLOOD GLUCOSE SELF-MONITORING/
41	BGSM.ti,ab.
42	(home glucose adj (test$ or monitor$)).ti,ab.
43	(self adj (test$ or monitor$)).ti,ab.
44	GLUCOSE TOLERANCE TEST/
45	(glucose adj (toleran$ or test$ or load$)).ti,ab.
46	OGTT.ti,ab.
47	(fasting adj plasma adj glucose).ti,ab.
48	FPG.ti,ab.
49	HEMOGLOBIN A, GLYCOSYLATED/

#	Searches
50	HbA1c.ti,ab.
51	(h?emoglobin? adj3 glycosylat$).ti,ab.
52	(glycated adj3 h?emoglobin?).ti,ab.
53	or/38-52
54	and/37,53
55	LETTER/
56	EDITORIAL/
57	NEWS/
58	exp HISTORICAL ARTICLE/
59	ANECDOTES AS TOPIC/
60	COMMENT/
61	CASE REPORT/
62	(letter or comment* or abstracts).ti.
63	or/55-62
64	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
65	63 not 64
66	ANIMALS/ not HUMANS/
67	exp ANIMALS, LABORATORY/
68	exp ANIMAL EXPERIMENTATION/
69	exp MODELS, ANIMAL/
70	exp RODENTIA/
71	(rat or rats or mouse or mice).ti.
72	or/65-71
73	54 not 72
74	limit 73 to english language
75	limit 74 to yr="2008 -Current"

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations April 25, 2013
Search Strategy: DiP_update_HbA1c_blood_glucose_HbA1c_monitor_values_mip_220413

#	Searches
1	((gestation$ or pregan$) adj3 diabet$).ti,ab.
2	(diabet$ or prediabet$ or pre?diabet$).ti,ab.
3	(T1DM or T2DM).ti,ab.
4	impaired glucose tolerance.ti,ab.
5	impaired fasting glucose.ti,ab.
6	impaired glucose regulation.ti,ab.
7	(IGT or IFG or IGR).ti,ab.
8	(glucose adj3 intoleran$).ti,ab.
9	hyperglyc?emi?.ti,ab.
10	or/2-9
11	(pregnan$ or gestation$).ti,ab.
12	(pre?natal$ or pre?conception or ante?natal$).ti,ab.
13	(pre adj natal$).ti,ab.

#	Searches
14	(pre adj conception).ti,ab.
15	(ante adj natal$).ti,ab.
16	or/11-15
17	and/10,16
18	or/1,17
19	(blood adj3 (glucose or sugar?)).ti,ab.
20	(glucose adj3 (test$ or monitor$ or assess$)).ti,ab.
21	OGTT.ti,ab.
22	(glucose adj (toleran$ or test$ or load$)).ti,ab.
23	fasting plasma glucose.ti,ab.
24	FPG.ti,ab.
25	(h?emoglobin? adj3 glycosylat$).ti,ab.
26	(glycated adj3 h?emoglobin?).ti,ab.
27	HbA1c.ti,ab.
28	or/19-27
29	and/18,28

E.4 Search 4: Screening for gestational diabetes in the first and second trimesters

A single search was conducted for 2 review questions

Review Question 6: What is the effectiveness of the following procedures in detecting glucose intolerance in the first trimester diagnosed using a 75g oral glucose tolerance test (OGTT):

- risk factor based screening
- urine test for glycosuria
- random blood glucose test
- 50g oral glucose challenge test
- fasting blood glucose test
- HbA1c test?

Review Question 7: What is the effectiveness of the following procedures in detecting glucose intolerance in the second trimester diagnosed using a 75g oral glucose tolerance test (OGTT):

- risk factor based screening
- urine test for glycosuria
- random blood glucose test
- 50g oral glucose challenge test
- fasting blood glucose test
- HbA1c test?

Database(s): Ovid MEDLINE(R) 1946 to February Week 2 2014
Search Strategy: **DiP_update_diagnosis_1st_2nd_trimester_RERUN1_medline_240214**

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	Non?diabetic hyperglyc?emi#.ti,ab.
19	NDH.ti,ab.
20	GLUCOSE INTOLERANCE/
21	or/6-20
22	PREGNANCY/
23	(pregnan$ or gestation$).ti,ab.
24	PREGNANT WOMEN/
25	or/22-24
26	and/21,25
27	or/5,26
28	RISK ASSESSMENT/ or RISK FACTORS/
29	MASS tr/
30	screen$.ti,ab.
31	or/29-30
32	and/28,31
33	(risk adj2 factor? adj2 screen$).ti,ab.
34	or/32-33
35	exp GLYCOSURIA/
36	((glucose or sugar$) adj2 urine).ti,ab.
37	GLUCOSE TOLERANCE TEST/
38	BLOOD GLUCOSE/an [Analysis]
39	((random or fast$ or oral) adj2 blood glucose).ti,ab.
40	"oral glucose tolerance test".ti,ab.
41	(OGTT or FPG or IFG).ti,ab.
42	HEMOGLOBIN A, GLYCOSYLATED/
43	HbA1c.ti,ab.
44	((glycated or glycosylated) adj2 (haemoglobin or hemoglobin)).ti,ab.

#	Searches
45	MATERNAL SERUM SCREENING TESTS/
46	or/34-45
47	and/27,46
48	LETTER/
49	EDITORIAL/
50	NEWS/
51	exp HISTORICAL ARTICLE/
52	ANECDOTES AS TOPIC/
53	COMMENT/
54	CASE REPORT/
55	(letter or comment* or abstracts).ti.
56	or/48-55
57	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
58	56 not 57
59	ANIMALS/ not HUMANS/
60	exp ANIMALS, LABORATORY/
61	exp ANIMAL EXPERIMENTATION/
62	exp MODELS, ANIMAL/
63	exp RODENTIA/
64	(rat or rats or mouse or mice).ti.
65	or/58-64
66	47 not 65
67	limit 66 to english language
68	limit 67 to yr="2012 -Current"

Database(s): **Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations** June 13, 2014

Search Strategy**:DiP_update_diagnosis_1st_2nd_trimester_mip_160614**

#	Searches
1	((gestation$ or pregnan$) adj3 diabet$).ti,ab.
2	GDM.ti,ab.
3	or/1-2
4	(T1DM or T2DM).ti,ab.
5	diabet$.ti,ab.
6	prediabet$.ti,ab.
7	impaired glucose tolerance.ti,ab.
8	IGT.ti,ab.
9	Impaired fasting glucose.ti,ab.
10	IFG.ti,ab.
11	Impaired glucose regulation.ti,ab.
12	IGR.ti,ab.

#	Searches
13	Non?diabetic hyperglyc?emi#.ti,ab.
14	NDH.ti,ab.
15	(glucose adj (toleran$ or intoleran$)).ti,ab.
16	or/4-15
17	(pregnan$ or gestation$).ti,ab.
18	and/16-17
19	or/3,18
20	(risk adj2 factor? adj5 screen$).ti,ab.
21	glycosuria.ti,ab.
22	((glucose or sugar$) adj2 urine).ti,ab.
23	glucose tolerance test?.ti,ab.
24	((random or fast$ or oral) adj2 blood glucose).ti,ab.
25	"oral glucose tolerance test".ti,ab.
26	(OGTT or FPG or IFG).ti,ab.
27	HbA1c.ti,ab.
28	((glycated or glycosylated) adj2 (haemoglobin or hemoglobin)).ti,ab.
29	or/20-28
30	and/19,29

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials January 2014
Search Strategy: **DiP_update_diagnosis_1st_2nd_trimester_RERUN1_cctr_240214**

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	Non?diabetic hyperglyc?emi#.ti,ab.
19	NDH.ti,ab.
20	GLUCOSE INTOLERANCE/
21	or/6-20

#	Searches
22	PREGNANCY/
23	(pregnan$ or gestation$).ti,ab.
24	PREGNANT WOMEN/
25	or/22-24
26	and/21,25
27	or/5,26
28	RISK ASSESSMENT/ or RISK FACTORS/
29	MASS SCREENING/
30	screen$.ti,ab.
31	or/29-30
32	and/28,31
33	(risk adj2 factor? adj2 screen$).ti,ab.
34	or/32-33
35	exp GLYCOSURIA/
36	((glucose or sugar$) adj2 urine).ti,ab.
37	GLUCOSE TOLERANCE TEST/
38	BLOOD GLUCOSE/an [Analysis]
39	((random or fast$ or oral) adj2 blood glucose).ti,ab.
40	"oral glucose tolerance test".ti,ab.
41	(OGTT or FPG or IFG).ti,ab.
42	HEMOGLOBIN A, GLYCOSYLATED/
43	HbA1c.ti,ab.
44	((glycated or glycosylated) adj2 (haemoglobin or hemoglobin)).i,ab.
45	MATERNAL SERUM SCREENING TESTS/
46	or/34-45
47	and/27,46
48	limit 47 to yr="2012 -Current"

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to December 2013, EBM Reviews - Database of Abstracts of Reviews of Effects 1st Quarter 2014
Search Strategy: **DiP_update_diagnosis_1st_2nd_trimester_RERUN1_cdsrdare_240214**

#	Searches
1	PREGNANCY IN DIABETICS.kw.
2	DIABETES, GESTATIONAL.kw.
3	(gestation$ adj3 diabet$).tw,tx.
4	GDM.tw,tx.
5	or/1-4
6	DIABETES MELLITUS.kw.
7	DIABETES INSIPIDUS.kw.
8	(T1DM or T2DM).tw,tx.
9	diabet$.ti.
10	PREDIABETIC STATE.kw.
11	prediabet$.tw,tx.

#	Searches
12	impaired glucose tolerance.tw,tx.
13	IGT.tw,tx.
14	Impaired fasting glucose.tw,tx.
15	IFG.tw,tx.
16	Impaired glucose regulation.tw,tx.
17	IGR.tw,tx.
18	Non?diabetic hyperglyc?emi#.tw,tx.
19	NDH.tw,tx.
20	GLUCOSE INTOLERANCE.kw.
21	or/6-20
22	PREGNANCY.kw.
23	(pregnan$ or gestation$).tw,tx.
24	PREGNANT WOMEN.kw.
25	or/22-24
26	and/21,25
27	or/5,26
28	(RISK ASSESSMENT or RISK FACTORS).kw.
29	MASS SCREENING.kw.
30	screen$.tw,tx.
31	or/29-30
32	and/28,31
33	(risk adj2 factor? adj2 screen$).tw,tx.
34	or/32-33
35	GlYCOSURIA.kw.
36	((glucose or sugar$) adj2 urine).ti,ab.
37	GLUCOSE TOLERANCE TEST.kw.
38	BLOOD GLUCOSE.kw.
39	((random or fast$ or oral) adj2 blood glucose).tw,tx.
40	"oral glucose tolerance test".tw,tx.
41	(OGTT or FPG or IFG).tw,tx.
42	HEMOGLOBIN A, GLYCOSYLATED.kw.
43	HbA1c.tw,tx.
44	((glycated or glycosylated) adj (haemoglobin or hemoglobin)).tw,tx.
45	MATERNAL SERUM SCREENING TESTS.kw.
46	or/34-45
47	and/27,46
48	("2012" or "2013" or "2014").dp.
49	and/47-48

Database(s): EBM Reviews - Health Technology Assessment 1st Quarter 2014
Search Strategy: **DiP_update_diagnosis_1st_2nd_trimester_RERUN1_hta_240214**

#	Searches
1	exp PREGNANCY IN DIABETICS/

#	Searches
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	Non?diabetic hyperglyc?emi#.tw.
19	NDH.tw.
20	GLUCOSE INTOLERANCE/
21	or/6-20
22	PREGNANCY/
23	(pregnan$ or gestation$).tw.
24	PREGNANT WOMEN/
25	or/22-24
26	and/21,25
27	or/5,26
28	RISK ASSESSMENT/ or RISK FACTORS/
29	MASS SCREENING/
30	screen$.tw.
31	or/29-30
32	and/28,31
33	(risk adj2 factor? adj2 screen$).tw.
34	or/32-33
35	exp GLYCOSURIA/
36	((glucose or sugar$) adj2 urine).ti,ab.
37	GLUCOSE TOLERANCE TEST/
38	BLOOD GLUCOSE/an [Analysis]
39	((random or fast$ or oral) adj2 blood glucose).tw.
40	"oral glucose tolerance test".tw.
41	(OGTT or FPG or IFG).tw.
42	HEMOGLOBIN A, GLYCOSYLATED/
43	HbA1c.tw.
44	((glycated or glycosylated) adj2 (haemoglobin or hemoglobin)).tw.
45	MATERNAL SERUM SCREENING TESTS/
46	or/34-45

#	Searches
47	and/27,46
48	("2012" or "2013" or "2014").dp.
49	nd 48

E.5 Search 5: Diagnostic criteria for gestational diabetes

Review Question 8: Which diagnostic criteria should be used to diagnose diabetes in pregnant women using a 75g OGTT: WHO or IADPSG?

Database(s): Ovid MEDLINE(R) 1946 to June Week 2 2012
Search Strategy: **DiP_update_WHO_IADPSG_medline_250612**

#	Searches
1	"International Association of the Diabetes and Pregnancy Study Group$".ti,ab.
2	IADPSG.ti,ab.
3	or/1-2
4	LETTER/
5	EDITORIAL/
6	NEWS/
7	exp HISTORICAL ARTICLE/
8	ANECDOTES AS TOPIC/
9	COMMENT/
10	CASE REPORT/
11	(letter or comment* or abstracts).ti.
12	or/4-11
13	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
14	12 not 13
15	ANIMALS/ not HUMANS/
16	exp ANIMALS, LABORATORY/
17	exp ANIMAL EXPERIMENTATION/
18	exp MODELS, ANIMAL/
19	exp RODENTIA/
20	(rat or rats or mouse or mice).ti.
21	or/14-20
22	3 not 21
23	limit 22 to english language

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations June 25, 2012
Search Strategy: **DiP_update_WHO_IADPSG_mip_250612**

#	Searches
1	"International Association of the Diabetes and Pregnancy Study Group$".ti,ab.
2	IADPSG.ti,ab.
3	or/1-2

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials June 2012
Search Strategy: **DiP_update_WHO_IADPSG_cctr_250612**

#	Searches
1	"International Association of the Diabetes and Pregnancy Study Group$".ti,ab.
2	IADPSG.ti,ab.
3	or/1-2

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to June 2012, EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2012
Search Strategy: **DiP_update_WHO_IADPSG_cdsrdare_250612**

#	Searches
1	"International Association of the Diabetes and Pregnancy Study Group$".tw,tx.
2	IADPSG.tw,tx.
3	or/1-2

Database(s): EBM Reviews - Health Technology Assessment 2nd Quarter 2012
Search Strategy: **DiP_update_WHO_IADPSG_hta_270612**

#	Searches
1	"International Association of the Diabetes and Pregnancy Study Group$".tw,tx.
2	IADPSG.tw,tx.
3	or/1-2

Database(s): Embase 1974 to 2012 Week 25
Search Strategy: **DiP_update_WHO_IADPSG_embase_250612**

#	Searches
1	"International Association of the Diabetes and Pregnancy Study Group$".ti,ab.
2	IADPSG.ti,ab.
3	or/1-2
4	conference abstract.pt.
5	letter.pt. or LETTER/
6	note.pt.
7	editorial.pt.
8	CASE REPORT/ or CASE STUDY/
9	(letter or comment* or abstracts).ti.

#	Searches
10	or/4-9
11	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
12	10 not 11
13	ANIMAL/ not HUMAN/
14	NONHUMAN/
15	exp ANIMAL EXPERIMENT/
16	exp EXPERIMENTAL ANIMAL/
17	ANIMAL MODEL/
18	exp RODENT/
19	(rat or rats or mouse or mice).ti.
20	or/12-19
21	3 not 20
22	limit 21 to english language

E.6 Search 6: Interventions for gestational diabetes

Review Question 9: What is the effectiveness of the following interventions (alone or in combination) in women with gestational diabetes:

- non-pharmacological interventions (diet and/or exercise)
- pharmacological interventions (metformin, glibenclamide and insulin)?

Database(s): Ovid MEDLINE(R) 1946 to March Week 3 2014 Search Strategy:

DiP_update_GDM_interventions_RERUN1_medline_270314

#	Searches
1	randomized controlled trial.pt.
2	controlled clinical trial.pt.
3	DOUBLE BLIND METHOD/
4	SINGLE BLIND METHOD/
5	RANDOM ALLOCATION/
6	or/1-5
7	((single or double or triple or treble) adj5 (blind$ or mask$)).tw,sh.
8	clinical trial.pt.
9	exp CLINICAL TRIAL/
10	exp CLINICAL TRIALS AS TOPIC/
11	(clinic$ adj5 trial$).tw,sh.
12	PLACEBOS/
13	placebo$.tw,sh.
14	random$.tw,sh.
15	or/7-14
16	or/6,15

#	Searches
17	META ANALYSIS/
18	META ANALYSIS AS TOPIC/
19	meta analysis.pt.
20	(metaanaly$ or meta-analy$ or (meta adj analy$)).tw,sh.
21	(systematic$ adj5 (review$ or overview$)).tw,sh.
22	(methodologic$ adj5 (review$ or overview$)).tw,sh.
23	or/17-22
24	review$.pt.
25	(medline or medlars or embase or cinahl or cochrane or psycinfo or psychinfo or psychlit or psyclit or "web of science" or "science citation" or scisearch).tw.
26	((hand or manual$) adj2 search$).tw.
27	(electronic database$ or bibliographic database$ or computeri?ed database$ or online database$).tw,sh.
28	(pooling or pooled or mantel haenszel).tw,sh.
29	(peto or dersimonian or der simonian or fixed effect).tw,sh.
30	or/25-29
31	and/24,30
32	or/23,31
33	letter.pt.
34	case report.tw.
35	comment.pt.
36	editorial.pt.
37	historical article.pt.
38	or/33-37
39	32 not 38
40	16 not 38
41	32 not 38
42	or/40-41
43	DIABETES, GESTATIONAL/th, dh, dt [Therapy, Diet Therapy, Drug Therapy]
44	(diabet$ adj3 ("pregnancy induced" or gestat$ or gravid$)).ti,ab.
45	GDM.ti,ab.
46	or/43-45
47	exp LIFE STYLE/
48	((life style$ or life?style$) adj3 (modif$ or chang$ or advi$ or therap$)).ti,ab.
49	WEIGHT LOSS/
50	WEIGHT REDUCTION PROGRAMS/
51	DIABETIC DIET/
52	DIET THERAPY/
53	DIET, REDUCING/
54	CALORIC RESTRICTION/
55	(diet$ adj2 (therap$ or advi$ or modif$ or chang$)).ti,ab.
56	(diet$ adj5 (diabet$ or carbohydrat$ or fat$ or weigh$ or sugar$ or glyc?em$ or restrict$ or reduc$ or hypocalor$)).ti,ab.
57	(weigh$ adj3 (los$ or reduc$)).ti,ab.
58	((calori$ or calory) adj3 (restrict$ or reduc$ or low)).ti,ab.
59	exp EXERCISE/

#	Searches
60	exp EXERCISE THERAPY/
61	exp EXERCISE MOVEMENT TECHNIQUES/
62	exp "PHYSICAL EDUCATION AND TRAINING"/
63	PHYSICAL FITNESS/
64	exp SPORTS/
65	(exercis$ or sport$ or kinesi?therap$).ti,ab.
66	(physic$ adj5 (activ$ or fit$)).ti,ab.
67	METFORMIN/
68	(metformin or glucophage or glucient or metsol or bolamyn or metabet).ti,ab.
69	GLYBURIDE/
70	(gl#bencl#mid? or gl#buride).ti,ab.
71	exp INSULIN/tu [Therapeutic Use]
72	exp INSULINS/tu [Therapeutic Use]
73	insulin$.ti,ab.
74	or/47-73
75	and/46,74
76	limit 75 to english language
77	LETTER/
78	EDITORIAL/
79	NEWS/
80	exp HISTORICAL ARTICLE/
81	ANECDOTES AS TOPIC/
82	COMMENT/
83	CASE REPORT/
84	(letter or comment* or abstracts).ti.
85	or/77-84
86	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
87	85 not 86
88	ANIMALS/ not HUMANS/
89	exp ANIMALS, LABORATORY/
90	exp ANIMAL EXPERIMENTATION/
91	exp MODELS, ANIMAL/
92	exp RODENTIA/
93	(rat or rats or mouse or mice).ti.
94	or/87-93
95	76 not 94
96	and/42,95
97	limit 96 to yr="2012 -Current"

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations June 20, 2012
DiP_update_GDM_interventions_mip_210612

Search Strategy:

#	Searches
1	(diabet$ adj3 ("pregnancy induced" or gestat$ or gravid$)).ti,ab.
2	GDM.ti,ab.
3	or/1-2
4	((life style$ or life?style$) adj3 (modif$ or chang$ or advi$ or therap$)).ti,ab.
5	(diet$ adj2 (therap$ or advi$ or modif$ or chang$)).ti,ab.
6	(diet$ adj5 (diabet$ or carbohydrat$ or fat$ or weigh$ or sugar$ or glyc?em$ or restrict$ or reduc$ or hypocalor$)).ti,ab.
7	(weigh$ adj3 (los$ or reduc$)).ti,ab.
8	((calori$ or calory) adj3 (restrict$ or reduc$ or low)).ti,ab.
9	(exercis$ or sport$ or kinesi?therap$).ti,ab.
10	(physic$ adj5 (activ$ or fit$)).ti,ab.
11	(metformin or glucophage or glucient or metsol or bolamyn or metabet).ti,ab.
12	(gl#bencl#mid? or gl#buride).ti,ab.
13	insulin$.ti,ab.
14	or/4-13
15	and/3,14

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials June 2012

DiP_update_GDM_interventions_cctr_200612

Search Strategy:

#	Searches
1	DIABETES, GESTATIONAL/
2	(diabet$ adj3 (pregnan$ or gestat$)).kw.
3	(diabet$ adj3 ("pregnancy induced" or gestat$ or gravid$)).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp LIFE STYLE/
7	(life style$ or life?style$).kw.
8	((life style$ or life?style$) adj3 (modif$ or chang$ or advi$ or therap$)).ti,ab.
9	WEIGHT LOSS/
10	WEIGHT REDUCTION PROGRAMS/
11	DIABETIC DIET/
12	DIET THERAPY/
13	DIET, REDUCING/
14	CALORIC RESTRICTION/
15	(diet$ adj2 (therap$ or advi$ or modif$ or chang$)).ti,ab,kw.
16	(diet$ adj5 (diabet$ or carbohydrat$ or fat$ or weigh$ or sugar$ or glyc?em$ or restrict$ or reduc$ or hypocalor$)).ti,ab,kw.
17	(weigh$ adj3 (los$ or reduc$)).ti,ab,kw.
18	((calori$ or calory) adj3 (restrict$ or reduc$ or low)).ti,ab,kw.
19	exp EXERCISE/
20	exp EXERCISE THERAPY/
21	exp EXERCISE MOVEMENT TECHNIQUES/

#	Searches
22	exp "PHYSICAL EDUCATION AND TRAINING"/
23	PHYSICAL FITNESS/
24	exp SPORTS/
25	(exercis$ or sport$ or kinesi?therap$).ti,ab,kw.
26	(physic$ adj5 (activ$ or fit$)).ti,ab,kw.
27	physical education.kw.
28	METFORMIN/
29	(metformin or glucophage or glucient or metsol or bolamyn or metabet).ti,ab,kw.
30	GLYBURIDE/
31	(gl#bencl#mid? or gl#buride).ti,ab,kw.
32	exp INSULIN/
33	exp INSULINS/
34	insulin$.ti,ab,kw.
35	or/6-34
36	and/5,35

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to June 2012, EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2012

DiP_update_GDM_interventions_cdsrdare_210612

Search Strategy:

#	Searches
1	(diabet$ adj3 (pregnan$ or gestat$)).kw.
2	(diabet$ adj3 ("pregnancy induced" or gestat$ or gravid$)).tw,tx.
3	GDM.tw,tx.
4	or/1-3
5	(life style$ or life?style$).kw.
6	((life style$ or life?style$) adj3 (modif$ or chang$ or advi$ or therap$)).tw,tx.
7	(diet$ adj2 (therap$ or advi$ or modif$ or chang$)).tw,tx.
8	(diet$ adj5 (diabet$ or carbohydrat$ or fat$ or weigh$ or sugar$ or glyc?em$ or restrict$ or reduc$ or hypocalor$)).tw,tx.
9	(weigh$ adj3 (los$ or reduc$)).tw,tx.
10	((calori$ or calory) adj3 (restrict$ or reduc$ or low)).tw,tx.
11	(exercis$ or sport$ or kinesi?therap$).tw,tx.
12	(physic$ adj5 (activ$ or fit$)).tw,tx.
13	physical education.kw.
14	(metformin or glucophage or glucient or metsol or bolamyn or metabet).tw,tx.
15	(gl#bencl#mid? or gl#buride).tw,tx.
16	insulin$.tw,tx.
17	or/5-16
18	and/4,17

Database(s): EBM Reviews - Health Technology Assessment 2nd Quarter 2012

DiP_update_GDM_interventions_hta_210612

Search Strategy:

#	Searches
1	DIABETES, GESTATIONAL/
2	(diabet$ adj3 ("pregnancy induced" or gestat$ or gravid$)).tw.
3	GDM.tw.
4	or/1-3
5	exp LIFE STYLE/
6	((life style$ or life?style$) adj3 (modif$ or chang$ or advi$ or therap$)).tw.
7	WEIGHT LOSS/
8	WEIGHT REDUCTION PROGRAMS/
9	DIABETIC DIET/
10	DIET THERAPY/
11	DIET, REDUCING/
12	CALORIC RESTRICTION/
13	(diet$ adj2 (therap$ or advi$ or modif$ or chang$)).tw.
14	(diet$ adj5 (diabet$ or carbohydrat$ or fat$ or weigh$ or sugar$ or glyc?em$ or restrict$ or reduc$ or hypocalor$)).tw.
15	(weigh$ adj3 (los$ or reduc$)).tw.
16	((calori$ or calory) adj3 (restrict$ or reduc$ or low)).tw.
17	exp EXERCISE/
18	exp EXERCISE THERAPY/
19	exp EXERCISE MOVEMENT TECHNIQUES/
20	exp "PHYSICAL EDUCATION AND TRAINING"/
21	PHYSICAL FITNESS/
22	exp SPORTS/
23	(exercis$ or sport$ or kinesi?therap$).tw.
24	(physic$ adj5 (activ$ or fit$)).tw.
25	METFORMIN/
26	(metformin or glucophage or glucient or metsol or bolamyn or metabet).tw.
27	GLYBURIDE/
28	(gl#bencl#mid? or gl#buride).tw.
29	exp INSULIN/
30	insulin$.tw.
31	or/5-30
32	and/4,31

Database(s): Embase 1974 to 2014 March 26
Search Strategy: **DiP_update_GDM_intervention_RERUN1_embase_270314**

#	Searches
1	CLINICAL TRIAL/ or "CLINICAL TRIAL (TOPIC)"/
2	(clinic$ adj5 trial$).ti,ab,sh.
3	SINGLE BLIND PROCEDURE/
4	DOUBLE BLIND PROCEDURE/

#	Searches
5	RANDOM ALLOCATION/
6	CROSSOVER PROCEDURE/
7	PLACEBO/
8	placebo$.ti,ab,sh.
9	random$.ti,ab,sh.
10	RANDOMIZED CONTROLLED TRIAL/ or "RANDOMIZED CONTROLLED TRIAL (TOPIC)"/
11	((single or double or triple or treble) adj (blind$ or mask$)).ti,ab,sh.
12	randomi?ed control$ trial$.tw.
13	or/1-12
14	META ANALYSIS/
15	((meta adj analy$) or metaanalys$ or meta-analy$).ti,ab,sh.
16	(systematic$ adj5 (review$ or overview$)).ti,sh,ab.
17	(methodologic$ adj5 (review$ or overview$)).ti,ab,sh.
18	or/14-17
19	review.pt.
20	(medline or medlars or embase).ab.
21	(scisearch or science citation index).ab.
22	(psychlit or psyclit or psychinfo or psycinfo or cinahl or cochrane).ab.
23	((hand or manual$) adj2 search$).tw.
24	(electronic database$ or bibliographic database$ or computeri?ed database$ or online database$).tw.
25	(pooling or pooled or mantel haenszel).tw.
26	(peto or dersimonian or "der simonian" or fixed effect).tw.
27	or/20-26
28	and/19,27
29	or/18,28
30	(book or conference paper or editorial or letter or note or proceeding or short survey).pt.
31	13 not 30
32	29 not 30
33	or/31-32
34	exp PREGNANCY DIABETES MELLITUS/th, dt [Therapy, Drug Therapy]
35	(diabet$ adj3 ("pregnancy induced" or gestat$ or gravid$)).ti,ab.
36	GDM.ti,ab.
37	or/34-36
38	LIFESTYLE/
39	LIFESTYLE MODIFICATION/
40	((life style$ or life?style$) adj3 (modif$ or chang$ or advi$ or therap$)).ti,ab.
41	WEIGHT REDUCTION/
42	DIABETIC DIET/
43	DIET THERAPY/
44	DIET RESTRICTION/
45	LOW CALORY DIET/
46	CALORIC RESTRICTION/
47	(diet$ adj2 (therap$ or advi$ or modif$ or chang$)).ti,ab.
48	(diet$ adj5 (diabet$ or carbohydrat$ or fat$ or weigh$ or sugar$ or glyc?em$ or restrict$ or reduc$ or hypocalor$)).ti,ab.

#	Searches
49	(weigh$ adj3 (los$ or reduc$)).ti,ab.
50	((calori$ or calory) adj3 (restrict$ or reduc$ or low)).ti,ab.
51	exp EXERCISE/
52	exp PHYSICAL ACTIVITY/
53	FITNESS/
54	exp KINESIOTHERAPY/
55	PHYSICAL EDUCATION/
56	exp SPORT/
57	(exercis$ or sport$ or kinesi?therap$).ti,ab.
58	(physic$ adj5 (activ$ or fit$)).ti,ab.
59	METFORMIN/
60	(metformin or glucophage or glucient or metsol or bolamyn or metabet).ti,ab.
61	GLIBENCLAMIDE/
62	(gl#bencl#mid? or gl#buride).ti,ab.
63	exp INSULIN DERIVATIVE/ct, dt [Clinical Trial, Drug Therapy]
64	insulin$.ti,ab.
65	or/38-64
66	and/37,65
67	limit 66 to english language
68	conference abstract.pt.
69	letter.pt. or LETTER/
70	note.pt.
71	editorial.pt.
72	CASE REPORT/ or CASE STUDY/
73	(letter or comment* or abstracts).ti.
74	or/68-73
75	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
76	74 not 75
77	ANIMAL/ not HUMAN/
78	NONHUMAN/
79	exp ANIMAL EXPERIMENT/
80	exp EXPERIMENTAL ANIMAL/
81	ANIMAL MODEL/
82	exp RODENT/
83	(rat or rats or mouse or mice).ti.
84	or/76-83
85	67 not 84
86	and/33,85
87	limit 86 to yr="2012 -Current"

E.7 Search 7: Antenatal continuous glucose monitoring

Review question 15: What is the effectiveness of continuous glucose monitoring in pregnant women with diabetes compared with intermittent capillary blood glucose monitoring?

Database(s): Ovid MEDLINE(R) 1946 to March Week 2 2013
Search Strategy:DiP_update_CGM_medline_260313

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).ti,ab.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	or/5,24
26	(continu$ adj2 glucose monitor$).ti,ab.
27	(ambulatory adj3 (glucose adj3 monitor$)).ti,ab.
28	(CGM or CGMS or CBGM).ti,ab.
29	EXTRACELLULAR FLUID/
30	interstitial.ti,ab.
31	(home glucose adj (test$ or monitor$)).ti,ab.
32	(self adj (test$ or monitor$)).ti,ab.
33	BLOOD GLUCOSE SELF- MONITORING/
34	BGSM.ti,ab.
35	intermittent.ti,ab.
36	IGM.ti,ab.
37	(ICGM or ICBGM).ti,ab.

#	Searches
38	or/26-37
39	and/25,38
40	LETTER/
41	EDITORIAL/
42	NEWS/
43	exp HISTORICAL ARTICLE/
44	ANECDOTES AS TOPIC/
45	COMMENT/
46	CASE REPORT/
47	(letter or comment* or abstracts).ti.
48	or/40-47
49	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
50	48 not 49
51	ANIMALS/ not HUMANS/
52	exp ANIMALS, LABORATORY/
53	exp ANIMAL EXPERIMENTATION/
54	exp MODELS, ANIMAL/
55	exp RODENTIA/
56	(rat or rats or mouse or mice).ti.
57	or/50-56
58	39 not 57
59	limit 58 to english language
60	limit 59 to yr="2008 -Current"

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations March 26, 2013 Search Strategy:DiP_update_CGM_mip_270313

#	Searches
1	(gestation$ adj3 diabet$).ti,ab.
2	GDM.ti,ab.
3	(diabet$ adj3 pregnan$).ti,ab.
4	or/1-3
5	(T1DM or T2DM).ti,ab.
6	diabet$.ti,ab.
7	prediabet$.ti,ab.
8	impaired glucose tolerance.ti,ab.
9	IGT.ti,ab.
10	Impaired fasting glucose.ti,ab.
11	IFG.ti,ab.
12	Impaired glucose regulation.ti,ab.
13	IGR.ti,ab.
14	or/5-13
15	(pregnan$ or gestation$).ti,ab.
16	and/14-15
17	or/4,16

#	Searches
18	(continu$ adj2 glucose monitor$).ti,ab.
19	(ambulatory adj3 (glucose adj3 monitor$)).ti,ab.
20	(CGM or CGMS or CBGM).ti,ab.
21	interstitial.ti,ab.
22	(home glucose adj (test$ or monitor$)).ti,ab.
23	(self adj (test$ or monitor$)).ti,ab.
24	("blood glucose" adj self adj monitor$).ti,ab.
25	BGSM.ti,ab.
26	intermittent.ti,ab.
27	IGM.ti,ab.
28	(ICGM or ICBGM).ti,ab.
29	or/18-28
30	and/17,29

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials March 2013 Search Strategy:DiP_update_CGM_cctr_260313

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).ti,ab.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	or/5,24
26	(continu$ adj2 glucose monitor$).ti,ab.
27	(ambulatory adj3 (glucose adj3 monitor$)).ti,ab.

#	Searches
28	(CGM or CGMS or CBGM).ti,ab.
29	EXTRACELLULAR FLUID/
30	interstitial.ti,ab.
31	(home glucose adj (test$ or monitor$)).ti,ab.
32	(self adj (test$ or monitor$)).ti,ab.
33	BLOOD GLUCOSE SELF- MONITORING/
34	BGSM.ti,ab.
35	intermittent.ti,ab.
36	IGM.ti,ab.
37	(ICGM or ICBGM).ti,ab.
38	or/26-37
39	and/25,38
40	limit 39 to yr="2008 -Current"

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to February 2013, EBM Reviews - Database of Abstracts of Reviews of Effects 1st Quarter 2013
Search Strategy:DiP_update_CGM_cdsrdare_260313

#	Searches
1	PREGNANCY IN DIABETICS.kw.
2	DIABETES, GESTATIONAL.kw.
3	(gestation$ adj3 diabet$).tw,tx.
4	GDM.tw,tx.
5	or/1-4
6	DIABETES MELLITUS.kw.
7	DIABETES INSIPIDUS.kw.
8	(T1DM or T2DM).tw,tx.
9	diabet$.tw,tx.
10	PREDIABETIC STATE.kw.
11	prediabet$.tw,tx.
12	impaired glucose tolerance.tw,tx.
13	IGT.tw,tx.
14	Impaired fasting glucose.tw,tx.
15	IFG.tw,tx.
16	Impaired glucose regulation.tw,tx.
17	IGR.tw,tx.
18	GLUCOSE INTOLERANCE.kw.
19	or/6-18
20	PREGNANCY.kw.
21	(pregnan$ or gestation$).tw,tx.
22	PREGNANT WOMEN.kw.
23	or/20-22
24	and/19,23

#	Searches
25	or/5,24
26	(continu$ adj2 glucose monitor$).tw,tx.
27	(ambulatory adj3 (glucose adj3 monitor$)).tw,tx.
28	(CGM or CGMS or CBGM).tw,tx.
29	EXTRACELLULAR FLUID.kw.
30	interstitial.tw,tx.
31	(home glucose adj (test$ or monitor$)).tw,tx.
32	(self adj (test$ or monitor$)).tw,tx.
33	BLOOD GLUCOSE SELF- MONITORING.kw.
34	BGSM.tw,tx.
35	intermittent.tw,tx.
36	IGM.tw,tx.
37	(ICGM or ICBGM).tw,tx.
38	or/26-37
39	and/25,38

Database(s): EBM Reviews - Health Technology Assessment 1st Quarter 2013 Search Strategy:DiP_update_CGM_hta_270313

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.tw.
10	PREDIABETIC STATE/
11	prediabet$.tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).tw.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	and/5,24

#	Searches
26	(continu$ adj2 glucose monitor$).tw.
27	(ambulatory adj3 (glucose adj3 monitor$)).tw.
28	(CGM or CGMS or CBGM).tw.
29	EXTRACELLULAR FLUID/
30	interstitial.tw.
31	(home glucose adj (test$ or monitor$)).tw.
32	(self adj (test$ or monitor$)).tw.
33	BLOOD GLUCOSE SELF- MONITORING/
34	BGSM.tw.
35	intermittent.tw.
36	IGM.tw.
37	(ICGM or ICBGM).tw.
38	or/26-37
39	and/25,38

Database(s): Embase 1974 to 2013 April 12
Search Strategy: DiP_update_CGM_embase_150413

#	Searches
1	PREGNANCY DIABETES MELLITUS/ or MATERNAL DIABETES MELLITUS/
2	(gestation$ adj3 diabet$).ti,ab.
3	or/1-2
4	DIABETES MELLITUS/ or IMPAIRED GLUCOSE TOLERANCE/ or INSULIN DEPENDENT DIABETES MELLITUS/ or JUVENILE DIABETES MELLITUS/ or NON INSULIN DEPENDENT DIABETES MELLITUS/
5	(T1DM or T2DM).ti,ab.
6	(IDDM or NIDDM).ti,ab.
7	diabet$.ti.
8	pre?diabet$.ti,ab.
9	impaired fasting glucose.ti,ab.
10	(IGT or IFG).ti,ab.
11	IGR.ti,ab.
12	GLUCOSE INTOLERANCE/
13	or/4-12
14	PREGNANCY/ or PREGNANT WOMAN/
15	(pregnan$ or gestation$).ti,ab.
16	or/14-15
17	and/13,16
18	or/3,17
19	(continu$ adj2 glucose monitor$).ti,ab.
20	(ambulatory adj3 (glucose adj3 monitor$)).ti,ab.
21	(CGM or CGMS or CBGM).ti,ab.
22	INTERSTITIAL FLUID/
23	(interstitial adj2 fluid?).ti,ab.
24	(home glucose adj (test$ or monitor$)).ti,ab.
25	(self adj (test$ or monitor$)).ti,ab.
26	BLOOD GLUCOSE MONITORING/
27	BGSM.ti,ab.

#	Searches
28	(intermittent adj3 monitor$).ti,ab.
29	IGM.ti,ab.
30	(ICGM or ICBGM).ti,ab.
31	or/19-30
32	and/18,31
33	conference abstract.pt.
34	letter.pt. or LETTER/
35	note.pt.
36	editorial.pt.
37	CASE REPORT/ or CASE STUDY/
38	(letter or comment* or abstracts).ti.
39	or/33-38
40	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
41	39 not 40
42	ANIMAL/ not HUMAN/
43	NONHUMAN/
44	exp ANIMAL EXPERIMENT/
45	exp EXPERIMENTAL ANIMAL/
46	ANIMAL MODEL/
47	exp RODENT/
48	(rat or rats or mouse or mice).ti.
49	or/41-48
50	32 not 49
51	limit 50 to english language
52	limit 51 to yr="2008 -Current"

E.8 Search 8: Antenatal specialist teams

Review question 16: What is the effectiveness of specialist teams for pregnant women with diabetes?

Database(s): Ovid MEDLINE(R) 1946 to December Week 4 2012
Search Strategy:DiP_update_specialist_care_medline_070113

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/

#	Searches
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	or/6-17
19	PREGNANCY/
20	(pregnan$ or gestation$).ti,ab.
21	PREGNANT WOMEN/
22	or/19-21
23	and/18,22
24	or/5,23
25	((unified or joint or combined or integrated or specialist or divided or centrali#ed) adj5 (care or clinic$)).ti,ab.
26	(specialist adj3 (team$ or clinic$)).ti,ab.
27	("diabetes-obstetrical" adj clinic$).ti,ab.
28	NURSE MIDWIVES/
29	COMMUNITY HEALTH NURSING/
30	and/28-29
31	(community adj (midwife or midwives or midwifery)).ti,ab.
32	or/25-27,30-31
33	and/24,32
34	LETTER/
35	EDITORIAL/
36	NEWS/
37	exp HISTORICAL ARTICLE/
38	ANECDOTES AS TOPIC/
39	COMMENT/
40	CASE REPORT/
41	(letter or comment* or abstracts).ti.
42	or/34-41
43	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
44	42 not 43
45	ANIMALS/ not HUMANS/
46	exp ANIMALS, LABORATORY/
47	exp ANIMAL EXPERIMENTATION/
48	exp MODELS, ANIMAL/
49	exp RODENTIA/
50	(rat or rats or mouse or mice).ti.
51	or/44-50
52	33 not 51

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations January 04, 2013
Search Strategy: DiP_update_specialist_care_mip_070113

#	Searches
1	(pregnan$ adj3 diabet$).ti,ab.
2	(gestation$ adj3 diabet$).ti,ab.
3	GDM.ti,ab.
4	or/1-3
5	(T1DM or T2DM).ti,ab.
6	diabet$.ti,ab.
7	prediabet$.ti,ab.
8	impaired glucose tolerance.ti,ab.
9	IGT.ti,ab.
10	Impaired fasting glucose.ti,ab.
11	IFG.ti,ab.
12	Impaired glucose regulation.ti,ab.
13	IGR.ti,ab.
14	or/5-13
15	(pregnan$ or gestation$).ti,ab.
16	and/14-15
17	or/4,16
18	((unified or joint or combined or integrated or specialist or divided or centrali#ed) adj5 (care or clinic$)).ti,ab.
19	(specialist adj3 (team$ or clinic$)).ti,ab.
20	("diabetes-obstetrical" adj clinic$).ti,ab.
21	(community adj (midwife or midwives or midwifery)).ti,ab.
22	or/18-21
23	and/17,22

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials December 2012
Search Strategy: DiP_update_specialist_care_cctr_070113

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.

#	Searches
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	or/6-17
19	PREGNANCY/
20	(pregnan$ or gestation$).ti,ab.
21	PREGNANT WOMEN/
22	or/19-21
23	and/18,22
24	or/5,23
25	((unified or joint or combined or integrated or specialist or divided or centrali#ed) adj5 (care or clinic$)).ti,ab.
26	(specialist adj3 (team$ or clinic$)).ti,ab.
27	("diabetes-obstetrical" adj clinic$).ti,ab.
28	NURSE MIDWIVES/
29	COMMUNITY HEALTH NURSING/
30	and/28-29
31	(community adj (midwife or midwives or midwifery)).ti,ab.
32	or/25-27,30-31
33	and/24,32

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to November 2012, EBM Reviews - Database of Abstracts of Reviews of Effects 4th Quarter 2012
Search Strategy: DiP_update_specialist_care_cdsrdare_070113

#	Searches
1	PREGNANCY IN DIABETICS.kw.
2	DIABETES, GESTATIONAL.kw.
3	(gestation$ adj3 diabet$).tw,tx.
4	GDM.ti,ab.
5	or/1-4
6	DIABETES MELLITUS.kw.
7	DIABETES INSIPIDUS.kw.
8	(T1DM or T2DM).tw,tx.
9	diabet$.tw,tx.
10	PREDIABETIC STATE.kw.
11	prediabet$.tw,tx.
12	impaired glucose tolerance.tw,tx.
13	IGT.tw,tx.
14	Impaired fasting glucose.tw,tx.
15	IFG.tw,tx.
16	Impaired glucose regulation.tw,tx.
17	IGR.tw,tx.
18	or/6-17

#	Searches
19	PREGNANCY.kw.
20	(pregnan$ or gestation$).tw,tx.
21	PREGNANT WOMEN.kw.
22	or/19-21
23	and/18,22
24	or/5,23
25	((unified or joint or combined or integrated or specialist or divided or centrali#ed) adj5 (care or clinic$)).tw,tx.
26	(specialist adj3 (team$ or clinic$)).tw,tx.
27	("diabetes-obstetrical" adj clinic$).tw,tx.
28	NURSE MIDWIVES.kw.
29	COMMUNITY HEALTH NURSING.kw.
30	and/28-29
31	(community adj (midwife or midwives or midwifery)).tw,tx.
32	or/25-27,30-31
33	and/24,32

Database(s): EBM Reviews - Health Technology Assessment 4th Quarter 2012
Search Strategy: DiP_update_specialist_care_hta_070113

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	or/6-17
19	PREGNANCY/
20	(pregnan$ or gestation$).tw.
21	PREGNANT WOMEN/
22	or/19-21
23	and/18,22
24	or/5,23

#	Searches
25	((unified or joint or combined or integrated or specialist or divided or centrali#ed) adj5 (care or clinic$)).tw.
26	(specialist adj3 (team$ or clinic$)).tw.
27	("diabetes-obstetrical" adj clinic$).tw.
28	NURSE MIDWIVES/
29	COMMUNITY HEALTH NURSING/
30	and/28-29
31	(community adj (midwife or midwives or midwifery)).tw.
32	or/25-27,30-31
33	and/24,32

Database(s): Embase 1974 to 2013 January 07
Search Strategy: DiP_update_specialist_care_embase_080113

#	Searches
1	PREGNANCY DIABETES MELLITUS/ or MATERNAL DIABETES MELLITUS/
2	(gestation$ adj3 diabet$).ti,ab.
3	or/1-2
4	DIABETES MELLITUS/ or IMPAIRED GLUCOSE TOLERANCE/ or INSULIN DEPENDENT DIABETES MELLITUS/ or JUVENILE DIABETES MELLITUS/ or NON INSULIN DEPENDENT DIABETES MELLITUS/
5	(T1DM or T2DM).ti,ab.
6	(IDDM or NIDDM).ti,ab.
7	diabet$.ti.
8	pre?diabet$.ti,ab.
9	impaired fasting glucose.ti,ab.
10	(IGT or IFG).ti,ab.
11	IGR.ti,ab.
12	GLUCOSE INTOLERANCE/
13	or/4-12
14	PREGNANCY/ or PREGNANT WOMEN/
15	(pregnan$ or gestation$).ti,ab.
16	or/14-15
17	and/13,16
18	or/3,17
19	(specialist adj3 (team$ or clinic$)).ti,ab.
20	((unified or joint or combined or integrated or specialist or divided or centrali#ed) adj5 (care or clinic$)).ti,ab.
21	NURSE MIDWIFE/
22	COMMUNITY HEALTH NURSING/
23	COMMUNITY/
24	or/22-23
25	and/21,24
26	(community adj3 (midwife or midwives or midwifery)).ti,ab.

#	Searches
27	("diabetes-obstetrical" adj clinic$).ti,ab.
28	or/19-20,25-27
29	and/18,28
30	limit 29 to english language

DiP_update_specialist_care_cinahl_090113

Wednesday, January 09, 2013 8:53:43 AM

#	Query
S47	S27 AND S45
S46	S27 AND S45
S45	S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S42 OR S43 OR S44
S44	AB (community N3 midwi?e*)
S43	TI (community N3 midwi?e*)
S42	S40 AND S41
S41	(MH "COMMUNITY HEALTH NURSING+")
S40	(MH "Nurse Midwifery")
S39	TI (diabetes?obstetrical) or AB (diabetes?obstetrical)
S38	TI (centrali?ed N3 clinic*) or AB (centrali?ed N3 clinic*)
S37	TI (centrali?ed N3 care) or AB (central?ed care)
S36	AB (unified N3 clinic*) or AB (unified N3 clinic*)
S35	TI (unified N3 care) or AB (unified N3 care)
S34	TI (integrated N3 care*) or AB (integrated N3 care*)
S33	TI (integrated N3 clinic*) or AB (integrated N3 clinic*)
S32	TI (joint N3 care) or AB (joint N3 care)
S31	TI (joint N3 clinic*) or AB (joint N3 clinic*)
S30	TI (combined N3 care) or AB (combined N3 care)
S29	TI (specialist N3 clinic*) or AB (specialist N3 clinic*)
S28	TI (specialist N3 team*) or AB (specialist N3 team*)
S27	S5 OR S26
S26	S20 AND S25
S25	S21 OR S22 OR S23 OR S24
S24	(MH "EXPECTANT MOTHERS")
S23	AB (pregnan* or gestation*)
S22	TI (pregnan* or gestation*)
S21	(MH "PREGNANCY")
S20	S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19
S19	(MH "GLUCOSE INTOLERANCE")
S18	AB (IGT or IFG or IGR)
S17	TI (IGT or IFG or IGR)
S16	AB ("impaired glucose regulation")

#	Query
S15	TI ("impaired glucose regulation")
S14	AB ("impaired fasting glucose")
S13	TI ("impaired fasting glucose")
S12	AB ("impaired glucose tolerance")
S11	TI ("impaired glucose tolerance")
S10	TI (prediabet*) or AB (prediabet*)
S9	(MH "PREDIABETIC STATE")
S8	TI diabet*
S7	TI (T1DM) or TI (T2DM)
S6	(MH "DIABETES MELLITUS+")
S5	S1 OR S2 OR S3 OR S4
S4	TI (GDM) or AB (GDM)
S3	AB (diabet* N3 pregnan*) or AB (diabet* N3 gestat*) or AB (diabet* N3 gravid*)
S2	TI (diabet* N3 pregnan*) or TI (diabet* N3 gestat*) or TI (diabet* N3 gravid*)
S1	MH DIABETES MELLITUS, GESTATIONAL

E.9 Search 9: Timing of birth

Review question 17: What is the gestational age-specific risk of intrauterine death in pregnancies with type 1, type 2 or gestational diabetes, and the optimal timing of birth?

Database(s): Ovid MEDLINE(R) 1946 to February Week 2 2013 Search Strategy:DiP_update_intrauterine_timing_medline_260213

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.

#	Searches
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).ti,ab.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	or/5,24
26	FETAL DEATH/
27	((foetal or fetal or fetus$ or foetus$) adj (death or dying or demise)).ti,ab.
28	(intrauterine adj2 death).ti,ab.
29	STILLBIRTH/
30	IUFD.ti,ab.
31	(stillbirth or still?born).ti,ab.
32	INFANT MORTALITY/
33	((peri?natal$ or neo?natal$) adj3 (death? or dying or mortality or demise)).ti,ab.
34	LABOR, INDUCED/
35	((induct$ or induc$) adj3 lab?or).ti,ab.
36	((elective or planned) adj2 (birth? or deliver$ or induct$ or caesar#an$ or cesar#an$)).ti,ab.
37	exp DELIVERY, OBSTETRIC/
38	WATCHFUL WAITING/
39	(expectant adj3 (manag$ or monitor$)).ti,ab.
40	or/26-39
41	GESTATIONAL AGE/
42	(gestation$ adj age?).ti,ab.
43	TIME FACTORS/
44	((time or timing) adj3 (birth or deliver$ or induction or inducted or cesarean? or caesarean or c?section?)).ti,ab.
45	((optimal or optimum) adj3 (time or timing)).ti,ab.
46	or/41-44
47	and/25,40,46
48	LETTER/
49	EDITORIAL/
50	NEWS/
51	exp HISTORICAL ARTICLE/
52	ANECDOTES AS TOPIC/
53	COMMENT/
54	CASE REPORT/
55	(letter or comment* or abstracts).ti.
56	or/48-55
57	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
58	56 not 57
59	ANIMALS/ not HUMANS/

#	Searches
60	exp ANIMALS, LABORATORY/
61	exp ANIMAL EXPERIMENTATION/
62	exp MODELS, ANIMAL/
63	exp RODENTIA/
64	(rat or rats or mouse or mice).ti.
65	or/58-64
66	47 not 65
67	limit 66 to english language
68	limit 67 to yr="2008 -Current"

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations February 25, 2013 Search Strategy:DiP_update_intrauterine_death_timing_mip_260213

#	Searches
1	(gestation$ adj3 diabet$).ti,ab.
2	GDM.ti,ab.
3	(diabet$ adj3 pregnan$).ti,ab.
4	or/1-3
5	(T1DM or T2DM).ti,ab.
6	diabet$.ti,ab.
7	prediabet$.ti,ab.
8	impaired glucose tolerance.ti,ab.
9	IGT.ti,ab.
10	Impaired fasting glucose.ti,ab.
11	IFG.ti,ab.
12	Impaired glucose regulation.ti,ab.
13	IGR.ti,ab.
14	or/5-13
15	(pregnan$ or gestation$).ti,ab.
16	and/14-15
17	or/4,16
18	((foetal or fetal or fetus$ or foetus$) adj (death or dying or demise)).ti,ab.
19	(intrauterine adj2 death).ti,ab.
20	IUFD.ti,ab.
21	(stillbirth or still?born).ti,ab.
22	((peri?natal$ or neo?natal$ or infant?) adj3 (death? or dying or mortality or demise)).ti,ab.
23	((induct$ or induc$) adj3 labo?r).ti,ab.
24	((elective or planned) adj5 (birth? or deliver$ or induct$ or caesar#an$ or cesar#an$)).ti,ab.
25	(obstetric adj3 deliver$).ti,ab.
26	(watchful adj2 waiting).ti,ab.
27	(expectant adj3 (manag$ or monitor$)).ti,ab.
28	or/18-27

#	Searches
29	(gestation$ adj age?).ti,ab.
30	((time or timing) adj3 (birth or deliver$ or induction or inducted or cesarean? or caesarean or c?section?)).ti,ab.
31	((optimal or optimum) adj3 (time or timing)).ti,ab.
32	or/29-31
33	and/17,28,32

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials January 2013 Search Strategy:DiP_update_intrauterine_death_timing_cctr_280213

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).ti,ab.
4	GDM.ti,ab.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).ti,ab.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.ti,ab.
12	impaired glucose tolerance.ti,ab.
13	IGT.ti,ab.
14	Impaired fasting glucose.ti,ab.
15	IFG.ti,ab.
16	Impaired glucose regulation.ti,ab.
17	IGR.ti,ab.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).ti,ab.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	or/5,24
26	FETAL DEATH/
27	((foetal or fetal or fetus$ or foetus$) adj (death or dying or demise)).ti,ab.
28	(intrauterine adj2 death).ti,ab.
29	STILLBIRTH/
30	IUFD.ti,ab.
31	(stillbirth or still?born).ti,ab.

#	Searches
32	INFANT MORTALITY/
33	((peri?natal$ or neo?natal$) adj3 (death? or dying or mortality or demise)).ti,ab.
34	LABOR, INDUCED/
35	((induct$ or induc$) adj3 labo?r).ti,ab.
36	((elective or planned) adj2 (birth? or deliver$ or induct$ or caesar#an$ or cesar#an$)).ti,ab.
37	exp DELIVERY, OBSTETRIC/
38	WATCHFUL WAITING/
39	(expectant adj3 (manag$ or monitor$)).ti,ab.
40	or/26-39
41	GESTATIONAL AGE/
42	(gestation$ adj age?).ti,ab.
43	TIME FACTORS/
44	((time or timing) adj3 (birth or deliver$ or induction or inducted or cesarean? or caesarean or c?section?)).ti,ab.
45	((optimal or optimum) adj3 (time or timing)).ti,ab.
46	or/41-44
47	and/25,40,46

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to January 2013, EBM Reviews - Database of Abstracts of Reviews of Effects 1st Quarter 2013 Search Strategy:DiP_update_intrauterine_death_timing_cdsrdare_280213

#	Searches
1	PREGNANCY IN DIABETICS.kw.
2	DIABETES, GESTATIONAL.kw.
3	(gestation$ adj3 diabet$).tw,tx.
4	GDM.tw,tx.
5	or/1-4
6	DIABETES MELLITUS.kw.
7	DIABETES INSIPIDUS.kw.
8	(T1DM or T2DM).tw,tx.
9	diabet$.ti.
10	PREDIABETIC STATE.kw.
11	prediabet$.tw,tx.
12	impaired glucose tolerance.tw,tx.
13	IGT.tw,tx.
14	Impaired fasting glucose.tw,tx.
15	IFG.tw,tx.
16	Impaired glucose regulation.tw,tx.
17	IGR.tw,tx.
18	GLUCOSE INTOLERANCE.kw.
19	or/6-18
20	PREGNANCY.kw.

#	Searches
21	(pregnan$ or gestation$).tw,tx.
22	PREGNANT WOMEN.kw.
23	or/20-22
24	and/19,23
25	or/5,24
26	FETAL DEATH.kw.
27	((foetal or fetal or fetus$ or foetus$) adj (death or dying or demise)).tw,tx.
28	(intrauterine adj2 death).tw,tx.
29	STILLBIRTH.kw.
30	IUFD.tw,tx.
31	(stillbirth or still?born).tw,tx.
32	[INFANT MORTALITY/]
33	((peri?natal$ or neo?natal$) adj3 (death? or dying or mortality or demise)).tw,tx.
34	LABOR, INDUCED.kw.
35	((induct$ or induc$) adj3 labo?r).tw,tx.
36	((elective or planned) adj2 (birth? or deliver$ or induct$ or caesar#an$ or cesar#an$)).tw,tx.
37	DELIVERY, OBSTETRIC.kw.
38	WATCHFUL WAITING.kw.
39	(expectant adj3 (manag$ or monitor$)).tw,tx.
40	or/26-39
41	GESTATIONAL AGE.kw.
42	(gestation$ adj age?).tw,tx.
43	TIME FACTORS.kw.
44	((time or timing) adj3 (birth or deliver$ or induction or inducted or cesarean? or caesarean or c?section?)).tw,tx.
45	((optimal or optimum) adj3 (time or timing)).tw,tx.
46	or/41-44
47	and/25,40,46

Database(s): EBM Reviews - Health Technology Assessment 1st Quarter 2013
Search Strategy:DiP_update_intrauterine_death_timing_hta_280213

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.tw.

#	Searches
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).tw.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	or/5,24
26	FETAL DEATH/
27	((foetal or fetal or fetus$ or foetus$) adj (death or dying or demise)).tw.
28	(intrauterine adj2 death).tw.
29	STILLBIRTH/
30	IUFD.tw.
31	(stillbirth or still?born).tw.
32	INFANT MORTALITY/
33	((peri?natal$ or neo?natal$) adj3 (death? or dying or mortality or demise)).tw.
34	LABOR, INDUCED/
35	((induct$ or induc$) adj3 labo?r).tw.
36	((elective or planned) adj2 (birth? or deliver$ or induct$ or caesar#an$ or cesar#an$)).tw.
37	exp DELIVERY, OBSTETRIC/
38	WATCHFUL WAITING/
39	(expectant adj3 (manag$ or monitor$)).tw.
40	or/26-39
41	GESTATIONAL AGE/
42	(gestation$ adj age?).tw.
43	TIME FACTORS/
44	((time or timing) adj3 (birth or deliver$ or induction or inducted or cesarean? or caesarean or c?section?)).tw.
45	((optimal or optimum) adj3 (time or timing)).tw.
46	or/41-44
47	and/25,40,46

Database(s): Embase 1974 to 2013 February 27
Search Strategy: DiP_update_intrauterine_death_timing_embase_270213

#	Searches
1	PREGNANCY DIABETES MELLITUS/ or MATERNAL DIABETES MELLITUS/

#	Searches
2	(gestation$ adj3 diabet$).ti,ab.
3	or/1-2
4	DIABETES MELLITUS/ or IMPAIRED GLUCOSE TOLERANCE/ or INSULIN DEPENDENT DIABETES MELLITUS/ or JUVENILE DIABETES MELLITUS/ or NON INSULIN DEPENDENT DIABETES MELLITUS/
5	(T1DM or T2DM).ti,ab.
6	(IDDM or NIDDM).ti,ab.
7	diabet$.ti.
8	pre?diabet$.ti,ab.
9	impaired fasting glucose.ti,ab.
10	(IGT or IFG).ti,ab.
11	IGR.ti,ab.
12	GLUCOSE INTOLERANCE/
13	or/4-12
14	PREGNANCY/ or PREGNANT WOMAN/
15	(pregnan$ or gestation$).ti,ab.
16	or/14-15
17	and/13,16
18	or/3,17
19	FETUS DEATH/ or STILLBIRTH/
20	((foetal or fetal or fetus$ or foetus$) adj (death or dying or demise)).ti,ab.
21	(intrauterine adj2 death).ti,ab.
22	IUFD.ti,ab.
23	(stillbirth or still?born).ti,ab.
24	((peri?natal$ or neo?natal$) adj3 (death? or dying or mortality or demise)).ti,ab.
25	NEWBORN DEATH/
26	LABOR INDUCTION/
27	((induct$ or induc$) adj3 lab?or).ti,ab.
28	((elective or planned) adj2 (birth? or deliver$ or induct$ or caesar#an$ or cesar#an$)).ti,ab.
29	exp DELIVERY/
30	WATCHFUL WAITING/
31	conservative treatment/ or watchful waiting/
32	(expectant adj3 (manag$ or monitor$)).ti,ab.
33	or/19-32
34	GESTATIONAL AGE/
35	(gestation$ adj age?).ti,ab.
36	TIME/
37	((time or timing) adj3 (birth or deliver$ or induction or inducted or cesarean? or caesarean or c?section?)).ti,ab.
38	((optimal or optimum) adj3 (time or timing)).ti,ab.
39	or/34-38
40	and/18,33,39
41	conference abstract.pt.
42	letter.pt. or LETTER/
43	note.pt.
44	editorial.pt.

#	Searches
45	CASE REPORT/ or CASE STUDY/
46	(letter or comment* or abstracts).ti.
47	or/41-46
48	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
49	47 not 48
50	ANIMAL/ not HUMAN/
51	NONHUMAN/
52	exp ANIMAL EXPERIMENT/
53	exp EXPERIMENTAL ANIMAL/
54	ANIMAL MODEL/
55	exp RODENT/
56	(rat or rats or mouse or mice).ti.
57	or/49-56
58	40 not 57
59	limit 58 to english language
60	limit 59 to yr="2008 -Current"

E.10 Search 10: Diagnostic accuracy and timing of postnatal testing

Review question 18: What is the effectiveness of the following tests in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care):

- fasting plasma glucose test
- HbA1c test
- 75 g OGTT?

Review question 19: What is the optimal timing of postnatal testing in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care)?

Database(s): Ovid MEDLINE(R) 1946 to June Week 4 2012
Search Strategy: DiP_update_postnatal_test_medline_090712_2

#	Searches
1	exp DIABETES, GESTATIONAL/
2	exp HYPERGLYCEMIA/
3	exp PREGNANCY/
4	PREGNANT WOMAN/
5	or/2-4
6	and/2,5
7	(glucose adj3 (intoleran$ or dysregulat$)).ti,ab.

#	Searches
8	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).ti,ab.
9	(GDM or HGP).ti,ab.
10	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).ti,ab.
11	(GDM or HGP or IGT or pre?diabet$ or HAPO).ti,ab.
12	or/7-11
13	or/1,6,12
14	POSTPARTUM PERIOD/
15	POSTNATAL CARE/
16	(postnatal$ or post?natal$ or puerper$ or post?partum).ti,ab.
17	((after or following) adj3 (birth$ or deliver$ or parturi$)).ti,ab.
18	AFTERCARE/
19	after?care.ti,ab.
20	or/14-19
21	MASS SCREENING/
22	BLOOD GLUCOSE/
23	GLUCOSE TOLERANCE TEST/
24	HEMOGLOBIN A, GLYCOSYLATED/
25	(FPG or OGTT or HbA1c).ti,ab.
26	((glucose or blood sugar$) adj5 (test$ or assessment$ or monitor$)).ti,ab.
27	((fasting or oral) adj3 glucose).ti,ab.
28	(plasma adj3 glucose).ti,ab.
29	(glucose adj (level$ or read$ or monitor$ or assess$ or check$)).ti,ab.
30	((glycosylated or glycated) adj3 h?emoglobin$).ti,ab.
31	or/21-30
32	and/13,20,31
33	LETTER/
34	EDITORIAL/
35	NEWS/
36	exp HISTORICAL ARTICLE/
37	ANECDOTES AS TOPIC/
38	COMMENT/
39	CASE REPORT/
40	(letter or comment* or abstracts).ti.
41	or/33-40
42	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
43	41 not 42
44	ANIMALS/ not HUMANS/
45	exp ANIMALS, LABORATORY/
46	exp ANIMAL EXPERIMENTATION/
47	exp MODELS, ANIMAL/
48	exp RODENTIA/
49	(rat or rats or mouse or mice).ti.
50	or/43-49
51	32 not 50
52	limit 51 to english language

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations July 06, 2012
Search Strategy: DiP_update_postnatal_test_mip_090712

#	Searches
1	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).ti,ab.
2	(glucose adj3 (impaired or dysregulat$)).ti,ab.
3	(GDM or HGP or IGT or pre?diabet$ or HAPO).ti,ab.
4	or/1-3
5	(postnatal$ or post?natal$ or puerper$ or post?partum).ti,ab.
6	((after or following or post$) adj3 (birth$ or deliver$ or parturi$)).ti,ab.
7	after?care.ti,ab.
8	or/5-7
9	screen$.ti,ab.
10	(FPG or OGTT or HbA1c).ti,ab.
11	((glucose or blood sugar$) adj5 (test$ or assessment$ or monitor$)).ti,ab.
12	((fasting or oral) adj3 glucose).ti,ab.
13	((plasma or blood) adj3 glucose).ti,ab.
14	(glucose adj (level$ or read$ or monitor$ or assess$ or check$)).ti,ab.
15	((glycosylated or glycated) adj3 h?emoglobin$).ti,ab.
16	or/9-15
17	and/4,8,16

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials June 2012
Search Strategy: DiP_update_postnatal_test_cctr_090712

#	Searches
1	exp DIABETES, GESTATIONAL/
2	exp HYPERGLYCEMIA/
3	(glucose adj3 (intoleran$ or dysregulat$)).ti,ab.
4	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).ti,ab.
5	(GDM or HGP).ti,ab.
6	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).ti,ab.
7	(GDM or HGP or IGT or pre?diabet$ or HAPO).ti,ab.
8	or/1-7
9	POSTPARTUM PERIOD/
10	POSTNATAL CARE/
11	(postnatal$ or post?natal$ or puerper$ or post?partum).ti,ab.
12	((after or following) adj3 (birth$ or deliver$ or parturi$)).ti,ab.
13	AFTERCARE/
14	after?care.ti,ab.
15	or/9-14
16	MASS SCREENING/
17	BLOOD GLUCOSE/
18	GLUCOSE TOLERANCE TEST/
19	HEMOGLOBIN A, GLYCOSYLATED/
20	(FPG or OGTT or HbA1c).ti,ab.
21	((glucose or blood sugar$) adj5 (test$ or assessment$ or monitor$)).ti,ab.

#	Searches
22	((fasting or oral) adj3 glucose).ti,ab.
23	(plasma adj3 glucose).ti,ab.
24	(glucose adj (level$ or read$ or monitor$ or assess$ or check$)).ti,ab.
25	((glycosylated or glycated) adj3 h?emoglobin$).ti,ab.
26	or/16-25
27	and/8,15,26

Database(s): EBM Reviews - Cochrane Database of Systematic Reviews 2005 to June 2012, EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2012
Search Strategy: DiP_update_postnatal_test_cdsrdare_090712

#	Searches
1	DIABETES, GESTATIONAL.kw.
2	HYPERGLYCEMIA.kw.
3	(glucose adj3 (intoleran$ or dysregulat$)).tw,tx.
4	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).tw,tx.
5	(GDM or HGP).tw,tx.
6	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).tw,tx.
7	(GDM or HGP or IGT or pre?diabet$ or HAPO).tw,tx.
8	or/1-7
9	POSTPARTUM PERIOD.kw.
10	POSTNATAL CARE.kw.
11	(postnatal$ or post?natal$ or puerper$ or post?partum).tw,tx.
12	((after or following) adj3 (birth$ or deliver$ or parturi$)).tw,tx.
13	AFTERCARE.tw.
14	after?care.tw,tx.
15	or/9-14
16	MASS SCREENING.kw.
17	BLOOD GLUCOSE.kw.
18	GLUCOSE TOLERANCE TEST.kw.
19	HEMOGLOBIN A, GLYCOSYLATED.kw.
20	(FPG or OGTT or HbA1c).tw,tx.
21	((glucose or blood sugar$) adj5 (test$ or assessment$ or monitor$)).tw,tx.
22	((fasting or oral) adj3 glucose).tw,tx.
23	(plasma adj3 glucose).tw,tx.
24	(glucose adj (level$ or read$ or monitor$ or assess$ or check$)).tw,tx.
25	((glycosylated or glycated) adj3 h?emoglobin$).tw,tx.
26	or/16-25
27	and/8,15,26

Database(s): EBM Reviews - Health Technology Assessment 1st Quarter 2014
Search Strategy: DiP_update_postnatal_test_RERUN1_hta_270214

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/

#	Searches
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.tw.
10	PREDIABETIC STATE/
11	prediabet$.tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	GLUCOSE INTOLERANCE/
19	HYPERGLYCEMIA/
20	hyperglyc?em?.tw.
21	or/6-20
22	PREGNANCY/
23	(pregnan$ or gestation$).tw.
24	PREGNANT WOMEN/
25	PRECONCEPTION CARE/
26	PRENATAL CARE/
27	pre?conception.tw.
28	(pre adj conception).tw.
29	pre?pregnancy.tw.
30	(pre adj pregnancy).tw.
31	(pre?natal$ or pre?conception or ante?natal).tw.
32	(pre adj natal$).tw.
33	(pre adj conception).tw.
34	(ante adj natal$).tw.
35	or/22-34
36	and/21,35
37	or/5,36
38	BLOOD GLUCOSE/
39	(blood adj3 (glucose or sugar?)).tw.
40	BLOOD GLUCOSE SELF-MONITORING/
41	BGSM.tw.
42	(home glucose adj (test$ or monitor$)).tw.
43	(self adj (test$ or monitor$)).tw.
44	GLUCOSE TOLERANCE TEST/
45	OGTT.tw.
46	(glucose adj (toleran$ or test$ or load$)).tw.
47	(fasting adj plasma adj glucose).tw.

#	Searches
48	FPG.tw.
49	HEMOGLOBIN A, GLYCOSYLATED/
50	HbA1c.tw.
51	(h?emoglobin? adj3 glycosylat$).tw.
52	(glycated adj3 h?emoglobin?).tw.
53	or/38-52
54	and/37,53

Database(s): Embase 1974 to 2012 July 06
Search Strategy: DiP_update_postnatal_test_embase_090712

#	Searches
1	PREGNANCY DIABETES MELLITUS/
2	IMPAIRED GLUCOSE TOLERANCE/
3	HYPERGLYCEMIA/
4	((diabet$ or hyperglyc?emi$) adj3 (gestat$ or pregnan$)).ti,ab.
5	(GDM or HGP or IGT or pre?diabet$ or HAPO).ti,ab.
6	or/1-5
7	PUERPERIUM/
8	POSTNATAL CARE/
9	(postnatal$ or post?natal$ or puerper$ or post?partum).ti,ab.
10	((after or follow$) adj3 (birth$ or deliver$ or parturi$)).ti,ab.
11	AFTERCARE/
12	after?care.ti,ab.
13	or/7-12
14	MASS SCREENING/
15	GLUCOSE BLOOD LEVEL/
16	exp GLUCOSE TOLERANCE TEST/
17	GLYCOSYLATED HEMOGLOBIN/
18	(FPG or OGTT or HbA1c).ti,ab.
19	((glucose or blood sugar$) adj5 (test$ or assess$ or monitor$)).ti,ab.
20	((fast$ or oral) adj3 glucose).ti,ab.
21	((glycosylated or glycated) adj3 h?emoglobin).ti,ab.
22	or/14-21
23	and/6,13,22
24	conference abstract.pt.
25	letter.pt. or LETTER/
26	note.pt.
27	editorial.pt.
28	CASE REPORT/ or CASE STUDY/
29	(letter or comment* or abstracts).ti.
30	or/24-29
31	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
32	30 not 31
33	ANIMAL/ not HUMAN/
34	NONHUMAN/

#	Searches
35	exp ANIMAL EXPERIMENT/
36	exp EXPERIMENTAL ANIMAL/
37	ANIMAL MODEL/
38	exp RODENT/
39	(rat or rats or mouse or mice).ti.
40	or/32-39
41	23 not 40
42	limit 41 to english language

E.11 Search 11: Health economics

A single Health Economics search was conducted across the whole guideline

Database(s): Ovid MEDLINE(R) 1946 to November Week 2 2012
Search Strategy: **DiP_update_population_search_HE_medline_151112**

#	Searches
1	ECONOMICS/
2	VALUE OF LIFE/
3	exp "COSTS AND COST ANALYSIS"/
4	exp ECONOMICS, HOSPITAL/
5	exp ECONOMICS, MEDICAL/
6	exp RESOURCE ALLOCATION/
7	ECONOMICS, NURSING/
8	ECONOMICS, PHARMACEUTICAL/
9	exp "FEES AND CHARGES"/
10	exp BUDGETS/
11	budget*.ti,ab.
12	cost*.ti,ab.
13	(economic* or pharmaco?economic*).ti,ab.
14	(price* or pricing*).ti,ab.
15	(financ* or fee or fees or expenditure* or saving*).ti,ab.
16	(value adj2 (money or monetary)).ti,ab.
17	resourc* allocat*.ti,ab.
18	(fund or funds or funding* or funded).ti,ab.
19	(ration or rations or rationing* or rationed).ti,ab.
20	ec.fs.
21	or/1-20
22	exp PREGNANCY IN DIABETICS/
23	DIABETES, GESTATIONAL/
24	(gestation$ adj3 diabet$).ti,ab.
25	GDM.ti,ab.

#	Searches
26	or/22-25
27	exp DIABETES MELLITUS/
28	exp DIABETES INSIPIDUS/
29	(T1DM or T2DM).ti,ab.
30	diabet$.ti.
31	PREDIABETIC STATE/
32	prediabet$.ti,ab.
33	impaired glucose tolerance.ti,ab.
34	IGT.ti,ab.
35	Impaired fasting glucose.ti,ab.
36	IFG.ti,ab.
37	Impaired glucose regulation.ti,ab.
38	IGR.ti,ab.
39	GLUCOSE INTOLERANCE/
40	or/27-39
41	PREGNANCY/
42	(pregnan$ or gestation$).ti,ab.
43	PREGNANT WOMEN/
44	or/41-43
45	and/40,44
46	or/26,45
47	and/21,46
48	LETTER/
49	EDITORIAL/
50	NEWS/
51	exp HISTORICAL ARTICLE/
52	ANECDOTES AS TOPIC/
53	COMMENT/
54	CASE REPORT/
55	(letter or comment* or abstracts).ti.
56	or/48-55
57	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
58	56 not 57
59	ANIMALS/ not HUMANS/
60	exp ANIMALS, LABORATORY/
61	exp ANIMAL EXPERIMENTATION/
62	exp MODELS, ANIMAL/
63	exp RODENTIA/
64	(rat or rats or mouse or mice).ti.
65	or/58-64
66	47 not 65
67	limit 66 to english language

Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials November 2012
Search Strategy: **DiP_update_population_search_HE_cctr_151112**

#	Searches
1	ECONOMICS/
2	VALUE OF LIFE/
3	exp "COSTS AND COST ANALYSIS"/
4	exp ECONOMICS, HOSPITAL/
5	exp ECONOMICS, MEDICAL/
6	exp RESOURCE ALLOCATION/
7	ECONOMICS, NURSING/
8	ECONOMICS, PHARMACEUTICAL/
9	exp "FEES AND CHARGES"/
10	exp BUDGETS/
11	budget*.ti,ab.
12	cost*.ti,ab.
13	(economic* or pharmaco?economic*).ti,ab.
14	(price* or pricing*).ti,ab.
15	(financ* or fee or fees or expenditure* or saving*).ti,ab.
16	(value adj2 (money or monetary)).ti,ab.
17	resourc* allocat*.ti,ab.
18	(fund or funds or funding* or funded).ti,ab.
19	(ration or rations or rationing* or rationed).ti,ab.
20	ec.fs.
21	or/1-20
22	exp PREGNANCY IN DIABETICS/
23	DIABETES, GESTATIONAL/
24	(gestation$ adj3 diabet$).ti,ab.
25	GDM.ti,ab.
26	or/22-25
27	exp DIABETES MELLITUS/
28	exp DIABETES INSIPIDUS/
29	(T1DM or T2DM).ti,ab.
30	diabet$.ti.
31	PREDIABETIC STATE/
32	prediabet$.ti,ab.
33	impaired glucose tolerance.ti,ab.
34	IGT.ti,ab.
35	Impaired fasting glucose.ti,ab.
36	IFG.ti,ab.
37	Impaired glucose regulation.ti,ab.
38	IGR.ti,ab.
39	GLUCOSE INTOLERANCE/
40	or/27-39
41	PREGNANCY/
42	(pregnan$ or gestation$).ti,ab.

#	Searches
43	PREGNANT WOMEN/
44	or/41-43
45	and/40,44
46	or/26,45
47	and/21,46

Database(s): EBM Reviews - Health Technology Assessment 4th Quarter 2012
Search Strategy: **EBM Reviews - Health Technology Assessment 4th Quarter 2012**

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).tw.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	or/5,24

Database(s): EBM Reviews - NHS Economic Evaluation Database 4th Quarter 2012
Search Strategy: **DiP_update_population_search_HE_nhseed_151112**

#	Searches
1	exp PREGNANCY IN DIABETICS/
2	DIABETES, GESTATIONAL/

#	Searches
3	(gestation$ adj3 diabet$).tw.
4	GDM.tw.
5	or/1-4
6	exp DIABETES MELLITUS/
7	exp DIABETES INSIPIDUS/
8	(T1DM or T2DM).tw.
9	diabet$.ti.
10	PREDIABETIC STATE/
11	prediabet$.tw.
12	impaired glucose tolerance.tw.
13	IGT.tw.
14	Impaired fasting glucose.tw.
15	IFG.tw.
16	Impaired glucose regulation.tw.
17	IGR.tw.
18	GLUCOSE INTOLERANCE/
19	or/6-18
20	PREGNANCY/
21	(pregnan$ or gestation$).tw.
22	PREGNANT WOMEN/
23	or/20-22
24	and/19,23
25	or/5,24

Database(s): Embase 1980 to 2012 Week 46
Search Strategy: **DiP_update_population_search_HE_embase_191112**

#	Searches
1	HEALTH ECONOMICS/
2	exp ECONOMIC EVALUATION/
3	exp HEALTH CARE COST/
4	exp FEE/
5	BUDGET/
6	FUNDING/
7	RESOURCE ALLOCATION/
8	budget*.ti,ab.
9	cost*.ti,ab.
10	(economic* or pharmaco?economic*).ti,ab.
11	(price* or pricing*).ti,ab.
12	(financ* or fee or fees or expenditure* or saving*).ti,ab.
13	(value adj2 (money or monetary)).ti,ab.
14	resourc* allocat*.ti,ab.
15	(fund or funds or funding* or funded).ti,ab.
16	(ration or rations or rationing* or rationed).ti,ab.
17	or/1-16

#	Searches
18	exp PREGNANCY DIABETES MELLITUS/
19	gestational diabet$.ti,ab.
20	GDM.ti,ab.
21	or/18-20
22	exp DIABETES MELLITUS/
23	diabet$.ti.
24	(T?1DM or T?2DM).ti,ab.
25	(IDDM or NIDDM).ti,ab.
26	IMPAIRED GLUCOSE TOLERANCE/
27	IGT.ti,ab.
28	impaired fasting glucose.ti,ab.
29	IFG.ti,ab.
30	impaired glucose regulat$.ti,ab.
31	IGR.ti,ab.
32	GLUCOSE INTOLERANCE/
33	or/22-32
34	PREGNANCY/ or FIRST TRIMESTER PREGNANCY/ or PREGNANT WOMAN/ or SECOND TRIMESTER PREGNANCY/ or THIRD TRIMESTER PREGNANCY/
35	(pregnan$ or gestation$).ti,ab.
36	or/34-35
37	and/33,36
38	or/21,37
39	and/17,38
40	limit 39 to english language

Appendix F:Summary of identified studies

Protocol Question	Total papers identified	Duplicates	Weeded out	Abandoned	Excluded	Included
1. What is the effectiveness of oral oestrogen-containing contraceptives in women with diabetes compared with women without diabetes?	1475	1	1421	3	41	8
2. What is the effectiveness of oral progestogen-containing contraceptives in women with diabetes compared with women without diabetes?	1475	1	1421	3	41	8
3. What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1 or type 2 diabetes who are planning pregnancy?	52	0	52	0	0	0
4. What are the target ranges for blood glucose in women with type 1 or type 2 diabetes who are planning pregnancy?	3297	0	3287	1	9	0
5. What is the target value for HbA1c in women with type 1 or type 2 diabetes who are planning pregnancy?	3295	0	3264	1	22	8
6. What is the effectiveness of the following procedures in detecting glucose intolerance in the first trimester diagnosed using a 75g OGTT	7479	1	7410	1	60	6
7. What is the effectiveness of the following procedures in detecting glucose intolerance in the second trimester diagnosed using a 75g OGTT	7481	3	7333	2	127	11
8. Which criteria should be used to diagnose gestational diabetes using the 75 g OGTT: World Health Organization (WHO) or International Association of	155	0	121	0	29	5

Protocol Question	Total papers identified	Duplicates	Weeded out	Abandoned	Excluded	Included
Diabetes and Pregnancy Study Groups (IADPSG)?						
9. What is the effectiveness of the following interventions (alone or in combination) in women with gestational diabetes: non-pharmacological or pharmacological	1762	0	1593	4	131	34
Q10. What is the effectiveness of blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?	3296	0	3253	1	36	6
Q11.What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for women with type 1, type 2 or gestational diabetes during pregnancy?	52	0	52	0	0	0
Q12. What are the target ranges for blood glucose in women with type 1, type 2 or gestational diabetes during pregnancy?	3296	0	3253	1	36	6
Q13. What is the effectiveness of HbA1c monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?	3267	0	3226	0	40	0
Q14. What is the target value for HbA1c in women with type 1, type 2 or gestational diabetes during pregnancy?	3296	0	3250	3	42	4
Q15. To assess whether continuous glucose monitoring during pregnancy is more effective than intermittent capillary blood glucose monitoring for improving: glycaemic control or maternal/fetal outcomes	593	1	555	0	29	5
Q16. What is the effectiveness of specialist teams for pregnant women with diabetes?	337	0	311	0	21	5
Q17. What is the gestational age-specific risk of intrauterine death in pregnancies with type 1, type 2 or gestational diabetes, and the optimal timing of birth?	1023	0	999	5	18	6
Q18. What is the effectiveness of the following tests in the	1317	1	1167	5	93	51

Protocol Question	Total papers identified	Duplicates	Weeded out	Abandoned	Excluded	Included
detection of glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care): FPG, OGTT, HbA1c						
Q19. What is the optimal timing of postnatal testing in detecting glucose intolerance after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care)?	1317	1	1167		93	51

Appendix G: List of excluded studies

G.1 Oral contraception containing oestrogen and/or progestogen

Excluded studies – Review questions 1 and 2	
Study	**Reason for Exclusion**
Use of hormonal contraception in women with coexisting medical conditions, Obstetrics and Gynecology, 107, 1453-1472, 2006	Narrative review with no new data. Individual studies were reviewed where relevant
Aznar,R., Lara,R., Zarco,D., Gonzalez,L., The effect of various contraceptive hormonal therapies in women with normal and diabetic oral glucose tolerance test, Contraception, 13, 299-311, 1976	Does not include relevant outcomes as specified in the protocol
Bacopoulou,F., Greydanus,D.E., Chrousos,G.P., Reproductive and contraceptive issues in chronically ill adolescents, European Journal of Contraception and Reproductive Health Care, 15, 389-404, 2010	Narrative review with no new data. Individual studies considered separately for inclusion where relevant
Charronprochownik,D., FAMILY-PLANNING BEHAVIOR IN YOUNG-WOMEN WITH IDDM, Diabetes, 45, 651-651, 1996	Does not report relevant outcomes
Charron-Prochownik,D., Sereika,S.M., Becker,D., White,N.H., Schmitt,P., Blair Powell III,A., Diaz,A.M., Jones,J., Herman,W.H., Rodgers Fischel ,A.F., McEwan,L., Dinardo,M., Guo,F, Downs,J., Long-Term Effects of the Booster-Enhanced READY-Girls Preconception Counseling Program on Intentions and Behaviors for Family Planning in Teens With Diabetes, Diabetes Care, Published ahead of print, October 15 2013, -, 2013	Intervention is not relevant (pre-conception counselling).

Excluded studies – Review questions 1 and 2	
Charron-Prochownik,D., Sereika,S.M., Falsetti,D., Wang,S.L., Becker,D., Jacober,S., Mansfield,J., White,N.H., Knowledge, attitudes and behaviors related to sexuality and family planning in adolescent women with and without diabetes, Pediatric Diabetes, 7, 267-273, 2006	Does not report relevant outcomes
Codner,E., Soto,N., Merino,P.M., Contraception, and pregnancy in adolescents with type 1 diabetes: a review, Pediatric Diabetes, 13, 108-123, 2012	Narrative review. Relevant studies have been considered for inclusion individually
Coster,S., Gulliford,M.C., Seed,P.T., Powrie,J.K., Swaminathan,R., Monitoring blood glucose control in diabetes mellitus: A systematic review, Health Technology Assessment, 4, i-84, 2000	Does not report outcomes of oral contraceptive use in women with or without diabetes
Croft,P., Hannaford,P.C., Risk factors for acute myocardial infarction in women: evidence from the Royal College of General Practitioners' oral contraception study, BMJ, 298, 165-168, 1989	Does not report myocardial infarction in women who take oral contraceptives by whether women have diabetes or not
Damm,P., Mathiesen,E., Clausen,T.D., Petersen,K.R., Contraception for women with diabetes mellitus, Metabolic Syndrome and Related Disorders, 3, 244-249, 2005	Narrative review. Individual studies have been reviewed where relevant
Duffy,T.J., Ray,R., Oral contraceptive use: prospective follow-up of women with suspected glucose intolerance, Contraception, 30, 197-208, 1984	Does not report the relevant outcomes as specified in the protocol
Falsetti,D., Charron-Prochownik,D., Serelka,S., Kitutu,J., Peterson,K., Becker,D., Jacober,S., Mansfield,J., White,N.H., Condom use, pregnancy, and STDs in adolescent females with and without type 1 diabetes, Diabetes Educator, 29, 135-143, 2003	Does not report outcomes separately for women who use contraception and women who do not use contraception
Farley,T.M., Collins,J., Schlesselman,J.J., Hormonal contraception and risk of cardiovascular disease. An international perspective. [47 refs], Contraception, 57, 211-230, 1998	Does not report a comparison of interest
Fontbonne,A., Basdevant,A., Faguer,B., Thomassin,M., Buchsenschutz,D., Contraceptive practice in 209 diabetic women regularly attending a specialized diabetes clinic, Diabete et Metabolisme, 13, 411-416, 1987	Does not report outcomes of interest
Gordon,C.M., Mansfield,M.J., Changing needs of the patient with diabetes mellitus during the teenage years, Current Opinion in Pediatrics, 8, 319-327, 1996	Narrative review with no new data. Individual studies considered separately for inclusion
Heyman,A., Arons,M., Quinn,M., Camplong,L., The role of oral contraceptive agents in cerebral arterial occlusion, Neurology, 19, 519-524, 1969	Does not report a comparison of interest
Jensen,G., Nyboe,J., Appleyard,M., Schnohr,P., Risk factors for acute myocardial infarction in Copenhagen, II: Smoking, alcohol intake, physical activity, obesity, oral contraception, diabetes, lipids, and blood pressure, European Heart Journal, 12, 298-308, 1991	Does not report a comparison of interest
Kirwan,J.F., Tsaloumas,M.D., Vinall,H., Prior,P., Kritzinger,E.E., Dodson,P.M., Sex hormone preparations and retinal vein occlusion, Eye, 11, 53-56, 1997	Did not include any women with diabetes
Kjaer,K., Hagen,C., Sando,S.H., Eshoj,O., Contraception in women with IDDM. An epidemiological study, Diabetes Care, 15, 1585-1590, 1992	Does not report outcomes of interest

Excluded studies – Review questions 1 and 2	
Klein,B.E., Klein,R., Moss,S.E., Mortality and hormone-related exposures in women with diabetes, Diabetes Care, 22, 248-252, 1999	Reports oral contraceptive use as a characteristic rather than comparison group - includes 'ever' and current users of oral contraceptives as one group
Lawrenson,R.A., Leydon,G.M., Williams,T.J., Newson,R.B., Feher,M.D., Patterns of contraception in UK women with Type 1 diabetes mellitus: a GP database study, Diabetic Medicine, 16, 395-399, 1999	Does not report outcomes separately for a comparison of interest
Lidegaard,O., Oral contraceptives, pregnancy and the risk of cerebral thromboembolism: the influence of diabetes, hypertension, migraine and previous thrombotic disease, British Journal of Obstetrics and Gynaecology, 102, 153-159, 1995	Does not report outcomes for women with diabetes who are taking oral contraceptives
Lidegaard,O., Edstrom,B., Kreiner,S., Oral contraceptives and venous thromboembolism: A five-year national case-control study, Contraception, 65, 187-196, 2002	Does not report a comparison of interest
Magill-Lewis,J., Cover story: One-Two Punch, Drug Topics, 148, 30-, 2004	Does not report a comparison of interest
Petersen,K.R., Pharmacodynamic effects of oral contraceptive steroids on biochemical markers for arterial thrombosis: Studies in non-diabetic women and in women with insulin-dependent diabetes mellitus, Danish Medical Bulletin, 49, 43-60, 2002	Narrative review with no new data. Individual studies were reviewed where relevant
Petersen,K.R., Skouby,S.O., Jespersen,J., Contraception guidance in women with pre-existing disturbances in carbohydrate metabolism, The European journal of contraception & reproductive health care : the official journal of the European Society of Contraception, 1, 53-59, 1996	Does not compare the use of oral contraceptives in women with and without diabetes. Data reported for women with diabetes who use oral contraceptives and women with diabetes who do not use oral contraceptives is a summary of the data reported in Skouby et al. (1986). The details from the full paper were included in the current review instead.
Petersen,K.R., Skouby,S.O., Sidelmann,J., Molsted-Pedersen,L., Jespersen,J., Effects of contraceptive steroids on cardiovascular risk factors in women with insulin-dependent diabetes mellitus, American Journal of Obstetrics and Gynecology, 171, 400-405, 1994	The women in this study are included in the Petersen (1995) study, which was included in the review for the guideline (see Petersen et al., 1995).
Radberg,T., Gustafson,A., Skryten,A., Karlsson,K., Oral contraception in diabetic women. Diabetes control, serum and high density lipoprotein lipids during low-dose progestogen, combined oestrogen/progestogen and non-hormonal contraception, ACTA ENDOCRINOL.(COPENHAGEN), 98, 246-251, 1981	Compares two groups of women, one of which was receiving a 50 microgramme dose of ethinyl estradiol, which is excluded from the guideline review as it is not used in current practice
Radberg,T., Gustafson,A., Skryten,A., Karlsson,K., Oral contraception in diabetic women. A cross-over study on serum and high density lipoprotein (HDL) lipids and diabetes control during progestogen and combined estrogen/progestogen contraception, Hormone and Metabolic Research, 14, 61-65, 1982	Compares two groups of women, one of which was receiving a 50 microgramme dose of ethinyl estradiol, which is excluded from the guideline review as it is not used in current practice
Rogovskaya,S., Rivera,R., Grimes,D.A., Chen,P.L., Pierre-Louis,B., Prilepskaya,V., Kulakov,V., Effect of a levonorgestrel intrauterine system on women with type 1 diabetes: a randomized trial, Obstetrics and Gynecology, 105, 811-815, 2005	Comparison of different types of intrauterine contraceptive devices. None of the women received oral contraceptives.

Excluded studies – Review questions 1 and 2	
Shawe,J., Lawrenson,R., Hormonal contraception in women with diabetes mellitus: Special considerations, Treatments in Endocrinology, 2, 321-330, 2003	Narrative review with no new data. Individual studies ordered where relevant
Shawe,J., Mulnier,H., Nicholls,P., Lawrenson,R., Use of hormonal contraceptive methods by women with diabetes, Primary care diabetes, 2, 195-199, 2008	Does not report consequences of oral contraceptive use, only the patterns of use in women with and without diabetes
Sidney,S., Siscovick,D.S., Petitti,D.B., Schwartz,S.M., Quesenberry,C.P., Psaty,B.M., Raghunathan,T.E., Kelaghan,J., Koepsell,T.D., Myocardial infarction and use of low-dose oral contraceptives: a pooled analysis of 2 US studies, Circulation, 98, 1058-1063, 1998	Does not report a comparison of interest
Siritho,S., Thrift,A.G., McNeil,J.J., You,R.X., Davis,S.M., Donnan,G.A., Risk of ischemic stroke among users of the oral contraceptive pill: The Melbourne Risk Factor Study (MERFS) Group, Stroke, 34, 1575-1580, 2003	Does not report oral contraceptive use in women with diabetes
Skouby,S.O., Oral contraceptives: effects on glucose and lipid metabolism in insulin-dependent diabetic women and women with previous gestational diabetes. A clinical and biochemical assessment. [112 refs], Danish Medical Bulletin, 35, 157-167, 1988	Does not report a comparison of interest
Snell-Bergeon,Janet K., Dabelea,Dana, Ogden,Lorraine G., Hokanson,John E., Kinney,Gregory L., Ehrlich,James, Rewers,Marian, Reproductive History and Hormonal Birth Control Use Are Associated with Coronary Calcium Progression in Women with Type 1 Diabetes Mellitus, Journal of Clinical Endocrinology & Metabolism, 93, 2142-2148, 2008	Not all women in the 'birth control' group were using birth control at the time of the study and baseline measurements - the group includes women who had used birth control at any point in the past. The study does not report how many women in the birth control group were using birth control at the time of the study. Not all women in the 'birth control' group were using oral contraceptives (around 80% were).
Spellacy,W.N., Buhi,W.C., Spellacy,C.E., Moses,L.E., Goldzieher,J.W., Glucose, insulin, and growth hormone studies in long-term users of oral contraceptives, American Journal of Obstetrics and Gynecology, 106, 173-182, 1970	Does not report a comparison of interest
Steel,J.M., Prepregnancy counseling and contraception in the insulin-dependent diabetic patient, Clinical Obstetrics and Gynecology, 28, 553-566, 1985	Narrative review with no new data. Individual studies considered separately where relevant
Virkar,K., Barsivala,V., Kulkarni,R.D., Correlation of clinical parameters with glucose tolerance tests in women taking oral contraceptives, Fertility and Sterility, 25, 569-574, 1974	Does not report a comparison of interest
Wiese,J., Osler,M., Contraception in diabetic patients, Acta Endocrinologica, Supplementum. 182, 87-89, 1974	Does not report a comparison of interest
Wingrave,S.J., Kay,C.R., Vessey,M.P., Oral contraceptives and diabetes mellitus, British Medical Journal, 1, 23-, 1979	Does not report a comparison of interest

G.2 Ketone monitoring in the preconception period

There were no excluded studies for review question 3.

G.3 Blood glucose target values in the preconception period

Excluded studies – Review question 4	
Study	Reason for Exclusion
Dong,L., Liu,E., Guo,J., Pan,L., Li,B., Leng,J., Zhang,C., Zhang,Y., Li,N., Hu,G., Relationship between maternal fasting glucose levels at 4-12 gestational weeks and offspring growth and development in early infancy, Diabetes Research and Clinical Practice, 102, 210-217, 2013	Only report mean SD for birth weight
Kitzmiller,J.L., Gavin,L.A., Gin,G.D., Jovanovic-Peterson,L., Main,E.K., Zigrang,W.D., Preconception care of diabetes. Glycemic control prevents congenital anomalies, JAMA, 265, 731-736, 1991	Data compared in pre-conception care women versus post-conception care. Data not analysed with respect to blood glucose values or targets.
Mills,J.L., Simpson,J.L., Driscoll,S.G., Jovanovic-Peterson,L., Van,Allen M., Aarons,J.H., Metzger,B., Bieber,F.R., Knopp,R.H., Holmes,L.B., Incidence of spontaneous abortion among normal women and insulin-dependent diabetic women whose pregnancies were identified within 21 days of conception, New England Journal of Medicine N.Engl.J.Med., 319, 1617-1623, 1988	No targets or thresholds given. Dichotomous data are not compared according to blood glucose values for mortality and miscarriages (diabetic versus non-diabetic women). Only mean blood glucose values are presented for comparative data for miscarriages.
The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus New England Journal of Medicine 1993	The study population is all adults, not pregnant women
The Diabetes Control and Complications Trial Research Group. Pregnancy outcomes in the Diabetes Control and Complications Trial. American Journal of Obstetrics and Gynecology 1996;174(4):1343–53.	This study specifies the blood glucose targets that were given for the intensive therapy group, but no target value details were specified for the conventional group
DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. British Medical Journal 2002;325:746–8.	The study population is adults with Type 1 diabetes, not pregnant women
Tieu,Joanna, Middleton,Philippa, Crowther,Caroline A., Preconception care for diabetic women for improving maternal and infant health, Cochrane Database of Systematic Reviews, -, 2011	Wrong intervention and no results reported
Wahabi,H.A., Alzeidan,R.A., Esmaeil,S.A., Pre-pregnancy care for women with pre-gestational diabetes mellitus: A systematic review and meta-analysis, BMC Public Health, 12, 2012	Systematic review of RCTs: intervention is care not HbA_{1c} target

G.4 HbA_{1c} target values in the preconception period

Excluded studies – Review question 5	
Study	Reason for Exclusion
Akhlaghi,F., Rajabian,R., Talebi,F., Correlation of HbA_{1c} and outcome of pregnancy in insulin dependent diabetic women,	Abstract in English but main article not in English.

Excluded studies – Review question 5	
Iranian Journal of Obstetrics, Gynecology and Infertility, 15, 1-6, 2012	
Cyganek,K., Hebda-Szydlo,A., Skupien,J., Katra,B., Janas,I., Borodako,A., Kaim,I., Klupa,T., Reron,A., Malecki,M.T., Glycemic control and pregnancy outcomes in women with type 2 diabetes from Poland. The impact of pregnancy planning and a comparison with type 1 diabetes subjects, Endocrine, 40, 243-249, 2011	Compares outcomes in type 1 diabetes versus type 2 diabetes and not according to HbA_{1c} values.
Glinianaia,S.V., Tennant,P.W.G., Bilous,R.W., Rankin,J., Bell,R., HbA_{1c} and birthweight in women with pre-conception type 1 and type 2 diabetes: A population-based cohort study, Diabetologia, 55, 3193-3203, 2012	No targets given. Threshold analysis is based on regression with only coefficients presented. Odds ratios for above/below an HbA_{1c} of 7% are presented for LGA risk but in relation to the interaction between peri-conception HbA_{1c} and during the third trimester. Shows an increased risk of LGA for HbA_{1c} increasing during pregnancy.
Gold,A.E., Reilly,R., Little,J., Walker,J.D., The effect of glycemic control in the pre-conception period and early pregnancy on birth weight in women with IDDM, Diabetes Care, 21, 535-538, 1998	No specified HbA_{1c} targets; no threshold analysis. Mean HbA_{1c} only.
Goldman,J.A., Dicker,D., Feldberg,D., Yeshaya,A., Samuel,N., Karp,M., Pregnancy outcome in patients with insulin-dependent diabetes mellitus with preconceptional diabetic control: a comparative study, American Journal of Obstetrics and Gynecology, 155, 293-297, 1986	No specified HbA_{1c} targets; no threshold analysis. Mean HbA_{1c} only. Neonatal hypoglycaemia, pre-eclampsia and Caesarean section are not relevant to the protocol.
Gutaj,P., Zawiejska,A., Wender-Ozegowska,E., Brazert,J., Maternal factors predictive of firsttrimester pregnancy loss in women with pregestational diabetes, Polskie Archiwum Medycyny Wewnetrznej, 123, 21-28, 2013	No specified HbA_{1c} targets; no threshold analysis. Mean HbA_{1c} only in miscarriage versus no miscarriage.
Holmes,V.A., Young,I.S., Patterson,C.C., Pearson,D.W., Walker,J.D., Maresh,M.J., McCance,D.R., Diabetes and Pre-eclampsia Intervention Trial Study Group., Optimal glycemic control, pre-eclampsia, and gestational hypertension in women with type 1 diabetes in the diabetes and pre-eclampsia intervention trial, Diabetes Care, 34, 1683-1688, 2011	No suitable outcomes reported according to the protocol
Jensen,D.M., Damm,P., Moelsted-Pedersen,L., Ovesen,P., Westergaard,J.G., Moeller,M., Beck-Nielsen,H., Outcomes in type 1 diabetic pregnancies: a nationwide, population-based study, Diabetes Care, 27, 2819-2823, 2004	No specified HbA_{1c} targets; no threshold analysis. Mean HbA_{1c} for serious outcome versus no serious outcome.
Klinke,J., Toth,E.L., Preconception care for women with type 1 diabetes, Canadian Family PhysicianCan.Fam.Physician, 49, 769-773, 2003	Systematic review with no data provided
Lisowski,L.A., Verheijen,P.M., Copel,J.A., Kleinman,C.S., Wassink,S., Visser,G.H., Meijboom,E.J., Congenital heart disease in pregnancies complicated by maternal diabetes mellitus. An international clinical collaboration, literature review, and meta-analysis. [64 refs], Herz, 35, 19-26, 2010	No targets/threshold analysis. Comparison is for congenital malformations in the offspring of diabetic versus non-diabetic women.
Miodovnik,M., Mimouni,F., Tsang,R.C., Ammar,E., Kaplan,L., Siddiqi,T.A., Glycemic control and spontaneous abortion in insulin-dependent diabetic women, Obstetrics and GynecologyObstet.Gynecol., 68, 366-369, 1986	No specified HbA_{1c} targets. Mean HbA_{1c} only was reported for abortion versus no abortion.

Excluded studies – Review question 5	
Rosenn,B., Miodovnik,M., Combs,C.A., Khoury,J., Siddiqi,T.A., Pre-conception management of insulin-dependent diabetes: improvement of pregnancy outcome, Obstetrics and GynecologyObstet.Gynecol., 77, 846-849, 1991	No specified HbA_{1c} targets; no threshold analysis. Mean HbA_{1c} in abortion versus no abortion.
Steel,J.M., Johnstone,F.D., Hepburn,D.A., Smith,A.F., Can prepregnancy care of diabetic women reduce the risk of abnormal babies?, BMJ, 301, 1070-1074, 1990	Outcomes not analysed in relation to HbA_{1c} levels
Tieu,Joanna, Middleton,Philippa, Crowther,Caroline A., Preconception care for diabetic women for improving maternal and infant health, Cochrane Database of Systematic Reviews, -, 2011	Wrong intervention and no results reported
Valuk,J., Factors influencing birth weight in infants of diabetic mothers., Diabetes, 35, 96A-, 1986	Abstract only.
Veres,M., Babes,A., Lacziko,S., Correlations between the values of maternal glycemia from the last trimester of pregnancy and fetal birth weight, Romanian Journal of Diabetes, Nutrition and Metabolic Diseases, 20, 259-265, 2013	Report associations using ROC analysis - not a threshold
Wahabi,H.A., Alzeidan,R.A., Bawazeer,G.A., Alansari,L.A., Esmaeil,S.A., Preconception care for diabetic women for improving maternal and fetal outcomes: A systematic review and meta-analysis, BMC Pregnancy and Childbirth, 10 , 2010. Article Number, -, 2010	Systematic review of RCTs: intervention is care not HbA_{1c} target
Wahabi,H.A., Alzeidan,R.A., Esmaeil,S.A., Pre-pregnancy care for women with pre-gestational diabetes mellitus: a systematic review and meta-analysis, BMC Public Health, 12, 792-, 2012	Systematic review of RCTs: intervention is care not HbA_{1c} target
Wong,V.W., Suwandarathne,H., Russell,H., Women with pre-existing diabetes under the care of diabetes specialist prior to pregnancy: are their outcomes better?, Australian and New Zealand Journal of Obstetrics and Gynaecology, 53, 207-210, 2013	Compares mean HbA_{1c} only in women who saw a specialist pre-conception vs. those who did not. No targets or thresholds used.

G.5 Screening for gestational diabetes in the first trimester

Excluded studies – Review question 6	
Study	Reason for Exclusion
Agarwal,M.M., Dhatt,G.S., Fasting plasma glucose as a screening test for gestational diabetes mellitus. [43 refs], Archives of Gynecology and Obstetrics, 275, 81-87, 2007	Systematic review: individual studies checked for inclusion
Agarwal,M.M., Dhatt,G.S., Punnose,J., Koster,G., Gestational diabetes in a high-risk population: using the fasting plasma glucose to simplify the diagnostic algorithm, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 120, 39-44, 2005	The majority of screening tests were performed in the second trimester (median 25 weeks, range 7-40 weeks)
Agarwal,M.M., Dhatt,G.S., Shah,S.M., Gestational diabetes mellitus: simplifying the international association of diabetes and pregnancy diagnostic algorithm using fasting plasma glucose, Diabetes Care, 33, 2018-2020, 2010	Excluded from this review because no screening test is performed in the first trimester

Excluded studies – Review question 6	
Alto,W.A., No need for routine glycosuria/proteinuria screen in pregnant women, Journal of Family Practice, 54, 978-983, 2005	Systematic review: individual studies checked for inclusion
Balaji,V., Balaji,M., Anjalakshi,C., Cynthia,A., Arthi,T., Seshiah,V., Inadequacy of fasting plasma glucose to diagnose gestational diabetes mellitus in Asian Indian women, Diabetes Research and Clinical Practice, 94, e21-e23, 2011	Excluded from this review because no screening test is performed in the first trimester
Balaji,V., Madhuri,B.S., Ashalatha,S., Sheela,S., Suresh,S., Seshiah,V., A_{1C} in gestational diabetes mellitus in Asian Indian women, Diabetes Care, 30, 1865-1867, 2007	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75g oral glucose tolerance test (WHO 1999) were used to diagnose gestational diabetes
Bartha,J.L., Martinez-Del-Fresno,P., Comino-Delgado,R., Early diagnosis of gestational diabetes mellitus and prevention of diabetes-related complications, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 109, 41-44, 2003	100g oral glucose tolerance test used as diagnostic test
Bartha,J.L., Martinez-Del-Fresno,P., Comino-Delgado,R., Gestational diabetes mellitus diagnosed during early pregnancy, American Journal of Obstetrics and Gynecology, 182, 346-350, 2000	100g oral glucose tolerance test used as diagnostic test
Berg,M., Adlerberth,A., Sultan,B., Wennergren,M., Wallin,G., Early random capillary glucose level screening and multidisciplinary antenatal teamwork to improve outcome in gestational diabetes mellitus, Acta Obstetricia et Gynecologica Scandinavica, 86, 283-290, 2007	Results are not analysed by trimester because 5 or 6 screening tests were performed throughout pregnancy from gestational week 8 onwards
Berger,H., Crane,J., Farine,D., Armson,A., De La,Ronde S., Keenan-Lindsay,L., Leduc,L., Reid,G., Van,Aerde J., Maternal-Fetal Medicine Committee, Executive and Coundil fo the Society of Obstetricians and Gynaecologists of Canada., Screening for gestational diabetes mellitus, Journal of Obstetrics and Gynaecology Canada: JOGC, 24, 894-912, 2002	Systematic review: individual studies checked for inclusion
Brody,S.C., Harris,R., Lohr,K., Screening for gestational diabetes: a summary of the evidence for the U.S. Preventive Services Task Force. [104 refs], Obstetrics and Gynecology, 101, 380-392, 2003	Systematic review: individual studies checked for inclusion
Buhling,K.J., Elze,L., Henrich,W., Starr,E., Stein,U., Siebert,G., Dudenhausen,J.W., The usefulness of glycosuria and the influence of maternal blood pressure in screening for gestational diabetes, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 113, 145-148, 2004	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Centre for Reviews and Dissemination., Screening for gestational diabetes: a systematic review and economic evaluation (Structured abstract), Database of Abstracts of Reviews of Effects, -, 2012	Abstract only: systematic review identified
Chamberlain,C., Yore,D., Li,H., Williams,E., Oldenburg,B., Oats,J., McNamara,B., Eades,S., Diabetes in pregnancy among indigenous women in Australia, Canada, New Zealand, and the United States: a method for systematic review of studies with different designs, BMC Pregnancy and Childbirth, 11, 104-, 2011	Protocol for systematic review only

Excluded studies – Review question 6	
Cheng,Y.W., Esakoff,T.F., Block-Kurbisch,I., Ustinov,A., Shafer,S., Caughey,A.B., Screening or diagnostic: markedly elevated glucose loading test and perinatal outcomes, Journal of Maternal-Fetal and Neonatal Medicine, 19, 729-734, 2006	Excluded from the guideline update because an oral glucose tolerance test was not used as diagnostic test
Farah,N., McGoldrick,A., Fattah,C., O'Connor,N., Kennelly,M.M., Turner,M.J., Body Mass Index (BMI) and glucose intolerance during pregnancy in white European women, Journal of Reproduction and Infertility, 13, 95-99, 2012	100g oral glucose tolerance test used as diagnostic test
Farrar,Diane, Duley,Lelia, Lawlor,Debbie A., Different strategies for diagnosing gestational diabetes to improve maternal and infant health, Cochrane Database of Systematic Reviews, -, 2012	Systematic review of methods of performing an oral glucose tolerance test: individual trials checked for inclusion
Fedele,D., Lapolla,A., A protocol of screening of gestational diabetes mellitus, Annali Dell'Istituto Superiore di Sanita, 33, 383-387, 1997	100g oral glucose tolerance test used as diagnostic test
Guedj,A.M., When should screening be performed for gestational diabetes?, Diabetes and Metabolism, 36, 652-657, 2010	Systematic review: individual studies checked for inclusion
Health,Technology Assessment, A clinical and economic evaluation of screening and diagnostic tests to identify and treat women with gestational diabetes: association between maternal risk factors, glucose levels, and adverse outcomes (Project record), Health Technology Assessment Database, -, 2014	Abstract of a protocol
Hieronimus,S., Le Meaux,J.P., Relevance of gestational diabetes mellitus screening and comparison of selective with universal strategies, Diabetes and Metabolism, 36, 575-586, 2010	Systematic review: individual studies checked for inclusion
Hillier,T.A., Vesco,K.K., Pedula,K.L., Beil,T.L., Whitlock,E.P., Pettitt,D.J., Screening for gestational diabetes mellitus: a systematic review for the U.S. Preventive Services Task Force. [21 refs][Summary for patients in Ann Intern Med. 2008 May 20;148(10):I60; PMID: 18490671], Annals of Internal Medicine, 148, 766-775, 2008	Systematic review: individual studies checked for inclusion
Hooper,D.E., Detecting GD and preeclampsia. Effectiveness of routine urine screening for glucose and protein, Journal of Reproductive Medicine, 41, 885-888, 1996	100g oral glucose tolerance test used as diagnostic test
Jensen,D.M., Damm,P., Sorensen,B., Molsted-Pedersen,L., Westergaard,J.G., Korsholm,L., Ovesen,P., Beck-Nielsen,H., Proposed diagnostic thresholds for gestational diabetes mellitus according to a 75-g oral glucose tolerance test. Maternal and perinatal outcomes in 3260 Danish women, Diabetic Medicine, #20, 51-57, 2003	Excluded from this review in the guideline update because no screening test is performed in the first trimester
Jorgensen,L.G., Schytte,T., Brandslund,I., Stahl,M., Petersen,P.H., Andersen,B., Fasting and post-glucose load--reference limits for peripheral venous plasma glucose concentration in pregnant women, Clinical Chemistry and Laboratory Medicine, 41, 187-199, 2003	Excluded from this review because the screening test was performed during the second and third trimesters
Langer,O., Brustman,L., Anyaegbunam,A., Mazze,R., The significance of one abnormal glucose tolerance test value on adverse outcome in pregnancy, American Journal of Obstetrics and Gynecology, 157, 758-763, 1987	Excluded from the guideline update because the 100g oral glucose tolerance test is used as the diagnostic test
Maegawa,Y., Sugiyama,T., Kusaka,H., Mitao,M., Toyoda,N., Screening tests for gestational diabetes in Japan in the 1st	The diagnostic criteria applied to the oral glucose tolerance test are

Excluded studies – Review question 6	
and 2nd trimester of pregnancy, Diabetes Research and Clinical Practice, 62, 47-53, 2003	not relevant according to the protocol
Mello,G., Parretti,E., Cioni,R., Lucchetti,R., Carignani,L., Martini,E., Mecacci,F., Lagazio,C., Pratesi,M., The 75-gram glucose load in pregnancy: relation between glucose levels and anthropometric characteristics of infants born to women with normal glucose metabolism, Diabetes Care, 26, 1206-1210, 2003	Excluded from the guideline update because the diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Minsart,A.F., Lescrainier,J.P., Vokaer,A., Selective versus universal screening for gestational diabetes mellitus: an evaluation of Naylor's model, Gynecologic and Obstetric Investigation, 68, 154-159, 2009	100g oral glucose tolerance test used as diagnostic test
Mortensen,H.B., Molsted-Pedersen,L., Kuhl,C., Backer,P., A screening procedure for diabetes in pregnancy, Diabete et Metabolisme, 11, 249-253, 1985	50g oral glucose tolerance test used as diagnostic test
Most,O.L., Kim,J.H., Arslan,A.A., Klauser,C., Maternal and neonatal outcomes in early glucose tolerance testing in an obstetric population in New York city, Journal of Perinatal Medicine, 37, 114-117, 2009	100g oral glucose tolerance test used as diagnostic test
Omori,Y., Minei,S., Uchigata,Y., Shimizu,M., Sanaka,M., Honda,M., Hirata,Y., Comparison of diagnostic criteria of IGT, borderline, and GDM. Blood glucose curve and IRI response, Diabetes, 40 Suppl 2, 30-34, 1991	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Ostlund,I., Hanson,U., Bjorklund,A., Hjertberg,R., Eva,N., Nordlander,E., Swahn,M.L., Wager,J., Maternal and fetal outcomes if gestational impaired glucose tolerance is not treated, Diabetes Care, 26, 2107-2111, 2003	Excluded from the guideline update because the diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Pugh,S.K., Poole,A.T., Hill,J.B., Magann,E.F., Chauhan,S.P., Morrison,J.C., Abnormal 1 hour glucose challenge test followed by a normal 3 hour glucose tolerance test: does it identify adverse pregnancy outcome?, Journal of the Mississippi State Medical Association, 51, 3-6, 2010	100g oral glucose tolerance test used as diagnostic test
Rehder,P.M., Pereira,B.G., E,SilvaJ.L.P., The prognostic value of a normal oral glucose tolerance test in pregnant women who tested positive at screening: A validation study, Diabetology and Metabolic Syndrome, 4, -, 2012	100g oral glucose tolerance test used as diagnostic test
Riskin-Mashiah,S., Damti,A., Younes,G., Auslender,R., First trimester fasting hyperglycemia as a predictor for the development of gestational diabetes mellitus, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 152, 163-167, 2010	100g oral glucose tolerance test used as diagnostic test
Riskin-Mashiah,S., Younes,G., Damti,A., Auslender,R., First-trimester fasting hyperglycemia and adverse pregnancy outcomes, Diabetes Care, 32, 1639-1643, 2009	100g oral glucose tolerance test used as diagnostic test
Sacks,D.A., Chen,W., Wolde-Tsadik,G., Buchanan,T.A., Fasting plasma glucose test at the first prenatal visit as a screen for gestational diabetes, Obstetrics and Gynecology, 101, 1197-1203, 2003	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Sacks,D.A., Greenspoon,J.S., bu-Fadil,S., Henry,H.M., Wolde-Tsadik,G., Yao,J.F., Toward universal criteria for gestational diabetes: the 75-gram glucose tolerance test in pregnancy, American Journal of Obstetrics and Gynecology, 172, 607-614, 1995	Excluded from this review in the guideline update because no screening test is performed in the first trimester
Saldana,T.M., Siega-Riz,A.M., Adair,L.S., Savitz,D.A., Thorp,J.M.,Jr., The association between impaired glucose	Excluded from the guideline update because 100g oral glucose

Excluded studies – Review question 6	
tolerance and birth weight among black and white women in central North Carolina, Diabetes Care, 26, 656-661, 2003	tolerance test used as diagnostic test
Scott,D.A., Loveman,E., McIntyre,L., Waugh,N., Screening for gestational diabetes: a systematic review and economic evaluation. [256 refs], Health Technology Assessment (Winchester, England), 6, 1-161, 2002	Systematic review: individual studies checked for inclusion
Sermer,M., Naylor,C.D., Farine,D., Kenshole,A.B., Ritchie,J.W., Gare,D.J., Cohen,H.R., McArthur,K., Holzapfel,S., Biringer,A., The Toronto Tri-Hospital Gestational Diabetes Project. A preliminary review, Diabetes Care, 21 Suppl 2, B33-B42, 1998	Excluded from the guideline update because the 100g oral glucose tolerance test is used as the diagnostic test
Seshiah,V., Balaji,V., Balaji,M.S., Panneerselvam,A., Thamizharasi,M., Arthi,T., Glycemic level at the first visit and prediction of GDM, Journal of the Association of Physicians of India, 55, 630-632, 2007	Excluded from this review because the screening test was performed at the first antenatal appointment which was in the second trimester
Seshiah,V., Cynthia,A., Balaji,V., Balaji,M.S., Ashalata,S., Sheela,R., Thamizharasi,M., Arthi,T., Detection and care of women with gestational diabetes mellitus from early weeks of pregnancy results in birth weight of newborn babies appropriate for gestational age, Diabetes Research and Clinical Practice, 80, 199-202, 2008	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75g oral glucose tolerance test (WHO 1994) were used to diagnose gestational diabetes
Shirazian,N., Emdadi,R., Mahboubi,M., Motevallian,A., Fazel-Sarjuei,Z., Sedighpour,N., Fadaki,S.F., Shahmoradi,N., Screening for gestational diabetes: usefulness of clinical risk factors, Archives of Gynecology and Obstetrics, 280, 933-937, 2009	Excluded because the diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Simmons,D., McElduff,A., McIntyre,H.D., Elrishi,M., Gestational diabetes mellitus: NICE for the U.S.? A comparison of the American Diabetes Association and the American College of Obstetricians and Gynecologists guidelines with the U.K. National Institute for Health and Clinical Excellence guidelines, Diabetes Care, 33, 34-37, 2010	Narrative review
Sutherland,H.W., Stowers,J.M., McKenzie,C., Simplifying the clinical problem of glycosuria in pregnancy, Lancet, 1, 1069-1071, 1970	The diagnostic test performed is an intravenous, and not an oral, glucose tolerance test
Syed,M., Javed,H., Yakoob,M.Y., Bhutta,Z.A., Effect of screening and management of diabetes during pregnancy on stillbirths, BMC Public Health, 11 Suppl 3, S2-, 2011	Systematic review: individual studies checked for inclusion
Tallarigo,L., Giampietro,O., Penno,G., Miccoli,R., Gregori,G., Navalesi,R., Relation of glucose tolerance to complications of pregnancy in nondiabetic women, New England Journal of Medicine, 315, 989-992, 1986	Excluded from the guideline update because the 100g oral glucose tolerance test is used as the diagnostic test
Teede,H.J., Harrison,C.L., Teh,W.T., Paul,E., Allan,C.A., Gestational diabetes: development of an early risk prediction tool to facilitate opportunities for prevention, Australian and New Zealand Journal of Obstetrics and Gynaecology, 51, 499-504, 2011	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Tieu,Joanna, Middleton,Philippa, McPhee,Andrew J., Crowther,Caroline A., Screening and subsequent management for gestational diabetes for improving maternal and infant health, Cochrane Database of Systematic Reviews, -, 2011	Systematic review: individual trials checked for inclusion
U.S, Preventive Services, Screening for gestational diabetes mellitus: U.S. Preventive Services Task Force recommendation statement.[Summary for patients in Ann	Recommendation statement : no relevant studies included

Excluded studies – Review question 6	
Intern Med. 2008 May 20;148(10):I60; PMID: 18490671], Annals of Internal Medicine, 148, 759-765, 2008	
van,Leeuwen M., Louwerse,M.D., Opmeer,B.C., Limpens,J., Serlie,M.J., Reitsma,J.B., Mol,B.W., Glucose challenge test for detecting gestational diabetes mellitus: a systematic review, BJOG: An International Journal of Obstetrics and Gynaecology, 119, 393-401, 2012	Systematic review : individual studies checked for inclusion
van,Leeuwen M., Opmeer,B.C., Yilmaz,Y., Limpens,J., Serlie,M.J., Mol,B.W., Accuracy of the random glucose test as screening test for gestational diabetes mellitus: a systematic review, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 154, 130-135, 2011	Systematic review : individual studies checked for inclusion
van,Leeuwen M., Opmeer,B.C., Zweers,E.J., van,Ballegooie E., ter Brugge,H.G., de Valk,H.W., Visser,G.H., Mol,B.W., External validation of a clinical scoring system for the risk of gestational diabetes mellitus, Diabetes Research and Clinical Practice, 85, 96-101, 2009	Excluded from this review because no relevant first trimester data are provided. An unknown number of women with gestational diabetes diagnosed in the first trimester are excluded from the study.
Virally,M., Laloi-Michelin,M., Methods for the screening and diagnosis of gestational diabetes mellitus between 24 and 28 weeks of pregnancy, Diabetes and Metabolism, 36, 549-565, 2010	Systematic review : individual studies checked for inclusion
Waugh,N., Royle,P., Clar,C., Henderson,R., Cummins,E., Hadden,D., Lindsay,R., Pearson,D., Screening for hyperglycaemia in pregnancy: A rapid update for the National Screening Committee, Health Technology Assessment, 14, 1-202, 2010	Systematic review : individual studies checked for inclusion
Weiss,P.A., Haeusler,M., Tamussino,K., Haas,J., Can glucose tolerance test predict fetal hyperinsulinism?, BJOG: An International Journal of Obstetrics and Gynaecology, 107, 1480-1485, 2000	Excluded from the guideline update because the 75g oral glucose tolerance test is not consistently used as diagnostic test for all subjects
Wijeyaratne,C.N., Ginige,S., Arasalingam,A., Egodage,C., Wijewardhena,K., Screening for gestational diabetes mellitus: the Sri Lankan experience, Ceylon Medical Journal, 51, 53-58, 2006	Excluded from this review because no screening test is performed in the first trimester
Wong,V.W., Garden,F., Jalaludin,B., Hyperglycaemia following glucose challenge test during pregnancy: when can a screening test become diagnostic?, Diabetes Research and Clinical Practice, 83, 394-396, 2009	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol

G.6 Screening for gestational diabetes in the second trimester

Excluded studies – Review question 7	
Study	Reason for Exclusion
Agarwal,M.M., Dhatt,G.S., Fasting plasma glucose as a screening test for gestational diabetes mellitus. [43 refs], Archives of Gynecology and Obstetrics, 275, 81-87, 2007	Systematic review: individual studies checked for inclusion
Agarwal,M.M., Dhatt,G.S., Othman,Y., Gupta,R., Gestational diabetes: fasting capillary glucose as a screening test in a multi-ethnic, high-risk population, Diabetic Medicine, 26, 760-765, 2009	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol

Excluded studies – Review question 7	
Agarwal,M.M., Dhatt,G.S., Safraou,M.F., Gestational diabetes: using a portable glucometer to simplify the approach to screening, Gynecologic and Obstetric Investigation, 66, 178-183, 2008	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Agarwal,M.M., Hughes,P.F., Ezimokhai,M., Screening for gestational diabetes in a high-risk population using fasting plasma glucose, International Journal of Gynaecology and Obstetrics, 68, 147-148, 2000	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Agarwal,M.M., Punnose,J., Screening for gestational diabetes in high-risk populations: The United Arab Emirates experience, Annals of Saudi Medicine, 21, 117-119, 2001	100g oral glucose tolerance test used as diagnostic test
Agarwal,M.M., Weigl,B., Hod,M., Gestational diabetes screening: the low-cost algorithm, International Journal of Gynaecology and Obstetrics, 115 Suppl 1, S30-S33, 2011	Narrative review
Al,Mahroos S., Nagalla,D.S., Yousif,W., Sanad,H., A population-based screening for gestational diabetes mellitus in non-diabetic women in Bahrain.[Erratum appears in Ann Saudi Med. 2005 Jul-Aug;25(4):352], Annals of Saudi Medicine, 25, 129-133, 2005	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Alberico,S., Strazzanti,C., De,Santo D., De,Seta F., Lenardon,P., Bernardon,M., Zicari,S., Guaschino,S., Gestational diabetes: universal or selective screening?, Journal of Maternal-Fetal and Neonatal Medicine, 16, 331-337, 2004	100g oral glucose tolerance test used as diagnostic test
Aldasouqi,S.A., Gossain,V.V., A proposal for a role of HbA in screening for gestational diabetes, Diabetic Medicine, 26, 833-834, 2009	No relevant data as it refers to a study where women are tested in the third trimester
Al-Saweer,A., Al-Sairfi,S., The use of glucose screen test alone in diagnosing gestational diabetes mellitus in Bahrain-preliminary report, Bahrain Medical Bulletin, 30, 49-51, 2008	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Alto,W.A., No need for routine glycosuria/proteinuria screen in pregnant women, Journal of Family Practice, 54, 978-983, 2005	Systematic review: individual studies checked for inclusion
Atia,H.C., Koren,Y., Weintraub,A.Y., Novack,L., Sheiner,E., Is a value of over 200mg/dL in the oral glucose tolerance test, a marker of severity in patients with gestational diabetes mellitus?, Journal of Maternal-Fetal and Neonatal Medicine, 26, 1259-1262, 2013	The study did not examine any screening tests prior to performing a diagnostic OGTT
Avalos,G.E., Owens,L.A., Dunne,F., Applying current screening tools for gestational diabetes mellitus to a european population: Is it time for change?, Diabetes Care, 36, 3040-3044, 2013	Insufficient data are presented to to derive relevant diagnostic data
Bakiner,O., Bozkirli,E., Ozsahin,K., Sariturk,C., Ertorer,E., Risk Factors That can Predict Antenatal Insulin Need in Gestational Diabetes, Journal of Clinical Medicine Research, 5, 381-388, 2013	Does not examine the diagnostic accuracy of screening tests to a diagnostic OGTT
Balaji,V., Balaji,M., Anjalakshi,C., Cynthia,A., Arthi,T., Seshiah,V., Inadequacy of fasting plasma glucose to diagnose gestational diabetes mellitus in Asian Indian women, Diabetes Research and Clinical Practice, 94, e21-e23, 2011	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75 gram oral glucose tolerance test were used to diagnose gestational diabetes

Excluded studies – Review question 7	
Balaji,V., Madhuri,B.S., Ashalatha,S., Sheela,S., Suresh,S., Seshiah,V., A_{1C} in gestational diabetes mellitus in Asian Indian women, Diabetes Care, 30, 1865-1867, 2007	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75 gram oral glucose tolerance test were used to diagnose gestational diabetes
Bartha,J.L., Martinez-Del-Fresno,P., Comino-Delgado,R., Early diagnosis of gestational diabetes mellitus and prevention of diabetes-related complications, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 109, 41-44, 2003	100 gram oral glucose tolerance test used as diagnostic test
Bartha,J.L., Martinez-Del-Fresno,P., Comino-Delgado,R., Gestational diabetes mellitus diagnosed during early pregnancy, American Journal of Obstetrics and Gynecology, 182, 346-350, 2000	100 gram oral glucose tolerance test used as diagnostic test
Bassaw,B., Mohammed,N., Ramsewak,S., Bassawh,L., Khan,A., Bhola,M., Chekuri,A., Pregnancy outcome among women universally screened for gestational diabetes mellitus with a lime-flavoured drink, Journal of Obstetrics and Gynaecology, 32, 422-425, 2012	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Benhalima,K., Van,Crombrugge P., Hanssens,M., Devlieger,R., Verhaeghe,J., Mathieu,C., Gestational diabetes: overview of the new consensus screening strategy and diagnostic criteria, Acta Clinica Belgica, 67, 255-261, 2012	Narrative review
Benjamin,F., Wilson,S.J., Deutsch,S., Seltzer,V.L., Droesch,K., Droesch,J., Effect of advancing pregnancy on the glucose tolerance test and on the 50-g oral glucose load screening test for gestational diabetes, Obstetrics and Gynecology, 68, 362-365, 1986	100g oral glucose tolerance test used as diagnostic test
Berg,M., Adlerberth,A., Sultan,B., Wennergren,M., Wallin,G., Early random capillary glucose level screening and multidisciplinary antenatal teamwork to improve outcome in gestational diabetes mellitus, Acta Obstetricia et Gynecologica Scandinavica, 86, 283-290, 2007	Results are not analysed by trimester because 5 or 6 screening tests were performed throughout pregnancy from gestational week 8 onwards
Berger,H., Crane,J., Farine,D., Armson,A., De La,Ronde S., Keenan-Lindsay,L., Leduc,L., Reid,G., Van,Aerde J., Maternal-Fetal Medicine Committee, Executive and Coundil fo the Society of Obstetricians and Gynaecologists of Canada., Screening for gestational diabetes mellitus, Journal of Obstetrics and Gynaecology Canada: JOGC, 24, 894-912, 2002	Systematic review: individual studies checked for inclusion
Brody,S.C., Harris,R., Lohr,K., Screening for gestational diabetes: a summary of the evidence for the U.S. Preventive Services Task Force. [104 refs], Obstetrics and Gynecology, 101, 380-392, 2003	Systematic review: individual studies checked for inclusion
Buhling,K.J., Elze,L., Henrich,W., Starr,E., Stein,U., Siebert,G., Dudenhausen,J.W., The usefulness of glycosuria and the influence of maternal blood pressure in screening for gestational diabetes, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 113, 145-148, 2004	The diagnostic test applied to the oral glucose tolerance test are not relevant according to the protocol
Capula,C., Chiefari,E., Vero,A., Arcidiacono,B., Iiritano,S., Puccio,L., Pullano,V., Foti,D.P., Brunetti,A., Vero,R., Gestational diabetes mellitus: screening and outcomes in southern italian pregnant women, Isrn Endocrinology Print, 2013, 387495-, 2013	The study did not examine the diagnostic accuracy of screening techniques but examined outcomes in selected and unselected populations

Excluded studies – Review question 7	
Catalano,P.M., McIntyre,H.D., Cruickshank,J.K., McCance,D.R., Dyer,A.R., Metzger,B.E., Lowe,L.P., Trimble,E.R., Coustan,D.R., Hadden,D.R., Persson,B., Hod,M., Oats,J.J., HAPO Study Cooperative Research Group., The hyperglycemia and adverse pregnancy outcome study: associations of GDM and obesity with pregnancy outcomes, Diabetes Care, 35, 780-786, 2012	Duplicate
Centre for Reviews and Dissemination., Screening for gestational diabetes: a systematic review and economic evaluation (Structured abstract), Database of Abstracts of Reviews of Effects, -, 2012	Abstract only: systematic review identified
Chamberlain,C., Yore,D., Li,H., Williams,E., Oldenburg,B., Oats,J., McNamara,B., Eades,S., Diabetes in pregnancy among indigenous women in Australia, Canada, New Zealand, and the United States: a method for systematic review of studies with different designs, BMC Pregnancy and Childbirth, 11, 104-, 2011	Protocol for systematic review only
Cheng,Y.W., Esakoff,T.F., Block-Kurbisch,I., Ustinov,A., Shafer,S., Caughey,A.B., Screening or diagnostic: markedly elevated glucose loading test and perinatal outcomes, Journal of Maternal-Fetal and Neonatal Medicine, 19, 729-734, 2006	Excluded from the guideline update because an oral glucose tolerance test was not used as diagnostic test
Cosson,E., Cussac-Pillegand,C., Benbara,A., Pharisien,I., Jaber,Y., Banu,I., Nguyen,M.T., Valensi,P., Carbillon,L., The diagnostic and prognostic performance of a selective screening strategy for gestational diabetes mellitus according to ethnicity in Europe, Journal of Clinical Endocrinology and Metabolism, 99, 996-1005, 2014	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Cosson,E., Benchimol,M., Carbillon,L., Pharisien,I., Paries,J., Valensi,P., Lormeau,B., Bolie,S., Uzan,M., Attali,J.R., Universal rather than selective screening for gestational diabetes mellitus may improve fetal outcomes, Diabetes and Metabolism, 32, 140-146, 2006	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Coustan,D.R., Widness,J.A., Carpenter,M.W., Rotondo,L., Pratt,D.C., The "breakfast tolerance test": screening for gestational diabetes with a standardized mixed nutrient meal, American Journal of Obstetrics and Gynecology, 157, 1113-1117, 1987	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Crete,J.E., Anasti,J.N., Diagnosis of gestational diabetes mellitus: can we avoid the glucose challenge test?, Journal of the American Association of Nurse Practitioners, 25, 329-333, 2013	100g oral glucose tolerance test used as diagnostic test
Davey,R.X., Hamblin,P.S., Selective versus universal screening for gestational diabetes mellitus: an evaluation of predictive risk factors, Medical Journal of Australia, 174, 118-121, 2001	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Dennedy,M.C., Avalos,G., O'Reilly,M.W., O'Sullivan,E.P., Dunne,F.P., The impact of maternal obesity on gestational outcomes, Irish Medical Journal, 105, 23-25, 2012	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Donovan,L., Hartling,L., Muise,M., Guthrie,A., Vandermeer,B., Dryden,D.M., Screening tests for gestational diabetes: a systematic review for the U.S. Preventive Services Task Force, Annals of Internal Medicine, 159, 115-122, 2013	Systematic review: individual studies checked for inclusion

Excluded studies – Review question 7	
Ezimokhai,M., Joseph,A., Bradley-Watson,P., Audit of pregnancies complicated by diabetes from one center five years apart with selective versus universal screening, Annals of the New York Academy of Sciences, 1084, 132-140, 2006	100 gram oral glucose tolerance test used as diagnostic test
Fadl,H., Ostlund,I., Nilsson,K., Hanson,U., Fasting capillary glucose as a screening test for gestational diabetes mellitus, BJOG: An International Journal of Obstetrics and Gynaecology, 113, 1067-1071, 2006	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Farah,N., McGoldrick,A., Fattah,C., O'Connor,N., Kennelly,M.M., Turner,M.J., Body Mass Index (BMI) and glucose intolerance during pregnancy in white European women, Journal of Reproduction and Infertility, 13, 95-99, 2012	100 gram oral glucose tolerance test used as diagnostic test
Farrar,Diane, Duley,Lelia, Lawlor,Debbie A., Different strategies for diagnosing gestational diabetes to improve maternal and infant health, Cochrane Database of Systematic Reviews, -, 2012	Systematic review of methods of performing an oral glucose tolerance test: individual trials checked for inclusion
Fedele,D., Lapolla,A., A protocol of screening of gestational diabetes mellitus, Annali Dell'Istituto Superiore di Sanita, 33, 383-387, 1997	100 gram oral glucose tolerance test used as diagnostic test
Gandhi,P., Farrell,T., Gestational diabetes mellitus (GDM) screening in morbidly obese pregnant women, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 159, 329-332, 2011	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Guedj,A.M., When should screening be performed for gestational diabetes?, Diabetes and Metabolism, 36, 652-657, 2010	Systematic review: individual studies checked for inclusion
Gobl,C.S., Bozkurt,L., Rivic,P., Schernthaner,G., Weitgasser,R., Pacini,G., Mittlbock,M., Bancher-Todesca,D., Lechleitner,M., Kautzky-Willer,A., A two-step screening algorithm including fasting plasma glucose measurement and a risk estimation model is an accurate strategy for detecting gestational diabetes mellitus, Diabetologia, 55, 3173-3181, 2012	Insufficient data presented to construct 2x2 contingency table
HAPO Study Cooperative Research Group, Metzger,B.E., Lowe,L.P., Dyer,A.R., Trimble,E.R., Chaovarindr,U., Coustan,D.R., Hadden,D.R., McCance,D.R., Hod,M., McIntyre,H.D., Oats,J.J., Persson,B., Rogers,M.S., Sacks,D.A., Hyperglycemia and adverse pregnancy outcomes, New England Journal of Medicine, 358, 1991-2002, 2008	OGTT results are interpreted categorically in the analyses presented rather than dichotomously using diagnostic criteria
Hartling,L., Dryden,D.M., Guthrie,A., Muise,M., Vandermeer,B., Aktary,W.M., Pasichnyk,D., Seida,J.C., Donovan,L., Screening and diagnosing gestational diabetes mellitus, Evidence Report/Technology Assessment, 1-327, 2012	Systematic review: individual studies checked for inclusion
Hayes,L., Bilous,R., Bilous,M., Brandon,H., Crowder,D., Emmerson,C., Lewis-Barned,N., Bell,R., Universal screening to identify gestational diabetes: A multi-centre study in the North of England, Diabetes Research and Clinical Practice, 100, e74-e77, 2013	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Health,Technology Assessment, A clinical and economic evaluation of screening and diagnostic tests to identify and treat women with gestational diabetes: association between maternal risk factors, glucose levels, and adverse outcomes	Abstract of a protocol

Excluded studies – Review question 7	
(Project record), Health Technology Assessment Database, -, 2014	
Hieronimus,S., Le Meaux,J.P., Relevance of gestational diabetes mellitus screening and comparison of selective with universal strategies, Diabetes and Metabolism, 36, 575-586, 2010	Systematic review: individual studies checked for inclusion
Hillier,T.A., Vesco,K.K., Pedula,K.L., Beil,T.L., Whitlock,E.P., Pettitt,D.J., Screening for gestational diabetes mellitus: a systematic review for the U.S. Preventive Services Task Force. [21 refs][Summary for patients in Ann Intern Med. 2008 May 20;148(10):I60; PMID: 18490671], Annals of Internal Medicine, 148, 766-775, 2008	Systematic review: individual studies checked for inclusion
Hooper,D.E., Detecting GD and preeclampsia. Effectiveness of routine urine screening for glucose and protein, Journal of Reproductive Medicine, 41, 885-888, 1996	100 gram oral glucose tolerance test used as diagnostic test
Jensen,D.M., Damm,P., Sorensen,B., Molsted-Pedersen,L., Westergaard,J.G., Korsholm,L., Ovesen,P., Beck-Nielsen,H., Proposed diagnostic thresholds for gestational diabetes mellitus according to a 75-g oral glucose tolerance test. Maternal and perinatal outcomes in 3260 Danish women, Diabetic Medicine, #20, 51-57, 2003	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75 gram oral glucose tolerance test were used to diagnose gestational diabetes
Jensen,D.M., Molsted-Pedersen,L., Beck-Nielsen,H., Westergaard,J.G., Ovesen,P., Damm,P., Screening for gestational diabetes mellitus by a model based on risk indicators: A prospective study, American Journal of Obstetrics and Gynecology, 189, 1383-1388, 2003	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Jenum,A.K., Mrokrid,K., Sletner,L., Vange,S., Torper,J.L., Nakstad,B., Voldner,N., Rognerud-Jensen,O.H., Berntsen,S., Mosdlo,A., Skrivarhaug,T., Vardal,M.H., Holme,I., Yajnik,C.S., Birkeland,K.I., Impact of ethnicity on gestational diabetes identified with the WHO and the modified International Association of Diabetes and Pregnancy Study Groups criteria: A population-based cohort study, European Journal of Endocrinology, 166, 317-324, 2012	Study examines the prevalence of different risk factors and ethnicities in women with gestational diabetes diagnosed using different criteria
Jorgensen,L.G., Schytte,T., Brandslund,I., Stahl,M., Petersen,P.H., Andersen,B., Fasting and post-glucose load--reference limits for peripheral venous plasma glucose concentration in pregnant women, Clinical Chemistry and Laboratory Medicine, 41, 187-199, 2003	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Jovanovic,L., Definition, size of the problem, screening and diagnostic criteria: who should be screened, cost-effectiveness, and feasibility of screening, International Journal of Gynaecology and Obstetrics, 104 Suppl 1, S17-S19, 2009	Narrative review
Jowett,N.I., Samanta,A.K., Burden,A.C., Screening for diabetes in pregnancy: is a random blood glucose enough?, Diabetic Medicine, 4, 160-163, 1987	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Juutinen,J., Hartikainen,A.L., Bloigu,R., Tapanainen,J.S., A retrospective study on 435 women with gestational diabetes: fasting plasma glucose is not sensitive enough for screening but predicts a need for insulin treatment, Diabetes Care, 23, 1858-1859, 2000	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Kalamegham,R., Nuwayhid,B.S., Mulla,Z.D., Prevalence of gestational fasting and postload single dysglycemia in Mexican-American women and their relative significance in	100 gram oral glucose tolerance test used as diagnostic test

Excluded studies – Review question 7	
identifying carbohydrate intolerance, American Journal of Perinatology, 27, 697-704, 2010	
Kalter-Leibovici,O., Freedman,L.S., Olmer,L., Liebermann,N., Heymann,A., Tal,O., Lerner-Geva,L., Melamed,N., Hod,M., Screening and diagnosis of gestational diabetes mellitus: critical appraisal of the new International Association of Diabetes in Pregnancy Study Group recommendations on a national level.[Erratum appears in Diabetes Care. 2012 Dec;35(12):2718], Diabetes Care, 35, 1894-1896, 2012	The study does not report any relevant outcomes
Kumar,M.M., Sharma,R., Gestational diabetes mellitus - Screening and diagnosis by one step procedure, Biosciences Biotechnology Research Asia, 9, 853-856, 2012	The study did not examine the diagnostic accuracy of screening techniques but examined outcomes in selected and unselected populations
Landon,M.B., Mele,L., Spong,C.Y., Carpenter,M.W., Ramin,S.M., Casey,B., Wapner,R.J., Varner,M.W., Rouse,D.J., Thorp,J.M., Sciscione,A., Catalano,P., Harper,M., Saade,G., Caritis,S.N., Sorokin,Y., Peaceman,A.M., Tolosa,J.E., Anderson,G.D., The relationship between maternal glycemia and perinatal outcome, Obstetrics and Gynecology, 117, 218-224, 2011	100 gram oral glucose tolerance test used as diagnostic test
Langer,O., Brustman,L., Anyaegbunam,A., Mazze,R., The significance of one abnormal glucose tolerance test value on adverse outcome in pregnancy, American Journal of Obstetrics and Gynecology, 157, 758-763, 1987	Excluded from the guideline update because the 100 gram oral glucose tolerance test is used as the diagnostic test
Lind,T., Anderson,J., Does random blood glucose sampling outdate testing for glycosuria in the detection of diabetes during pregnancy?, British Medical Journal Clinical Research Ed., 289, 1569-1571, 1984	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Loke,D.F., Chua,S., Kek,L.P., Thai,A.C., Ratnam,S.S., Glycosylated hemoglobins in pregnant women with normal and abnormal glucose tolerance, Gynecologic and Obstetric Investigation, 37, 25-29, 1994	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Lowe,L.P., Coustan,D.R., Metzger,B.E., Hadden,D.R., Dyer,A.R., Hod,M., Lowe,J., Oats,J.J.N., McCance,D.R., Persson,B., Lappin,T.R.J., Trimble,E.R., Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study: Associations of maternal A_{1C} and glucose with pregnancy outcomes, Diabetes Care, 35, 574-580, 2012	OGTT results are not interpreted using any diagnostic criteria in the analyses presented
Maegawa,Y., Sugiyama,T., Kusaka,H., Mitao,M., Toyoda,N., Screening tests for gestational diabetes in Japan in the 1st and 2nd trimester of pregnancy, Diabetes Research and Clinical Practice, 62, 47-53, 2003	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Mello,G., Parretti,E., Cioni,R., Lucchetti,R., Carignani,L., Martini,E., Mecacci,F., Lagazio,C., Pratesi,M., The 75-gram glucose load in pregnancy: relation between glucose levels and anthropometric characteristics of infants born to women with normal glucose metabolism, Diabetes Care, 26, 1206-1210, 2003	Excluded from the guideline update because the diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol.
Minsart,A.F., Lescrainier,J.P., Vokaer,A., Selective versus universal screening for gestational diabetes mellitus: an evaluation of Naylor's model, Gynecologic and Obstetric Investigation, 68, 154-159, 2009	100 gram oral glucose tolerance test used as diagnostic test

Excluded studies – Review question 7	
Mortensen,H.B., Molsted-Pedersen,L., Kuhl,C., Backer,P., A screening procedure for diabetes in pregnancy, Diabete et Metabolisme, 11, 249-253, 1985	50 gram oral glucose tolerance test used as diagnostic test
Moses,R.G., Moses,J., Davis,W.S., Gestational diabetes: do lean young caucasian women need to be tested?, Diabetes Care, 21, 1803-1806, 1998	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Most,O.L., Kim,J.H., Arslan,A.A., Klauser,C., Maternal and neonatal outcomes in early glucose tolerance testing in an obstetric population in New York city, Journal of Perinatal Medicine, 37, 114-117, 2009	100 gram oral glucose tolerance test used as diagnostic test
Nasrat,A.A., Johnstone,F.D., Hasan,S.A., Is random plasma glucose an efficient screening test for abnormal glucose tolerance in pregnancy?, British Journal of Obstetrics and Gynaecology, 95, 855-860, 1988	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Nucci,L.B., Schmidt,M.I., Duncan,B.B., Fuchs,S.C., Fleck,E.T., Santos Britto,M.M., Nutritional status of pregnant women: prevalence and associated pregnancy outcomes, Rev Saude Publica, 35, 502-507, 2001	No relevant data
Omori,Y., Minei,S., Uchigata,Y., Shimizu,M., Sanaka,M., Honda,M., Hirata,Y., Comparison of diagnostic criteria of IGT, borderline, and GDM. Blood glucose curve and IRI response, Diabetes, 40 Suppl 2, 30-34, 1991	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Ostlund,I., Hanson,U., Bjorklund,A., Hjertberg,R., Eva,N., Nordlander,E., Swahn,M.L., Wager,J., Maternal and fetal outcomes if gestational impaired glucose tolerance is not treated, Diabetes Care, 26, 2107-2111, 2003	Excluded from the guideline update because the diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Pintaudi,B., Di,Vieste G., Corrado,F., Lucisano,G., Pellegrini,F., Giunta,L., Nicolucci,A., D'Anna,R., Di,Benedetto A., Improvement of selective screening strategy for gestational diabetes through a more accurate definition of high-risk groups, European Journal of Endocrinology, 170, 87-93, 2014	Study does not report results for risk factors that are relevant to the protocol
Poomalar,G.K., Rangaswamy,V., A comparison of fasting plasma glucose and glucose challenge test for screening of gestational diabetes mellitus, Journal of Obstetrics and Gynaecology, 33, 447-450, 2013	Includes women in the second and third trimester but does not report results separately for these groups
Pugh,S.K., Poole,A.T., Hill,J.B., Magann,E.F., Chauhan,S.P., Morrison,J.C., Abnormal 1 hour glucose challenge test followed by a normal 3 hour glucose tolerance test: does it identify adverse pregnancy outcome?, Journal of the Mississippi State Medical Association, 51, 3-6, 2010	100 gram oral glucose tolerance test used as diagnostic test
Rehder,P.M., Pereira,B.G., E,SilvaJ.L.P., The prognostic value of a normal oral glucose tolerance test in pregnant women who tested positive at screening: A validation study, Diabetology and Metabolic Syndrome, 4, -, 2012	100 gram oral glucose tolerance test used as diagnostic test
Reichelt,A.J., Spichler,E.R., Branchtein,L., Nucci,L.B., Franco,L.J., Schmidt,M.I., Fasting plasma glucose is a useful test for the detection of gestational diabetes. Brazilian Study of Gestational Diabetes (EBDG) Working Group, Diabetes Care, 21, 1246-1249, 1998	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Rey,E., Hudon,L., Michon,N., Boucher,P., Ethier,J., Saint-Louis,P., Fasting plasma glucose versus glucose challenge test: screening for gestational diabetes and cost effectiveness, Clinical Biochemistry, 37, 780-784, 2004	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol

Excluded studies – Review question 7	
Riskin-Mashiah,S., Younes,G., Damti,A., Auslender,R., First-trimester fasting hyperglycemia and adverse pregnancy outcomes, Diabetes Care, 32, 1639-1643, 2009	100 gram oral glucose tolerance test used as diagnostic test
Roberts,R.N., McManus,J., Dobbs,S., Hadden,D.R., A standardised breakfast tolerance test in pregnancy: comparison with the 75 g oral glucose tolerance test in unselected mothers and in those with impaired glucose tolerance, Ulster Medical Journal, 66, 18-23, 1997	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Sacks,D.A., Chen,W., Wolde-Tsadik,G., Buchanan,T.A., Fasting plasma glucose test at the first prenatal visit as a screen for gestational diabetes, Obstetrics and Gynecology, 101, 1197-1203, 2003	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Sacks,D.A., Greenspoon,J.S., bu-Fadil,S., Henry,H.M., Wolde-Tsadik,G., Yao,J.F., Toward universal criteria for gestational diabetes: the 75-gram glucose tolerance test in pregnancy, American Journal of Obstetrics and Gynecology, 172, 607-614, 1995	No relevant outcomes
Saldana,T.M., Siega-Riz,A.M., Adair,L.S., Savitz,D.A., Thorp,J.M.,Jr., The association between impaired glucose tolerance and birth weight among black and white women in central North Carolina, Diabetes Care, 26, 656-661, 2003	Excluded from the guideline update because 100 gram oral glucose tolerance test used as diagnostic test
Savona-Ventura,C., Vassallo,J., Marre,M., Karamanos,B.G., Erratum: A composite risk assessment model to screen for gestational diabetes mellitus among Mediterranean women (International Journal of Gynecology and Obstetrics (2013) 120 (240-244)), International Journal of Gynecology and Obstetrics, 122, 88-, 2013	No relevant data presented
Savona-Ventura,C., Vassallo,J., Marre,M., Karamanos,B.G., A composite risk assessment model to screen for gestational diabetes mellitus among Mediterranean women, International Journal of Gynecology and Obstetrics, 120, 240-244, 2013	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Schaas,C.M., Titianu,M., Stamatian,M., Onofriescu,M., Relations between perinatal outcomes and gestational diabetes, Gineco.eu, 9, 167-169, 2013	The diagnostic criteria applied to the oral glucose tolerance test are not reported
Scott,D.A., Loveman,E., McIntyre,L., Waugh,N., Screening for gestational diabetes: a systematic review and economic evaluation. [256 refs], Health Technology Assessment (Winchester, England), 6, 1-161, 2002	Systematic review: individual studies checked for inclusion
Scott,D.A., Loveman,E., McIntyre,L., Waugh,N., Screening for gestational diabetes: a systematic review and economic evaluation (Structured abstract), Health Technology Assessment Database, -, 2012	Systematic review: individual studies checked for inclusion
Sermer,M., Naylor,C.D., Farine,D., Kenshole,A.B., Ritchie,J.W., Gare,D.J., Cohen,H.R., McArthur,K., Holzapfel,S., Biringer,A., The Toronto Tri-Hospital Gestational Diabetes Project. A preliminary review, Diabetes Care, 21 Suppl 2, B33-B42, 1998	Excluded from the guideline update because the 100 gram oral glucose tolerance test is used as the diagnostic test
Seshiah,V., Balaji,V., Balaji,M.S., Panneerselvam,A., Thamizharasi,M., Arthi,T., Glycemic level at the first visit and prediction of GDM, Journal of the Association of Physicians of India, 55, 630-632, 2007	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75 gram oral glucose tolerance test were used to diagnose gestational diabetes
Seshiah,V., Cynthia,A., Balaji,V., Balaji,M.S., Ashalata,S., Sheela,R., Thamizharasi,M., Arthi,T., Detection and care of women with gestational diabetes mellitus from early weeks of	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75

Excluded studies – Review question 7	
pregnancy results in birth weight of newborn babies appropriate for gestational age, Diabetes Research and Clinical Practice, 80, 199-202, 2008	gram oral glucose tolerance test (WHO 1994) were used to diagnose gestational diabetes
Sevket,O., Ates,S., Uysal,O., Molla,T., Dansuk,R., Kelekci,S., To evaluate the prevalence and clinical outcomes using a one-step method versus a two-step method to screen gestational diabetes mellitus, Journal of Maternal-Fetal and Neonatal Medicine, 27, 36-41, 2014	The comparison made in this study is not relevant according to the protocol
Sharma,K., Wahi,P., Gupta,A., Jandial,K., Bhagat,R., Gupta,R., Gupta,S., Singh,J., Single glucose challenge test procedure for diagnosis of gestational diabetes mellitus: a Jammu cohort study, Journal of the Association of Physicians of India, 61, 558-559, 2013	This study considers the use of the Glucose Challenge Test as a diagnostic test, rather than an OGTT
Shirazian,N., Emdadi,R., Mahboubi,M., Motevallian,A., Fazel-Sarjuei,Z., Sedighpour,N., Fadaki,S.F., Shahmoradi,N., Screening for gestational diabetes: usefulness of clinical risk factors, Archives of Gynecology and Obstetrics, 280, 933-937, 2009	Excluded because the diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol.
Simmons,D., McElduff,A., McIntyre,H.D., Elrishi,M., Gestational diabetes mellitus: NICE for the U.S.? A comparison of the American Diabetes Association and the American College of Obstetricians and Gynecologists guidelines with the U.K. National Institute for Health and Clinical Excellence guidelines, Diabetes Care, 33, 34-37, 2010	Narrative review
Siribaddana,S.H., Deshabandu,R., Rajapakse,D., Silva,K., Fernando,D.J., The prevalence of gestational diabetes in a Sri Lankan antenatal clinic, The Ceylon medical journal, 43, 88-91, 1998	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Sutherland,H.W., Stowers,J.M., McKenzie,C., Simplifying the clinical problem of glycosuria in pregnancy, Lancet, 1, 1069-1071, 1970	The diagnostic test performed is an intravenous, and not an oral, glucose tolerance test
Syed,M., Javed,H., Yakoob,M.Y., Bhutta,Z.A., Effect of screening and management of diabetes during pregnancy on stillbirths, BMC Public Health, 11 Suppl 3, S2-, 2011	Systematic review: individual studies checked for inclusion
Tallarigo,L., Giampietro,O., Penno,G., Miccoli,R., Gregori,G., Navalesi,R., Relation of glucose tolerance to complications of pregnancy in nondiabetic women, New England Journal of Medicine, 315, 989-992, 1986	Excluded from the guideline update because the 100 gram oral glucose tolerance test is used as the diagnostic test
Tam,W.H., Rogers,M.S., Yip,S.K., Lau,T.K., Leung,T.Y., Which screening test is the best for gestational impaired glucose tolerance and gestational diabetes mellitus?, Diabetes Care, 23, 1432-, 2000	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Tan,P.C., Ling,L.P., Omar,S.Z., The 50-g glucose challenge test and pregnancy outcome in a multiethnic Asian population at high risk for gestational diabetes, International Journal of Gynaecology and Obstetrics, 105, 50-55, 2009	Approximately half of all screening was performed after gestational week 28 and many of these tests were undertaken well into the third trimester
Teede,H.J., Harrison,C.L., Teh,W.T., Paul,E., Allan,C.A., Gestational diabetes: development of an early risk prediction tool to facilitate opportunities for prevention, Australian and New Zealand Journal of Obstetrics and Gynaecology, 51, 499-504, 2011	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Teh,W.T., Teede,H.J., Paul,E., Harrison,C.L., Wallace,E.M., Allan,C., Risk factors for gestational diabetes mellitus: implications for the application of screening guidelines,	The diagnostic criteria applied to the oral glucose tolerance test are

Excluded studies – Review question 7	
Australian and New Zealand Journal of Obstetrics and Gynaecology, 51, 26-30, 2011	not relevant according to the protocol
Tieu,Joanna, McPhee,Andrew J., Crowther,Caroline A., Middleton,Philippa, Screening and subsequent management for gestational diabetes for improving maternal and infant health, Cochrane Database of Systematic Reviews, -, 2014	Cochrane systematic review inclide studies checked for reevance here. 1 quasi RCT used 100g OGTT and 3 RCTs examined different loading doses of glucose in screening tests
Tieu,Joanna, Middleton,Philippa, McPhee,Andrew J., Crowther,Caroline A., Screening and subsequent management for gestational diabetes for improving maternal and infant health, Cochrane Database of Systematic Reviews, -, 2011	Systematic review: individual trials checked for inclusion
Torloni,M.R., Betran,A.P., Horta,B.L., Nakamura,M.U., Atallah,A.N., Moron,A.F., Valente,O., Prepregnancy BMI and the risk of gestational diabetes: a systematic review of the literature with meta-analysis. [102 refs], Obesity Reviews, 10, 194-203, 2009	Systematic review: individual studies checked for inclusion
Tran,T.S., Hirst,J.E., Do,M.A., Morris,J.M., Jeffery,H.E., Early prediction of gestational diabetes mellitus in Vietnam: clinical impact of currently recommended diagnostic criteria, Diabetes Care, 36, 618-624, 2013	No relevant diagnostic accuracy data are reported
Tripathi,R., Tolia,N., Gupta,V.K., Mala,Y.M., Ramji,S., Tyagi,S., Screening for gestational diabetes mellitus: a prospective study in a tertiary care institution of North India, Journal of Obstetrics and Gynaecology Research, 38, 351-357, 2012	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
U.S, Preventive Services, Screening for gestational diabetes mellitus: U.S. Preventive Services Task Force recommendation statement.[Summary for patients in Ann Intern Med. 2008 May 20;148(10):I60; PMID: 18490671], Annals of Internal Medicine, 148, 759-765, 2008	Recommendation statement: no relevant studies included
van,Leeuwen M., Louwerse,M.D., Opmeer,B.C., Limpens,J., Serlie,M.J., Reitsma,J.B., Mol,B.W., Glucose challenge test for detecting gestational diabetes mellitus: a systematic review, BJOG: An International Journal of Obstetrics and Gynaecology, 119, 393-401, 2012	Systematic review: individual studies checked for inclusion
van,Leeuwen M., Opmeer,B.C., Yilmaz,Y., Limpens,J., Serlie,M.J., Mol,B.W., Accuracy of the random glucose test as screening test for gestational diabetes mellitus: a systematic review, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 154, 130-135, 2011	Systematic review: individual studies checked for inclusion
van,Leeuwen M., Opmeer,B.C., Zweers,E.J., van,Ballegooie E., ter Brugge,H.G., de Valk,H.W., Visser,G.H., Mol,B.W., Estimating the risk of gestational diabetes mellitus: a clinical prediction model based on patient characteristics and medical history, BJOG: An International Journal of Obstetrics and Gynaecology, 117, 69-75, 2010	The clinical prediction model developed would not be of use in clinical practice
van,Leeuwen M., Zweers,E.J., Opmeer,B.C., van,Ballegooie E., ter Brugge,H.G., de Valk,H.W., Mol,B.W., Visser,G.H., Comparison of accuracy measures of two screening tests for gestational diabetes mellitus, Diabetes Care, 30, 2779-2784, 2007	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Van,LeeuwenM, Vijgen,S., Opmeer,B.C., Evers,I., Mol,B.W., Cost-effectiveness analysis of screening for GDM, American Journal of Obstetrics and Gynecology, 201, S109-, 2009	Abstract only

Excluded studies – Review question 7	
Virally,M., Laloi-Michelin,M., Methods for the screening and diagnosis of gestational diabetes mellitus between 24 and 28 weeks of pregnancy, Diabetes and Metabolism, 36, 549-565, 2010	Systematic review: individual studies checked for inclusion
Wagaarachchi,P.T., Fernando,L., Premachadra,P., Fernando,D.J., Screening based on risk factors for gestational diabetes in an Asian population, Journal of Obstetrics & GynaecologyJ Obstet Gynaecol, 21, 32-34, 2001	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Waugh,N., Royle,P., Clar,C., Henderson,R., Cummins,E., Hadden,D., Lindsay,R., Pearson,D., Screening for hyperglycaemia in pregnancy: A rapid update for the National Screening Committee, Health Technology Assessment, 14, 1-202, 2010	Systematic review: individual studies checked for inclusion
Weiss,P.A., Haeusler,M., Tamussino,K., Haas,J., Can glucose tolerance test predict fetal hyperinsulinism?, BJOG: An International Journal of Obstetrics and Gynaecology, 107, 1480-1485, 2000	Excluded from the guideline update because the 75 gram oral glucose tolerance test is not consistently used as diagnostic test for all subjects
Wijeyaratne,C.N., Ginige,S., Arasalingam,A., Egodage,C., Wijewardhena,K., Screening for gestational diabetes mellitus: the Sri Lankan experience, Ceylon Medical Journal, 51, 53-58, 2006	Only the 2 hour plasma glucose values and not the fasting plasma glucose values derived from a 75g oral glucose tolerance test (WHO 1999) were used to diagnose gestational diabetes
Wong,T., Ross,G.P., Jalaludin,B.B., Flack,J.R., The clinical significance of overt diabetes in pregnancy, Diabetic Medicine, 30, 468-474, 2013	The diagnostic criteria and tests applied are not relevant according to the protocol
Wong,V.W., Garden,F., Jalaludin,B., Hyperglycaemia following glucose challenge test during pregnancy: when can a screening test become diagnostic?, Diabetes Research and Clinical Practice, 83, 394-396, 2009	The diagnostic criteria applied to the oral glucose tolerance test are not relevant according to the protocol
Zhu,W.W., Fan,L., Yang,H.X., Kong,L.Y., Su,S.P., Wang,Z.L., Hu,Y.L., Zhang,M.H., Sun,L.Z., Mi,Y., Du,X.P., Zhang,H., Wang,Y.H., Huang,Y.P., Zhong,L.R., Wu,H.R., Li,N., Wang,Y.F., Kapur,A., Fasting plasma glucose at 24-28 weeks to screen for gestational diabetes mellitus: new evidence from China, Diabetes Care, 36, 2038-2040, 2013	No relevant data are reported. Letter that compares testing fasting plasma glucose and fasting capillary glucose

G.7 Diagnostic criteria for gestational diabetes

Excluded studies – Review question 8	
Study	Reason for Exclusion
Agarwal,M.M., Weigl,B., Hod,M., Gestational diabetes screening: the low-cost algorithm, International Journal of Gynaecology and Obstetrics, 115 Suppl 1, S30-S33, 2011	No comparison between World Health Organization (WHO) and International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria reported
Balaji,V., Balaji,M., Anjalakshi,C., Cynthia,A., Arthi,T., Seshiah,V., Inadequacy of fasting plasma glucose to diagnose gestational diabetes mellitus in Asian Indian women, Diabetes Research and Clinical Practice, 94, e21-e23, 2011	The WHO diagnosis of gestational diabetes used in this study is based solely on 2 hour plasma glucose results from the oral glucose tolerance test (OGTT) and does not

Excluded studies – Review question 8	
	incorporate fasting plasma glucose (FPG) test results
Black,M.H., Sacks,D.A., Xiang,A.H., Lawrence,J.M., Clinical outcomes of pregnancies complicated by mild gestational diabetes mellitus differ by combinations of abnormal oral glucose tolerance test values, Diabetes Care, 33, 2524-2530, 2010	No comparison between WHO and IADPSG criteria reported
Blatt,A.J., Nakamoto,J.M., Kaufman,H.W., Gaps in diabetes screening during pregnancy and postpartum, Obstetrics and Gynecology, 117, 61-68, 2011	No comparison between WHO and IADPSG criteria reported
Catalano,P.M., McIntyre,H.D., Cruickshank,J.K., McCance,D.R., Dyer,A.R., Metzger,B.E., Lowe,L.P., Trimble,E.R., Coustan,D.R., Hadden,D.R., Persson,B., Hod,M., Oats,J.J., HAPO Study Cooperative Research Group., The hyperglycemia and adverse pregnancy outcome study: associations of GDM and obesity with pregnancy outcomes, Diabetes Care, 35, 780-786, 2012	No comparison between WHO and IADPSG criteria reported
Disse,E., Graeppi-Dulac,J., Joncour-Mills,G., Dupuis,O., Thivolet,C., Heterogeneity of pregnancy outcomes and risk of LGA neonates in Caucasian females according to IADPSG criteria for gestational diabetes mellitus, Diabetes and Metabolism, 39, 132-138, 2013	Relevant diagnostic accuracy or outcome data comparing WHO and IADPSG diagnostic criteria are not available
Falavigna,M., Prestes,I., Schmidt,M.I., Duncan,B.B., Colagiuri,S., Roglic,G., Impact of gestational diabetes mellitus screening strategies on perinatal outcomes: a simulation study, Diabetes Research and Clinical Practice, 99, 358-365, 2013	Relevant diagnostic accuracy or outcome data comparing WHO and IADPSG diagnostic criteria are not available
Flack,J.R., Ross,G.P., Ho,S., McElduff,A., Recommended changes to diagnostic criteria for gestational diabetes: impact on workload, Australian and New Zealand Journal of Obstetrics and Gynaecology, 50, 439-443, 2010	No comparison between WHO and IADPSG criteria reported
Harrison,C.L., Lombard,C.B., Teede,H.J., Understanding health behaviours in a cohort of pregnant women at risk of gestational diabetes mellitus: an observational study, BJOG: An International Journal of Obstetrics and Gynaecology, 119, 731-738, 2012	No comparison between WHO and IADPSG criteria reported
Hartling,L., Dryden,D.M., Guthrie,A., Muise,M., Vandermeer,B., Aktary,W.M., Pasichnyk,D., Seida,J.C., Donovan,L., Screening and diagnosing gestational diabetes mellitus, Evidence Report/Technology Assessment, 1-327, 2012	Systematic review: individual studies checked for inclusion
Huynh,J., Ratnaike,S., Bartalotta,C., Permezel,M., Houlihan,C., Challenging the glucose challenge test, Australian and New Zealand Journal of Obstetrics and Gynaecology, 51, 22-25, 2011	No comparison between WHO and IADPSG criteria reported
International Association of Diabetes and Pregnancy Study Groups Consensus Panel, Metzger,B.E., Gabbe,S.G., Persson,B., Buchanan,T.A., Catalano,P.A., Damm,P., Dyer,A.R., Leiva,A., Hod,M., Kitzmiler,J.L., Lowe,L.P., McIntyre,H.D., Oats,J.J., Omori,Y., Schmidt,M.I., International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. [57 refs], Diabetes Care, 33, 676-682, 2010	No comparison between WHO and IADPSG criteria reported
Jenum,A.K., Morkrid,K., Sletner,L., Vangen,S., Torper,J.L., Nakstad,B., Voldner,N., Rognerud-Jensen,O.H., Berntsen,S.,	Duplicate

Excluded studies – Review question 8	
Mosdol,A., Skrivarhaug,T., Vardal,M.H., Holme,I., Yajnik,C.S., Birkeland,K.I., Impact of ethnicity on gestational diabetes identified with the WHO and the modified International Association of Diabetes and Pregnancy Study Groups criteria: a population-based cohort study.[Erratum appears in Eur J Endocrinol. 2012 Mar;166(3):561 Note: Vange, Siri [corrected to Vangen, Siri]], European Journal of Endocrinology, 166, 317-324, 2012	
Jenum,A.K., Morkrid,K., Sletner,L., Vange,S., Torper,J.L., Nakstad,B., Voldner,N., Rognerud-Jensen,O.H., Berntsen,S., Mosdol,A., Skrivarhaug,T., Vardal,M.H., Holme,I., Yajnik,C.S., Birkeland,K.I., Impact of ethnicity on gestational diabetes identified with the WHO and the modified International Association of Diabetes and Pregnancy Study Groups criteria: A population-based cohort study (European Journal of Endocrinology (2012) 166, (317-324)), European Journal of Endocrinology, 166, 561-, 2012	The correction made in this erratum statement is not relevant to this review question
Kalter-Leibovici,O., Freedman,L.S., Olmer,L., Liebermann,N., Heymann,A., Tal,O., Lerner-Geva,L., Melamed,N., Hod,M., Screening and diagnosis of gestational diabetes mellitus: Critical appraisal of the new International Association of Diabetes in Pregnancy Study Group recommendations on a national level (Diabetes Care (2012) 35, (1894-1896), Diabetes Care, 35, 2718-, 2012	Erratum statement for an excluded study
Kalter-Leibovici,O., Freedman,L.S., Olmer,L., Liebermann,N., Heymann,A., Tal,O., Lerner-Geva,L., Melamed,N., Hod,M., Screening and diagnosis of gestational diabetes mellitus: critical appraisal of the new International Association of Diabetes in Pregnancy Study Group recommendations on a national level.[Erratum appears in Diabetes Care. 2012 Dec;35(12):2718], Diabetes Care, 35, 1894-1896, 2012	No comparison between WHO and IADPSG criteria reported(IADPSG criteria only are used)
Kendrick,J.M., Screening and diagnosing gestational diabetes mellitus revisited: implications from HAPO, Journal of Perinatal and Neonatal Nursing, 25, 226-232, 2011	Narrative review
Lieberman,N., Kalter-Leibovici,O., Hod,M., Global adaptation of IADPSG recommendations: a national approach, International Journal of Gynaecology and Obstetrics, 115 Suppl 1, S45-S47, 2011	Narrative review
Morikawa,M., Yamada,T., Yamada,T., Akaishi,R., Nishida,R., Cho,K., Minakami,H., Change in the number of patients after the adoption of IADPSG criteria for hyperglycemia during pregnancy in Japanese women, Diabetes Research and Clinical Practice, 90, 339-342, 2010	No comparison between WHO and IADPSG criteria reported
Moses,R.G., Gestational diabetes mellitus: implications of an increased frequency with IADPSG criteria, Diabetes Care, 35, 461-462, 2012	Narrative review
Moses,R.G., Morris,G.J., Petocz,P., San,Gil F., Garg,D., The impact of potential new diagnostic criteria on the prevalence of gestational diabetes mellitus in Australia, Medical Journal of Australia, 194, 338-340, 2011	No comparison between WHO and IADPSG criteria reported
O'Sullivan,E.P., Avalos,G., O'Reilly,M., Dennedy,M.C., Gaffney,G., Dunne,F., Atlantic,D.I.P., Atlantic Diabetes in Pregnancy (DIP): the prevalence and outcomes of gestational diabetes mellitus using new diagnostic criteria, Diabetologia, 54, 1670-1675, 2011	The FPG threshold used to diagnose gestational diabetes according to the WHO criteria is lower in this study than in the WHO definition used in the review question

Excluded studies – Review question 8	
Reyes-Munoz,E., Parra,A., Castillo-Mora,A., Ortega-Gonzalez,C., Effect of the diagnostic criteria of the international association of diabetes and pregnancy study groups on the prevalence of gestational diabetes mellitus in urban mexican women: A cross-sectional study, Endocrine Practice, 18, 146-151, 2012	No comparison between WHO and IADPSG criteria reported
Sacks,D.A., Hadden,D.R., Maresh,M., Deerochanawong,C., Dyer,A.R., Metzger,B.E., Lowe,L.P., Coustan,D.R., Hod,M., Oats,J.J., Persson,B., Trimble,E.R., HAPO Study Cooperative Research Group., Frequency of gestational diabetes mellitus at collaborating centers based on IADPSG consensus panel-recommended criteria: the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study, Diabetes Care, 35, 526-528, 2012	No comparison between WHO and IADPSG criteria reported
Savona-Ventura,C., Vassallo,J., Marre,M., Karamanos,B.G., MGSD:GDM Study Group., Hyperglycaemia in pregnancy in Mediterranean women, Acta Diabetologica, 49, 473-480, 2012	No comparison between WHO and IADPSG criteria reported
Seshiah,V., Balaji,V., Shah,S.N., Joshi,S., Das,A.K., Sahay,B.K., Banerjee,S., Zargar,A.H., Balaji,M., Diagnosis of gestational diabetes mellitus in the community, Journal of the Association of Physicians of India, 60, 15-17, 2012	The WHO diagnosis of gestational diabetes used in this study is based solely on 2 hour plasma glucose results from the oral glucose tolerance test (OGTT) and does not incorporate fasting plasma glucose (FPG) test results
Tran,T.S., Hirst,J.E., Do,M.A., Morris,J.M., Jeffery,H.E., Early prediction of gestational diabetes mellitus in Vietnam: clinical impact of currently recommended diagnostic criteria, Diabetes Care, 36, 618-624, 2013	Relevant diagnostic accuracy or outcome data comparing WHO and IADPSG diagnostic criteria are not available
Wendland,E.M., Torloni,M.R., Falavigna,M., Trujillo,J., Dode,M.A., Campos,M.A., Duncan,B.B., Schmidt,M.I., Gestational diabetes and pregnancy outcomes--a systematic review of the World Health Organization (WHO) and the International Association of Diabetes in Pregnancy Study Groups (IADPSG) diagnostic criteria, BMC Pregnancy and Childbirth, 12, 23-, 2012	Duplicate
Wendland,E.M., Duncan,B.B., Mengue,S.S., Schmidt,M.I., Lesser than diabetes hyperglycemia in pregnancy is related to perinatal mortality: a cohort study in Brazil, BMC Pregnancy and Childbirth, 11, 92-, 2011	Population and perinatal mortality outcomes in this study reported in Wendland 2012

G.8 Interventions for gestational diabetes

Excluded studies – Review question 9	
Study	Reason for Exclusion
Afaghi,A., Ghanei,L., Ziaee,A., Effect of low glycemic load diet with and without wheat bran on glucose control in gestational diabetes mellitus: A randomized trial, Indian Journal of Endocrinology and Metabolism, 17, 689-692, 2013	The only outcome reported is maternal blood glucose therefore not relevant to review protocol.

Excluded studies – Review question 9	
Algert,S., Shragg,P., Hollingsworth,D.R., Moderate caloric restriction in obese women with gestational diabetes, Obstetrics and Gynecology, 65, 487-491, 1985	Cohort study.
Alwan,Nisreen, Tuffnell,Derek J., West,Jane, Treatments for gestational diabetes, Cochrane Database of Systematic Reviews, -, 2011	Systematic review - checked for relevant trials
Anjalakshi,C., Balaji,V., Balaji,M.S., Seshiah,V., A prospective study comparing insulin and glibenclamide in gestational diabetes mellitus in Asian Indian women, Diabetes Research and Clinical Practice, 76, 474-475, 2007	No relevant outcomes
Bahado-Singh,R.O., Mele,L., Landon,M.B., Ramin,S.M., Carpenter,M.W., Casey,B., Wapner,R.J., Varner,M.W., Rouse,D.J., Thorp,Jr, Sciscione,A., Catalano,P., Harper,M., Saade,G., Caritis,S.N., Peaceman,A.M., Tolosa,J.E., Fetal male gender and the benefits of treatment of mild gestational diabetes mellitus, American Journal of Obstetrics and Gynecology, 206, 422-422, 2012	No relevant results
Balaji,V., Balaji,M.S., Alexander,C., Ashalata,S., Sheela,Suganthi R., Suresh,S., Seshiah,V., Premixed insulin aspart 30 (Biasp 30) vs. premixed human insulin 30 (BHI 30) in gestational diabetes mellitus--a pilot study, Journal of the Association of Physicians of India, 58, 99-101, 2010	Comparison not relevant (insulin vs insulin)
Balaji,V., Balaji,M.S., Alexander,C., Ashalata,S., Suganthi,R.S., Suresh,S., Seshiah,V., Premixed insulin aspart 30 (biasp 30) vs premixed human insulin 30 (bhi 30) in gestational diabetes mellitus a[Euro sign]" a pilot study, Journal of the Associations of the Physicians of India, 58, 96-97, 2010	Comparison not relevant (insulin vs insulin)
Barbour,L.A., Van Pelt,R.E., Brumbaugh,D.E., Hernandez,T.L., Friedman,J.E., Comment on: Rowan et al. Metformin in Gestational diabetes: The Offspring Follow-Up (MiG TOFU): body composition at 2 years of age. Diabetes Care 2011;34:2279-2284, Diabetes Care, 35, e28-, 2012	Not a randomised controlled trial
Blachier,A., Alberti,C., Korb,D., Schmitz,T., Patrick,V., Christine,B., Oury,J.F., Sibony,O., Diet or medically treated gestational diabetes: is there any difference for obstetrical and neonatal complications? A French cohort study, Journal of Perinatal Medicine, 42, 315-319, 2014	Not a randomised controlled trial (prospective cohort)
Bochner,C.J., Medearis,A.L., Williams,J.,III, Castro,L., Hobel,C.J., Wade,M.E., Early third-trimester ultrasound screening in gestational diabetes to determine the risk of macrosomia and labor dystocia at term, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 157, 703-708, 1987	Cohort study.
Bonomo,M., Cetin,I., Pisoni,M.P., Faden,D., Mion,E., Taricco,E., Nobile de,Santis M., Radaelli,T., Motta,G., Costa,M., Solerte,L., Morabito,A., Flexible treatment of gestational diabetes modulated on ultrasound evaluation of intrauterine growth: a controlled randomized clinical trial, Diabetes and MetabolismDiabetes Metab., 30, 237-244, 2004	Not relevant to protocol (ultrasound).
Botta,R.M., Di Giovanni,B.M., Cammilleri,F., Taravella,V., Predictive factors for insulin treatment in women with	Cohort study.

Excluded studies – Review question 9	
diagnosis of gestational diabetes, Annali Dell'Istituto Superiore di Sanita, 33, 403-406, 1997	
Buchanan,T.A., Kjos,S.L., Montoro,M.N., Wu,P.Y., Madrilejo,N.G., Gonzalez,M., Nunez,V., Pantoja,P.M., Xiang,A., Use of fetal ultrasound to select metabolic therapy for pregnancies complicated by mild gestational diabetes, Diabetes Care, 17, 275-283, 1994	Not relevant to protocol (ultrasound).
Buchanan,T.A., Kjos,S.L., Montoro,M.N., Wu,P.Y., Madrilejo,N.G., Gonzalez,M., Nunez,V., Pantoja,P.M., Xiang,A., Use of fetal ultrasound to select metabolic therapy for pregnancies complicated by mild gestational diabetes, Diabetes Care, 17, 275-283, 1994	The population (Hispanic women) is not relevant to the United Kingdom population of women with gestational diabetes.
Buchbinder,A., Miodovnik,M., Khoury,J., Sibai,B.M., Is the use of insulin lispro safe in pregnancy?, The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians, 11, 232-237, 2002	Narrative review
Bung,P., Artal,R., Khodiguian,N., [Regular exercise therapy in disorders of carbohydrate metabolism in pregnancy--results of a prospective, randomized longitudinal study], Geburtshilfe und Frauenheilkunde, 53, 188-193, 1993	In German
Bung,P., Artal,R., Khodiguian,N., Kjos,S., Exercise in gestational diabetes. An optional therapeutic approach?, Diabetes, 40 Suppl 2, 182-185, 1991	Comparison not relevant to protocol.
Casson,I.F., Outcomes of pregnancy in insulin dependent diabetic women: results of a five year population cohort study, British Medical JournalBMJ, 315, 275-278, 1997	Not relevant to protocol (insulin comparison).
Caughey,A.B., Management of diabetes in pregnancy, Advanced Studies in Medicine, 6, 309-318, 2006	Narrative review
Centre for Reviews and Dissemination., Oral hypoglycemic agents vs insulin in management of gestational diabetes: a systematic review and metaanalysis (Structured abstract), Database of Abstracts of Reviews of Effects, -, 2012	Original study identified
Ceysens,Gilles, Rouiller,Dominique, Boulvain,Michel, Exercise for diabetic pregnant women, Cochrane Database of Systematic Reviews, -, 2009	Systematic review - checked for relevant studies - exercise
Chasan-Taber,L., Marcus,B.H., Stanek,E.,III, Ciccolo,J.T., Marquez,D.X., Solomon,C.G., Markenson,G., A randomized controlled trial of prenatal physical activity to prevent gestational diabetes: design and methods, Journal of Women's Health, 18, 851-859, 2009	Protocol only.
Cheung,N.W., Smith,B.J., van der Ploeg,H.P., Cinnadaio,N., Bauman,A., A pilot structured behavioural intervention trial to increase physical activity among women with recent gestational diabetes, Diabetes Research and Clinical Practice, 92, e27-e29, 2011	Intervention not relevant (intervention delivered postpartum)
Clapp III,J.E., Effect of dietary carbohydrate on the glucose and insulin response to mixed caloric intake and exercise in both nonpregnant and pregnant women, Diabetes Care, 21, B107-B112, 1998	No relevant outcomes - glucose
Clapp,J.F.,III, Maternal carbohydrate intake and pregnancy outcome, Proceedings of the Nutrition SocietyProc.Nutr.Soc., 61, 45-50, 2002	Literature review.

Excluded studies – Review question 9	
Conway,D.L., Gonzales,O., Skiver,D., Use of glyburide for the treatment of gestational diabetes: the San Antonio experience, Journal of Maternal-Fetal and Neonatal MedicineJ Matern Fetal Neonatal Med, 15, 51-55, 2004	Cohort study.
Cummins,E., Royle,P., Snaith,A., Greene,A., Robertson,L., McIntyre,L., Waugh,N., Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation (Structured abstract), Health Technology Assessment Database, -, 2012	No comparison to insulin
Deveer,R., Deveer,M., Akbaba,E., Engin-Ustun,Y., Aydogan,P., Celikkaya,H., Danisman,N., Mollamahmutoglu,L., The effect of diet on pregnancy outcomes among pregnant with abnormal glucose challenge test, European Review for Medical and Pharmacological Sciences, 17, 1258-1261, 2013	Randomisation was performed using days of the week therefore this is a quasi-randomised trial and does not match the review protocol.
Dornan,T., Hollis,S., Critical appraisal of published research evidence: treatment of gestational diabetes. [19 refs], Diabetic Medicine, Suppl 3, 1-5, 2001	No relevant results reported
Dornhorst,A., Frost,G., The principles of dietary management of gestational diabetes: reflection on current evidence., Journal of Human Nutrition and DieteticsJ Hum Nutr Diet, 15, 145-156, 2002	Narrative review.
Dornhorst,A., Nicholls,J.S., Probst,F., Paterson,C.M., Hollier,K.L., Elkeles,R.S., Beard,R.W., Calorie restriction for treatment of gestational diabetes, Diabetes, 40 Suppl 2, 161-164, 1991	Observational study.
Dornhorst,A., Frost,G., The principles of dietary management of gestational diabetes: reflection on current evidence. [94 refs], Journal of Human Nutrition and Dietetics, 15, 145-156, 2002	Narrative review
Edson,E.J., Bracco,O.L., Vambergue,A., Koivisto,V., Managing diabetes during pregnancy with insulin lispro: a safe alternative to human insulin, Endocrine Practice, 16, 1020-1027, 2010	Comparison not relevant (insulin vs insulin)
Elnour,A.A., El,Mugammar,I, Jaber,T., Revel,T., McElnay,J.C., Pharmaceutical care of patients with gestational diabetes mellitus, Journal of Evaluation in Clinical Practice, 14, 131-140, 2008	Comparison not relevant
Falavigna,M., Schmidt,M., Trujillo,J., Alves,L., Wendland,E., Torloni,M., Colagiuri,S., Duncan,B., Effectiveness of gestational diabetes treatment: a systematic review with quality of evidence assessment, Diabetes Research and Clinical Practice, 98, 396-405, 2012	Systematic review - checked for relevant studies. Three already included in NCC review, one previously excluded. Four were requested, of these two were included and two excluded (O'Sullivan 1966 and 1974).
Ferrara,A., Hedderson,M.M., Albright,C.L., Ehrlich,S.F., Quesenberry,C.P.,Jr., Peng,T., Feng,J., Ching,J., Crites,Y., A pregnancy and postpartum lifestyle intervention in women with gestational diabetes mellitus reduces diabetes risk factors: a feasibility randomized control trial, Diabetes Care, 34, 1519-1525, 2011	No relevant outcomes
Fraser,R.B., The effect of pregnancy on the normal range of the oral glucose tolerance in Africans, East African Medical Journal, 58, 90-94, 1981	Response to oral glucose tolerance test in pregnant versus non-pregnant women.

Excluded studies – Review question 9	
Fraser,R.B., Ford,F.A., Lawrence,G.F., Insulin sensitivity in third trimester pregnancy. A randomized study of dietary effects, British Journal of Obstetrics and GynaecologyBr.J.Obstet.Gynaecol., 95, 223-229, 1988	Mixed population of pregnant and non-pregnant women - data not presented separately and no relevant outcomes.
Gillen,L., Tapsell,L.C., Martin,G.S., Daniells,S., Knights,S., Moses,R.G., The type and frequency of consumption of carbohydrate-rich foods may play a role in the clinical expression of insulin resistance during pregnancy, Nutrition and Dietetics: Journal of the Dietitians Association of Australia, 59, 135-143, 2002	Case control study.
Gillmer,M.D.G., Maresh,M., Beard,R.W., Low energy diets in the treatment of gestational diabetes, Acta Endocrinologica, Supplement, 112, 44-49, 1986	Only reports mean values for neonatal glucose and birth weight.
Giuffrida,F, Castro,A.,Atallah,A., Dib,S., Diet plus insulin compared to diet alone in the treatment of gestational diabetes mellitus: a systematic review, Brazilian Journal of Medical and Biological Research, 36, 1297-1300, 2003	Systematic review. 5 studies already included in the NCC review. One other study was previously excluded.
Giuffrida,F.M.A., Castro,A.A., Atallah,A.N., Dib,S.A., Diet plus insulin compared to diet alone in the treatment of gestational diabetes mellitus: A systematic review, Brazilian Journal of Medical and Biological Research, 36, 1297-1300, 2003	Systematic review - checked for relevant studies
Gojnic,M., Perovic,M., Pervulov,M., Ljubic,A., The effects of adjuvant insulin therapy among pregnant women with IGT who failed to achieve the desired glycemia levels by diet and moderate physical activity, Journal of Maternal-Fetal and Neonatal Medicine, 25, 2028-2034, 2012	Comparison not relevant and no detail provided about the content of the diet therefore not helpful in informing recommendations.
Gui,J., Liu,Q., Feng,L., Metformin vs insulin in the management of gestational diabetes: a meta-analysis, PLoS ONE [Electronic Resource], 8, e64585-, 2013	Meta-analysis: 3 studies already included in NCC review, 2 identified separately in reruns search and included as individual studies.
Han,S., Crowther,C.A., Middleton,P., Heatley,E., Different types of dietary advice for women with gestational diabetes mellitus, Cochrane Database of Systematic Reviews, 3, CD009275-, 2013	Of the included studies: 4 were already included in the original NCC review, 2 had previously been weeded out, 2 had previously been excluded. One further study by Grant (2011) was requested (same study as for the review by Mohd Yusof).
Han,Shanshan, Crowther,Caroline A., Middleton,Philippa, Interventions for pregnant women with hyperglycaemia not meeting gestational diabetes and type 2 diabetes diagnostic criteria, Cochrane Database of Systematic Reviews, -, 2012	Cochrane review. All four studies included separately in NCC review.
Hartling,L., Dryden,D.M., Guthrie,A., Muise,M., Vandermeer,B., Donovan,L., Benefits and harms of treating gestational diabetes mellitus: a systematic review and meta-analysis for the U.S. Preventive Services Task Force and the National Institutes of Health Office of Medical Applications of Research, Annals of Internal Medicine, 159, 123-129, 2013	Systematic review. Includes cohort studies which are not relevant to the NCC protocol. All RCTs included are already included in the NCC review.
Hassan,J.A., Karim,N., Sheikh,Z., Metformin prevents macrosomia and neonatal morbidity in gestational diabetes, Pakistan Journal of Medical Sciences, 28, 384-389, 2012	Allocation is alternate therefore is not random. Quasi-randomised trial.
Heller,S., McCance,D.R., Moghissi,E., Nazeri,A., Kordonouri,O., Diversity in diabetes: the role of insulin	Comparison not relevant (insulin vs insulin)

Excluded studies – Review question 9	
aspart, Diabetes/Metabolism Research Reviews, 28, 50-61, 2012	
Hernandez,T.L., Van Pelt,R.E., Anderson,M.A., Daniels,L.J., West,N.A., Donahoo,W.T., Friedman,J.E., Barbour,L.A., A higher-complex carbohydrate diet in gestational diabetes mellitus achieves glucose targets and lowers postprandial lipids: a randomized crossover study, Diabetes Care, 37, 1254-1262, 2014	No relevant outcomes. Mean maternal glucose and AUC only.
Ho,F.L.W., Liew,C.F., Cunanan,E.C., Lee,K.O., Oral hypoglycaemic agents for diabetes in pregnancy - An appraisal of the current evidence for oral anti-diabetic drug use in pregnancy, Annals of the Academy of Medicine Singapore, 36, 672-678, 2007	Systematic review - checked for relevant studies within class drugs
Horvath,K., Koch,K., Jeitler,K., Matyas,E., Bender,R., Bastian,H., Lange,S., Siebenhofer,A., Effects of treatment in women with gestational diabetes mellitus: Systematic review and meta-analysis, BMJ, 340, 796-, 2010	Systematic review - checked for relevant studies
Hutchinson,A., Haugabrook,C., Long,L., Mason,L., Kipikasa,J., Adair,D., A comparison of glyburide/metformin and insulin for gestational diabetes, American Journal of Obstetrics and Gynecology, 199, S200, 2008-, 2008	Conference proceedings.
Ilic,S., Jovanovic,L., Pettitt,D.J., Comparison of the effect of saturated and monounsaturated fat on postprandial plasma glucose and insulin concentration in women with gestational diabetes mellitus, American Journal of Perinatology, 16, 489-495, 1999	No relevant outcomes.
Jacobson,G.F., Ramos,G.A., Ching,J.Y., Kirby,R.S., Ferrara,A., Field,D.R., Comparison of glyburide and insulin for the management of gestational diabetes in a large managed care organization, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 193, 118-124, 2005	Cohort study.
Jacqueminet,S., Jannot-Lamotte,M.F., Therapeutic management of gestational diabetes, Diabetes and Metabolism, 36, 658-671, 2010	No relevant outcomes
Jovanovic,L., Howard,C., Pettitt,D., Zisser,H., Ospina,P., Insulin aspart vs. regular human insulin in basal/bolus therapy for patients with gestational diabetes mellitus: safety and efficacy, Diabetologia, 48, A 317-, 2005	Conference proceedings.
Jovanovic,L., Ilic,S., Pettitt,D.J., Hugo,K., Gutierrez,M., Bowsher,R.R., Bastyr,E.J.,III, Metabolic and immunologic effects of insulin lispro in gestational diabetes, Diabetes Care, 22, 1422-1427, 1999	Not relevant to protocol (insulin comparison).
Jovanovic,L., Howard,C., Pettitt,D., Zisser,H., Ospina,P., Insulin aspart vs. regular human insulin in basal/bolus therapy for patients with gestational diabetes mellitus: safety and efficacy, Diabetologia, 48, A317, 2005-, 2005	Conference procnot relevanteedings
Jovanovic,L., Ilic,S., Pettitt,D.J., Hugo,K., Gutierrez,M., Bowsher,R.R., Bastyr,E.J.,III, Metabolic and immunologic effects of insulin lispro in gestational diabetes, Diabetes Care, 22, 1422-1427, 1999	Comparison not relevant (insulin vs insulin)
Kaveh,M., Kiani,A., Salehi,M., Amouei,S., Impact of education on nutrition and exercise on the level of knowledge and metabolic control indicators (FBS & PPBS) of gestational diabetes mellitus (GDM) patients, Iranian	In Persian

Excluded studies – Review question 9	
Journal of Endocrinology and Metabolism, 13, 442-449, 2012	
Kitzmiller,J.L., Elixhauser,A., Carr,S., Major,C.A., de,Veciana M., ng-Kilduff,L., Weschler,J.M., Assessment of costs and benefits of management of gestational diabetes mellitus, Diabetes Care, 21 Suppl 2, B123-B130, 1998	Not a randomised contolled trial not relevant
Kjos,S.L., Schaefer-Graf,U., Sardesi,S., Peters,R.K., Buley,A., Xiang,A.H., Bryne,J.D., Sutherland,C., Montoro,M.N., Buchanan,T.A., A randomized controlled trial using glycemic plus fetal ultrasound parameters versus glycemic parameters to determine insulin therapy in gestational diabetes with fasting hyperglycemia.[see comment], Diabetes Care, 24, 1904-1910, 2001	Not relevant to protocol (ultrasound).
Kjos,S.L., Schaefer-Graf,U., Sardesi,S., Peters,R.K., Buley,A., Xiang,A.H., Bryne,J.D., Sutherland,C., Montoro,M.N., Buchanan,T.A., A randomized controlled trial using glycemic plus fetal ultrasound parameters versus glycemic parameters to determine insulin therapy in gestational diabetes with fasting hyperglycemia, Diabetes Care, 24, 1904-1910, 2001	Comparison not relevant
Knopp,R.H., Magee,M.S., Raisys,V., Benedetti,T., Bonet,B., Hypocaloric diets and ketogenesis in the management of obese gestational diabetic women. [63 refs], Journal of the American College of Nutrition, 10, 649-667, 1991	Outcomes not relevant
Korpi-Hyovalti,E.A., Laaksonen,D.E., Schwab,U.S., Vanhapiha,T.H., Vihla,K.R., Heinonen,S.T., Niskanen,L.K., Feasibility of a lifestyle intervention in early pregnancy to prevent deterioration of glucose tolerance, BMC Public Health, Vol.11, pp.179, 2011., -, -32676	Comparison not relevant
Kremer,C.J., Duff,P., Glyburide for the treatment of gestational diabetes, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 190, 1438-1439, 2004	Cohort study.
Landon,M.B., Is there a benefit to the treatment of mild gestational diabetes mellitus?. [20 refs], American Journal of Obstetrics and Gynecology, 202, 649-653, 2010	Narrative review
Lauszus,F.F., Rasmussen,O.W., Henriksen,J.E., Klebe,J.G., Jensen,L., Lauszus,K.S., Hermansen,K., Effect of a high monounsaturated fatty acid diet on blood pressure and glucose metabolism in women with gestational diabetes mellitus, European Journal of Clinical Nutrition, 55, 436-443, 2001	No relevant outcomes.
Lepercq,J., Lin,J., Hall,G.C., Wang,E., Dain,M.P., Riddle,M.C., Home,P.D., Meta-Analysis of Maternal and Neonatal Outcomes Associated with the Use of Insulin Glargine versus NPH Insulin during Pregnancy, Obstetrics and Gynecology International, 2012, 649070-, 2012	Comparison not relevant (insulin vs insulin)
Lesser,K.B., Gruppuso,P.A., Terry,R.B., Carpenter,M.W., Exercise fails to improve postprandial glycemic excursion in women with gestational diabetes, Journal of Maternal-Fetal MedicineJ.Matern.Fetal Med., 5, 211-217, 1996	One-off acute exercise period with 14 hour follow-up.
Lewis,B.A., Martinson,B.C., Sherwood,N.E., Avery,M.D., A pilot study evaluating a telephone-based exercise intervention for pregnant and postpartum women, Journal of Midwifery and Women's Health, 56, 127-131, 2011	Population not relevant

Excluded studies – Review question 9	
Li,D.F., Wong,V.C., O'Hoy,K.M., Yeung,C.Y., Ma,H.K., Is treatment needed for mild impairment of glucose tolerance in pregnancy? A randomized controlled trial, British Journal of Obstetrics and Gynaecology, 94, 851-854, 1987	Women were assigned to treatment groups using alternate allocation (quasi-randomised trial).
Lim,J.M.H., Tayob,Y., O'Brien,P.M.S., Shaw,R.W., A comparison between the pregnancy outcome of women with Gestation Diabetes treated with Glibenclamide and those treated with insulin, Medical Journal of Malaysia, 52, 377-381, 1997	Not a randomised controlled trial
Lin,J., Lepercq,J., Hall,G., Dain,M.P., Riddle,M.C., Home,P.D., A meta-analysis of maternal outcomes in pregnant women using insulin glargine compared with NPH insulin, Diabetologia, 54, S487-S488, 2011	Comparison not relevant (insulin vs insulin)
Lombard,C., Harrison,C., Teede,H., A randomized controlled trial investigating self-weighing and the prevention of excess weight gain in early pregnancy, Endocrine Reviews, 32, -, 2011	Population not relevant
Louie,J.C., Brand-Miller,J.C., Markovic,T.P., Ross,G.P., Moses,R.G., Glycemic index and pregnancy: a systematic literature review, Journal of Nutrition and Metabolism, 2010, 282464-, 2010	Systematic review of the literature but not of the published data i.e. no data analysis.
Madden,S.G., Loeb,S.J., Smith,C.A., An integrative literature review of lifestyle interventions for the prevention of type II diabetes mellitus. [38 refs], Journal of Clinical Nursing, 17, 2243-2256, 2008	Systematic review - checked for relevant studies.
Maresh,M., Gillmer,M.D.G., Beard,R.W., The effect of diet and insulin on metabolic profiles of women with gestational diabetes mellitus, Diabetes, 34, 88-93, 1985	Quasi-randomised trial which uses alternate allocation to assign treatment groups.
McFarland,M.B., Langer,O., Conway,D.L., Berkus,M.D., Dietary therapy for gestational diabetes: how long is long enough?, Obstetrics and Gynecology, 93, 978-982, 1999	Not a randomised controlled trial.
Mecacci,F., Carignani,L., Cioni,R., Bartoli,E., Parretti,E., La,Torre P., Scarselli,G., Mello,G., Maternal metabolic control and perinatal outcome in women with gestational diabetes treated with regular or lispro insulin: comparison with non-diabetic pregnant women, European Journal of Obstetrics, Gynecology and Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 111, 19-24, 2003	Not relevant to protocol (insulin comparison).
Mecacci,F., Carignani,L., Cioni,R., Bartoli,E., Parretti,E., La,Torre P., Scarselli,G., Mello,G., Maternal metabolic control and perinatal outcome in women with gestational diabetes treated with regular or lispro insulin: comparison with non-diabetic pregnant women, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 111, 19-24, 2003	Comparison not relevant (insulin vs insulin)
Mohd Yusof,B.N., Firouzi,S., Mohd,Shariff Z., Mustafa,N., Mohamed Ismail,N.A., Kamaruddin,N.A., Weighing the evidence of low glycemic index dietary intervention for the management of gestational diabetes mellitus: an Asian perspective, International Journal of Food Sciences and Nutrition, 65, 144-150, 2014	Systematic review. Two of the included studies were already included in the original NCC review. One further study by Grant (2011) was requested.
Moore,L,Briery,C., Martin,R., Hood,E., Bofill,J, Morrison,J., Metformin (M) vs. Insulin (I) in A2 Diabetics. A Randomized Clinical Trial, American Journal of Obstetrics and GynecologyAm J Obstet Gynecol, 191, S8-, 2004	Abstract only and population included in Moore 2007.

Excluded studies – Review question 9	
Moore,L., Clokey,D., Curet,L., A randomized controlled trial of metformin and glyburide in gestational diabetes, American Journal of Obstetrics and Gynecology, 199, S34, 2008-, 2008	Conference proceedings.
Moore,L., Clokey,D., Robinson,A., A randomized trial of metformin compared to glyburide in the treatment of gestational diabetes [abstract], American Journal of Obstetrics and Gynecology, 193, S92, 2005-, 2005	Conference abstract only.
Moretti,M.E., Rezvani,M., Koren,G., Safety of glyburide for gestational diabetes: A meta-analysis of pregnancy outcomes, Annals of Pharmacotherapy, 42, 483-490, 2008	Systematic review - checked for relevant studies.
Moss,J.R., Crowther,C.A., Hiller,J.E., Willson,K.J., Robinson,J.S., Australian Carbohydrate Intolerance Study in Pregnant Women Group, Costs and consequences of treatment for mild gestational diabetes mellitus - evaluation from the ACHOIS randomised trial, BMC Pregnancy and Childbirth, Vol.7, pp.27, 2007., -, -32676	No relevant outcomes.
Nachum,Z., Ben-Shlomo,I., Weiner,E., Shalev,E., Twice daily versus four times daily insulin dose regimens for diabetes in pregnancy: randomised controlled trial, BMJ, 319, 1223-1227, 1999	Comparison not relevant (insulin vs insulin)
Nicholson,W., Bolen,S., Witkop,C.T., Neale,D., Wilson,L., Bass,E., Benefits and risks of oral diabetes agents compared with insulin in women with gestational diabetes: A systematic review, Obstetrics and Gynecology, 113, 193-205, 2009	Systematic review - checked for relevant studies.
Nicholson,W.K., Wilson,L.M., Witkop,C.T., Baptiste-Roberts,K., Bennett,W.L., Bolen,S., Barone,B.B., Golden,S.H., Gary,T.L., Neale,D.M., Bass,E.B., Therapeutic management, delivery, and postpartum risk assessment and screening in gestational diabetes. [107 refs], Evidence Report/Technology Assessment, 1-96, 2008	Systematic review - checked for relevant studies.
Nolan,C.J., Improved glucose tolerance in gestational diabetic women on a low fat, high unrefined carbohydrate diet, Australian and New Zealand Journal of Obstetrics and Gynaecology, 24, 174-177, 1984	No relevant outcomes.
Ostman,E.M., Frid,A.H., Groop,L.C., Bjorck,I.M.E., A dietary exchange of common bread for tailored bread of low glycaemic index and rich in dietary fibre improved insulin economy in young women with impaired glucose tolerance, European Journal of Clinical NutritionEur.J.Clin.Nutr., 60, 334-341, 2006	Women were not pregnant: history of gestational diabetes and at risk for type 2 diabetes.
O'Sullivan,J.B., Gellis,S.S., Dandrow,R.V., Tenney,B.O., The potential diabetic and her treatment in pregnancy, Obstetrics and gynecologyObstet Gynecol, 27, 683-689, 1966	Incorrect comparison according to review protocol - diet plus insulin versus standard care.
O'Sullivan,J.B., Mahan,C.M., Insulin treatment and high risk groups, Diabetes Care, 3, 482-485, 1980	Not a randomised controlled trial.
O'Sullivan,J.B., Mahan,C.M., Charles,D., Dandrow,R.V., Medical treatment of the gestational diabetic, Obstetrics and Gynecology, 43, 817-821, 1974	Incorrect comparison according to review protocol - diet plus insulin versus standard care.
Pantalone,K.M., Faiman,C., Olansky,L., Insulin glargine use during pregnancy, Endocrine Practice, 17, 448-455, 2011	Comparison not relevant (insulin vs insulin)

Excluded studies – Review question 9	
Perez-Ferre,N., Galindo,M., Fernandez,M.D., Velasco,V., de la Cruz,M.J., Martin,P., del,Valle L., Calle-Pascual,A.L., A Telemedicine system based on Internet and short message service as a new approach in the follow-up of patients with gestational diabetes, Diabetes Research and Clinical Practice, 87, e15-e17, 2010	No relevant outcomes
Perichart-Perera,O., Balas-Nakash,M., Rodriguez-Cano,A., Legorreta-Legorreta,J., Parra-Covarrubias,A., Vadillo-Ortega,F., Low glycemic index carbohydrates versus all types of carbohydrates for treating diabetes in pregnancy: A randomized clinical trial to evaluate the effect of glycemic control, International Journal of Endocrinology, 2012 , 2012. Article Number, -, 2012	Most outcomes are nutrient-based. The need for insulin is reported as mean dosages not the number of women who received insulin. Type 2 diabetes and GDM data are not reported separately.
Peterson,C.M., Jovanovic-Peterson,L., Randomized crossover study of 40% vs. 55% carbohydrate weight loss strategies in women with previous gestational diabetes mellitus and non-diabetic women of 130-200% ideal body weight, Journal of the American College of NutritionJ.Am.Coll.Nutr., 14, 369-375, 1995	Women not pregnant: history of gestational diabetes.
Pettitt,D.J., Ospina,P., Kolaczynski,J.W., Jovanovic,L., Comparison of an insulin analog, insulin aspart, and regular human insulin with no insulin in gestational diabetes mellitus, Diabetes Care, 26, 183-186, 2003	Not relevant to protocol (insulin comparison).
Pettitt,D.J., Ospina,P., Howard,C., Zisser,H., Jovanovic,L., Efficacy, safety and lack of immunogenicity of insulin aspart compared with regular human insulin for women with gestational diabetes mellitus, Diabetic Medicine, 24, 1129-1135, 2007	Comparison not relevant (insulin vs insulin)
Pollex,E., Moretti,M.E., Koren,G., Feig,D.S., Safety of insulin glargine use in pregnancy: a systematic review and meta-analysis, Annals of Pharmacotherapy, 45, 9-16, 2011	Comparison not relevant (insulin vs insulin)
Poolsup,N., Suksomboon,N., Amin,M., Effect of treatment of gestational diabetes mellitus: A systematic review and meta-analysis, PloS one, 9, -, 2014	Systematic review. Studies checked for eligibility: 6 already included in NCC review, 4 excluded.
Poyhonen-Alho,M., Teramo,K., Kaaja,R., Treatment of gestational diabetes with short- or long-acting insulin and neonatal outcome: a pilot study, Acta Obstetricia et Gynecologica ScandinavicaActa Obstet.Gynecol.Scand., 81, 258-259, 2002	Not relevant to protocol (insulin comparison).
Reece,E.A., Hagay,Z., Gay,L.J., O'Connor,T., DeGennaro,N., Homko,C.J., Wiznitzer,A., A randomized clinical trial of a fiber-enriched diabetic diet vs. the standard American Diabetes Association-recommended diet in the management of diabetes mellitus in pregnancy, Journal of Maternal-Fetal Investigation, 5, 8-12, 1995	No relevant outcomes.
Rosenberg,V.A., Eglinton,G.S., Rauch,E.R., Skupski,D.W., Intrapartum maternal glycemic control in women with insulin requiring diabetes: a randomized clinical trial of rotating fluids versus insulin drip, American Journal of Obstetrics and Gynecology, 195, 1095-1099, 2006	Comparison not relevant
Rossi,G., Somigliana,E., Moschetta,M., Bottani,B., Barbieri,M., Vignali,M., Adequate timing of fetal ultrasound to guide metabolic therapy in mild gestational diabetes mellitus. Results from a randomized study, Acta Obstetricia et Gynecologica ScandinavicaActa Obstet.Gynecol.Scand., 79, 649-654, 2000	Not relevant to protocol (ultrasound).

Excluded studies – Review question 9	
Rowan,J.A., MiG,Investigators, A trial in progress: gestational diabetes. Treatment with metformin compared with insulin (the Metformin in Gestational Diabetes [MiG] trial).[Erratum appears in Diabetes Care. 2007 Dec;30(12):3154], Diabetes Care, 30 Suppl 2, S214-S219, 2007	no relevant results
Sacks,D.A., Chen,W., Wolde-Tsadik,G., Buchanan,T.A., When is fasting really fasting? The influence of time of day, interval after a meal, and maternal body mass on maternal glycemia in gestational diabetes, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 181, 904-911, 1999	Cohort study.
Sameshima,H., Kamitomo,M., Kajiya,S., Kai,M., Ikenoue,T., Insulin-meal interval and short-term glucose fluctuation in tightly controlled gestational diabetes mellitus, The Journal of maternal-fetal medicine, 10, 241-245, 2001	Not relevant to protocol (insulin comparison).
Schaefer-Graf,U.M., Kjos,S.L., Fauzan,O.H., Buhling,K.J., Siebert,G., Buhrer,C., Ladendorf,B., Dudenhausen,J.W., Vetter,K., A randomized trial evaluating a predominantly fetal growth-based strategy to guide management of gestational diabetes in Caucasian women., Diabetes Care, 27, 297-302, 2004	Not relevant to protocol (ultrasound).
Schuster,M.W., Chauhan,S.P., McLaughlin,B.N., Perry,Jr, Morrison,J.C., Comparison of insulin regimens and administration modalities in pregnancy complicated by diabetes, Journal of the Mississippi State Medical Association, 39, 208-212, 1998	Comparison not relevant.
Silva,J.C., Bertini,A.M., Taborda,W., Becker,F., Bebber,F.R., Aquim,G.M., Viesi,J.M., [Glibenclamide in the treatment for gestational diabetes mellitus in a compared study to insulin], Arquivos brasileiros de endocrinologia e metabologia, 51, 541-546, 2007	In Portuguese
Silva,J.C., Pacheco,C., Bizato,J., de Souza,B.V., Ribeiro,T.E., Bertini,A.M., Metformin compared with glyburide for the management of gestational diabetes, International Journal of Gynaecology and Obstetrics, 111, 37-40, 2010	Comparison not relevant (oral drugs vs oral drugs) within class diet
Smits,M.W., Paulk,T.H., Kee,C.C., Assessing the impact of an outpatient education program for patients with gestational diabetes, Diabetes EducatorDiabetes Educ., 21, 129-134, 1995	Descriptive study.
Symons,Downs D., Ulbrecht,J.S., Understanding exercise beliefs and behaviors in women with gestational diabetes mellitus, Diabetes Care, 29, 236-240, 2006	Retrospective study.
Tempe,A., Mayanglambam,R.D., Glyburide as treatment option for gestational diabetes mellitus, Journal of Obstetrics and Gynaecology Research, 39, 1147-1152, 2013	Alternate allocation used therefore not truly random (quasi-randomised trial).
Thomas,J., Metformin safe treatment for gestational diabetes, Australian Journal of Pharmacy, 90, 73-, 2009	Narrative review
Thomaz de,Lima H., Lopes,Rosado E., Ribeiro Neves,P.A., Correa Monteiro,Machado R., Mello de,Oliveira L., Saunders,C., Systematic review; Nutritional therapy in gestational diabetes mellitus, Nutricion Hospitalaria, 28, 1806-1814, 2013	Systematic review. All included were checked for eligibility: 4 were already included in the original NCC review, 1 was weeded out (trial of guidelines not specific diets).

Excluded studies – Review question 9	
Tieu,J., Crowther,C.A., Middleton,P., Dietary advice in pregnancy for preventing gestational diabetes mellitus. [47 refs], Cochrane Database of Systematic Reviews, CD006674-, 2008	Population not relevant (i.e. not women after GDM diagnosed).
Tieu,Joanna, Crowther,Caroline A., Middleton,Philippa, Dietary advice in pregnancy for preventing gestational diabetes mellitus, Cochrane Database of Systematic Reviews, -, 2011	Population not relevant (i.e. not women after GDM diagnosed).
Todorova,K., Palaveev,O., Petkova,V.B., Stefanova,M., Dimitrova,Z., A pharmacoeconomical model for choice of a treatment for pregnant women with gestational diabetes, Acta Diabetologica, 44, 144-148, 2007	Not a randomised controlled trial
Vanky,E., Salvesen,K.A., Heimstad,R., Fougner,K.J., Romundstad,P., Carlsen,S.M., Metformin reduces pregnancy complications without affecting androgen levels in pregnant polycystic ovary syndrome women: results of a randomized study, Human Reproduction, 19, 1734-1740, 2004	Population not relevant
Waheed,S., Malik,F.P., Mazhar,S.B., Efficacy of metformin versus insulin in the management of pregnancy with diabetes, Jcpsp, Journal of the College of Physicians and Surgeons - Pakistan, 23, 866-869, 2013	No relevant outcomes reported. The study addresses efficacy only of glucose and HbA_{1c} control.
Walkinshaw,Stephen A., Dietary regulation for 'gestational diabetes', Cochrane Database of Systematic Reviews, -, 2010	Withdrawn Cochrane review
Wechter,D.J., Kaufmann,R.C., Amankwah,K.S., Rightmire,D.A., Eardley,S.P., Verhulst,S., Zinzilieta,M., Young,J., Teich,J., Singleton,J.A., Prevention of neonatal macrosomia in gestational diabetes by the use of intensive dietary therapy and home glucose monitoring, American Journal of Perinatology, 8, 131-134, 1991	Cohort study.
Wein,P., Beischer,N., Harris,C., Permezel,M., A trial of simple versus intensified dietary modification for prevention of progression to diabetes mellitus in women with impaired glucose tolerance, Australian and New Zealand Journal of Obstetrics and Gynaecology, 39, 162-166, 1999	Long-term follow-up only. Women included were not pregnant.
Wensel,T.M., Role of metformin in the treatment of gestational diabetes, Annals of Pharmacotherapy, 43, 939-943, 2009	Systematic review - checked for relevant studies
Yogev,Y., Ben-Haroush,A., Chen,R., Rosenn,B., Hod,M., Langer,O., Undiagnosed asymptomatic hypoglycemia: diet, insulin, and glyburide for gestational diabetic pregnancy, Obstetrics and GynecologyObstet.Gynecol., 104, 88-93, 2004	Cohort study.
Zeng,Y.C., Li,M.J., Chen,Y., Jiang,L., Wang,S.M., Mo,X.L., Li,B.Y., The use of glyburide in the management of gestational diabetes mellitus: A meta-analysis, Advances in Medical Sciences, 59, 95-101, 2014	Systematic review. Studies checked for eligibility: 3 already included in NCC review, 2 excluded

G.9 Antenatal blood glucose monitoring

Excluded studies – Review question 10	
Study	Reason for Exclusion
Carmody,D., Doyle,A., Firth,R.G., Byrne,M.M., Daly,S., Mc,Auliffe F., Foley,M., Coulter-Smith,S., Kinsley,B.T., Teenage pregnancy in type 1 diabetes mellitus, Pediatric Diabetes, 11, 111-115, 2010	Comparison of teenagers and older women. Does not compare monitoring strategies
Coster,S., Gulliford,M.C., Seed,P.T., Powrie,J.K., Swaminathan,R., Monitoring blood glucose control in diabetes mellitus: a systematic review, Health Technology Assessment Database, 4, -, 2000	Included studies were checked for relevance. Four had already been excluded by the NCC in original searches, three had been included. Three other studies were requested and of these one was included (Varner) and two excluded (Goldstein, Stubbs).
Crowther,C.A., Hague,W.M., Middleton,P.F., Baghurst,P.A., McPhee,A.J., Tran,T.S., Yelland,L.N., Ashwood,P., Han,S., Dodd,J.M., Robinson,J.S., IDEAL Study Group., The IDEAL study: investigation of dietary advice and lifestyle for women with borderline gestational diabetes: a randomised controlled trial - study protocol, BMC Pregnancy and Childbirth, 12, 106-, 2012	Protocol only
Crowther,C.A., Hiller,J.E., Moss,J.R., McPhee,A.J., Jeffries,W.S., Robinson,J.S., Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) Trial Group., Effect of treatment of gestational diabetes mellitus on pregnancy outcomes, New England Journal of Medicine, 352, 2477-2486, 2005	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Dalfra,M.G., Chilelli,N.C., Di,CianniG, Mello,G., Lencioni,C., Biagioni,S., Scalese,M., Sartore,G., Lapolla,A., Glucose fluctuations during gestation: An additional tool for monitoring pregnancy complicated by diabetes, International Journal of Endocrinology, 2013 , 2013. Article Number, -, 2013	Continuous glucose monitoring only.
di Biase,N., Napoli,A., Sabbatini,A., Borrello,E., Buongiorno,A.M., Fallucca,F., Telemedicine in the treatment of diabetic pregnancy, Annali Dell'Istituto Superiore di Sanita, 33, 347-351, 1997	Women in both groups used the same monitoring strategy
Durnwald,C.P., Mele,L., Spong,C.Y., Ramin,S.M., Varner,M.W., Rouse,D.J., Sciscione,A., Catalano,P., Saade,G., Sorokin,Y., Tolosa,J.E., Casey,B., Anderson,G.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network (MFMU), Glycemic characteristics and neonatal outcomes of women treated for mild gestational diabetes, Obstetrics and Gynecology, 117, 819-827, 2011	Does not compare monitoring strategies
Feig,D.S., Cleave,B., Tomlinson,G., Long-term effects of a diabetes and pregnancy program: does the education last?, Diabetes Care, 29, 526-530, 2006	Does not compare monitoring strategies
Garner,P., Okun,N., Keely,E., Wells,G., Perkins,S., Sylvain,J., Belcher,J., A randomized controlled trial of strict glycemic control and tertiary level obstetric care versus routine obstetric care in the management of gestational diabetes: a pilot study, American Journal of Obstetrics and GynecologyAm J Obstet Gynecol, 177, 190-195, 1997	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Gill,Madeleine G., Nguyen,ThuyMy N., Bain,Emily, Crowther,Caroline A., Middleton,Philippa, Home versus hospital glucose monitoring for gestational diabetes during	Protocol only.

Excluded studies – Review question 10	
pregnancy, Cochrane Database of Systematic Reviews, -, 2014	
Glinianaia,S.V., Tennant,P.W.G., Bilous,R.W., Rankin,J., Bell,R., HbA_{1c} and birthweight in women with pre-conception type 1 and type 2 diabetes: A population-based cohort study, Diabetologia, 55, 3193-3203, 2012	Non-comparative study
Goldstein,A., Elliott,J., Lederman,S., Worcester,B., Russell,P., Linzey,E.M., Economic effects of self-monitoring of blood glucose concentrations by women with insulin-dependent diabetes during pregnancy, Journal of Reproductive Medicine, 27, 449-450, 1982	Economic data on hospital stay only.
Gutaj,P., Zawiejska,A., Wender-Ozegowska,E., Brazert,J., Maternal factors predictive of firsttrimester pregnancy loss in women with pregestational diabetes, Polskie Archiwum Medycyny Wewnetrznej, 123, 21-28, 2013	Does not compare monitoring strategies
Hanson,U., Persson,B., Enochsson,E., Lennerhagen,P., Lindgren,F., Lundstrom,V., Lunell,N.O., Nilsson,B.A., Nilsson,L., Stangenberg,M., Self-monitoring of blood glucose by diabetic women during the third trimester of pregnancy, American Journal of Obstetrics and GynecologyAm J Obstet Gynecol, 150, 817-821, 1984	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Hiramatsu,Y., Shimizu,I., Omori,Y., Nakabayashi,M., JGA (Japan Glycated Albumin) Study Group., Determination of reference intervals of glycated albumin and hemoglobin A_{1c} in healthy pregnant Japanese women and analysis of their time courses and influencing factors during pregnancy, Endocrine Journal, 59, 145-151, 2012	Does not compare monitoring strategies
Inkster,M.E., Fahey,T.P., Donnan,P.T., Leese,G.P., Mires,G.J., Murphy,D.J., Poor glycated haemoglobin control and adverse pregnancy outcomes in type 1 and type 2 diabetes mellitus: systematic review of observational studies, BMC Pregnancy and Childbirth, 6, 30-, 2006	Does not compare monitoring strategies
Jovanovic,L., The role of continuous glucose monitoring in gestational diabetes mellitus, Diabetes Technology and Therapeutics, 2 Suppl 1, S67-S71, 2000	Not relevant to this question - considered for inclusion in the continuous blood glucose monitoring review
Jovanovic,L., Peterson,C.M., Saxena,B.B., Dawood,M.Y., Saudek,C.D., Feasibility of maintaining normal glucose profiles in insulin-dependent pregnant diabetic women, American Journal of Medicine, 68, 105-112, 1980	Non-comparative study
Jovanovic,L., Savas,H., Mehta,M., Trujillo,A., Pettitt,D.J., Frequent monitoring of A_{1C} during pregnancy as a treatment tool to guide therapy, Diabetes Care, 34, 53-54, 2011	Non-comparative study
Jovanovic,L., Druzin,M., Peterson,C.M., Effect of euglycemia on the outcome of pregnancy in insulin-dependent diabetic women as compared with normal control subjects, American Journal of Medicine, 71, 921-927, 1981	Initially a trial of blood glucose vs. urine monitoring which was stopped early. All women were switched to blood glucose monitoring. Comparison group is non-diabetic women.
Jovanovic,L.G., Using meal-based self-monitoring of blood glucose as a tool to improve outcomes in pregnancy complicated by diabetes. [25 refs], Endocrine Practice, 14, 239-247, 2008	Narrative review with no new data
Kerssen,A., De Valk,H.W., Visser,G.H., Do HbA(1)c levels and the self-monitoring of blood glucose levels adequately	Not relevant to this question - comparison of continuous glucose

Excluded studies – Review question 10	
reflect glycaemic control during pregnancy in women with type 1 diabetes mellitus?, Diabetologia, 49, 25-28, 2006	monitoring and intermittent monitoring
Kong,G.W., Tam,W.H., Chan,M.H., So,W.Y., Lam,C.W., Yiu,I.P., Loo,K.M., Li,C.Y., Comparison in the performance of glucose meters in blood glucose monitoring during pregnancy, Gynecologic and Obstetric Investigation, 69, 264-269, 2010	Compares different types of meters. Does not compare monitoring strategies
Laird,J., McFarland,K.F., Fasting blood glucose levels and initiation of insulin therapy in gestational diabetes, Endocrine Practice, 2, 330-332, 1996	Does not compare monitoring strategies
Landon,M.B., Spong,C.Y., Thom,E., Carpenter,M.W., Ramin,S.M., Casey,B., Wapner,R.J., Varner,M.W., Rouse,D.J., Thorp,J.M.,Jr., Sciscione,A., Catalano,P., Harper,M., Saade,G., Lain,K.Y., Sorokin,Y., Peaceman,A.M., Tolosa,J.E., Anderson,G.B., Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-fetal Medicine Units Network., A multicenter, randomized trial of treatment for mild gestational diabetes, New England Journal of Medicine, 361, 1339-1348, 2009	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Mendez-Figueroa,H., Daley,J., Lopes,V.V., Coustan,D.R., Comparing daily versus less frequent blood glucose monitoring in patients with mild gestational diabetes, Journal of Maternal-Fetal and Neonatal Medicine, 26, 1268-1272, 2013	Outcome not relevant to protocol (time until initiation of pharmacological therapy).
Middleton,Philippa, Crowther,Caroline A., Simmonds,Lucy, Different intensities of glycaemic control for pregnant women with pre-existing diabetes, Cochrane Database of Systematic Reviews, -, 2012	Does not compare monitoring strategies
Moy,Ming Foong, Ray,Amita, Buckley,Brian S., Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes, Cochrane Database of Systematic Reviews, -, 2012	Protocol only
Moy,F.M., Ray,A., Buckley,B.S., Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes, Cochrane Database of Systematic Reviews, 4, CD009613-, 2014	Systematic review. Studies checked for eligibility: 2 already included in NCC review, 2 weeded out, 4 excluded, 1 requested to check (Wojcicki, 2001).
Peacock,I., Hunter,J.C., Walford,S., Allison,S.P., Davison,J., Clarke,P., Symonds,E.M., Tattersall,R.B., Self-monitoring of blood glucose in diabetic pregnancy, British Medical Journal, 2, 1333-1336, 1979	Does not compare monitoring strategies
Pelaez-Crisologo,Ma, Castillo-Torralba,M.G.A.G., Festin,M.R., Different techniques of blood glucose monitoring in women with gestational diabetes for improving maternal and infant health, Cochrane Database of Systematic Reviews, 2009. Article Number, -, 2009	Protocol only
Rackham,O., Paize,F., Weindling,A.M., Cause of death in infants of women with pregestational diabetes mellitus and the relationship with glycemic control, Postgraduate Medicine, 121, 26-32, 2009	Does not compare monitoring strategies
Secher,A.L., Ringholm,L., Andersen,H.U., Damm,P., Mathiesen,E.R., The effect of real-time continuous glucose monitoring in pregnant women with diabetes: a randomized controlled trial, Diabetes Care, 36, 1877-1883, 2013	Monitoring performed is not intermittent
Stubbs,S.M., Brudenell,J.M., Pyke,D.A., Watkins,P.J., Stubbs,W.A., Alberti,K.G., Management of the pregnant	Comparison is blood glucose monitoring vs. urine monitoring

Excluded studies – Review question 10	
diabetic: home or hospital, with or without glucose meters?, Lancet, 1, 1122-1124, 1980	therefore is not relevant to the protocol.
Sturrock,N.D., Fay,T.N., Pound,N., Kirk,B.A., Danks,L.E., Analysis of 44,279 blood glucose estimations in relation to outcomes in 80 pregnant diabetic women, Journal of Obstetrics and Gynaecology, 21, 253-257, 2001	Does not compare monitoring strategies
Syed,M., Javed,H., Yakoob,M.Y., Bhutta,Z.A., Effect of screening and management of diabetes during pregnancy on stillbirths, BMC Public Health, 11 Suppl 3, S2-, 2011	Does not provide enough detail regarding the included studies. Included studies considered separately for inclusion in the NCC review.
Wechter,D.J., Kaufmann,R.C., Amankwah,K.S., Rightmire,D.A., Eardley,S.P., Verhulst,S., Zinzilieta,M., Young,J., Teich,J., Singleton,J.A., Prevention of neonatal macrosomia in gestational diabetes by the use of intensive dietary therapy and home glucose monitoring, American Journal of Perinatology, 8, 131-134, 1991	Does not compare monitoring strategies
Wilson,N., Ashawesh,K., Kulambil Padinjakara,R.N., Anwar,A., The multidisciplinary diabetes-endocrinology clinic and postprandial blood glucose monitoring in the management of gestational diabetes: impact on maternal and neonatal outcomes, Experimental and Clinical Endocrinology and Diabetes, 117, 486-489, 2009	Not clear which monitoring strategy/ies the 1 hour postprandial measurement is compared to
Wong,M.L., Butson,S., Gatling,W., Masding,M.G., The management of women with gestational diabetes can be stratified according to diagnostic oral glucose tolerance test results, Practical Diabetes International, 25, 61-63, 2008	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Yogev,Y., Chen,R., Ben-Haroush,A., Phillip,M., Jovanovic,L., Hod,M., Continuous glucose monitoring for the evaluation of gravid women with type 1 diabetes mellitus, Obstetrics and Gynecology, 101, 633-638, 2003	Not relevant to this question. Comparison of continuous glucose monitoring and intermittent monitoring
Young,B.C., Ecker,J.L., Fetal macrosomia and shoulder dystocia in women with gestational diabetes: Risks amenable to treatment?, Current Diabetes Reports, 13, 12-18, 2013	Narrative review. No new data.

G.10 Antenatal ketone monitoring

There were no excluded studies for review question 11

G.11 Antenatal blood glucose targets

Excluded studies – Review question 12	
Study	Reason for Exclusion
Anderberg,E., Kallen,K., Berntorp,K., The impact of gestational diabetes mellitus on pregnancy outcome comparing different cut-off criteria for abnormal glucose tolerance, Acta Obstetricia et Gynecologica Scandinavica, 89, 1532-1537, 2010	Compares different levels of glucose tolerance in relation to GDM diagnosis. Analysis based on an OGTT (one off test). No targets given.
Aschwald,C.L., Catanzaro,R.B., Weiss,E.P., Gavard,J.A., Steitz,K.A., Mostello,D.J., Large-for-gestational-age infants of type 1 diabetic mothers: an effect of preprandial	Outcome (macrosomia) not reported with respect to target values.

Excluded studies – Review question 12	
hyperglycemia?, Gynecological Endocrinology, 25, 653-660, 2009	
Cohen,O., Keidar,N., Simchen,M., Weisz,B., Dolitsky,M., Sivan,E., Macrosomia in well controlled CSII treated Type I diabetic pregnancy, Gynecological Endocrinology, 24, 611-613, 2008	States glycaemic control within guidelines but does not state explicitly these ref. values
Dalfra,M.G., Sartore,G., Di,Cianni G., Mello,G., Lencioni,C., Ottanelli,S., Sposato,J., Valgimigli,F., Scuffi,C., Scalese,M., Lapolla,A., Glucose variability in diabetic pregnancy, Diabetes Technology and Therapeutics, 13, 853-859, 2011	No threshold analysis; mean values. Most comparisons are for type 1 versus gestational diabetes versus controls.
Damm,P., Mersebach,H., Rastam,J., Kaaja,R., Hod,M., McCance,D.R., Mathiesen,E.R., Poor pregnancy outcome in women with type 1 diabetes is predicted by elevated HbA_{1c} and spikes of high glucose values in the third trimester, Journal of Maternal-Fetal and Neonatal Medicine, 27, 149-154, 2014	The association between glucose and outcomes was determined using regression to obtain a risk threshold. Plasma glucose values upon which regression results were based were any value > 11mmol/l rather than being specific to meal times.
Dicker,D., Feldberg,D., Samuel,N., Yeshaya,A., Karp,M., Goldman,J.A., Spontaneous abortion in patients with insulin-dependent diabetes mellitus: the effect of preconceptional diabetic control, American Journal of Obstetrics and Gynecology, 158, 1161-1164, 1988	No target levels or thresholds given. Mean blood glucose for abortion versus pregnancy > 22 weeksâ™ gestation
Durnwald,C., Glycemic characteristics of women treated for mild gestational diabetes and perinatal outcomes, American Journal of Obstetrics and Gynecology, 201, S107-, 2009	Conference abstract
Durnwald,C.P., Mele,L., Spong,C.Y., Ramin,S.M., Varner,M.W., Rouse,D.J., Sciscione,A., Catalano,P., Saade,G., Sorokin,Y., Tolosa,J.E., Casey,B., Anderson,G.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network (MFMU), Glycemic characteristics and neonatal outcomes of women treated for mild gestational diabetes, Obstetrics and Gynecology, 117, 819-827, 2011	Outcomes are related to median blood glucose values and change over time only, not to a threshold. No targets given.
Figueroa,D., Landon,M.B., Mele,L., Spong,C.Y., Ramin,S.M., Casey,B., Wapner,R.J., Varner,M.W., Thorp,J.M.,Jr., Sciscione,A., Catalano,P., Harper,M., Saade,G., Caritis,S.N., Sorokin,Y., Peaceman,A.M., Tolosa,J.E., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network., Relationship between 1-hour glucose challenge test results and perinatal outcomes, Obstetrics and Gynecology, 121, 1241-1247, 2013	Analysis based on glucose screening results only. Comparison group is women with negative screening test results.
Fotinos,C., Dodson,S., French,L., Does tight control of blood glucose in pregnant women with diabetes improve neonatal outcomes?., Journal of Family PracticeJ.Fam.Pract., 53, 838-841, 2004	Narrative review which combines dietary interventions, pre-conception care and pregnancy care. Studies checked for inclusion. None relevant. One relevant Cochrane review was checked - studies have already been included (Farrag
Fuhrmann,K., Treatment of pregnant insulin-dependent diabetic women, Acta Endocrinologica, Supplementum. 277, 74-76, 1986	Does not examine outcomes by target values or by threshold. The per cent of women who achieved targets is not given by target level but by whether

Excluded studies – Review question 12	
	targets were assigned before or during pregnancy.
Fuhrmann,K., Reiher,H., Semmler,K., Glockner,E., The effect of intensified conventional insulin therapy before and during pregnancy on the malformation rate in offspring of diabetic mothers, Experimental and Clinical Endocrinology, 83, 173-177, 1984	Does not examine outcomes by target values or by threshold. The per cent of women who achieved targets is not given by target level but by whether targets were assigned before or during pregnancy.
HAPO Study Cooperative Research Group, Metzger,B.E., Lowe,L.P., Dyer,A.R., Trimble,E.R., Chaovarindr,U., Coustan,D.R., Hadden,D.R., McCance,D.R., Hod,M., McIntyre,H.D., Oats,J.J., Persson,B., Rogers,M.S., Sacks,D.A., Hyperglycemia and adverse pregnancy outcomes, New England Journal of Medicine, 358, 1991-2002, 2008	The study examined the relationship of 75g OGTT glucose values (a one off test) and outcomes in a population of pregnant women. Women who had values diagnostic (at the time of the study) of GDM and diabetes were excluded. The study was used in order to redefine GDM diagnostic criteria and as such includes women with what was then considered to be normal blood glucose values. The women were not being treated to control their blood glucose values.
Jensen,D.M., Damm,P., Moelsted-Pedersen,L., Ovesen,P., Westergaard,J.G., Moeller,M., Beck-Nielsen,H., Outcomes in type 1 diabetic pregnancies: a nationwide, population-based study, Diabetes Care, 27, 2819-2823, 2004	No specified targets. Compares outcomes in women who self-monitored daily or at any time during pregnancy versus those who did not.
Jensen,D.M., Korsholm,L., Ovesen,P., Beck-Nielsen,H., Molsted-Pedersen,L., Damm,P., Adverse pregnancy outcome in women with mild glucose intolerance: is there a clinically meaningful threshold value for glucose?, Acta Obstetricia et Gynecologica Scandinavica, 87, 59-62, 2008	DiagnosticTreatment threshold levels not self-monitoring thresholds.
Jovanovic,L., Druzin,M., Peterson,C.M., Effect of euglycemia on the outcome of pregnancy in insulin-dependent diabetic women as compared with normal control subjects, American Journal of Medicine, 71, 921-927, 1981	No thresholds suggested. Comparator group is non-diabetic women. Initially this study was a trial of urine versus blood glucose monitoring which was stopped early due to ethics.
Jovanovic-Peterson,L., Peterson,C.M., Reed,G.F., Metzger,B.E., Mills,J.L., Knopp,R.H., Aarons,J.H., Maternal postprandial glucose levels and infant birth weight: the Diabetes in Early Pregnancy Study. The National Institute of Child Health and Human Development--Diabetes in Early Pregnancy Study, American Journal of Obstetrics and Gynecology, 164, 103-111, 1991	No target levels given â“ mean blood glucose values only per trimester. Comparator group is non-diabetic women.
Karlsson,K., Kjellmer,I., The outcome of diabetic pregnancies in relation to the mother's blood sugar level, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 112, 213-220, 1972	A minority of the women (12.5%) were diagnosed with GDM during pregnancy with an intravenous glucose test. The remainder had pre-existing diabetes (Whiteâ™s classification). For calculation of mean blood glucose, all women were tested three times daily in hospital between 30-32 weeks using a laboratory method. These values were used to calculate mean blood glucose in all women with available data. The paper

Excluded studies – Review question 12	
	does not specify the times when the 3 samples were taken or relate these to meal times. Target values were not given to women.
Kerenyi,Z., Tamas,G., Kivimaki,M., Peterfalvi,A., Madarasz,E., Bosnyak,Z., Tabak,A.G., Maternal glycemia and risk of large-for-gestational-age babies in a population-based screening, Diabetes Care, 32, 2200-2205, 2009	The study reported the relationship between fasting blood glucose values obtained during a diagnostic 75g OGTT between 22 and 30 weeksâ™ to determine whether the woman had GDM (a one off test). None of the women were being treated at the time of the study to control their blood glucose values. Women had blood glucose levels below those diagnostic of GDM.
Kitzmiller,J.L., Gavin,L.A., Gin,G.D., Jovanovic-Peterson,L., Main,E.K., Zigrang,W.D., Preconception care of diabetes. Glycemic control prevents congenital anomalies, JAMA, 265, 731-736, 1991	Comparison is pre-pregnancy vs. pregnancy education. Outcome (neonatal mortality) not analysed with respect to target values.
Langer,O., Rodriguez,D.A., Xenakis,E.M., McFarland,M.B., Berkus,M.D., Arrendondo,F., Intensified versus conventional management of gestational diabetes., American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 170, 1036-1046, 1994	Comparison is of management strategies to attain metabolic goals and is not a comparison of different thresholds
Middleton,Philippa, Crowther,Caroline A., Simmonds,Lucy, Different intensities of glycaemic control for pregnant women with pre-existing diabetes, Cochrane Database of Systematic Reviews, -, 2012	Cochrane review. Individual studies were checked for inclusion or exclusion and are reported separately.
Miodovnik,M., High spontaneous premature labour rate in insulin-dependent diabetic women: An association with poor glycaemic control., Scientific abstracts of the seventh Annual Meeting of the Society for Perinatal Obstretrics, Lake Buena Vista, Florida, February 5-7, -, 1987	Mean HbA1 values for preterm labour.
Most,O., Langer,O., Gestational diabetes: Maternal weight gain in relation to fetal growth, treatment modality, BMI and glycemic control, Journal of Maternal-Fetal and Neonatal Medicine, 25, 2458-2463, 2012	Does not examine the effects of blood glucose levels on outcomes (maternal weight gain). Large for gestational age is reported with respect to weight gain not blood glucose.
Parretti,E., Mecacci,F., Papini,M., Cioni,R., Carignani,L., Mignosa,M., La Torre,P., Mello,G., Third-trimester maternal glucose levels from diurnal profiles in nondiabetic pregnancies: correlation with sonographic parameters of fetal growth, Diabetes Care, 24, 1319-1323, 2001	The population is in pregnant women who do not have diabetes.
Prutsky,G.J., Domecq,J.P., Wang,Z., Carranza Leon,B.G., Elraiyah,T., Nabhan,M., Sundaresh,V., Vella,A., Montori,V.M., Murad,M.H., Glucose targets in pregnant women with diabetes: a systematic review and meta-analysis, Journal of Clinical Endocrinology and Metabolism, 98, 4319-4324, 2013	Included studies are all GDM intervention papers and not related to targets achieved/recorded. Women in each arm therefore received differing treatments in each study.
Riskin-Mashiah,S., Younes,G., Damti,A., Auslender,R., First-trimester fasting hyperglycemia and adverse pregnancy outcomes, Diabetes Care, 32, 1639-1643, 2009	Women with pre-existing diabetes or a high fasting blood glucose were excluded. GDM was reported as an outcome in women with normal fasting blood glucose values. LGA was also reported as an outcome in women with

Excluded studies – Review question 12	
	normal fasting blood glucose. LGA is not only reported in women who developed GDM but also those who were not diabetic. It is not possible to separate out the GDM patients.
Rosenn,B., Minor congenital malformations in infants of insulin-diabetic women: association with poor glycaemic control., Obstetrics and GynecologyObstet.Gynecol., 76, 745-749, 1990	Thresholds are not examined in the data analysis. Mean blood glucose only for congenital malformation versus no malformation.
Rosenn,B., Miodovnik,M., Combs,C.A., Khoury,J., Siddiqi,T.A., Glycemic thresholds for spontaneous abortion and congenital malformations in insulin-dependent diabetes mellitus, Obstetrics and GynecologyObstet.Gynecol., 84, 515-520, 1994	Outcomes not relevant to protocol
Rosenn,B.M., Miodovnik,M., Holcberg,G., Khoury,J.C., Siddiqi,T.A., Hypoglycemia: the price of intensive insulin therapy for pregnant women with insulin-dependent diabetes mellitus, Obstetrics and Gynecology, 85, 417-422, 1995	Does not examine outcomes by target values or threshold â" abortions, hypoglycaemic episodes and malformations are reported with respect to gestational age. Does not quantify no. of women not achieving glycaemic control target. Targets were the same for all women.
Savona-Ventura,C., Craus,J., Vella,K., Grima,S., Lowest threshold values for the 75g oral glucose tolerance test in pregnancy, Malta Medical Journal, 22, 18-20, 2010	Data were analysed based on the results of a 75g OGTT during the third trimester for diagnosis of GDM (a one off test). None of the women were being treated at the time of the study to control their blood glucose values.
Sturrock,N.D., Fay,T.N., Pound,N., Kirk,B.A., Danks,L.E., Analysis of 44,279 blood glucose estimations in relation to outcomes in 80 pregnant diabetic women, Journal of Obstetrics and Gynaecology, 21, 253-257, 2001	Does not quantify numbero. of women not achieving glycaemic control target. No comparative data â" mean blood glucose values only and correlational data only for blood glucose with respect to birth weight. Targets were the same for all women.
Valuk,J., Factors influencing birth weight in infants of diabetic mothers., Diabetes, 35, 96A-, 1986	Abstract only.
Veres,M., Babes,A., Lacziko,S., Correlations between the values of maternal glycemia from the last trimester of pregnancy and fetal birth weight, Romanian Journal of Diabetes, Nutrition and Metabolic Diseases, 20, 259-265, 2013	Report associations using ROC analysis - not a threshold.
Wendland,E.M., Duncan,B.B., Mengue,S.S., Schmidt,M.I., Lesser than diabetes hyperglycemia in pregnancy is related to perinatal mortality: a cohort study in Brazil, BMC Pregnancy and Childbirth, 11, 92-, 2011	Data were analysed based on the results of a 75g OGTT during the third trimester for diagnosis of GDM (a one off test). None of the women were being treated at the time of the study to control their blood glucose values. The study reports the correlation of both mean fasting glucose levels and mean 2h glucose levels to neonatal mortality rather than looking at specific thresholds. Wrong population.
Wendland,E.M., Torloni,M.R., Falavigna,M., Trujillo,J., Dode,M.A., Campos,M.A., Duncan,B.B., Schmidt,M.I., Gestational diabetes and pregnancy outcomes--a systematic review of the World Health Organization	Comparison is outcomes in women with GDM versus those without GDM based on different diagnostic criteria. Study populations are non-diabetic

Excluded studies – Review question 12	
(WHO) and the International Association of Diabetes in Pregnancy Study Groups (IADPSG) diagnostic criteria, BMC Pregnancy and Childbirth, 12, 23-, 2012	women or mixed with no subgroup analyses by glucose threshold. No targets.

G.12 Antenatal HbA_{1c} monitoring

Excluded studies – Review question 13	
Study	Reason for Exclusion
Bancroft,K., Tuffnell,D.J., Mason,G.C., Rogerson,L.J., Mansfield,M., A randomised controlled pilot study of the management of gestational impaired glucose tolerance, BJOG: An International Journal of Obstetrics and Gynaecology, 107, 959-963, 2000	Does not compare HbA_{1c} monitoring strategies
Carmody,D., Doyle,A., Firth,R.G., Byrne,M.M., Daly,S., Mc,Auliffe F., Foley,M., Coulter-Smith,S., Kinsley,B.T., Teenage pregnancy in type 1 diabetes mellitus, Pediatric Diabetes, 11, 111-115, 2010	Comparison of teenagers and older women. Does not compare monitoring strategies
Crowther,C.A., Hague,W.M., Middleton,P.F., Baghurst,P.A., McPhee,A.J., Tran,T.S., Yelland,L.N., Ashwood,P., Han,S., Dodd,J.M., Robinson,J.S., IDEAL Study Group., The IDEAL study: investigation of dietary advice and lifestyle for women with borderline gestational diabetes: a randomised controlled trial - study protocol, BMC Pregnancy and Childbirth, 12, 106-, 2012	Protocol only
Crowther,C.A., Hiller,J.E., Moss,J.R., McPhee,A.J., Jeffries,W.S., Robinson,J.S., Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) Trial Group., Effect of treatment of gestational diabetes mellitus on pregnancy outcomes, New England Journal of Medicine, 352, 2477-2486, 2005	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
de Veciana,M., Major,C.A., Morgan,M.A., Asrat,T., Toohey,J.S., Lien,J.M., Evans,A.T., Postprandial versus preprandial blood glucose monitoring in women with gestational diabetes mellitus requiring insulin therapy, New England Journal of MedicineN.Engl.J.Med., 333, 1237-1241, 1995	Does not compare HbA_{1c} monitoring strategies
di Biase,N., Napoli,A., Sabbatini,A., Borrello,E., Buongiorno,A.M., Fallucca,F., Telemedicine in the treatment of diabetic pregnancy, Annali Dell'Istituto Superiore di Sanita, 33, 347-351, 1997	Women in both groups used the same monitoring strategy
Durnwald,C.P., Mele,L., Spong,C.Y., Ramin,S.M., Varner,M.W., Rouse,D.J., Sciscione,A., Catalano,P., Saade,G., Sorokin,Y., Tolosa,J.E., Casey,B., Anderson,G.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network (MFMU), Glycemic characteristics and neonatal outcomes of women treated for mild gestational diabetes, Obstetrics and Gynecology, 117, 819-827, 2011	Does not compare monitoring strategies
Espersen,T., Klebe,J.G., Self-monitoring of blood glucose in pregnant diabetics. A comparative study of	Does not compare HbA_{1c} monitoring strategies

Excluded studies – Review question 13	
the blood glucose level and course of pregnancy in pregnant diabetics on an out-patient regime before and after the introduction of methods for home analysis of blood glucose, Acta Obstetricia et Gynecologica Scandinavica, 64, 11-14, 1985	
Feig,D.S., Cleave,B., Tomlinson,G., Long-term effects of a diabetes and pregnancy program: does the education last?, Diabetes Care, 29, 526-530, 2006	Does not compare monitoring strategies
Garner,P., Okun,N., Keely,E., Wells,G., Perkins,S., Sylvain,J., Belcher,J., A randomized controlled trial of strict glycemic control and tertiary level obstetric care versus routine obstetric care in the management of gestational diabetes: a pilot study, American Journal of Obstetrics and GynecologyAm J Obstet Gynecol, 177, 190-195, 1997	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Glinianaia,S.V., Tennant,P.W.G., Bilous,R.W., Rankin,J., Bell,R., HbA_{1c} and birthweight in women with pre-conception type 1 and type 2 diabetes: A population-based cohort study, Diabetologia, 55, 3193-3203, 2012	Non-comparative study
Goldberg,J.D., Franklin,B., Lasser,D., Jornsay,D.L., Hausknecht,R.U., Ginsberg-Fellner,F., Berkowitz,R.L., Gestational diabetes: impact of home glucose monitoring on neonatal birth weight, American Journal of Obstetrics and Gynecology, 154, 546-550, 1986	Does not compare HbA_{1c} monitoring strategies
Gutaj,P., Zawiejska,A., Wender-Ozegowska,E., Brazert,J., Maternal factors predictive of firsttrimester pregnancy loss in women with pregestational diabetes, Polskie Archiwum Medycyny Wewnetrznej, 123, 21-28, 2013	Does not compare monitoring strategies
Hanson,U., Persson,B., Enochsson,E., Lennerhagen,P., Lindgren,F., Lundstrom,V., Lunell,N.O., Nilsson,B.A., Nilsson,L., Stangenberg,M., Self-monitoring of blood glucose by diabetic women during the third trimester of pregnancy, American Journal of Obstetrics and GynecologyAm J Obstet Gynecol, 150, 817-821, 1984	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Hawkins,J.S., Casey,B.M., Lo,J.Y., Moss,K., McIntire,D.D., Leveno,K.J., Weekly compared with daily blood glucose monitoring in women with diet-treated gestational diabetes, Obstetrics and Gynecology, 113, 1307-1312, 2009	Does not compare HbA_{1c} monitoring strategies
Hiramatsu,Y., Shimizu,I., Omori,Y., Nakabayashi,M., JGA (Japan Glycated Albumin) Study Group., Determination of reference intervals of glycated albumin and hemoglobin A_{1c} in healthy pregnant Japanese women and analysis of their time courses and influencing factors during pregnancy, Endocrine Journal, 59, 145-151, 2012	Does not compare monitoring strategies
Inkster,M.E., Fahey,T.P., Donnan,P.T., Leese,G.P., Mires,G.J., Murphy,D.J., Poor glycated haemoglobin control and adverse pregnancy outcomes in type 1 and type 2 diabetes mellitus: systematic review of observational studies, BMC Pregnancy and Childbirth, 6, 30-, 2006	Does not compare monitoring strategies

Excluded studies – Review question 13	
Jovanovic,L., The role of continuous glucose monitoring in gestational diabetes mellitus, Diabetes Technology and Therapeutics, 2 Suppl 1, S67-S71, 2000	Not relevant to this question - considered for inclusion in the continuous blood glucose monitoring review
Jovanovic,L., Peterson,C.M., Saxena,B.B., Dawood,M.Y., Saudek,C.D., Feasibility of maintaining normal glucose profiles in insulin-dependent pregnant diabetic women, American Journal of Medicine, 68, 105-112, 1980	Non-comparative study
Jovanovic,L., Savas,H., Mehta,M., Trujillo,A., Pettitt,D.J., Frequent monitoring of A_{1C} during pregnancy as a treatment tool to guide therapy, Diabetes Care, 34, 53-54, 2011	Non-comparative study
Jovanovic,L.G., Using meal-based self-monitoring of blood glucose as a tool to improve outcomes in pregnancy complicated by diabetes. [25 refs], Endocrine Practice, 14, 239-247, 2008	Narrative review with no new data
Kerssen,A., De Valk,H.W., Visser,G.H., Do HbA(1)c levels and the self-monitoring of blood glucose levels adequately reflect glycaemic control during pregnancy in women with type 1 diabetes mellitus?, Diabetologia, 49, 25-28, 2006	Not relevant to this question - comparison of continuous glucose monitoring and intermittent monitoring
Kong,G.W., Tam,W.H., Chan,M.H., So,W.Y., Lam,C.W., Yiu,I.P., Loo,K.M., Li,C.Y., Comparison in the performance of glucose meters in blood glucose monitoring during pregnancy, Gynecologic and Obstetric Investigation, 69, 264-269, 2010	Compares different types of meters. Does not compare monitoring strategies
Laird,J., McFarland,K.F., Fasting blood glucose levels and initiation of insulin therapy in gestational diabetes, Endocrine Practice, 2, 330-332, 1996	Does not compare monitoring strategies
Landon,M.B., Spong,C.Y., Thom,E., Carpenter,M.W., Ramin,S.M., Casey,B., Wapner,R.J., Varner,M.W., Rouse,D.J., Thorp,J.M.,Jr., Sciscione,A., Catalano,P., Harper,M., Saade,G., Lain,K.Y., Sorokin,Y., Peaceman,A.M., Tolosa,J.E., Anderson,G.B., Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-fetal Medicine Units Network., A multicenter, randomized trial of treatment for mild gestational diabetes, New England Journal of Medicine, 361, 1339-1348, 2009	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Langer,O., Rodriguez,D.A., Xenakis,E.M., McFarland,M.B., Berkus,M.D., Arrendondo,F., Intensified versus conventional management of gestational diabetes, American Journal of Obstetrics and Gynecology, 170, 1036-1046, 1994	Does not compare HbA_{1c} monitoring strategies
Manderson,J.G., Patterson,C.C., Hadden,D.R., Traub,A.I., Ennis,C., McCance,D.R., Preprandial versus postprandial blood glucose monitoring in type 1 diabetic pregnancy: a randomized controlled clinical trial, American Journal of Obstetrics and Gynecology, 189, 507-512, 2003	Does not compare HbA_{1c} monitoring strategies
Middleton,Philippa, Crowther,Caroline A., Simmonds,Lucy, Different intensities of glycaemic control for pregnant women with pre-existing diabetes, Cochrane Database of Systematic Reviews, -, 2012	Does not compare monitoring strategies

Excluded studies – Review question 13	
Moy,Ming Foong, Ray,Amita, Buckley,Brian S., Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes, Cochrane Database of Systematic Reviews, -, 2012	Protocol only
Peacock,I., Hunter,J.C., Walford,S., Allison,S.P., Davison,J., Clarke,P., Symonds,E.M., Tattersall,R.B., Self-monitoring of blood glucose in diabetic pregnancy, British Medical Journal, 2, 1333-1336, 1979	Does not compare monitoring strategies
Pelaez-Crisologo,Ma, Castillo-Torralba,M.G.A.G., Festin,M.R., Different techniques of blood glucose monitoring in women with gestational diabetes for improving maternal and infant health, Cochrane Database of Systematic Reviews, 2009. Article Number, -, 2009	Protocol only
Rackham,O., Paize,F., Weindling,A.M., Cause of death in infants of women with pregestational diabetes mellitus and the relationship with glycemic control, Postgraduate Medicine, 121, 26-32, 2009	Does not compare monitoring strategies
Sturrock,N.D., Fay,T.N., Pound,N., Kirk,B.A., Danks,L.E., Analysis of 44,279 blood glucose estimations in relation to outcomes in 80 pregnant diabetic women, Journal of Obstetrics and Gynaecology, 21, 253-257, 2001	Does not compare monitoring strategies
Syed,M., Javed,H., Yakoob,M.Y., Bhutta,Z.A., Effect of screening and management of diabetes during pregnancy on stillbirths, BMC Public Health, 11 Suppl 3, S2-, 2011	Does not provide enough detail regarding the included studies. Included studies considered separately for inclusion in the NCC review.
Wechter,D.J., Kaufmann,R.C., Amankwah,K.S., Rightmire,D.A., Eardley,S.P., Verhulst,S., Zinzilieta,M., Young,J., Teich,J., Singleton,J.A., Prevention of neonatal macrosomia in gestational diabetes by the use of intensive dietary therapy and home glucose monitoring, American Journal of Perinatology, 8, 131-134, 1991	Does not compare monitoring strategies
Weisz,B., Shrim,A., Homko,C.J., Schiff,E., Epstein,G.S., Sivan,E., One hour versus two hours postprandial glucose measurement in gestational diabetes: a prospective study, Journal of Perinatology, 25, 241-244, 2005	Does not compare HbA_{1c} monitoring strategies
Wilson,N., Ashawesh,K., Kulambil Padinjakara,R.N., Anwar,A., The multidisciplinary diabetes-endocrinology clinic and postprandial blood glucose monitoring in the management of gestational diabetes: impact on maternal and neonatal outcomes, Experimental and Clinical Endocrinology and Diabetes, 117, 486-489, 2009	Not clear which monitoring strategy/ies the 1 hour postprandial measurement is compared to
Wong,M.L., Butson,S., Gatling,W., Masding,M.G., The management of women with gestational diabetes can be stratified according to diagnostic oral glucose tolerance test results, Practical Diabetes International, 25, 61-63, 2008	Monitoring is compared as part of a larger package of care - it is not possible to determine the effects of monitoring alone
Yogev,Y., Chen,R., Ben-Haroush,A., Phillip,M., Jovanovic,L., Hod,M., Continuous glucose monitoring for the evaluation of gravid women with type 1 diabetes mellitus, Obstetrics and Gynecology, 101, 633-638, 2003	Not relevant to this question. Comparison of continuous glucose monitoring and intermittent monitoring

Excluded studies – Review question 13	
Young,B.C., Ecker,J.L., Fetal macrosomia and shoulder dystocia in women with gestational diabetes: Risks amenable to treatment?, Current Diabetes Reports, 13, 12-18, 2013	Narrative review. No new data.

G.13 Antenatal HbA_{1c} targets

Excluded studies – Review question 14	
Study	Reason for Exclusion
Anderberg,E., Kallen,K., Berntorp,K., The impact of gestational diabetes mellitus on pregnancy outcome comparing different cut-off criteria for abnormal glucose tolerance, Acta Obstetricia et Gynecologica Scandinavica, 89, 1532-1537, 2010	Blood glucose data only
Arumugam,K., Abdul,Majeed N., Glycated haemoglobin is a good predictor of neonatal hypoglycaemia in pregnancies complicated by diabetes, Malaysian Journal of Pathology, 33, 21-24, 2011	Women were not given pre-specified targets for HbA_{1c} - ROC analysis was used to determine risk for different HbA_{1c} values. No effect size was calculable – only sensitivity and specificity were presented for each HbA_{1c} value.
Aschwald,C.L., Catanzaro,R.B., Weiss,E.P., Gavard,J.A., Steitz,K.A., Mostello,D.J., Large-for-gestational-age infants of type 1 diabetic mothers: an effect of preprandial hyperglycemia?, Gynecological Endocrinology, 25, 653-660, 2009	Outcome not reported in relation to targets set for HbA_{1c}. Results are presented according to the percentage of women with blood glucose above the target which accurately predicts the outcome (macrosomia).
Balsells,M., Garcia-Patterson,A., Gich,I., Corcoy,R., Maternal and fetal outcome in women with type 2 versus type 1 diabetes mellitus: a systematic review and metaanalysis. [53 refs], Journal of Clinical Endocrinology and Metabolism, 94, 4284-4291, 2009	Compares outcomes in type 1 diabetes versus type 2 diabetes and not according to HbA_{1c} target values.
Carmody,D., Doyle,A., Firth,R.G., Byrne,M.M., Daly,S., Mc,Auliffe F., Foley,M., Coulter-Smith,S., Kinsley,B.T., Teenage pregnancy in type 1 diabetes mellitus, Pediatric Diabetes, 11, 111-115, 2010	No threshold analysis; outcomes not assessed in relation to HbA_{1c} levels. Mean HbA_{1c} only. Comparison is between teenagers and adults.
Cohen,O., Keidar,N., Simchen,M., Weisz,B., Dolitsky,M., Sivan,E., Macrosomia in well controlled CSII treated Type I diabetic pregnancy, Gynecological Endocrinology, 24, 611-613, 2008	No targets; outcomes not analysed by HbA_{1c} level/threshold - mean HbA_{1c} values only. Study is correlational.
Combs,C.A., Gunderson,E., Kitzmiller,J.L., Gavin,L.A., Main,E.K., Relationship of fetal macrosomia to maternal postprandial glucose control during pregnancy., Diabetes Care, 15, 1251-1257, 1992	No specified HbA_{1c} targets - mean HbA_{1c} values only.
Cyganek,K., Hebda-Szydlo,A., Katra,B., Skupien,J., Klupa,T., Janas,I., Kaim,I., Sieradzki,J., Reron,A., Malecki,M.T., Glycemic control and selected pregnancy outcomes in type 1 diabetes women on continuous subcutaneous insulin infusion and multiple daily injections: the significance of pregnancy planning, Diabetes Technology and Therapeutics, 12, 41-47, 2010	No specified HbA_{1c} targets; no threshold analysis mean HbA_{1c} values only in planned vs. unplanned pregnancies.

Excluded studies – Review question 14	
Dalfra,M.G., Sartore,G., Di,Cianni G., Mello,G., Lencioni,C., Ottanelli,S., Sposato,J., Valgimigli,F., Scuffi,C., Scalese,M., Lapolla,A., Glucose variability in diabetic pregnancy, Diabetes Technology and Therapeutics, 13, 853-859, 2011	No threshold analysis; mostly blood glucose data. Mean HbA_{1c} only. Most comparisons are for type 1 versus gestational diabetes versus controls.
Damm,P., Mersebach,H., Rastam,J., Kaaja,R., Hod,M., McCance,D.R., Mathiesen,E.R., Poor pregnancy outcome in women with type 1 diabetes is predicted by elevated HbA_{1c} and spikes of high glucose values in the third trimester, Journal of Maternal-Fetal and Neonatal Medicine, 27, 149-154, 2014	Data for the % of LGA births by HbA_{1c} category is presented. The total number of LGA births (n = 88) is reported however it is not possible to calculate how many non-LGA births occurred in each HbA_{1c} category therefore RRs are not calculable.
de Veciana,M., Major,C.A., Morgan,M.A., Asrat,T., Toohey,J.S., Lien,J.M., Evans,A.T., Postprandial versus preprandial blood glucose monitoring in women with gestational diabetes mellitus requiring insulin therapy, New England Journal of MedicineN.Engl.J.Med., 333, 1237-1241, 1995	No specified HbA_{1c} targets; outcomes not analysed according to HbA_{1c} levels. Comparison is pre- versus post-prandial monitoring.
Diabetes and Pregnancy Group,France, French multicentric survey of outcome of pregnancy in women with pregestational diabetes, Diabetes Care, 26, 2990-2993, 2003	HbA_{1c} represents pre-pregnancy glycaemic control.
Dicker,D., Feldberg,D., Samuel,N., Yeshaya,A., Karp,M., Goldman,J.A., Spontaneous abortion in patients with insulin-dependent diabetes mellitus: the effect of preconceptional diabetic control, American Journal of Obstetrics and Gynecology, 158, 1161-1164, 1988	No specified HbA_{1c} targets or thresholds - mean HbA_{1c} values per trimester only for abortion versus pregnancy > 22 weeks' gestation.
Evers,I.M., De Valk,H.W., Mol,B.W.J., Ter Braak,E.W.M.T., Visser,G.H.A., Macrosomia despite good glycaemic control in Type I diabetic pregnancy; results of a nationwide study in The Netherlands, Diabetologia, 45, 1484-1489, 2002	No specific targets given; outcome reported as mean HbA_{1c} levels in macrosomia vs. no macrosomia
Glinianaia,S.V., Tennant,P.W.G., Bilous,R.W., Rankin,J., Bell,R., HbA_{1c} and birthweight in women with pre-conception type 1 and type 2 diabetes: A population-based cohort study, Diabetologia, 55, 3193-3203, 2012	No targets given. Threshold analysis is based on regression with only coefficients presented. Odds ratios for above/below an HbA_{1c} of 7% are presented for LGA risk but in relation to the interaction between peri-conception HbA_{1c} and during the third trimester. Shows an increased risk of LGA for HbA_{1c} increasing during pregnancy.
Greene,M.F., Hare,J.W., Cloherty,J.P., Benacerraf,B.R., Soeldner,J.S., First-trimester hemoglobin A1 and risk for major malformation and spontaneous abortion in diabetic pregnancy.[see comment], Teratology, 39, 225-231, 1989	No relevant outcomes reported
Gutaj,P., Zawiejska,A., Wender-Ozegowska,E., Brazert,J., Maternal factors predictive of firsttrimester pregnancy loss in women with pregestational diabetes, Polskie Archiwum Medycyny Wewnetrznej, 123, 21-28, 2013	No specified HbA_{1c} targets; no threshold analysis. Mean HbA_{1c} only in miscarriage versus no miscarriage. Outcome not relevant to protocol.
Holmes,V.A., Young,I.S., Patterson,C.C., Pearson,D.W., Walker,J.D., Maresh,M.J., McCance,D.R., Diabetes and Pre-eclampsia Intervention Trial Study Group., Optimal glycemic control, pre-eclampsia, and gestational hypertension in women with type 1 diabetes in the diabetes and pre-eclampsia intervention trial, Diabetes Care, 34, 1683-1688, 2011	Results were presented in four categories as ORs for each group vs. the reference group of optimal control (OR = 1). No single threshold for HbA_{1c} was presented and dichotomisation could not be

Excluded studies – Review question 14	
	applied. Numbers of events were not reported for each category.
Inkster,M.E., Fahey,T.P., Donnan,P.T., Leese,G.P., Mires,G.J., Murphy,D.J., Poor glycated haemoglobin control and adverse pregnancy outcomes in type 1 and type 2 diabetes mellitus: systematic review of observational studies, BMC Pregnancy and Childbirth, 6, 30-, 2006	Systematic review-; one relevant study (Vaarasmaki) obtained for further analysis. Other studies did not report relevant outcomes relevant to the protocol.
Jensen,D.M., Damm,P., Moelsted-Pedersen,L., Ovesen,P., Westergaard,J.G., Moeller,M., Beck-Nielsen,H., Outcomes in type 1 diabetic pregnancies: a nationwide, population-based study, Diabetes Care, 27, 2819-2823, 2004	No specified HbA_{1c} targets; no threshold analysis. Mean HbA_{1c} for serious outcome versus no serious outcome.
Jovanovic,L., Druzin,M., Peterson,C.M., Effect of euglycemia on the outcome of pregnancy in insulin-dependent diabetic women as compared with normal control subjects, American Journal of Medicine, 71, 921-927, 1981	No specified HbA_{1c} targets or thresholds given. Comparator group is non-diabetic women. Initially this study was a trial of urine versus blood glucose monitoring which was stopped early due to ethics.
Jovanovic,L., Savas,H., Mehta,M., Trujillo,A., Pettitt,D.J., Frequent monitoring of A_{1C} during pregnancy as a treatment tool to guide therapy, Diabetes Care, 34, 53-54, 2011	Monitoring data only
Jovanovic-Peterson,L., Peterson,C.M., Reed,G.F., Metzger,B.E., Mills,J.L., Knopp,R.H., Aarons,J.H., Maternal postprandial glucose levels and infant birth weight: the Diabetes in Early Pregnancy Study. The National Institute of Child Health and Human Development--Diabetes in Early Pregnancy Study, American Journal of Obstetrics and Gynecology, 164, 103-111, 1991	No specified HbA_{1c} targets – mean HbA_{1c} values only per trimester. Comparator group is non-diabetic women.
Klinke,J., Toth,E.L., Preconception care for women with type 1 diabetes, Canadian Family PhysicianCan.Fam.Physician, 49, 769-773, 2003	Systematic review with no data provided.
Lisowski,L.A., Verheijen,P.M., Copel,J.A., Kleinman,C.S., Wassink,S., Visser,G.H., Meijboom,E.J., Congenital heart disease in pregnancies complicated by maternal diabetes mellitus. An international clinical collaboration, literature review, and meta-analysis. [64 refs], Herz, 35, 19-26, 2010	No targets/threshold analysis; no relevant outcomes reported (congenital malformations only).
Lucas,M.J., Leveno,K.J., Williams,M.L., Raskin,P., Whalley,P.J., Early pregnancy glycosylated hemoglobin, severity of diabetes, and fetal malformations, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 161, 426-431, 1989	No relevant outcomes reported
Manderson,J.G., Patterson,C.C., Hadden,D.R., Traub,A.I., Ennis,C., McCance,D.R., Preprandial versus postprandial blood glucose monitoring in type 1 diabetic pregnancy: a randomized controlled clinical trial, American Journal of Obstetrics and Gynecology, 189, 507-512, 2003	No specified HbA_{1c} targets; randomisation to monitoring not targets
Miller,E., Hare,J.W., Cloherty,J.P., Dunn,P.J., Gleason,R.E., Soeldner,J.S., Kitzmiller,J.L., Elevated maternal hemoglobin A_{1c} in early pregnancy and major congenital anomalies in infants of diabetic mothers, New England Journal of MedicineN.Engl.J.Med., 304, 1331-1334, 1981	No relevant outcomes reported
Mills,J.L., Simpson,J.L., Driscoll,S.G., Jovanovic-Peterson,L., Van,Allen M., Aarons,J.H., Metzger,B., Bieber,F.R., Knopp,R.H., Holmes,L.B., Incidence of spontaneous abortion among normal women and insulin-dependent diabetic women whose pregnancies were identified within 21 days of	Not HbA_{1c} - HbA1a1; also no targets specified. Mean HbA1a1 in diabetic versus non-diabetic women.

Excluded studies – Review question 14	
conception, New England Journal of MedicineN.Engl.J.Med., 319, 1617-1623, 1988	
Miodovnik,M., Mimouni,F., Tsang,R.C., Ammar,E., Kaplan,L., Siddiqi,T.A., Glycemic control and spontaneous abortion in insulin-dependent diabetic women, Obstetrics and GynecologyObstet.Gynecol., 68, 366-369, 1986	Mean HbA1 values for preterm labour - outcome not relevant to protocol.
Miodovnik,M., Skillman,C., Holroyde,J.C., Butler,J.B., Wendel,J.S., Siddiqi,T.A., Elevated maternal glycohemoglobin in early pregnancy and spontaneous abortion among insulin-dependent diabetic women, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 153, 439-442, 1985	No relevant outcomes reported; no targets set; threshold analysis uses clinically irrelevant value of 12%
Miodovnik,M., Mimouni,F., Siddiqi,T.A., Berk,M.A., Wittekind,C., High spontaneous premature labour rate in insulin-dependent diabetic women: An association with poor glycaemic control, Obstet Gynecol., 72:175, 1988	Mean HbA1 values for preterm labour - outcome not relevant to protocol.
Nielsen,G.L., Moller,M., Sorensen,H.T., HbA_{1c} in early diabetic pregnancy and pregnancy outcomes: A Danish population-based cohort study of 573 pregnancies in women with type 1 diabetes, Diabetes Care, 29, 2612-2616, 2006	All outcomes are grouped together as good or adverse in comparative analyses.
Rackham,O., Paize,F., Weindling,A.M., Cause of death in infants of women with pregestational diabetes mellitus and the relationship with glycemic control, Postgraduate Medicine, 121, 26-32, 2009	No threshold analysis; polynomial regressions only for infant death. Comparison for most outcomes is type 1 versus type 2 diabetes.
Rosenn,B., Minor congenital malformations in infants of insulin-diabetic women: association with poor glycaemic control., Obstetrics and GynecologyObstet.Gynecol., 76, 745-749, 1990	Blood glucose targets only; mean HbA_{1c} only for congenital malformation versus no malformation.
Rosenn,B., Miodovnik,M., Combs,C.A., Khoury,J., Siddiqi,T.A., Glycemic thresholds for spontaneous abortion and congenital malformations in insulin-dependent diabetes mellitus, Obstetrics and GynecologyObstet.Gynecol., 84, 515-520, 1994	No specified HbA_{1c} targets - ROC analysis of mean HbA_{1c} values to obtain thresholds for increased risk of malformations. Outcome not relevant to protocol.
Rowan,J.A., Gao,W., Hague,W.M., McIntyre,H.D., Glycemia and its relationship to outcomes in the metformin in gestational diabetes trial, Diabetes Care, 33, 9-16, 2010	No specified HbA_{1c} targets; HbA_{1c} at baseline only
Starikov,R.S., Inman,K., Chien,E.K., Anderson,B.L., Rouse,D.J., Lopes,V., Coustan,D.R., Can hemoglobin A_{1c} in early pregnancy predict adverse pregnancy outcomes in diabetic patients?, Journal of Diabetes and its Complications, 28, 203-207, 2014	Women were not given pre-specified targets for HbA_{1c}
Sturrock,N.D., Fay,T.N., Pound,N., Kirk,B.A., Danks,L.E., Analysis of 44,279 blood glucose estimations in relation to outcomes in 80 pregnant diabetic women, Journal of Obstetrics and Gynaecology, 21, 253-257, 2001	No specified HbA_{1c} targets or thresholds. No comparative data - correlational for HbA_{1c} with respect to birth weight.
Suhonen,L., Hiilesmaa,V., Teramo,K., Glycaemic control during early pregnancy and fetal malformations in women with type I diabetes mellitus, Diabetologia, 43, 79-82, 2000	No relevant outcomes reported
Wyse,L.J., Jones,M., Mandel,F., Relationship of glycosylated hemoglobin, fetal macrosomia, and birthweight macrosomia, American Journal of Perinatology, 11, 260-262, 1994	No specified HbA_{1c} targets used in analysis. HbA_{1c} value of 6.3% is reported with respect to ultrasound markers only not the per cent of large for gestational age babies.
Ylinen,K., Aula,P., Stenman,U.H., Kesaniemi-Kuokkanen,T., Teramo,K., Risk of minor and major fetal malformations in	No relevant outcomes reported

Excluded studies – Review question 14	
diabetics with high haemoglobin A_{1c} values in early pregnancy, British Medical JournalBMJ, 289, 345-346, 1984	

G.14 Antenatal continuous glucose monitoring

Excluded studies – Review question 15	Reason for Exclusion
Cao,X., Wang,Z., Yang,C., Mo,X., Xiu,L., Li,Y., Xiao,H., Comprehensive intensive therapy for Chinese gestational diabetes benefits both newborns and mothers, Diabetes Technology and Therapeutics, 14, 1002-1007, 2012	Does not compare continuous glucose monitoring with intermittent capillary blood glucose monitoring
Centre for Reviews and Dissemination., The effect of continuous subcutaneous glucose monitoring (CGMS) versus intermittent whole blood finger-stick glucose monitoring (SBGM) on hemoglobin A_{1c} (HbA_{1c}) levels in type 1 diabetic patients: a systematic review (Structured abstract), Database of Abstracts of Reviews of Effects, -, 2013	Structured abstract. Full paper not ordered as women who were pregnant were excluded by the authors.
Centre for Reviews and Dissemination., Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data (Structured abstract), Database of Abstracts of Reviews of Effects, -, 2013	Structured abstract. Full paper ordered separately for consideration.
Centre for Reviews and Dissemination., Monitoring blood glucose control in diabetes mellitus: a systematic review (Structured abstract), Database of Abstracts of Reviews of Effects, -, 2013	Structured abstract. Full paper ordered separately for consideration.
Centre for Reviews and Dissemination., Self-monitoring of blood glucose as part of a multi-component therapy among non-insulin requiring type 2 diabetes patients: a meta-analysis (1966 - 2004) (Structured abstract), Database of Abstracts of Reviews of Effects, -, 2013	Structured abstract. Full paper not ordered as the authors excluded women who were pregnant.
Chen,R., Yogev,Y., Ben-Haroush,A., Jovanovic,L., Hod,M., Phillip,M., Continuous glucose monitoring for the evaluation and improved control of gestational diabetes mellitus, Journal of Maternal-Fetal and Neonatal Medicine, 14, 256-260, 2003	Data for hypoglycaemia are reported with respect to treatment with insulin not us of CGM. No other relevant outcomes are reported.
Coster,S., Gulliford,M.C., Seed,P.T., Powrie,J.K., Swaminathan,R., Monitoring blood glucose control in diabetes mellitus: A systematic review, Health Technology Assessment, 4, i-84, 2000	Published prior to the 2008 guideline
Coster,S., Gulliford,M.C., Seed,P.T., Powrie,J.K., Swaminathan,R., Monitoring blood glucose control in diabetes mellitus: a systematic review (Structured abstract), Health Technology Assessment Database, -, 2013	Structured abstract. Full paper ordered for consideration.
De,Block C., Keenoy,B., Van,Gaal L., A review of current evidence with continuous glucose monitoring in patients with diabetes, Journal of Diabetes Science and Technology, 2, 718-727, 2008	Narrative review with no new data. Cited studies were considered separately for inclusion.

Excluded studies – Review question 15	Reason for Exclusion
Ghio,A., Lencioni,C., Romero,F., A real-time continuous glucose monitoring for diabetic women during the delivery, Diabetologia, 52, S462-, 2009	Abstract only.
Greven,Wendela L., Hoeks,Lette B., de Valk,Harold, Continuous glucose monitoring systems for type 2 diabetes mellitus, Cochrane Database of Systematic Reviews, -, 2010	Cochrane review protocol. Full review not searched for as studies of pregnant women were excluded by the authors.
Hewapathirana,N.M., O'Sullivan,E., Murphy,H.R., Role of continuous glucose monitoring in the management of diabetic pregnancy, Current Diabetes Reports, 13, 34-42, 2013	Narrative review with no new data. Cited studies considered for inclusion.
Jovanovic,L., The role of continuous glucose monitoring in gestational diabetes mellitus, Diabetes Technology and Therapeutics, 2 Suppl 1, S67-S71, 2000	Does not compare intermittent and continuous glucose monitoring
Kerssen,Anneloes, de Valk,Harold W., Visser,Gerard H.A., Day-to-day glucose variability during pregnancy in women with Type 1 diabetes mellitus: glucose profiles measured with the Continuous Glucose Monitoring System, BJOG : an international journal of obstetrics and gynaecologyBJOG, 111, 919-924, 2004	No relevant outcomes.
Kitzmiller,J.L., Block,J.M., Brown,F.M., Catalano,P.M., Conway,D.L., Coustan,D.R., Gunderson,E.P., Herman,W.H., Hoffman,L.D., Inturrisi,M., Jovanovic,L.B., Kjos,S.I., Knopp,R.H., Montoro,M.N., Ogata,E.S., Paramsothy,P., Reader,D.M., Rosenn,B.M., Thomas,A.M., Kirkman,M.S., Managing preexisting diabetes for pregnancy: summary of evidence and consensus recommendations for care, Diabetes Care, 31, 1060-1079, 2008	Consensus paper with no new data
Langendam,M., Luijf,Y.M., Hooft,L., Devries,J.H., Mudde,A.H., Scholten,R.J., Continuous glucose monitoring systems for type 1 diabetes mellitus, Cochrane Database of Systematic Reviews, 1, CD008101-, 2012	None of the included studies reported on women who were pregnant
Lee-Parritz,A., New technologies for the management of pregestational diabetes mellitus, Obstetrical and Gynecological Survey, 67, 167-175, 2012	Narrative review. Cited studies considered for inclusion separately.
McLachlan,Kylie, Jenkins,Alicia, O'Neal,David, The role of continuous glucose monitoring in clinical decision-making in diabetes in pregnancy, Australian and New Zealand Journal of Obstetrics and Gynaecology, , 186-190, 2007	Does not compare continuous glucose monitoring with intermittent capillary blood glucose monitoring
Moy,Ming Foong, Ray,Amita, Buckley,Brian S., Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes, Cochrane Database of Systematic Reviews, -, 2012	Protocol rather than a full review. Cochrane Pregnancy and Childbirth group report this review is progressing slowly. Publication date of the full review is unknown.
Moy,F.M., Ray,A., Buckley,B.S., Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes, Cochrane Database of Systematic Reviews, 4, CD009613-, 2014	Systematic review. Studies checked for eligibility for this review
Murphy,H.R., Raynian,G., Lewis,K., Kelly,S., Johal,B., Duffield,K., Fowler,D., Campbell,P.J., Temple,R.C., Effectiveness of continuous glucose monitoring in pregnant women with diabetes: Randomized clinical trial, Obstetrical and Gynecological Survey, 64, 216-218, 2009	Abstract. Full paper ordered for consideration.
PelaezCrisologo,Cristina Ma, CastilloTorralba,Geraldine Maria, Festin,Mario R., Different techniques of blood glucose monitoring in women with gestational diabetes for improving	Protocol rather than a full review. Cochrane Pregnancy and Childbirth group report this review

Excluded studies – Review question 15	Reason for Exclusion
maternal and infant health, Cochrane Database of Systematic Reviews, -, 2009	has stalled and likely to be withdrawn from the Cochrane library.
Pickup,J.C., Freeman,S.C., Sutton,A.J., Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data, BMJ, 343, d3805-, 2011	Excluded studies of pregnant women
Purins,A., Hiller,J.E., Continuous glucose monitoring in pregnant women with diabetes, Adelaide Health Technology Assessment (AHTA) on behalf of National Horizon Scanning Unit (HealthPACT and MSAC), -, 2009	Review with no new data. Individual study references considered separately for inclusion.
Purins,A., Hiller,J.E., Continuous glucose monitoring in pregnant women with diabetes (Structured abstract), Health Technology Assessment Database, -, 2013	Structured abstract. Full paper ordered for consideration.
Secher,A.L., Ringholm,L., Andersen,H.U., Damm,P., Mathiesen,E.R., The effect of real-time continuous glucose monitoring in pregnant women with diabetes: a randomized controlled trial, Diabetes Care, 36, 1877-1883, 2013	Duplicate of Secher study already included in this review.
Secher,A.L., Stage,E., Ringholm,L., Barfred,C., Damm,P., Mathiesen,E.R., Real-time continuous glucose monitoring as a tool to prevent severe hypoglycaemia in selected pregnant women with Type 1 diabetes - an observational study, Diabetic Medicine, 31, 352-356, 2014	Study design is observational not an RCT. The protocol specifies that non-randomised studies will only be included if RCTs are not available. All other studies included in the review are RCTs therefore this study is not eligible for inclusion.
Voormolen,D.N., DeVries,J.H., Evers,I.M., Mol,B.W., Franx,A., The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review, Obstetrical and Gynecological Survey, 68, 753-763, 2013	Systematic review. Studies checked for inclusion: 4 previously included, 2 previously weeded out, one previously excluded, 3 new papers were requested and subsequently excluded (Chen, Kerssen, Ghio).
Voormolen,D.N., Devries,J.H., Franx,A., Mol,B.W., Evers,I.M., Effectiveness of continuous glucose monitoring during diabetic pregnancy (GlucoMOMS trial); a randomised controlled trial, BMC Pregnancy and Childbirth, 12, 164-, 2012	Protocol for a future trial - no data reported

G.15 Antenatal specialist teams

Excluded studies – Review question 16	
Study	Reason for Exclusion

Excluded studies – Review question 16	
Anderberg,E., Berntorp,K., Crang-Svalenius,E., Diabetes and pregnancy: women's opinions about the care provided during the childbearing year, Scandinavian Journal of Caring Sciences, 23, 161-170, 2009	Does not compare opinions for different types/models of care
Carvalheiro,M., Diabetes in pregnancy: state of the art in the Mediterranean countries, Portugal, Annali Dell'Istituto Superiore di Sanita, 33, 303-306, 1997	Does not compare different types/models of care
Dunne,F.P., Audit of the recommendations of care for pregnant women with diabetes mellitus in the West Midlands, UK, Practical Diabetes International, 15, 230-232, 1998	Does not compare outcomes from different types/models of care
Dunne,F.P., Avalos,G., Durkan,M., Mitchell,Y., Gallacher,T., Keenan,M., Hogan,M., Carmody,L.A., Gaffney,G., TLANTIC,D.I.P., ATLANTIC DIP: pregnancy outcomes for women with type 1 and type 2 diabetes, Irish Medical Journal, 105, 6-9, 2012	Study compares pregnant women with diabetes to the background pregnant population. Some data and information from this study is relevant to an included study, and has been extracted and flagged where used.
Finlay,A., Heddle,M., Hundley,V., Mowat,L., Lang,G., Pearson,D., Research. Continuity of carer during pregnancy for diabetic women, British Journal of Midwifery, 8, 207-214, 2000	Does not compare types of specialist care in pregnant women with diabetes
Fox,R., Watson,J., Close,C., Evans,K., Moran,S., Integrated care pathway for diabetes in pregnancy, Journal of Integrated Care Pathways, 8, 27-40, 2004	Does not compare types of care
Gayle,C., Germain,S., Marsh,M.S., Rajasingham,D., Brackenridge,A., Carroll,P., Amiel,S.A., Thomas,S., Comparing pregnancy outcomes for intensive versus routine antenatal treatment of gestational diabetes based on a 75gram oral glucose tolerance test 2-hour blood glucose 7.8 - 8.9mmol/l, Diabetologia, 53, S435-, 2010	Abstract - full paper not available
Gayle,C., Germain,S., Marsh,M.S., Rajasingham,D., Carroll,P., Brackenridge,A., Amiel,S.A., Thomas,S., Management of gestational diabetes using the World Health Organisation (WHO) criteria in a diabetes antenatal clinic benefit women compared to routine care based on European Association for the Study of Diabetes (EASD) criteria. A comparison of treatment based on an oral glucose tolerance test 2-hour blood glucose 7.8 - 8.9 mmol/l, Diabetic Medicine, 27, 35-, 2010	Abstract - full paper not available
Harris,G.D., White,R.D., Diabetes management and exercise in pregnant patients with diabetes, Clinical Diabetes, 23, 165-168, 2005	Narrative review. Does not compare types of care.
Hjelm,K., Berntorp,K., Frid,A., Aberg,A., Apelqvist,J., Beliefs about health and illness in women managed for gestational diabetes in two organisations, Midwifery, 24, 168-182, 2008	Does not report outcomes of interest to the GDG - qualitative study of women's beliefs about health and illness
Kavvoura,F.K., Graham,D., Crowley,R., Simpson,H., Street,P., Elsheikh,M., Diabetes antenatal care at a large district general hospital: An audit from 1997 to 2010, Diabetic Medicine, 29, 153-, 2012	Abstract - full paper not available
Mills,L.S., Naylor,G., Developing diabetes in pregnancy, the clinical demands increase: Working in new and novel ways, Diabetic Medicine, 27, 168-, 2010	Abstract - full paper not available
Owens,L., Avalos,G., Dunne,F., Atlantic dip-closing the loop: A change in clinical practice can improve outcomes	Conference abstract. Full paper (Owens, 2012) considered separately for inclusion.

Excluded studies – Review question 16	
in pregestational diabetes mellitus, Irish Journal of Medical Science, 181, S356-, 2012	
Owens,L.A., Avalos,G., Carmody,L., Dunne,F., Dip,A., Atlantic dip-closing the loop: A change in clinical practice can improve outcomes for women with pre-gestational diabetes mellitus, Diabetes, 61, A338-, 2012	Conference abstract. Full paper considered separately for inclusion (Owens, 2012).
Owens,Lisa A., Avalos,Gloria, Kirwan,Breda, Carmody,Louise, Dunne,Fidelma, ATLANTIC DIP: Closing the Loop: A change in clinical practice can improve outcomes for women with pregestational diabetes, Diabetes Care, 35, 1669-1671, 2012	Same study reported in Owens (2012) with more detail, which is included in the guideline review
Ridout,J., Roberts,C., Cox,K., Gable,D., Triage of referrals in the first six months of a fully integrated community intermediate care service for Type 2 diabetes: The westminster diabetes partnership, Diabetic Medicine, 26, 198-, 2009	Does not report outcomes when comparing types of care. Abstract.
Steel,J.M., Johnstone,F.D., Hepburn,D.A., Smith,A.F., Can prepregnancy care of diabetic women reduce the risk of abnormal babies?, BMJ, 301, 1070-1074, 1990	Comparison of pre-pregnancy advice, not care during pregnancy
Stenhouse,E., Letherby,G., Stephen,N., Being a pregnant woman with diabetes: Managing the process, Diabetic Medicine, 27, 171-, 2010	Abstract - full paper not available
Stenhouse,E., Millward,A., Wylie,J., An exploration of infant feeding choices for qwomen whose pregnancy is complicated by gestational diabetes, Diabetic Medicine, 28, 175-, 2011	Abstract - full paper not available
Wylie,J., Millward,A., Stenhouse,E., Pregnant women's understanding and knowledge of gestational diabetes and the impact of diagnosis on their pregnancy experience, Diabetic Medicine, 28, 175-, 2011	Abstract - full paper not available
York,R., Brown,L.P., Samuels,P., Finkler,S.A., Jacobsen,B., Persely,C.A., Swank,A., Robbins,D., A randomized trial of early discharge and nurse specialist transitional follow-up care of high-risk childbearing women, Nursing Research, 46, 254-261, 1997	Comparison of different types of care after hospitalisation.

G.16 Timing of birth

Excluded studies: Review question 17	
Study	Reason for Exclusion
Boulvain,Michel, Stan,Catalin M., Irion,Olivier, Elective delivery in diabetic pregnant women, Cochrane Database of Systematic Reviews, -, 2009	Systematic review: checked for relevant studies
Catalano,P.M., Sacks,D.A., Timing of indicated late preterm and early-term birth in chronic medical complications: diabetes, Seminars in Perinatology, 35, 297-301, 2011	Narrative review. No novel data is presented
Coleman,T.L., Randall,H., Graves,W., Lindsay,M., Vaginal birth after cesarean among women with gestational diabetes, American Journal of Obstetrics and GynecologyAm.J.Obstet.Gynecol., 184, 1104-1107, 2001	The outcomes examined for the comparison (of women with and without gestational

Excluded studies: Review question 17	
	diabetes) are not relevant to the protocol
Conway,D.L., Langer,O., Elective delivery of infants with macrosomia in diabetic women: reduced shoulder dystocia versus increased cesarean deliveries, American Journal of Obstetrics and GynecologyAm J Obstet Gynecol, 178, 922-925, 1998	The comparison of caesarean section with induction of labour during elective delivery is not relevant to the protocol
Garabedian,C., Deruelle,P., Delivery (timing, route, peripartum glycemic control) in women with gestational diabetes mellitus, Diabetes and Metabolism, 36, 515-521, 2010	A review performed to inform guideline recommendations: checked for relevant references
Hod,M., Bar,J., Peled,Y., Fried,S., Katz,I., Itzhak,M., Ashkenazi,S., Schindel,B., Ben Rafael,Z., Antepartum management protocol. Timing and mode of delivery in gestational diabetes, Diabetes Care, 21, B113-B117, 1998	A comparison of obstetric management protocols during different time periods is presented and is not relevant to the comparison specified in the protocol(elective delivery versus expectant management)
Hod,Moshe, Merlob,Paul, Friedman,Shmuel, Schoenfeld,Alex, Ovadia,Jardena, Gestational Diabetes Mellitus: A Survey of Perinatal Complications in the 1980s, Diabetes, 40, 74-78, 1991	The outcomes examined for the comparison (of women with and without pre-gestational or gestational diabetes) are not relevant to the protocol
Hod,Moshe, Rabinerson,David, Kaplan,Bari, Peled,Yoav, Bar,Jacob, Shindel,Bella, Merlob,Paul, Ovadia,Jardena, Neri,Alexander, Perinatal complications following gestational diabetes mellitus how âsweetâ is ill?, Acta Obstetricia et Gynecologica ScandinavicaActa Obstet Gynecol Scand, 75, 809-815, 1996	The outcomes examined for the comparison (of women with and without pre-gestational or gestational diabetes) are not relevant to the protocol
Kock,K., Kock,F., Klein,K., Bancher-Todesca,D., Helmer,H., Diabetes mellitus and the risk of preterm birth with regard to the risk of spontaneous preterm birth, Journal of Maternal-Fetal and Neonatal Medicine, 23, 1004-1008, 2010	The outcomes examined for the comparison (of women with and without pre-gestational or gestational diabetes) are not relevant to the protocol
Lopez-de-Andres,A., Carrasco-Garrido,P., Gil-de-Miguel,A., Hernandez-Barrera,V., Jimenez-Garcia,R., Trends in deliveries in women with gestational diabetes in Spain, 2001-2008, Diabetes Research and Clinical Practice, 91, e27-e29, 2011	No comparative data that is relevant to the protocol is presented
Lurie,S., Matzkel,A., Weissman,A., Gotlibe,Z., Friedman,A., Outcome of pregnancy in class A1 and A2 gestational diabetic patients delivered beyond 40 weeks' gestation, American Journal of Perinatology, 9, 484-488, 1992	The comparisons examined (deliveries at <40weeks in women with gestational diabetes and at >40weeks in women with and without gestational diabetes) were not relevant to the protocol
Naylor,C.D., Sermer,M., Chen,E., Sykora,K., Cesarean delivery in relation to birth weight and gestational glucose tolerance. Pathophysiology or practice style?, JAMA: the journal of the American Medical AssociationJAMA, 275, 1165-1170, 1996	The outcomes examined for the comparison (of women with and without gestational diabetes) are not relevant to the protocol
Nicholson,W.K., Wilson,L.M., Witkop,C.T., Baptiste-Roberts,K., Bennett,W.L., Bolen,S., Barone,B.B., Golden,S.H., Gary,T.L., Neale,D.M., Bass,E.B., Therapeutic management, delivery, and postpartum risk assessment and screening in gestational	Systematic review: checked for relevant studies

Excluded studies: Review question 17	
diabetes. [107 refs], Evidence Report/Technology Assessment, 1-96, 2008	
Nordlander,E., Hanson,U., Persson,B., Factors influencing neonatal morbidity in gestational diabetic pregnancy, British journal of obstetrics and gynaecology, 96, 671-678, 1989	The outcomes examined for the comparison (of women with and without gestational diabetes) are not relevant to the protocol
Peled,Y., Perri,T., Chen,R., Pardo,J., Bar,J., Hod,M., Gestational diabetes mellitus--implications of different treatment protocols, Journal of Pediatric Endocrinology, 17, 847-852, 2004	The comparison examined is of obstetric management protocols during different time periods and is not relevant to the protocol(comparison of expectant management versus elective delivery)
Rayburn,W.F., Sokkary,N., Clokey,D.E., Moore,L.E., Curet,L.B., Consequences of routine delivery at 38 weeks for A-2 gestational diabetes, Journal of Maternal-Fetal and Neonatal Medicine, 18, 333-337, 2005	The comparison examined (women with A1 vs A2 gestational diabetes) is not relevant to the protocol
Witkop,C.T., Neale,D., Wilson,L.M., Bass,E.B., Nicholson,W.K., Active compared with expectant delivery management in women with gestational diabetes: a systematic review. [15 refs][Erratum appears in Obstet Gynecol. 2020 Feb;115(2 Pt 1):387], Obstetrics and Gynecology, 113, 206-217, 2009	Systematic review: checked for any relevant studies

G.17 Diagnostic accuracy and timing of postnatal testing

Excluded studies – Review questions 18 and 19	
Study	Reason for Exclusion
Albareda,M., Caballero,A., Badell,G., Rodriguez-Espinosa,J., Ordonez-Llanos,J., de,Leiva A., Corcoy,R., Metabolic syndrome at follow-up in women with and without gestational diabetes mellitus in index pregnancy, Metabolism: Clinical and Experimental, 54, 1115-1121, 2005	National Cholesterol Education Program (NCEP) 2001 criteria - study evaluates the prevalence of fasting glucose >=6.1mmol/l and other metabolic syndrome components in women with gestational diabetes compared to women without gestational diabetes
Ali,Z., Alexis,S.D., Occurrence of diabetes mellitus after gestational diabetes mellitus in Trinidad, Diabetes Care, 13, 527-529, 1990	Pospartum OGTT results assessed by WHO 1980 criteria
Baker,A.M., Brody,S.C., Salisbury,K., Schectman,R., Hartmann,K.E., Postpartum glucose tolerance screening in women with gestational diabetes in the state of North Carolina, North Carolina Medical Journal, 70, 14-19, 2009	No relevant data
Beischer,N.A., Wein,P., Sheedy,M.T., Dargaville,R., Studies of postnatal diabetes mellitus in women who had gestational diabetes. Part 1. Estimation of the prevalence of unrecognized	WHO 1985 criteria used to define postnatal diabetes

Excluded studies – Review questions 18 and 19	
prepregnancy diabetes mellitus, Australian and New Zealand Journal of Obstetrics and Gynaecology, 37, 412-419, 1997	
Benjamin,E., Winters,D., Mayfield,J., Gohdes,D., Diabetes in pregnancy in Zuni Indian women. Prevalence and subsequent development of clinical diabetes after gestational diabetes, Diabetes Care, 16, 1231-1235, 1993	Postnatal diabetes defined by the NDDG criteria
Bennett,W.L., Bolen,S., Wilson,L.M., Bass,E.B., Nicholson,W.K., Performance characteristics of postpartum screening tests for type 2 diabetes mellitus in women with a history of gestational diabetes mellitus: a systematic review. [38 refs], Journal of Women's Health, 18, 979-987, 2009	Review paper - individual studies have been checked for inclusion
Bian,X., Gao,P., Xiong,X., Xu,H., Qian,M., Liu,S., Risk factors for development of diabetes mellitus in women with a history of gestational diabetes mellitus, Chinese Medical Journal, 113, 759-762, 2000	WHO 1985 criteria used to define diabetes
Buchanan,T.A., Xiang,A.H., Kjos,S.L., Trigo,E., Lee,W.P., Peters,R.K., Antepartum predictors of the development of type 2 diabetes in Latino women 11-26 months after pregnancies complicated by gestational diabetes, Diabetes, 48, 2430-2436, 1999	WHO 1985 criteria used to define postnatal diabetes
Bukulmez,O., Durukan,T., Postpartum oral glucose tolerance tests in mothers of macarosomic infants: inadequacy of current antenatal test criteria in detecting prediabetic state, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 86, 29-34, 1999	Article not of relevance for review question
Burt,R.L., Leake,N.H., Oral glucose tolerance test during pregnancy and the early puerperium, Obstetrics and Gynecology, 33, 48-53, 1969	No relevant data
Catalano,P.M., Vargo,K.M., Bernstein,I.M., Amini,S.B., Incidence and risk factors associated with abnormal postpartum glucose tolerance in women with gestational diabetes, American Journal of Obstetrics and Gynecology, 165, 914-919, 1991	Postpartum OGTT results were assessed according to the NDDG criteria (not the same cut-offs as the WHO 1999 criteria)
Cho,N.H., Jang,H.C., Park,H.K., Cho,Y.W., Waist circumference is the key risk factor for diabetes in Korean women with history of gestational diabetes, Diabetes Research and Clinical Practice, 71, 177-183, 2006	Postpartum OGTT results were assessed according to the NDDG criteria
Chodick,G., Elchalal,U., Sella,T., Heymann,A.D., Porath,A., Kokia,E., Shalev,V., The risk of overt diabetes mellitus among women with gestational diabetes: a population-based study, Diabetic Medicine, 27, 779-785, 2010	Subjects underwent 50g glucose challenge tests not OGTT by the WHO criteria
Cocilovo,G., Tomasi,F., Guerra,S., Zampini,A., Cocurullo,A., Risk factors associated with persistence of glucose intolerance one year after gestational diabetes, Diabete et Metabolisme, 16, 187-191, 1990	Postpartum OGTT values were assessed by NDDG criteria
Committee on Obstetric Practice., ACOG Committee Opinion No. 435: postpartum screening for abnormal glucose tolerance in women who had gestational diabetes mellitus, Obstetrics and Gynecology, 113, 1419-1421, 2009	Opinion piece - no relevant data
Coustan,D.R., Carpenter,M.W., O'Sullivan,P.S., Carr,S.R., Gestational diabetes: predictors of subsequent disordered glucose metabolism, American Journal of Obstetrics and Gynecology, 168, 1139-1144, 1993	Criteria used to define postnatal diabetes and IGT similar to the NDDG criteria

Excluded studies – Review questions 18 and 19	
Cypryk,K., Czupryniak,L., Wilczynski,J., Lewinski,A., Diabetes screening after gestational diabetes mellitus: poor performance of fasting plasma glucose, Acta Diabetologica, 41, 5-8, 2004	WHO 1985 criteria used to diagnose gestational diabetes
Dacus,J.V., Meyer,N.L., Muram,D., Stilson,R., Phipps,P., Sibai,B.M., Gestational diabetes: postpartum glucose tolerance testing, American Journal of Obstetrics and Gynecology, 171, 927-931, 1994	Postpartum OGTT results were assessed according to the NDDG criteria (not the same cut-offs as the WHO 1999 criteria)
Dalfra,M.G., Lapolla,A., Masin,M., Giglia,G., Dalla,Barba B., Toniato,R., Fedele,D., Antepartum and early postpartum predictors of type 2 diabetes development in women with gestational diabetes mellitus, Diabetes and Metabolism, 27, 675-680, 2001	WHO 1980 criteria used to define postnatal diabetes
Damm,P., Gestational diabetes mellitus and subsequent development of overt diabetes mellitus. [176 refs], Danish Medical Bulletin, 45, 495-509, 1998	Review paper - individual studies checked for inclusion
Damm,P., Kuhl,C., Bertelsen,A., Molsted-Pedersen,L., Predictive factors for the development of diabetes in women with previous gestational diabetes mellitus, American Journal of Obstetrics and Gynecology, 167, 607-616, 1992	WHO 1985 criteria used to define postnatal diabetes
Dornhorst,A., Bailey,P.C., Anyaoku,V., Elkeles,R.S., Johnston,D.G., Beard,R.W., Abnormalities of glucose tolerance following gestational diabetes, Quarterly Journal of Medicine, 77, 1219-1228, 1990	WHO 1985 criteria used to define postnatal diabetes
Efendic,S., Hanson,U., Persson,B., Wajngot,A., Luft,R., Glucose tolerance, insulin release, and insulin sensitivity in normal-weight women with previous gestational diabetes mellitus, Diabetes, 36, 413-419, 1987	Criteria for postpartum OGTT unclear - study defines results in terms of normal, borderline and decreased OGTT. Cut-offs for these categories do not match the WHO 1999 criteria
Farrell,J., Forrest,J.M., Storey,G.N., Yue,D.K., Shearman,R.P., Turtle,J.R., Gestational diabetes--infant malformations and subsequent maternal glucose tolerance, Australian and New Zealand Journal of Obstetrics and Gynaecology, 26, 11-16, 1986	WHO 1980 criteria used to define postnatal diabetes
Feig,D.S., Zinman,B., Wang,X., Hux,J.E., Risk of development of diabetes mellitus after diagnosis of gestational diabetes.[Erratum appears in CMAJ. 2008 Aug 12;179(4):344], CMAJ Canadian Medical Association Journal, 179, 229-234, 2008	It is unclear whether diabetes was diagnosed on the basis of FPG, OGTT or another method. Also, study does not distinguish between type 1 and 2 diabetes.
Flack,J.R., Payne,T.J., Ross,G.P., Post-partum glucose tolerance assessment in women diagnosed with gestational diabetes: Evidence supporting the need to undertake an oral glucose tolerance test, Diabetic Medicine, 27, 243-244, 2010	Criteria used to assess postpartum OGTT not reported
Fuchtenbusch,M., Ferber,K., Standl,E., Ziegler,A.G., Prediction of type 1 diabetes postpartum in patients with gestational diabetes mellitus by combined islet cell autoantibody screening: a prospective multicenter study, Diabetes, 46, 1459-1467, 1997	Postnatal test results interpreted according to the WHO 1985 criteria
Fuhrmann,K., Targets in oral glucose tolerance testing, Carbohydrate Metabolism in Pregnancy and the Newborn IV, 227-238, 1989	No relevant data: study examines the reproducibility of the 75g OGTT during pregnancy not postnatally
Grant,P.T., Oats,J.N., Beischer,N.A., The long-term follow-up of women with gestational diabetes, Australian and New Zealand Journal of Obstetrics and Gynaecology, 26, 17-22, 1986	WHO 1980 criteria used to define postnatal diabetes

Excluded studies – Review questions 18 and 19	
Greenberg,L.R., Moore,T.R., Murphy,H., Gestational diabetes mellitus: antenatal variables as predictors of postpartum glucose intolerance, Obstetrics and Gynecology, 86, 97-101, 1995	Postpartum OGTT results were assessed according to the NDDG criteria (not the same cut-offs as the WHO 1999 criteria)
Gunderson,E.P., Matias,S.L., Hurston,S.R., Dewey,K.G., Ferrara,A., Quesenberry,C.P.,Jr., Lo,J.C., Sternfeld,B., Selby,J.V., Study of Women, Infant Feeding, and Type 2 diabetes mellitus after GDM pregnancy (SWIFT), a prospective cohort study: methodology and design, BMC Public Health, 11, 952-, 2011	No relevant data
Hadden,D., The development of diabetes and its relation to pregnancy: the long term and short term historical viewpoint, Carbohydrate Metabolism in Pregnancy and the Newborn IV, 1-8, 1989	No relevant data
Hale,N.L., Probst,J.C., Liu,J., Martin,A.B., Bennett,K.J., Glover,S., Postpartum Screening for Diabetes among Medicaid-Eligible South Carolina Women with Gestational Diabetes, Womens Health Issues, 22, e163-e169, 2012	No relevant data - article focuses on rates of postpartum screening
Henry, O.A; Beischer, N.A,, Long-term implications of gestational diabetes for the mother, Baillereâ™s Clinical Obstetrics and Gynecology, 461-483, 1991	Criteria used to define postnatal diabetes not reported but unlikely to be the WHO 1999 criteria as article was published in 1991
Hunger-Dathe,W., Mosebach,N., Samann,A., Wolf,G., Muller,U.A., Prevalence of impaired glucose tolerance 6 years after gestational diabetes, Experimental and Clinical Endocrinology and Diabetes, 114, 11-17, 2006	Postpartum OGTT results assessed according to German guidelines (not the WHO criteria)
Hunt,K.J., Logan,S.L., Conway,D.L., Korte,J.E., Postpartum screening following GDM: how well are we doing?. [41 refs], Current Diabetes Reports, 10, 235-241, 2010	No relevant data
Jang,H.C., Gestational diabetes in Korea: incidence and risk factors of diabetes in women with previous gestational diabetes, Diabetes and Metabolism Journal, 35, 1-7, 2011	Review article - individual studies have been checked for inclusion
Jarvela,I.Y., Juutinen,J., Koskela,P., Hartikainen,A.L., Kulmala,P., Knip,M., Tapanainen,J.S., Gestational diabetes identifies women at risk for permanent type 1 and type 2 diabetes in fertile age: predictive role of autoantibodies, Diabetes Care, 29, 607-612, 2006	No OGTT data during follow-up. Diagnosis of diabetes was based on questionnaire information and on the use of oral antihyperglycaemic medication
Kakad,R., Anwar,A., Dyer,P., Webber,J., Dale,J., Fasting plasma glucose is not sufficient to detect ongoing glucose intolerance after pregnancy complicated by gestational diabetes, Experimental and Clinical Endocrinology and Diabetes, 118, 234-236, 2010	Although the article states the WHO criteria were used, the cut-offs reported do not match the WHO criteria exactly (normal: FPG<6.0, 2-hour glucose <7.8, IFG: FPG 6.0-7.0, 2-hour glucose <7.8, IGT: FPG<7.0, 2-hour glucose 7.8-11.0, Diabetes: FPG>/=7.1 or 2-hour glucose >/=11.0mmol/l)
Kaufmann,R.C., Schleyhahn,F.T., Huffman,D.G., Amankwah,K.S., Gestational diabetes diagnostic criteria: long-term maternal follow-up, American Journal of Obstetrics and Gynecology, 172, 621-625, 1995	A modified form of the NDDG criteria used to define participants as normal, glucose intolerant or diabetic
Kaufmann,R.C., Smith,T., Bochantin,T., Khardori,R., Evans,M.S., Steahly,L., Failure to obtain follow-up testing for gestational	NDDG criteria used to define glucose intolerance

Excluded studies – Review questions 18 and 19	
diabetic patients in a rural population, Obstetrics and Gynecology, 93, 734-737, 1999	
Kim,C., Newton,K.M., Knopp,R.H., Gestational diabetes and the incidence of type 2 diabetes: a systematic review. [55 refs], Diabetes Care, 25, 1862-1868, 2002	Review paper - individual studies checked for inclusion
Kjos,S.L., Buchanan,T.A., Greenspoon,J.S., Montoro,M., Bernstein,G.S., Mestman,J.H., Gestational diabetes mellitus: the prevalence of glucose intolerance and diabetes mellitus in the first two months post partum, American Journal of Obstetrics and Gynecology, 163, 93-98, 1990	Postpartum OGTT results were assessed according to the NDDG criteria (not the same cut-offs as the WHO 1999 criteria)
Kjos,S.L., Peters,R.K., Xiang,A., Henry,O.A., Montoro,M., Buchanan,T.A., Predicting future diabetes in Latino women with gestational diabetes. Utility of early postpartum glucose tolerance testing, Diabetes, 44, 586-591, 1995	NDDG criteria used to define diabetes
Ko,G.T., Chan,J.C., Tsang,L.W., Li,C.Y., Cockram,C.S., Glucose intolerance and other cardiovascular risk factors in chinese women with a history of gestational diabetes mellitus, Australian and New Zealand Journal of Obstetrics and Gynaecology, 39, 478-483, 1999	WHO 1985 criteria used to define postnatal diabetes
Kwak,S.H., Kim,H.S., Choi,S.H., Lim,S., Cho,Y.M., Park,K.S., Jang,H.C., Kim,M.Y., Cho,N.H., Metzger,B.E., Subsequent pregnancy after gestational diabetes mellitus: frequency and risk factors for recurrence in Korean women, Diabetes Care, 31, 1867-1871, 2008	No relevant data - study aims to determine the frequency of recurrent gestational diabetes and to find risk factors that can predict the recurrence of gestational diabetes in women with previous gestational diabetes
Lam,K.S., Li,D.F., Lauder,I.J., Lee,C.P., Kung,A.W., Ma,J.T., Prediction of persistent carbohydrate intolerance in patients with gestational diabetes, Diabetes Research and Clinical Practice, 12, 181-186, 1991	WHO 1980 criteria used to define postnatal diabetes
Lee,C.P., Wong,H.S., Chan,F.Y., Pun,T.C., To,W.K., Lam,Y.H., Baldwin,S., Wong,V.C.W., Long-term prognosis of women with abnormal glucose tolerance in pregnancy, Australian and New Zealand Journal of Obstetrics and Gynaecology, 34, 507-510, 1994	Postpartum OGTT results assessed by modified WHO criteria. Normal (fasting <6.0mmol/l, 2 hour <8mmol/l), IGT (fasting <8mmol/l, 2 hour >/=8 and <11.0mmol/l), Diabetes (>/=8.0, 2 hour any level or any level >/=11.0)
Lee,K.F., Mak,M.W., Lau,K.O., Chung,H.H., Risk of development of diabetes mellitus in Chinese women with persistently impaired glucose tolerance after gestational diabetes, Hong Kong Medical Journal, 17, 195-201, 2011	Study aims to find out after gestational diabetes, how many women with postpartum IGT progress to diabetes (women who have not returned to normoglycaemia after pregnancy)
Linne,Y., Barkeling,B., Rossner,S., Natural course of gestational diabetes mellitus: long term follow up of women in the SPAWN study, BJOG: An International Journal of Obstetrics and Gynaecology, 109, 1227-1231, 2002	Postnatal diabetes defined by 2-hour blood glucose value >10mmol/l (not the WHO criteria)
LOVE,E.J., STEVENSON,J.A., KINCH,R.A., EVALUATION OF ORAL AND INTRAVENOUS GLUCOSE TOLERANCE TESTS FOR THE DIAGNOSIS OF "PREDIABETES" IN THE	Article not of relevance

Excluded studies – Review questions 18 and 19	
PUERPERIUM, American Journal of Obstetrics and Gynecology, 88, 283-290, 1964	
Mazze,R.S., Langer,O., Primary, secondary, and tertiary prevention. Program for diabetes in pregnancy, Diabetes Care, 11, 263-268, 1988	Criteria used to define postnatal diabetes not reported
McGrath,N.M., Coats,A., Barach,O., Improved post-partum follow-up of patients with gestational diabetes mellitus using HbA_{1c}, Diabetic Medicine, 30, 1264-1265, 2013	Criteria used to assess the postpartum OGTT results are not reported
Mehmet,S., Fincher,S., Ibrahim,S., NICE challenge on postnatal reclassification of glucose tolerance in women previously diagnosed with gestational diabetes mellitus, Practical Diabetes International, 27, 346-348, 2010	Name of the criteria used to assess postpartum OGTTs was not explicitly stated. Cut-offs given were similar but not exactly the same as WHO 1999: FPG <6.0, FPG 6.0-6.9, FPG>/=7.0, 2-hour PG <7.8, 2-hour PG 7.8-11.0, 2-hour PG >/=11.1. Corresponding categories (IFG, IGT, Diabetes)for these cut-offs were not reported in the article
Mestman,J.H., Anderson,G.V., Guadalupe,V., Follow-up study of 360 subjects with abnormal carbohydrate metabolism during pregnancy, Obstetrics and Gynecology, 39, 421-425, 1972	Criteria for interpreting postpartum OGTT were those proposed by Fajans (non-WHO)
Metzger,B.E., Bybee,D.E., Freinkel,N., Phelps,R.L., Radvany,R.M., Vaisrub,N., Gestational diabetes mellitus. Correlations between the phenotypic and genotypic characteristics of the mother and abnormal glucose tolerance during the first year postpartum, Diabetes, 34 Suppl 2, 111-115, 1985	100g postpartum OGTTs were interpreted by criteria similar to those recommended by the NDDG
Metzger,B.E., Cho,N.H., Roston,S.M., Radvany,R., Prepregnancy weight and antepartum insulin secretion predict glucose tolerance five years after gestational diabetes mellitus, Diabetes Care, 16, 1598-1605, 1993	Postpartum OGTT results were assessed by the NDDG criteria
Mohamed,N., Dooley,J., Gestational diabetes and subsequent development of NIDDM in aboriginal women of northwestern Ontario, International Journal of Circumpolar Health, 57 Suppl 1, 355-358, 1998	Diabetes was defined according to WHO standards by either an abnormal 75g glucose tolerance test, fasting and 2 hour postprandial or a random blood glucose. Article does not state whether the 1985 or 1999 criteria were used but unlikely to be 1999 criteria because the article was published in 1998
Morrison,M.K., Collins,C.E., Lowe,J.M., Postnatal testing for diabetes in Australian women following gestational diabetes mellitus, Australian and New Zealand Journal of Obstetrics and Gynaecology, 49, 494-498, 2009	No relevant data
Mukerji,G., Chiu,M., Shah,B.R., Impact of gestational diabetes on the risk of diabetes following pregnancy among Chinese and South Asian women, Diabetologia, 55, 2148-2153, 2012	Diagnostic criteria used to assess the postpartum OGTT results are not reported
Nicholson,W.K., Wilson,L.M., Witkop,C.T., Baptiste-Roberts,K., Bennett,W.L., Bolen,S., Barone,B.B., Golden,S.H., Gary,T.L., Neale,D.M., Bass,E.B., Therapeutic management, delivery, and	Individual studies have been checked for inclusion

Excluded studies – Review questions 18 and 19	
postpartum risk assessment and screening in gestational diabetes. [107 refs], Evidence Report/Technology Assessment, 1-96, 2008	
Oats,J.N., Beischer,N.A., The persistence of abnormal glucose tolerance after delivery, Obstetrics and Gynecology, 75, 397-401, 1990	WHO 1985 criteria used to classify postnatal diabetes
O'Sullivan,J.B., Diabetes mellitus after GDM, Diabetes, 40 Suppl 2, 131-135, 1991	All studies in this review were published before 1990 and so they could not have used the WHO 1999 criteria
O'Sullivan,J.B., The Boston gestational diabetes studies: review and perspectives, Carbohydrate metabolism in pregnancy and the newborn, 287-294, 1989	WHO 1985 criteria used to define postnatal diabetes
Persson,B., Hanson,U., Hartling,S.G., Binder,C., Follow-up of women with previous GDM. Insulin, C-peptide, and proinsulin responses to oral glucose load, Diabetes, 40 Suppl 2, 136-141, 1991	WHO 1985 criteria used to define postnatal diabetes
Peters,R.K., Kjos,S.L., Xiang,A., Buchanan,T.A., Long-term diabetogenic effect of single pregnancy in women with previous gestational diabetes mellitus, Lancet, 347, 227-230, 1996	Postpartum OGTT values were assessed according to the NDDG criteria
Pettitt,D.J., Knowler,W.C., Baird,H.R., Bennett,P.H., Gestational diabetes: infant and maternal complications of pregnancy in relation to third-trimester glucose tolerance in the Pima Indians, Diabetes Care, 3, 458-464, 1980	OGTT was performed during the third trimester of pregnancy, not postnatally
Pettitt,D.J., Narayan,K.M., Hanson,R.L., Knowler,W.C., Incidence of diabetes mellitus in women following impaired glucose tolerance in pregnancy is lower than following impaired glucose tolerance in the non-pregnant state, Diabetologia, 39, 1334-1337, 1996	WHO 1985 criteria used to define postnatal diabetes
Picon,M.J., Murri,M., Munoz,A., Fernandez-Garcia,J.C., Gomez-Huelgas,R., Tinahones,F.J., Hemoglobin A_{1c} versus oral glucose tolerance test in postpartum diabetes screening, Diabetes Care, 35, 1648-1653, 2012	Criteria used to assess the postpartum OGTT results are not similar to WHO 1999 criteria
Pierce,M.B., Modder,J., Mortagy,I., Hughes,H., Springett,A., Baldeweg,S., Follow-up of women with gestational diabetes in England, Archives of Disease in Childhood: Fetal and Neonatal Edition, 95, Fa38-Fa39, 2010	Conference abstract
Reidy,J., Chalupka,S., Gestational diabetes-what comes next?, AAOHN Journal, 58, 80-, 2010	No relevant data
Retnakaran,R., Qi,Y., Connelly,P.W., Sermer,M., Hanley,A.J., Zinman,B., Risk of early progression to prediabetes or diabetes in women with recent gestational dysglycaemia but normal glucose tolerance at 3-month postpartum, Clinical Endocrinology, 73, 476-483, 2010	Incidence data is presented in terms of prediabetes/diabetes. Though cut-off in article for diabetes matches the WHO criteria, the prediabetes (IGT) cut-off does not match WHO.
Retnakaran,R., Qi,Y., Sermer,M., Connelly,P.W., Hanley,A.J., Zinman,B., Glucose intolerance in pregnancy and future risk of pre-diabetes or diabetes, Diabetes Care, 31, 2026-2031, 2008	Study focuses on how antenatal factors predict dysglycaemia at 3 months' postpartum
Retnakaran,R., Qi,Y., Sermer,M., Connelly,P.W., Zinman,B., Hanley,A.J., Isolated hyperglycemia at 1 hour on oral glucose tolerance test in pregnancy resembles gestational diabetes mellitus in predicting postpartum metabolic dysfunction, Diabetes Care, 31, 1275-1281, 2008	Study focuses on how isolated hyperglycaemia at 1 hour on OGTT during pregnancy resembles gestational diabetes in predicting postpartum metabolic dysfunction

Excluded studies – Review questions 18 and 19	
Russell,M.A., Phipps,M.G., Olson,C.L., Welch,H.G., Carpenter,M.W., Rates of postpartum glucose testing after gestational diabetes mellitus, Obstetrics and Gynecology, 108, 1456-1462, 2006	Cut-off for postpartum diabetes does not exactly match the WHO criteria (>7 or >11.1 instead of >=).
Saleh,A.K., Moussa,M.A., Hathout,H., Postpartum glycated hemoglobin A_{1c} and glucose tolerance test in mothers of large babies, International Journal of Gynaecology and Obstetrics, 26, 5-9, 1988	Population not of interest - focus is on women with large babies not women with gestational diabetes
Salzberger,M., Sharon,A., Liban,E., Significance of the oral glucose tolerance test performed on the third day after delivery for the diagnosis of diabetes in pregnancy, Israel Journal of Medical Sciences, 11, 629-631, 1975	Article examines the significance of the OGTT in diagnosing diabetes in pregnancy not postnatal diabetes
Sameshima,H., Higo,T., Ikenoue,T., Longitudinal changes in plasma glucose values of the 75-g glucose tolerance test in triplet pregnancies, American Journal of Perinatology, 21, 49-55, 2004	No relevant data
Seghieri,G., Tesi,F., De,Bellis A., Anichini,R., Fabbri,G., Seghieri,M., Franconi,F., Long term predictors of post-partum glucose metabolism in women with gestational diabetes mellitus, Experimental and Clinical Endocrinology and Diabetes, 118, 485-489, 2010	IGT or type 2 diabetes was diagnosed on the basis of a 2-hour plasma glucose at OGTT of >=7.8mmol/l
Shah,B., Lowe,J., Inadequate screening for type 2 diabetes following pregnancy complicated by gestational diabetes, Canadian Journal of Diabetes, 33, 192-, 2009	Conference abstract
Shah,B.R., Lipscombe,L.L., Feig,D.S., Lowe,J.M., Missed opportunities for type 2 diabetes testing following gestational diabetes: a population-based cohort study, BJOG: An International Journal of Obstetrics and Gynaecology, 118, 1484-1490, 2011	No relevant data
Sinha,B., Brydon,P., Taylor,R.S., Hollins,A., Munro,A., Jenkins,D., Dunne,F., Maternal ante-natal parameters as predictors of persistent postnatal glucose intolerance: a comparative study between Afro-Caribbeans, Asians and Caucasians, Diabetic Medicine, 20, 382-386, 2003	Criteria used to define postpartum OGTT results not reported
Smirnakis,K.V., Chasan-Taber,L., Wolf,M., Markenson,G., Ecker,J.L., Thadhani,R., Postpartum diabetes screening in women with a history of gestational diabetes, Obstetrics and Gynecology, 106, 1297-1303, 2005	No relevant data
Stage,E., Ronneby,H., Damm,P., Lifestyle change after gestational diabetes, Diabetes Research and Clinical Practice, 63, 67-72, 2004	Postnatal criteria used to define diabetes and IGT not reported
Stangenberg,M., Agarwal,N., Rahman,F., Sheth,K., al,Sedeiry S., De,Vol E., Frequency of HLA genes and islet cell antibodies (ICA) and result of postpartum oral glucose tolerance tests (OGTT) in Saudi Arabian women with abnormal OGTT during pregnancy, Diabetes Research, 14, 9-13, 1990	Postnatal OGTT evaluated according to the WHO criteria. Assuming this refers to the WHO 1985/1980 criteria because the article was published in 1990 (i.e. before publication of the WHO 1999 criteria)
Steinhart,J.R., Sugarman,J.R., Connell,F.A., Gestational diabetes is a herald of NIDDM in Navajo women. High rate of abnormal glucose tolerance after GDM, Diabetes Care, 20, 943-947, 1997	WHO 1985 criteria used to define postnatal diabetes
Tan,Y.Y., Yeo,S.H., Liauw,P.C., Is postnatal oral glucose tolerance testing necessary in all women with gestational diabetes, Singapore Medical Journal, 37, 384-388, 1996	WHO 1985 criteria used to define postnatal diabetes

Excluded studies – Review questions 18 and 19	
tley-Lewis,R., Levkoff,S., Stuebe,A., Seely,E.W., Gestational diabetes mellitus: Postpartum opportunities for the diagnosis and prevention of type 2 diabetes mellitus, Nature Clinical Practice Endocrinology and Metabolism, 4, 552-558, 2008	Review paper discussing current guidelines for postpartum screening, how they might be implemented, and who should take responsibility for screening women at risk of type 2 diabetes (no relevant data)
Vitoratos,N., Salamalekis,E., Loghis,S., Kassanos,D., Giannaris,D., Creatsas,G., Changes of glucose tolerance after delivery in women with gestational diabetes, Clinical and Experimental Obstetrics and Gynecology, 27, 212-214, 2000	WHO 1985 criteria used to define postnatal diabetes
Wein,P., Beischer,N.A., Sheedy,M.T., Studies of postnatal diabetes mellitus in women who had gestational diabetes. Part 2. Prevalence and predictors of diabetes mellitus after delivery, Australian and New Zealand Journal of Obstetrics and Gynaecology, 37, 420-423, 1997	WHO 1985 criteria used to define postnatal diabetes
Weinert,L.S., Mastella,L.S., Oppermann,M.L., Silveiro,S.P., Guimaraes,L.S., Reichelt,A.J., Postpartum glucose tolerance status 6 to 12 weeks after gestational diabetes mellitus: a Brazilian cohort, Arquivos Brasileiros de Endocrinologia e Metabologia, 58, 197-204, 2014	Criteria used to assess the postpartum OGTT results are not similar to WHO 1999 criteria
Werner,E.F., Tarabulsi,G., Han,C., Satin,A., Early postpartum diabetes screening for women with gestational diabetes mellitus, Obstetrics and Gynecology, 123 Suppl 1, 82S-, 2014	Abstract
Zonenberg,A., Telejko,B., Topolska,J., Szelachowska,M., Zarzycka,B., Modzelewska,A., Nikolajuk,A., Kinalska,I., Gorska,M., Factors predisposing to disturbed carbohydrate tolerance in patients with previous gestational diabetes mellitus, Diabetologia Doswiadczalna i Kliniczna, 6, 143-150, 2006	Timing of postnatal test not reported. Also, postpartum OGTT values were assessed according to Polish Diabetes Association guidelines

Appendix H: Evidence Tables

Evidence tables are in separate **Appendices - set 2.**

Appendix I: Minimally Important Differences

I.1 Preconception care

Table 5: MIDs for continuous outcomes for the review of oral contraception in women with diabetes compared to those without diabetes

Outcome	MID
Filtration fraction	0.01
Glomerular filtration rate	0.51
Plasma renin activity	0.005
RPF	9.685
Urine NA	0.51
Urine protein	22.68
Fasting glucose (mg/dl)	18.09
Fasting glucose (mmol/l)	1
Mean arterial pressure	1.02

Table 6: MIDs for mean change from baseline for outcomes to 3 months in women with diabetes using or not using oral contraceptives

Baseline to 3 months

Outcome	Group	Author	MID
HbA1c (%)	Combi low estrogen OC TYPE 1	Grigoryan	0.204
HbA1c (%)	Combi low estrogen OC TYPE 2	Grigoryan	0.272

Outcome	Group	Author	MID
HbA1c (%)	Combi standard OC TYPE 1	Grigoryan	0.127
HbA1c (%)	Combi standard OC TYPE 2	Grigoryan	0.222
HbA1c (%)	Combi low progestogen OC TYPE 1	Grigoryan	0.127
HbA1c (%)	Combi low progestogen OC TYPE 2	Grigoryan	0.249
HbA1c (%)	IUD group TYPE 1	Grigoryan	0.296
HbA1c (%)	IUD group TYPE 2	Grigoryan	0.06
HbA1c (%)	No contraceptives	Grigoryan	0.241
Total cholesterol (mmol/l)	OC	Diab	0.416
Total cholesterol (mmol/l)	IUD	Diab	0.105
Total cholesterol (mmol/l)	OC	Petersen	NC
Total cholesterol (mmol/l)	No OC	Petersen	NC
HDL cholesterol/total cholesterol (mmol/l)	OC	Petersen	NC
HDL cholesterol/total cholesterol (mmol/l)	No OC	Petersen	NC
HDL cholesterol (mmol/l)	OC	Diab	0.19
HDL cholesterol (mmol/l)	IUD	Diab	0.14
HDL cholesterol (mmol/l)	OC	Petersen	NC
HDL cholesterol (mmol/l)	No OC	Petersen	NC
HDL2 cholesterol (mmol/l)	OC	Petersen	NC
HDL2 cholesterol (mmol/l)	No OC	Petersen	NC
HDL3 cholesterol (mmol/l)	OC	Petersen	NC
HDL3 cholesterol (mmol/l)	No OC	Petersen	NC
Triglycerides (mmol/l)	OC	Diab	0.388
Triglycerides (mmol/l)	IUD	Diab	0.288
Triglycerides (mmol/l)	OC	Petersen	NC
Triglycerides (mmol/l)	No OC	Petersen	NC
Triglycerides (mmol/l)	Monophasic combined LD OC	Skouby	NC
Triglycerides (mmol/l)	Progestogen only OC	Skouby	NC
Systolic blood pressure (mmHg)	OC	Diab	0.083
Systolic blood pressure (mmHg)	IUD	Diab	0.111

Outcome	Group	Author	MID
Diastolic blood pressure (mmHg)	OC	Diab	NC
Diastolic blood pressure (mmHg)	IUD	Diab	NC

Table 7: MIDs for mean change from baseline for outcomes to 6 months in women with diabetes using or not using oral contraceptives

Baseline to 6 months

Outcome	Group	Author	MID
HbA1c (%)	Monophasic combined LD OC	Skouby	0.356
HbA1c (%)	Progestogen only OC	Skouby	0.385
HbA1c (%)	Triphasic combined OC	Skouby	0.243
HbA1c (%)	Monophasic HD combined OC	Skouby	0.282
HbA1c (%)	Combi low estrogen OC TYPE 1	Grigoryan	0.175
HbA1c (%)	Combi low estrogen OC TYPE 2	Grigoryan	0.204
HbA1c (%)	Combi standard OC TYPE 1	Grigoryan	0.127
HbA1c (%)	Combi standard OC TYPE 2	Grigoryan	0.279
HbA1c (%)	Combi low progestogen OC TYPE 1	Grigoryan	0.175
HbA1c (%)	Combi low progestogen OC TYPE 2	Grigoryan	0.226
HbA1c (%)	IUD group TYPE 1	Grigoryan	0.127
HbA1c (%)	IUD group TYPE 2	Grigoryan	0.342
HbA1c (%)	No contraceptives	Grigoryan	0.274
Total cholesterol (mmol/l)	OC	Diab	0.378
Total cholesterol (mmol/l)	IUD	Diab	0.241
Total cholesterol (mmol/l)	OC	Petersen	NC
Total cholesterol (mmol/l)	No OC	Petersen	NC
HDL cholesterol/total cholesterol (mmol/l)	Monophasic combined LD OC	Skouby	0.049
HDL cholesterol/total cholesterol (mmol/l)	Progestogen only OC	Skouby	0.049

Outcome	Group	Author	MID
HDL cholesterol/total cholesterol (mmol/l)	Triphasic combined OC	Skouby	0.049
HDL cholesterol/total cholesterol (mmol/l)	Monophasic combined HD OC	Skouby	0.049
HDL cholesterol/total cholesterol (mmol/l)	OC	Petersen	NC
HDL cholesterol/total cholesterol (mmol/l)	No OC	Petersen	NC
HDL cholesterol (mmol/l)	OC	Diab	0.175
HDL cholesterol (mmol/l)	IUD	Diab	0.143
HDL cholesterol (mmol/l)	OC	Petersen	NC
HDL cholesterol (mmol/l)	No OC	Petersen	NC
HDL cholesterol (mmol/l)	Monophasic combined LD OC	Skouby	0.055
HDL cholesterol (mmol/l)	Progestogen only OC	Skouby	0.052
HDL cholesterol (mmol/l)	Triphasic combined OC	Skouby	0.049
HDL cholesterol (mmol/l)	Monophasic combined HD OC	Skouby	0.073
HDL2 cholesterol (mmol/l)	OC	Petersen	NC
HDL2 cholesterol (mmol/l)	No OC	Petersen	NC
HDL3 cholesterol (mmol/l)	OC	Petersen	NC
HDL3 cholesterol (mmol/l)	No OC	Petersen	NC
LDL cholesterol (mmol/l)	Monophasic combined LD OC	Skouby	0.194
LDL cholesterol (mmol/l)	Progestogen only OC	Skouby	0.101
LDL cholesterol (mmol/l)	Triphasic combined OC	Skouby	0.127
LDL cholesterol (mmol/l)	Monophasic combined HD OC	Skouby	0.195
LDL cholesterol (mmol/l)	OC	Diab	0.448
LDL cholesterol (mmol/l)	IUD	Diab	0.32
LDL cholesterol (mmol/l)	OC	Petersen	NC
LDL cholesterol (mmol/l)	No OC	Petersen	NC
VLDL cholesterol (mmol/l)	OC	Petersen	NC
VLDL cholesterol (mmol/l)	No OC	Petersen	NC
VLDL cholesterol (mmol/l)	Monophasic combined LD OC	Skouby	0.091
VLDL cholesterol (mmol/l)	Progestogen only OC	Skouby	0.05
VLDL cholesterol (mmol/l)	Triphasic combined OC	Skouby	0.05

Outcome	Group	Author	MID
VLDL cholesterol (mmol/l)	Monophasic combined HD OC	Skouby	0.053
Triglycerides (mmol/l)	OC	Diab	0.084
Triglycerides (mmol/l)	IUD	Diab	0.082
Triglycerides (mmol/l)	OC	Petersen	NC
Triglycerides (mmol/l)	No OC	Petersen	NC
Triglycerides (mmol/l)	Monophasic combined LD OC	Skouby	0.208
Triglycerides (mmol/l)	Progestogen only OC	Skouby	0.053
Triglycerides (mmol/l)	Triphasic combined OC	Skouby	0.128
Triglycerides (mmol/l)	Monophasic HD combined OC	Skouby	0.083
Free fatty acids (mmol/l)	Monophasic combined LD OC	Skouby	58.663
Free fatty acids (mmol/l)	Progestogen only OC	Skouby	79.434
Free fatty acids (mmol/l)	Triphasic combined OC	Skouby	59.837
Free fatty acids (mmol/l)	Monophasic HD combined OC	Skouby	73.043
Systolic blood pressure (mmHg)	OC	Diab	1.765
Systolic blood pressure (mmHg)	IUD	Diab	1.801
Diastolic blood pressure (mmHg)	OC	Diab	1.92
Diastolic blood pressure (mmHg)	IUD	Diab	2.391

Table 8: MIDs for mean change from baseline for outcomes to 9 months in women with diabetes using or not using oral contraceptives

Baseline to 9 months

Outcome	Group	Author	MID
HbA1c (%)	Combi low estrogen OC TYPE 1	Grigoryan	0.149
HbA1c (%)	Combi low estrogen OC TYPE 2	Grigoryan	0.251
HbA1c (%)	Combi standard OC TYPE 1	Grigoryan	0.232
HbA1c (%)	Combi standard OC TYPE 2	Grigoryan	0.201

Outcome	Group	Author	MID
HbA1c (%)	Combi low progestogen OC TYPE 1	Grigoryan	0.233
HbA1c (%)	Combi low progestogen OC TYPE 2	Grigoryan	0.188
HbA1c (%)	IUD group TYPE 1	Grigoryan	0.244
HbA1c (%)	IUD group TYPE 2	Grigoryan	0.279
HbA1c (%)	No contraceptives	Grigoryan	0.325
Total cholesterol (mmol/l)	OC	Diab	0.385
Total cholesterol (mmol/l)	IUD	Diab	0.206
HDL cholesterol (mmol/l)	OC	Diab	0.181
HDL cholesterol (mmol/l)	IUD	Diab	0.101

Table 9: MIDs for mean change from baseline for outcomes to 3 months in women with diabetes using or not using oral contraceptives

Baseline to 12 months

Outcome	Group	Author	MID
HbA1c (%)	OC	Petersen	NC
HbA1c (%)	No OC	Petersen	NC
HbA1c (%)	Combi low estrogen OC TYPE 1	Grigoryan	0.233
HbA1c (%)	Combi low estrogen OC TYPE 2	Grigoryan	0.3
HbA1c (%)	Combi standard OC TYPE 1	Grigoryan	0.172
HbA1c (%)	Combi standard OC TYPE 2	Grigoryan	0.174
HbA1c (%)	Combi low progestogen OC TYPE 1	Grigoryan	0.173
HbA1c (%)	Combi low progestogen OC TYPE 2	Grigoryan	0.278
HbA1c (%)	IUD group TYPE 1	Grigoryan	0.263
HbA1c (%)	IUD group TYPE 2	Grigoryan	0.264
HbA1c (%)	No contraceptives	Grigoryan	0.228
Total cholesterol (mmol/l)	OC	Petersen	NC
Total cholesterol (mmol/l)	No OC	Petersen	NC
HDL cholesterol/total cholesterol (mmol/l)	OC	Petersen	NC

Outcome	Group	Author	MID
HDL cholesterol/total cholesterol (mmol/l)	No OC	Petersen	NC
HDL cholesterol (mmol/l)	OC	Petersen	NC
HDL cholesterol (mmol/l)	No OC	Petersen	NC
HDL2 cholesterol (mmol/l)	OC	Petersen	NC
HDL2 cholesterol (mmol/l)	No OC	Petersen	NC
HDL3 cholesterol (mmol/l)	OC	Petersen	NC
HDL3 cholesterol (mmol/l)	No OC	Petersen	NC
LDL cholesterol (mmol/l)	OC	Petersen	NC
LDL cholesterol (mmol/l)	No OC	Petersen	NC
VLDL cholesterol (mmol/l)	OC	Petersen	NC
VLDL cholesterol (mmol/l)	No OC	Petersen	NC
Triglycerides (mmol/l)	OC	Petersen	NC
Triglycerides (mmol/l)	No OC	Petersen	NC
Free fatty acids (mmol/l)	OC	Petersen	NC
Free fatty acids (mmol/l)	No OC	Petersen	NC
Arterial blood pressure (mmHg)	OC	Petersen	NC
Arterial blood pressure (mmHg)	No OC	Petersen	NC

I.2 Continuous glucose monitoring

Table 10: MIDs for continuous outcomes for the review of continuous glucose monitoring

Outcome	MID
Gestational age at birth	0.65
HbA1c (28 to 32 weeks)	0.36
HbA1c (32 to 36 weeks)	0.36
Mean glucose level	0.45
Days in NICU per treated neonate	0.86

I.3 Antenatal specialist teams

Table 11: MIDs for continuous outcomes for the review of antenatal specialist teams

	MID
HbA1c in the first trimester in women with Type 1 or 2 diabetes	0.415
HbA1c in the second trimester in women with Type 1 or 2 diabetes	0.465

Appendix J: GRADE profiles

J.1 Preconception care

Table 12: GRADE profile for adverse outcomes of oral oestrogen-containing contraceptives and oral progestogen-containing contraceptives in women with diabetes compared with women without diabetes

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	With diabetes	Without diabetes	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Worsening of retinopathy and/or nephropathy											
Filtration fraction											
Women with type 1 or type 2 diabetes											
1	12	10	NA	MD 0.0 higher	Very low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision [b]	Yes[c,d,e]

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	With diabetes	Without diabetes	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Ahmed et al., 2005)				(0.0 to 0.1 higher)[a]							
Glomerular filtration rate (ml·minutej·1.73 mk; median of readings at 10, 5, and 0 minutes before administration of oral captopril[f])											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NA	MD 2 lower (21.1 lower to 17.1 higher)[a]	Very low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision [b]	Yes[c,d,e]
Microalbuminuria (%)											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	6/9 (67%)	0/10 (0%)	RR 14.3 (0.8 to 271.1)[a]	NC	Low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	Yes[c,d,e]
Plasma renin activity (ng Ang I·mlj·hour-j)											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NA	MD 0.0 higher (0.4 lower to 0.4 higher)a	Very low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision [b]	Yes [c,d,e]
Renal plasma flow (ml·minutej·1.73 mk; median of readings at 10, 5, and 0 minutes before administration of oral captoprili)											

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	With diabetes	Without diabetes	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NA	MD 38 lower (105.7 lower to 29.7 higher)[a]	Very low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[c,d,e]
Urine sodium excretion rate (mmol/24 hours)											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NA	MD 2 lower (75.6 lower to 71.6 higher)[a]	Very low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[c,d,e]
Urine protein excretion rate (mg/24 hours)											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NA	MD 89 higher (3.0 higher to 175.0 higher)[a]	Low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	Yes[c,d,e]
Change in HbA_{1c}											
HbA_{1c} (%)											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NC	NC	Low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	NC	Yes[c,d,e]

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	With diabetes	Without diabetes	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Fasting plasma glucose (mmol/l)											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NA	MD 3.9 higher (1.6 higher to 6.3 higher)[a]	Low	Observational	No serious risk of bias	No serious inconsistency	Serious indirectness[g]	No serious imprecision	Yes[c,d,e]
Arterial thromboembolic disease											
Myocardial infarction											
Type of diabetes not known											
1 (Tanis et al., 2001)	5/7 (71%)	94/439 (21%)	RR 3.4 (2.0 to 5.5)[a]	514 more per 1000 (214 more to 964 more)[a]	Low	Case control	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	Yes[h,l]
Hypertension											
Mean arterial pressure (mmHg)											
Women with type 1 or type 2 diabetes											
1 (Ahmed et al., 2005)	12	10	NA	MD 4 lower (9.4 lower to 1.4 higher)[a]	Very low	Observational	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[c,d,e]

MD mean difference, NA not applicable, NC Not calculable, RR risk ratio

a Calculated by the NCC-WCH based on results reported in the paper
b Confidence interval for the MD crosses the line of no effect (MD = 0) and the minimally important difference (50% of the combined standard deviation of the two groups at baseline)
c 11 of the 12 women in the diabetes group had type 1 diabetes
d Conducted in the United States of America. Ethnicity of the participants was not reported.

e The women included in the study used different types of oral contraceptives. The mean oestrogen content was 31.0 micrograms (SD 1.9) for women with diabetes and 30.5micrograms (SD 2.1) for women without diabetes, and the mean progesterone content was 0.34mg (SD 0.11) for women with diabetes and 0.36mg (SD 0.12) for women without diabetes.
f Administration of oral captopril is not relevant in this review question and the results reported are baseline measurements
g Fasting plasma glucose is reported as a proxy for change in HbA_{1c} as there were limited data reported for HbA_{1c}
h Conducted in the Netherlands. 94% of the myocardial infarction group and 93% of the control group were white. The ethnicity of the other participants was not reported.
i The dosage of oral contraceptives used was not reported, but the study only included women who used oral contraceptives containing 30 micrograms of ethinyl oestradiol

Table 13: GRADE profile for worsening of retinopathy and/or nephropathy in women with diabetes using oral contraceptives compared with women with diabetes not using oral contraceptives

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Using oral contraceptives	Not using oral contraceptives	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Worsening of retinopathy											
Worsening by 1 eye grade											
Oestrogen and progestogen combined oral contraceptives vs. no oral contraceptives											
Women with type 1 diabetes											
1 (Garg et al., 1994)	9/40 (23%)	8/39 (21%)	RR 1.1 (0.5 to 2.6)a	21 more per 1000 (from 103 fewer to 328 more)a	Very low	Case-control	No serious limitations	No serious inconsistencyb	No serious indirectnessc	Serious imprecisiond	Yese, f
Worsening by > 1 eye grade											
Oestrogen and progestogen combined oral contraceptives vs. no oral contraceptives											
Women with type 1 diabetes											
1 (Garg et al., 1994)	8/40 (20%)	6/39 (15%)	RR 1.3 (0.5 to 3.4)a	46 more per 1000	Very low	Case-control	No serious limitations	No serious inconsistencyb	No serious indirectnessc	Serious imprecisiond	Yese, f

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Using oral contraceptives	Not using oral contraceptives	Relative (95% confidence interval)	Absolute (95% confidence interval)							
				(from 77 fewer to 369 more)a							
Mild to minimal diabetic retinopathy											
Oral contraceptives (type not reported) vs. no oral contraceptives											
Women with type 1 diabetes											
1 (Klein et al., 1990)	147/351 (42%)	88/214 (41%)	RR 1.0 (0.8 to 1.3)a	8 more per 1000 (from 82 fewer to 103 more)a	Very low	Observational	Very serious limitationsg	No serious inconsistencyb	Serious indirectnessh	Serious imprecisionnd	Yese, i
Moderate to severe retinopathy											
Oral contraceptives (type not reported) vs. no oral contraceptives											
Women with type 1 diabetes											
1 (Klein et al., 1990)	74/351 (21%)	43/214 (20%)	RR 1.1 (0.8 to 1.5)[a]	10 more per 1000 (from 50 fewer to 94 more)[a]	Very low	Observational	Very serious limitationsg	No serious inconsistency[b]	Serious indirectness[h]	Serious imprecision[d]	Yese, i
Proliferative retinopathy											
Oral contraceptives (type not reported) vs. no oral contraceptives											
Women with type 1 diabetes											
1 (Klein et al., 1990)	91/351 (26%)	52/214 (24%)	RR 1.1 (0.8 to 1.4)[a]	17 more per 1000 (from 49 fewer to 107 more)[a]	Very low	Observational	Very serious limitationsg	No serious inconsistency[b]	Serious indirectness[h]	No serious imprecision	Yese, i
Worsening of nephropathy											
Worsening of renal/microalbuminuria status											

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Using oral contraceptives	Not using oral contraceptives	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Oestrogen and progestogen combined oral contraceptives vs. no oral contraceptives											
Women with type 1 diabetes											
1 (Garg et al., 1994)	5/41 (12%)	3/40 (8%)	RR 1.6 (0.4 to 6.4)[a]	47 more per 1000 from 44 fewer to 403 more)[a]	Very low	Case-control	No serious limitations	No serious inconsistency[b]	No serious indirectness[c]	Serious imprecision[d]	Yes[e, f]
Microalbuminuria at baseline											
Oestrogen and progestogen combined oral contraceptives vs. unspecified nonhormonal contraceptives											
Women with type 1 diabetes											
1 (Petersen et al., 1995)	2/22 (9%)	3/20 (15%)	RR 0.6 (0.1 to 3.5)[a]	59 fewer per 1000 (from 134 fewer to 369 more)[a]	Very low	Case-control	Serious limitations[j]	No serious inconsistency[b]	Serious indirectnessk	Serious imprecision[d]	Yes[l, m]
Microalbuminuria at 12 months											
Oestrogen and progestogen combined oral contraceptives vs. unspecified nonhormonal contraceptives											
Women with type 1 diabetes											
1 (Petersen et al., 1995)	2/22 (9%)	2/20 (10%)	RR 0.9 (0.1 to 6.2)[a]	9 fewer per 1000 (from 87 fewer to 521 more)[a]	Very low	Case-control	Serious limitations[j]	No serious inconsistency[b]	Serious indirectness[k]	Serious imprecision[d]	Yes[l, m]
Albumin excretion rate 20 to 200 micrograms/min											
Oestrogen and progestogen combined oral contraceptives vs. no oral contraceptives											

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Using oral contraceptives	Not using oral contraceptives	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Women with type 1 diabetes											
1 (Garg et al., 1994)	10/43 (23%)	4/43 (9%)	RR 2.5 (0.9 to 7.4)[a]	140 more per 1000 (from 14 fewer to 592 more)[a]	Very low	Case-control	No serious limitations[s]	No serious inconsistency[b]	Serious indirectness[n]	Serious imprecision[d]	Yes[e, f]
Albumin excretion rate > 200 micrograms/min											
Oestrogen and progestogen combined oral contraceptives vs. no oral contraceptives											
Women with type 1 diabetes											
1 (Garg et al., 1994)	0/43 (0%)	2/43 (5%)	RR 0.2 (0.0 to 4.1)[a]	37 fewer per 1000 (from 46 fewer to 142 more)[a]	Very low	Case-control	No serious limitations	No serious inconsistency[b]	Serious indirectness[n]	Serious imprecision[d]	Yes[e, f]

NA not applicable, NC Not calculable, RR risk ratio

[a] Calculated by the NCC-WCH based on results reported in the paper

[b] Single study analysis

[c] Study met population and outcome criteria specified in the review protocol

[d] Confidence interval for the RR crosses the line of no effect (RR = 1) and RR = 0.75 and/or RR = 1.25

[e] Conducted in the United States of America. Ethnicity of the participants was not reported.

[f] The dosages of oestrogen and/or progestogen in the oral contraceptives were not reported. However, all women were using low-dose preparations containing 0.05mg or less of ethinyl oestradiol (or mestranol) and a progestin

[g] Attempts were not made within the design or analysis to balance the comparison groups for potential confounders, and participants were not blinded. It is unclear whether the groups were comparable at baseline, received the same care apart from taking oral contraceptives, or whether clinicians were blinded to treatment allocation or other confounding factors.

[h] Data does not reflect a worsening of retinopathy, only the degree of retinopathy at the time of data collection

[i] The dosages of oestrogen and/or progestogen in the oral contraceptives were not reported.

[j] The main potential confounders were not identified or taken into account in the design and analysis of the study

[k] Data does not reflect a worsening of nephropathy, only the number of women with microalbuminuria at the time of data collection

[l] Conducted in Denmark. Ethnicity of the participants was not reported.

[m] The women received 30 micrograms ethinyl oestradiol and 75 micrograms gestodene

[n] Data do not reflect a worsening of nephropathy, only the number of women with an albumin excretion rate in the specified range at the time of data collection

Table 14: GRADE profile for change in HbA_{1c} in women with diabetes using oral contraceptives compared with women with diabetes not using oral contraceptives (single time point data)

Number of studies	Number of women	Mean Value (%)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		Oral contraceptives group	No oral contraceptives group	Relative (95% confidence interval)	Absolute (95% confidence interval)							
HbA_{1c} (%)												
Oestrogen and progestogen combined oral contraceptives vs. no oral contraceptives												
Women with type 1 diabetes												
1 (Garg et al., 1994)	43 in each group	12.0 (SD 2.0)	12.0 (SD 2.0)	NA	Mean difference 0.0 (0.9 lower to 0.9 higher)[a]	Very low	Case-control	No serious limitations	No serious inconsistency[b]	Serious indirectness[c]	No serious imprecision	Yes[d, e]

NA not applicable, NC Not calculable, SD standard deviation
a Calculated by the NCC-WCH based on results reported in the paper
b Single study analysis
c Data does not reflect a change in HbA_{1c}, only the HbA_{1c} value at the time of data collection
d Conducted in the United States of America. Ethnicity of the participants was not reported.
e The dosages of oestrogen and/or progestogen in the oral contraceptives were not reported. However, all women were using low-dose preparations containing 0.05mg or less of ethinyl oestradiol (or mestranol) and a progestin

Table 15: GRADE profile for change in HbA_{1c} in women with diabetes using oral contraceptives compared with women with diabetes not using oral contraceptives (multiple time point data)

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
HbA_{1c} (%)												
From baseline to 2 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	9.5 (SD 0.7)	8.2 (SD 0.3)	NA	Mean difference 1.3 lower (0.8 lower to 1.8 lower)[a]	Moderate	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectnessd	No serious imprecision	Yese, [f, g]
1 (Skouby et al., 1986)	10	8.6 (SD 0.7)	9.4 (SD 0.6)	NA	Mean difference 0.8 higher (0.2 higher to 1.4 higher)[a]	Moderate	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision	Yese, [f, h]
1 (Skouby et al., 1986)	9	9.1 (SD 0.5)	9 (SD 0.5)	NA	Mean difference 0.1 lower (0.4 lower to 0.6 higher)a	Low	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yese, [f, j]
Oral contraceptives – progestogen only												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	9	8.9 (SD 0.5)	7.4 (SD 0.9)	NA	Mean difference 1.5 lower (0.8 lower to 2.2 lower)[a]	Moderate	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision	Yes[e, k]
From baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Grigoryan et al., 2006)	10	7.5 (SD 0.3)	7.6 (SD 0.2)	NA	Mean difference 0.1 higher (0.1 lower to 0.3 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, n]
1 (Grigoryan et al., 2006)	14	7.5 (SD 0.3)	7.6 (SD 0.5)	NA	Mean difference 0.1 higher (0.2 lower to 0.4 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]
1 (Grigoryan et al., 2006)	12	7.5 (SD 0.3)	7.6 (SD 0.2)	NA	Mean difference 0.1 higher (0.1 lower to 0.3 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, p]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Women with type 2 diabetes												
1 (Grigoryan et al., 2006)	10	7.7 (SD 0.4)	7.8 (SD 0.5)	NA	Mean difference 0.1 higher (0.3 lower to 0.5 higher)a	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, n]
1 (Grigoryan et al., 2006)	14	7.6 (SD 0.5)	7.5 (SD 0.6)	NA	Mean difference 0.1 lower (0.3 lower to 0.5 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]
1 (Grigoryan et al., 2006)	9	7.3 (SD 0.4)	7.4 (SD 0.6)	NA	Mean difference 0.1 higher (0.4 lower to 0.6 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes [f, m, p]
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 diabetes												
1 (Grigoryan et al., 2006)	11	7.8 (SD 0.3)	7.7 (SD 0.8)	NA	Mean difference 0.1 lower (0.6 lower to 0.4 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[i]
Women with type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Grigoryan et al., 2006)	11	7.5 (SD 0.7)	7.7 (SD 0.4)	NA	Mean difference 0.2 higher (0.3 lower to 0.7 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[i]
No contraception												
Women with type 1 or type 2 diabetes												
1 (Grigoryan et al., 2006)	40	7.7 (SD 0.6)	7.5 (SD 0.3)	NA	Mean difference 0.2 lower (0.4 lower to 0.0 higher)[a]	Moderate	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision	Yes[m, q]
From baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	9.5 (SD 0.7)	9.1 (SD 0.7)	NA	Mean difference 0.4 lower (1.1 lower to 0.3 lower)[a]	Moderate	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision	Yes[e, f, g]
1 (Skouby et al., 1986)	10	8.6 (SD 0.7)	8.8 (SD 0.4)	NA	Mean difference 0.2 higher	Low	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[e, f, h]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					(0.3 lower to 0.7 higher)[a]							
1 (Skouby et al., 1986)	9	9.1 (SD 0.5)	9.1 (SD 0.5)	NA	Mean difference 0 (0.5 lower to 0.5 higher)[a]	Low	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[e, f, j]
1 (Grigoryan et al., 2006)	10	7.5 (SD 0.3)	7.4 (SD 0.2)	NA	Mean difference 0.1 lower (0.3 lower to 0.1 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, n]
1 (Grigoryan et al., 2006)	14	7.5 (SD 0.3)	7.4 (SD 0.4)	NA	Mean difference 0.1 lower (0.4 lower to 0.2 higher)a	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]
1 (Grigoryan et al., 2006)	12	7.5 (SD 0.3)	7.4 (SD 0.4)	NA	Mean difference 0.1 lower (0.4 lower to 0.2 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, p]
Women with type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Grigoryan et al., 2006)	10	7.7 (SD 0.4)	7.6 (SD 0.7)	NA	Mean difference 0.1 lower (0.6 lower to 0.4 higher)a	Low	Randomised trial	Serious limitationsl	No serious inconsistencyc	No serious indirectnesd	Serious impreciseni	Yes[f, m, n]
1 (Grigoryan et al., 2006)	14	7.6 (SD 0.5)	7.7 (SD 0.3)	NA	Mean difference 0.1 higher (0.2 lower to 0.4 higher)a	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]
1 (Grigoryan et al., 2006)	9	7.3 (SD 0.4)	7.5 (SD 0.5)	NA	Mean difference 0.2 higher (0.3 lower to 0.7 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, p]
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	8.9 (SD 0.5)	9.5 (SD 0.9)	NA	Mean difference 0.6 higher (0.1 lower to 1.3 higher)[a]	Low	Randomised trial	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[e, k]
Non-oral contraceptives – intrauterine contraceptive device												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Women with type 1 diabetes												
1 (Grigoryan et al., 2006)	11	7.8 (SD 0.3)	7.9 (SD 0.2)	NA	Mean difference 0.1 higher (0.1 lower to 0.3 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[i]
Women with type 2 diabetes												
1 (Grigoryan et al., 2006)	11	7.5 (SD 0.7)	7.5 (SD 0.7)	NA	Mean difference 0.0 (0.6 lower to 0.6 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[i]
No contraceptives												
Women with type 1 or type 2 diabetes												
1 (Grigoryan et al., 2006)	40	7.7 (SD 0.6)	7.7 (SD 0.5)	NA	Mean difference 0.0 (0.3 lower to 0.3 higher)[a]	Moderate	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision	Yes[m, q]
From baseline to 9 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1	10	7.5 (SD 0.3)	7.6 (SD 0.6)	NA	Mean difference	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, n]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Grigoryan et al., 2006)					0.1 higher (SD 0.4 lower to 0.6 higher)a							
1 (Grigoryan et al., 2006)	14	7.5 (SD 0.3)	7.6 (SD 0.3)	NA	Mean difference 0.1 higher (0.1 lower to 0.3 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]
1 (Grigoryan et al., 2006)	12	7.5 (SD 0.3)	7.6 (SD 0.6)	NA	Mean difference 0.1 higher (0.3 lower to 0.5 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, p]
Women with type 2 diabetes												
1 (Grigoryan et al., 2006)	10	7.7 (SD 0.4)	7.5 (SD 0.4)	NA	Mean difference 0.2 lower (0.6 lower to 0.2 higher)a	Low	Randomised trial	Serious limitations l	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, n]
1 (Grigoryan et al., 2006)	14	7.6 (SD 0.5)	7.4 (SD 0.5)	NA	Mean difference 0.2 lower	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					(0.6 lower to 0.2 higher)a							
1 (Grigoryan et al., 2006)	9	7.3 (SD 0.4)	7.6 (SD 0.3)	NA	Mean difference 0.3 higher (0.1 lower to 0.7 higher)a	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, p]
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 diabetes												
1 (Grigoryan et al., 2006)	11	7.8 (SD 0.3)	7.5 (SD 0.6)	NA	Mean difference 0.3 lower (0.7 lower to 0.1 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[i]
Women with type 2 diabetes												
1 (Grigoryan et al., 2006)	11	7.5 (SD 0.7)	7.6 (SD 0.4)	NA	Mean difference 0.1 higher (0.4 lower to 0.6 higher)a	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[i]
No contraceptives												
Women with type 1 and type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Grigoryan et al., 2006)	40	7.7 (SD 0.6)	7.6 (SD 0.7	NA	Mean difference 0.1 higher (0.4 lower to 0.6 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[m, q]
From baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 8.2 (IQR NR)	Median 8.4 (IQR NR)	NA	Median difference 0.2 higher (NC)[a]	Very low	Case-control	Serious limitations[r]	No serious inconsistency[c]	No serious indirectness[d]	NCs	Yes[e, t]
1 (Grigoryan et al., 2006)	10	7.5 (SD 0.3)	7.5 (SD 0.4)	NA	Mean difference 0.0 (0.3 lower to 0.3 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, n]
1 (Grigoryan et al., 2006)	14	7.5 (SD 0.3)	7.5 (SD 0.6)	NA	Mean difference 0.0 (0.4 lower to 0.4 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]
1	12	7.5 (SD 0.3)	7.5 (SD 0.4)	NA	Mean difference 0.0	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, p]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Grigoryan et al., 2006)					(0.3 lower to 0.3 higher)[a]							
Women with type 2 diabetes												
1 (Grigoryan et al., 2006)	10	7.7 (SD 0.4)	7.6 (SD 0.3)	NA	Mean difference 0.1 lower (0.4 lower to 0.2 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[ni]	Yesf, m, n
1 (Grigoryan et al., 2006)	14	7.6 (SD 0.5)	7.5 (SD 0.7)	NA	Mean difference 0.1 lower (0.6 lower to 0.4 higher)a	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[f, m, o]
1 (Grigoryan et al., 2006)	9	7.3 (SD 0.4)	7.4 (SD 0.7)	NA	Mean difference 0.1 higher (0.5 lower to 0.7 higher)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision	Yes[f, m, p]
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 diabetes												
1 (Grigoryan et al., 2006)	11	7.8 (SD 0.3)	7.8 (SD 0.7)	NA	Mean difference 0.0	Low	Randomised trial	Serious limitations[l]	No serious inconsistencyc	No serious indirectness[d]	Serious imprecision[i]	Yes[i]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					(0.5 lower to 0.5 higher)[a]							
Women with type 2 diabetes												
1 (Grigoryan et al., 2006)	11	7.5 (SD 0.7)	7.4 (SD 0.3)	NA	Mean difference 0.1 lower (0.6 lower to 0.4 more)[a]	Low	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yes[i]
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 8.5 (IQR NR)	Median 8.2 (IQR NR)	NA	Median difference 0.3 lower (NC)a	Very low	Case-control	Serious limitations[r]	No serious inconsistency[c]	No serious indirectness[d]	NC[s]	Yes[e]
No contraceptives												
Women with type 1 or type 2 diabetes												
1 (Grigoryan et al., 2006)	40	7.7 (SD 0.6)	7.5 (SD 0.2)	NA	Median difference 0.2 lower (0.4 lower to 0.0)[a]	Moderate	Randomised trial	Serious limitations[l]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision	Yes[m, q]

IQR interquartile range, NA not applicable, NC not calculable, SD standard deviation, NR not reported
a Calculated by the NCC-WCH based on results reported in the paper
b It is unclear whether an appropriate method of randomisation was used, whether there was adequate concealment of allocation to groups, whether comparison groups received the same care apart from the use of oral contraceptives, whether participants were blinded, and whether clinicians were blinded.
c Single study analysis
d Study met population and outcome criteria specified in the review protocol

e Conducted in Denmark. Ethnicity of the participants was not reported.
f Different groups of women are presented from the same study for the same outcome as they received different dosages of oestrogen and/or progestogen
g These women received 35 micrograms ethinyl E2 (EE2) and 500 micrograms of norethindrone
h These women received 4mg of 17β-oestradiol (E2), 2mg of oestradiol, and 3mg of norethindrone
i Confidence interval for the MD crosses the line of no effect (MD = 0) and the minimally important difference (50% of the combined standard deviation of the group at baseline and N months)
j These women received a combination of 30 micrograms of EE2 + 50 micrograms of levonorgestrel for the first 6 days, 40 micrograms of EE2 + 75 micrograms of levonorgestrel for the next 5 days, and 30 micrograms of EE2 + 125 micrograms of levonorgestrel during the last 10 days for each treatment cycle
k These women received 300 micrograms of norethindrone
l It is unclear whether an appropriate method of randomisation was used, whether there was adequate concealment of allocation, whether the groups were comparable at baseline, whether the groups received the same care apart from the type of contraception used, whether participants and/or clinicians were kept blind to the type of contraceptive they were using, whether investigators were kept blind to important confounding and prognostic factors.
m Conducted in Russia. Ethnicity of the participants was not reported.
n These women received 30 micrograms ethinylestradiol and 150 micrograms desogestrel
o These women received 20 micrograms ethinylestradiol and 150 micrograms desogestrel
p These women received 30 micrograms ethinylestradiuol and 75 micorgrams gestodene
q It was not reported how many of these women had type 1 and how many of these women had type 2 diabetes
r The main potential confounders were not identified or taken into account in the design and analysis of the study
s Confidence intervals for the median difference could not be calculated and so imprecision could not be calculated
t 30 micrograms ethinyl oestradiol and 75 micrograms gestodene

Table 16: GRADE profile for incidence of dyslipidaemia in women with diabetes using oral contraceptives compared with women with diabetes not using oral contraceptives (single time point data)

Number of studies	Number of women	Mean Value (%)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		Oral contraceptives group	No oral contraceptives group	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Cholesterol (mmol/l)												
Oestrogen and progestogen combined oral contraceptives vs. no oral contraceptives												
Women with type 1 diabetes												
1 (Garg et al., 1994)	43 in each group	4.8 (SD 0.9)	4.6 (SD 0.7)	NA	Mean difference 0.1 higher (0.2 lower to 0.5 higher)[a]	Very low	Case-control	No serious limitations	No serious inconsistency[b]	Very serious indirectness[c]	Serious imprecision[d]	Yes[e, f]

NA not applicable, SD standard deviation

a Calculated by the NCC-WCH based on results reported in the paper

b Single study analysis

c Data do not reflect a change in incidence of dyslipidaemia, only the cholesterol value at the time of data collection. Cholesterol is reported as a proxy for incidence of dyslipidaemia as there were no data reported for dyslipidaemia

d Confidence interval for the MD crosses the line of no effect (MD = 0) and the minimally important difference (50% of the combined standard deviation of the group at baseline and N months)

e Conducted in the United States of America. Ethnicity of the participants was not reported.

f The dosages of oestrogen and/or progestogen in the oral contraceptives were not reported. However, all women were using low-dose preparations containing 0.05mg or less of ethinyl estradiol (or mestranol) and a progestin

Table 17: GRADE profile for incidence of dyslipidaemia in women with diabetes using oral contraceptives compared with women with diabetes not using oral contraceptives (multiple time point data)

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Total cholesterol (mmol/l)												
Baseline to 1 month												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 4.9 (IQR NR)	Median 4.6 (IQR NR)	NA	Median difference 0.3 lower (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[d]	NC[e]	Yes[f, g]
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 5.4 (IQR NR)	Median 5.2 (IQR NR)	NA	Median difference 0.2 lower (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[d]	NC[e]	Yes[f]
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 4.9 (IQR NR)	Median 4.6 (IQR NR)	NA	Median difference 0.3 lower (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[i]	NC[e]	Yesf, g
Women with type 1 or type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Diab et al., 2000)	20	5.4 (SD 0.8)	5.1 (SD 0.9)	NA	Mean difference 0.4 lower (0.9 lower to 0.2 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[si]	Serious imprecision[j]	Yes[k, g]
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	5.8 (SD 0.1)	5.5 (SD 0.2)	NA	Mean difference 0.4 lower (0.9 lower to 0.2 lower)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[i]	No serious imprecision	Yes[k]
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 5.4 (IQR NR)	Median 5.1 (IQR NR)	NA	Median difference 0.3 lower (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[i]	NC[e]	Yes[f]
Baseline to 6 months												
Oral contraceptives –oestrogen and progestogen combined												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	22 at baseline, 19 at 6 months	Median 4.9 (IQR NR)	Median 4.7 (IQR NR)	NA	Median difference 0.2 lower (NC)a	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[i]	NC[e]	Yes[f, g]
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	5.4 (SD 0.8)	5.3 (SD 0.8)	NA	Mean difference 0.1 lower (0.6 lower to 0.4 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[i]	Serious imprecisionj	Yesk, g
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	5.8 (SD 0.1)	5.4 (SD 0.6)	NA	Mean difference 0.4 lower (0.6 lower to 0.1 lower)[a]	Very low	Observational	Serious limitationsh	No serious inconsistency[c]	Serious indirectness[i]	No serious imprecision	Yes[k]
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et	20 at baseline, 19	Median 5.4 (IQR NR)	Median 5.3	NA	Median differenc	Very low	Case-control	Serious limitationsb	No serious inconsistency[c]	Serious indirectness[i]	NC[e]	Yes[f]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
al., 1995)	at 6 months		(IQR NR)		e 0.1 lower (NC)[a]							
Baseline to 9 months												
Oral contraceptives –oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	5.4 (SD 0.8)	5.2 (SD 0.8)	NA	Mean difference 0.2 lower (0.7 lower to 0.3 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[i]	Serious imprecision[j]	Yesk, g
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	5.8 (SD 0.1)	5.7 (SD 0.6)	NA	Mean difference 0.1 lower (0.4 lower to 0.1 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistencyc	Serious indirectnessi	Serious imprecision[j]	Yes[k]
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	22 at baseline, 17 at 12 months	Median 4.9 (IQR NR)	Median 4.5 (IQR NR)	NA	Median difference 0.4 lower (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[i]	NC[e]	Yes[f, g]
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 12 months	Median 5.4 (IQR NR)	Median 5.1 (IQR NR)	NA	Median difference 0.3 lower (NC) [a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[i]	NC[e]	Yes[f]
HDL cholesterol (mmol/l)												
Baseline to 1 month												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 1.4 (IQR NR)	Median 1.4 (IQR NR)	NA	Median difference 0.1 higher (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[l]	NC[e]	Yes[f, g]
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et	20	Median 1.6 (IQR NR)	Median 1.7 (IQR NR)	NA	Median difference 0.1 higher	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[l]	NC[e]	Yes[f]

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
al., 1995)					(NC) [a]							
Baseline to 2 months												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	1.4 (SD 0.1)	1.6 (SD 0.1)	NA	Mean difference 0.2 higher (from 0.1 higher to 0.3 higher)[a]	Low	Randomised trial	Serious limitationsm	No serious inconsistency[c]	Serious indirectness[l]	No serious imprecision	Yesf, n, o
1 (Skouby et al., 1986)	10	1.5 (SD 0.1)	1.4 (SD 0.1)	NA	Mean difference 0.2 lower (from 0.3 lower to 0.1 lower)[a]	Low	Randomised trial	Serious limitations[m]	No serious inconsistency[c]	Serious indirectness[l]	No serious imprecision	Yes[f, n, p]
1 (Skouby et al., 1986)	9	1.5 (SD 0.1)	1.6 (SD 0.1)	NA	Mean difference 0.1 higher (0.0 lower to 0.2 higher)[a]	Low	Randomised trial	Serious limitations[m]	No serious inconsistency[c]	Serious indirectness[l]	No serious imprecision	Yesf, n, q
Oral contraceptives – progestogen only												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	1.2 (SD 0.1)	1.2 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)[a]	Low	Randomised trial	Serious limitations[m]	No serious inconsistency[c]	Serious indirectness[l]	Serious imprecision[j]	Yes[f, r]
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 1.4 (IQR NR)	Median 1.5 (IQR NR)	NA	Median difference 0.1 higher (NC) [a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[l]	NC[e]	Yes[f, g]
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.1 (SD 0.2)	1.4 (SD 0.4)	NA	Mean difference 0.3 higher (0.1 higher to 0.5 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[l]	No serious imprecision	Yes[k, g]
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Diab et al., 2000)	20	1.1 (SD 0.2)	1.1 (SD 0.3)	NA	Mean difference 0.1 higher (0.1 lower to 0.2 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[l]	Serious imprecision[nj]	Yesk
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 1.6 (IQR NR)	Median 1.8 (IQR NR)	NA	Median difference 0.1 higher (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[l]	NC[e]	Yes[f]
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 19 at 6 months	Median 1.4 (IQR NR)	Median 1.5 (IQR NR)	NA	Median difference 0.1 higher (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[l]	NC[e]	Yesf, g
1 (Skouby et al., 1986)	10	1.4 (SD 0.1)	1.5 (SD 0.1)	NA	Mean difference 0.1 higher	Low	Randomised trial	Serious limitations[m]	No serious inconsistency[c]	Serious indirectness[l]	Serious imprecision[j]	Yesf, n, o

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					(0.0 lower to 0.2 higher)[a]							
1 (Skouby et al., 1986)	10	1.5 (SD 0.1)	1.3 (SD 0.1)	NA	Mean difference 0.2 lower (0.3 lower to 0.1 lower)[a]	Low	Randomised trial	Serious limitationsm	No serious inconsistency[c]	Serious indirectness[l]	No serious imprecision	Yesf, n, p
1 (Skouby et al., 1986)	9	1.5 (SD 0.1)	1.5 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)[a]	Low	Randomised trial	Serious limitations[m]	No serious inconsistency[c]	Serious indirectness[l]	Serious imprecision[j]	Yes[f, n, q]
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.1 (SD 0.2)	1.4 (SD 0.4)	NA	Mean difference 0.3 higher (0.1 higher to 0.5 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[l]	No serious imprecision	Yesk, g
Oral contraceptives – progestogen only												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	9	1.2 (SD 0.1)	1.3 (SD 0.1)	NA	Mean difference 0.1 higher (0.0 lower to 0.2 higher)[a]	Low	Randomised trial	Serious limitations[m]	No serious inconsistency[c]	Serious indirectness[l]	No serious imprecision	Yes[f, r]
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.1 (SD 0.2)	1.2 (SD 0.3)	NA	Mean difference 0.1 lower (0.1 lower to 0.3 higher)[a]	Very low	Observational	Serious limitations[h]	No serious inconsistency[c]	Serious indirectness[l]	Serious imprecision[j]	Yes[k]
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 6 months	Median 1.6 (IQR NR)	Median 1.7 (IQR NR)	NA	Median difference 0.1 higher (NC)[a]	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[l]	NC[e]	Yes[f]
Baseline to 9 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Diab et al., 2000)	20	1.1 (SD 0.2)	1.5 (SD 0.4)	NA	Mean difference 0.4 higher (0.2 higher to 0.6 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessl	No serious imprecision	Yesk, g
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.1 (SD 0.2)	1.1 (SD 0.2)	NA	Mean difference 0.0 (0.2 lower to 0.1 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessl	Serious imprecisionj	Yesk
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 17 at 9 months	Median 1.4 (IQR NR)	Median 1.5 (IQR NR)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessl	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	20 at baseline, 19 at 9 months	Median 1.6 (IQR NR)	Median 1.9 (IQR NR)	NA	Median difference 0.3 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessl	NCe	Yesf
HDL cholesterol/total cholesterol (mmol/l)												
Baseline to 1 month												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.3 (IQR NR)	Median 0.3 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessss	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.3 (IQR NR)	Median 0.3 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessss	NCe	Yesf
Baseline to 2 months												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	0.3 (SD 0.1)	0.3 (SD 0.1)	NA	Mean difference 0.0	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, n, o

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					(0.1 lower to 0.1 higher)a							
1 (Skouby et al., 1986)	10	0.3 (SD 0.1)	0.3 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, n, p
1 (Skouby et al., 1986)	9	0.3 (SD 0.1)	0.3 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, n, q
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	0.3 (SD 0.1)	0.2 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, r
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	22	Median 0.3 (IQR NR)	Median 0.3 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessss	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.3 (IQR NR)	Median 0.3 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessss	NCe	Yesf
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 19 at 6 months	Median 0.3 (IQR NR)	Median 0.3 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessss	NCe	Yesf, g
1 (Skouby et al., 1986)	10	0.3 (SD 0.1)	0.3 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, n, o

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	10	0.3 (SD 0.1)	0.3 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, n, p
1 (Skouby et al., 1986)	9	0.3 (SD 0.1)	0.3 (SD 0.1)	NA	Mean difference 0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, n, q
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	0.3 (SD 0.1)	0.3 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessss	Serious imprecisionj	Yesf, r
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 6	Median 0.3 (IQR NR)	Median 0.3 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessss	NCe	Yesf

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
	months											
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 17 at 9 months	Median 0.3 (IQR NR)	Median 0.3 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectness	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 9 months	Median 0.3 (IQR NR)	Median 0.4 (IQR NR)	NA	Median difference 0.1 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectness	NCe	Yesf
HDL2 cholesterol (mmol/l)												
Baseline to 1 month												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.6 (IQR NR)	Median 0.7 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnesst	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.9 (IQR NR)	Median 0.8 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessf	NCe	Yesf
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.6 (IQR NR)	Median 0.6 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessf	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.9 (IQR NR)	Median 0.8 (IQR NR)	NA	Median difference 0.1 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessf	NCe	Yesf
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 19 at 6	Median 0.6 (IQR NC)	Median 0.7 (IQR NC)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessf	NCe	Yesf, g

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
	months											
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 6 months	Median 0.9 (IQR NC)	Median 0.9 (IQR NC)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnesst	NCe	Yesf
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 17 at 9 months	Median 0.6 (IQR NR)	Median 0.5 (IQR NR)	NA	Median difference 0.1 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnesst	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 9 months	Median 0.9 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnesst	NCe	Yesf
HDL3 cholesterol (mmol/l)												
Baseline to 1 month												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.8 (IQR NR)	Median 0.8 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.8 (IQR NR)	Median 0.8 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.8 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.8 (IQR NR)	Median 0.8 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 19 at 6 months	Median 0.8 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 6 months	Median 0.8 (IQR NR)	Median 0.8 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 17 at 9 months	Median 0.8 (IQR NR)	Median 1.0 (IQR NR)	NA	Median difference 0.2 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	20 at baseline, 19 at 9 months	Median 0.8 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessu	NCe	Yesf
LDL cholesterol (mmol/l)												
Baseline to 1 month												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 3.2 (IQR NR)	Median 2.6 (IQR NR)	NA	Median difference 0.6 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 3.3 (IQR NR)	Median 3.2 (IQR NR)	NA	Median difference 0.1 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf
Baseline to 2 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	3.1 (SD 0.3)	3.4 (SD 0.4)	NA	Mean difference 0.2 higher	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesf, n, o

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					(0.1 lower to 0.6 higher)a							
1 (Skouby et al., 1986)	10	3.2 (SD 0.4)	3.0 (SD 0.3)	NA	Mean difference 0.2 lower (0.5 lower to 0.2 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesf, n, p
1 (Skouby et al., 1986)	9	3.2 (SD 0.2)	3.2 (SD 0.3)	NA	Mean difference 0.1 lower (0.3 lower to 0.2 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	No serious imprecision	Yesf, n, q
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	3.3 (SD 0.2)	3.5 (SD 0.4)	NA	Mean difference 0.2 higher (0.1 lower to 0.5 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesf, r
Baseline to 3 months												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 3.2 (IQR NR)	Median 2.6 (IQR NR)	NA	Median difference 0.6 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf, g
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	3.6 (SD 0.7)	3.3 (SD 0.8)	NA	Mean difference 0.2 lower (0.7 lower to 0.3 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesk, g
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	3.5 (SD 0.5)	3.3 (SD 0.7)	NA	Mean difference 0.2 lower (0.6 lower to 0.2 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesk
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	20	Median 3.3 (IQR NR)	Median 3.2 (IQR NR)	NA	Median difference 0.1 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 19 at 6 months	Median 3.2 (IQR NR)	Median 2.6 (IQR NR)	NA	Median difference 0.6 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf, g
1 (Skouby et al., 1986)	10	3.1 (SD 0.3)	3.5 (SD 0.4)	NA	Mean difference 0.4 higher (0.0 lower to 0.7 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesf, n, o
1 (Skouby et al., 1986)	10	3.2 (SD 0.4)	3.1 (SD 0.4)	NA	Mean difference 0.1 lower (0.4 lower to 0.3 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesf, n, p

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	9	3.2 (SD 0.2)	3.4 (SD 0.3)	NA	Mean difference 0.2 higher (0.1 lower to 0.4 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesf, n, q
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	3.6 (SD 0.7)	3.0 (SD 1.0)	NA	Mean difference 0.6 lower (1.1 lower to 0.0 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesk, g
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	3.3 (SD 0.2)	3.2 (SD 0.2)	NA	Mean difference 0.1 lower (from 0.3 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesf, r
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Diab et al., 2000)	20	3.5 (SD 0.5)	3.3 (SD 0.8)	NA	Mean difference 0.3 lower (0.7 lower to 0.2 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesk
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 6 months	Median 3.3 (IQR NR)	Median 3.1 (IQR NR)	NA	Median difference 0.2 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf
Baseline to 9 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	3.6 (SD 0.7)	2.8 (SD 0.7)	NA	Mean difference 0.8 lower (1.3 lower to 0.4 lower)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesk, g
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Diab et al., 2000)	20	3.5 (SD 0.5)	3.4 (SD 0.4)	NA	Mean difference 0.1 lower (0.4 lower to 0.2 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessv	Serious imprecisionj	Yesk
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 17 at 9 months	Median 3.2 (IQR NR)	Median 2.5 (IQR NR)	NA	Median difference 0.7 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 9 months	Median 3.3 (IQR NR)	Median 2.9 (IQR NR)	NA	Median difference 0.4 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessv	NCe	Yesf
VLDL cholesterol (mmol/l)												
Baseline to 1 month												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	22	Median 0.4 (IQR NR)	Median 0.5 (IQR NR)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessw	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.4 (IQR NR)	Median 0.4 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessw	NCe	Yesf
Baseline to 2 months												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	0.6 (SD 0.1)	0.7 (SD 0.2)	NA	Mean difference 0.1 higher (0.0 lower to 0.3 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	Serious imprecisionj	Yesf, n, o
1 (Skouby et al., 1986)	10	0.5 (SD 0.1)	0.4 (SD 0.1)	NA	Mean difference 0.1 lower (0.2 lower to	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	Serious imprecisionj	Yesf, n, p

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					0.0 higher)a							
1 (Skouby et al., 1986)	9	0.6 (SD 0.1)	0.6 (SD 0.2)	NA	Mean difference 0.1 higher (0.1 lower to 0.2 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	Serious imprecisionj	Yesf, n, q
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	0.6 (SD 0.1)	0.8 (SD 0.1)	NA	Mean difference 0.2 higher (0.1 higher to 0.3 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	No serious imprecision	Yesf, r
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.4 (IQR NR)	Median 0.6 (IQR NR)	NA	Median difference 0.2 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessw	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	20	Median 0.4 (IQR NR)	Median 0.4 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessw	NCe	Yesf
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 19 at 6 months	Median 0.4 (IQR NR)	Median 0.5 (IQR NR)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessw	NCe	Yesf, g
1 (Skouby et al., 1986)	10	0.6 (SD 0.1)	0.9 (SD 0.1)	NA	Mean difference 0.3 higher (0.2 higher to 0.4 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	No serious imprecision	Yesf, n, o
1 (Skouby et al., 1986)	10	0.5 (SD 0.1)	0.4 (SD 0.1)	NA	Mean difference 0.1 lower (0.2 lower to 0.0 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	Serious imprecisionj	Yesf, n, p

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	9	0.6 (SD 0.1)	0.5 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	Serious imprecisionj	Yesf, n, q
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	0.6 (SD 0.1)	0.5 (SD 0.1)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessw	Serious imprecisionj	Yesf, r
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 6 months	Median 0.4 (IQR NR)	Median 0.4 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessw	NCe	Yesf
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1	22 at baseline, 17	Median 0.4	Median 0.5	NA	Median differenc	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessw	NCe	Yesf, g

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Petersen et al., 1995)	at 9 months	(IQR NR)	(IQR NR)		e 0.1 higher (NC)a							
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 9 months	Median 0.4 (IQR NR)	Median 0.4 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[w]	NCe	Yesf
Triglycerides (mmol/l)												
Baseline to 1 month												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.9 (IQR NR)	Median 1.0 (IQR NR)	NA	Median difference 0.1 higher (NC)a	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[x]	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 1.0 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitations[b]	No serious inconsistency[c]	Serious indirectness[x]	NCe	Yesf
Baseline to 2 months												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	1.3 (SD 0.2)	1.6 (SD 0.3)	NA	Mean difference 0.3 higher (0.1 higher to 0.5 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	No serious imprecision	Yesf, n, o
1 (Skouby et al., 1986)	10	1.1 (SD 0.2)	0.9 (SD 0.1)	NA	Mean difference 0.1 lower (0.3 lower to 0.0 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	Serious imprecisionj	Yesf, n, p
1 (Skouby et al., 1986)	9	1.3 (SD 0.3)	1.4 (SD 0.4)	NA	Mean difference 0.1 higher (0.2 lower to 0.5 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	Serious imprecisionj	Yesf, n, q
Oral contraceptives – progestogen only												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	9	1.3 (SD 0.1)	1.7 (SD 0.3)	NA	Mean difference 0.4 higher (0.2 higher to 0.6 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	No serious imprecision	Yesf, r
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.9 (IQR NR)	Median 1.2 (IQR NR)	NA	Median difference 0.3 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessx	NCe	Yesf, g
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.4 (SD 0.2)	1.6 (SD 0.1)	NA	Mean difference 0.1 higher (0.0 lower to 0.2 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessx	No serious imprecision	Yesk, g
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1	20	1.5	1.6	NA	Mean differenc	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessx	Serious imprecisionj	Yesk

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Diab et al., 2000)		(SD 0.2)	(SD 0.3)		e 0.1 higher (0.1 lower to 0.2 higher)a							
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 1.0 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.1 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessx	NCe	Yesf
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 19 at 6 months	Median 0.9 (IQR NR)	Median 1.1 (IQR NR)	NA	Median difference 0.2 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessx	NCe	Yesf, g
1 (Skouby et al., 1986)	10	1.3 (SD 0.2)	1.9 (SD 0.3)	NA	Mean difference 0.6 higher (0.4 higher to 0.9 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	No serious imprecision	Yesf, n, o

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	10	1.1 (SD 0.2)	1.0 (SD 0.1)	NA	Mean difference 0.1 lower (0.3 lower to 0.0 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	Serious imprecisionj	Yesf, n, p
1 (Skouby et al., 1986)	9	1.3 (SD 0.3)	1.1 (SD 0.2)	NA	Mean difference 0.2 lower (0.3 lower to 0.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	Serious imprecisionj	Yesf, n, q
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.4 (SD 0.2)	1.6 (SD 0.1)	NA	Mean difference 0.2 higher (0.1 higher to 0.3 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessx	No serious imprecision	Yesk, g
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1	9	1.3 (SD 0.1)	1.2 (SD 0.1)	NA	Mean difference 0.1 lower	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessx	Serious imprecisionj	Yesf, r

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Skouby et al., 1986)					(0.2 lower to 0.0 higher)a							
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.5 (SD 0.2)	1.5 (SD 0.2)	NA	Mean difference 0.0 (0.1 lower to 0.1 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessx	No serious imprecision	Yesk
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 6 months	Median 1.0 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.1 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessx	NCe	Yesf
Baseline to 9 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.4 (SD 0.2)	1.7 (SD 0.1)	NA	Mean difference 0.2 higher (0.2 higher to	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessx	No serious imprecision	Yesk, g

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
					0.3 higher)a							
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	1.5 (SD 0.2)	1.5 (SD 0.2)	NA	Mean difference 0.0 (0.1 lower to 0.2 higher)a	Very low	Observational	Serious limitationsh	No serious inconsistencyc	Serious indirectnessx	Serious imprecisionj	Yesk
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22 at baseline, 17 at 9 months	Median 0.9 (IQR NR)	Median 1.1 (IQR NR)	NA	Median difference 0.2 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessx	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20 at baseline, 19 at 9 months	Median 1.0 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.1 lower (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessx	NCe	Yesf
Free fatty acids (mmol/l)												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Baseline to 2 months												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	854.0 (SD 99.0)	996.0 (SD 112.0)	NA	Mean difference 142.0 higher (42.7 higher to 241.3 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	No serious imprecision	Yesf, n, o
1 (Skouby et al., 1986)	10	986.0 (SD 151.0)	814.0 (SD 100.0)	NA	Mean difference 172.0 lower (292.3 lower to 51.7 lower)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	No serious imprecision	Yesf, n, p
1 (Skouby et al., 1986)	9	594.0 (SD 61.0)	452.0 (SD 151.0)	NA	Mean difference 142.0 lower (257.1 lower to 26.9 lower)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	No serious imprecision	Yesf, n, q
Oral contraceptives – progestogen only												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Skouby et al., 1986)	9	969.0 (SD 138.0)	1030.0 (SD 251.0)	NA	Mean difference 61 higher (141.4 lower to 263.4 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	Serious imprecisionj	Yesf, r
Baseline to 6 months												
Oral contraceptives - oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	10	854.0 (SD 99.0)	756.0 (SD 118.0)	NA	Mean difference 98.0 lower (200.0 lower to 4.3 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	Serious imprecisionj	Yesf, n, o
1 (Skouby et al., 1986)	10	986.0 (SD 151.0)	1033.0 (SD 145.0)	NA	Mean difference 47.0 higher (92.1 lower to 186.1 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	Serious imprecisionj	Yesf, n, p
1	9	594.0 (SD 61.0)	761.0 (SD 105.0)	NA	Mean difference 167.0 higher	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	No serious imprecision	Yesf, n, q

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At X months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Skouby et al., 1986)					(81.2 higher to 252.8 higher)a							
Oral contraceptives – progestogen only												
Women with type 1 diabetes												
1 (Skouby et al., 1986)	9	969.0 (SD 138.0)	783.0 (SD 123.0)	NA	Mean difference 186.0 lower (316.6 lower to 55.3 higher)a	Low	Randomised trial	Serious limitationsm	No serious inconsistencyc	Serious indirectnessy	Serious imprecisionj	Yesf, r
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	22	Median 0.9 (IQR NR)	Median 0.9 (IQR NR)	NA	Median difference 0.0 (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessy	NCe	Yesf, g
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 0.9 (IQR NR)	Median 1.1 (IQR NR)	NA	Median difference 0.2 higher (NC)a	Very low	Case-control	Serious limitationsb	No serious inconsistencyc	Serious indirectnessy	NCe	Yesf

Table 18: GRADE profile for hypertension in women with diabetes using oral contraceptives compared with women with diabetes not using oral contraceptives (single time point data)

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Using oral contraceptives	Not using oral contraceptives	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Diastolic blood pressure											
Borderline elevated systolic blood pressure (defined as systolic blood pressure above the 90th percentile for age on at least two separate visits) (after use of oral contraceptives for ≥ 1 year)											
Women with type 1 diabetes											
1 (Garg et al., 1994)	12/43 (28%)	16/43 (37%)	RR 0.8 (0.4 to 1.4)a	93 fewer per 1000 (from 223 fewer to 145 more)	Very low	Case-control	No serious limitations	No serious inconsistency[b]	Very serious indirectness[c]	Serious imprecision[d]	Yes[e, f]
Borderline elevated diastolic blood pressure (defined as diastolic blood pressure above the 90th percentile for age on at least two separate visits) (after use of oral contraceptives for ≥ 1 year)											
Women with type 1 diabetes											
1 (Garg et al., 1994)	23/43 (54%)	23/43 (54%)	RR 1.0 (0.7 to 1.5)a	0 fewer per 1000 (from 177 fewer to 257 more)	Very low	Case-control	No serious limitations	No serious inconsistency[b]	Very serious indirectness[s]	Serious imprecisiond	Yes[e, f]

RR risk ratio
a Calculated by the NCC-WCH based on results reported in the paper
b Single study analysis
c Diastolic blood pressure is reported as a proxy for hypertension as there were no data reported for hypertension. Data do not reflect a change in hypertension, only the mean diastolic blood pressure value at the time of data collection
d Confidence interval for the RR crosses the line of no effect (RR = 1) and RR = 0.75 and/or RR = 1.25
e Conducted in the United States of America. Ethnicity of the participants was not reported.
f The dosages of oestrogen and/or progestogen in the oral contraceptives were not reported. However, all women were using low-dose preparations containing 0.05mg or less of ethinyl estradiol (or mestranol) and a progestin

Table 19: GRADE profile for hypertension in women with diabetes using oral contraceptives compared with women with diabetes not using oral contraceptives (multiple time point data)

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Systolic blood pressure (mmHg)												
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	113.0 (SD 4.4)	112.0 (SD 4.1)	NA	Mean difference 1.0 lower (3.7 lower to 1.7 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf, g, h
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	112.0 (SD 4.1)	110.0 (SD 2.2)	NA	Mean difference 2.0 lower (4.1 lower to 0.1 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf, g
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1	20	113.0 (SD 4.4)	112.0 (SD 2.3)	NA	Mean difference 1.0 lower	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf, g, h

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Diab et al., 2000)					(3.3 lower to 1.3 higher)a							
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	112.0 (SD 4.1)	111.0 (SD 3.1)	NA	Mean difference 1.0 lower (3.3 lower to 1.3 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf, g
Baseline to 9 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	113.0 (SD 4.4)	112.0 (SD 3.3)	NA	Mean difference 1.0 lower (3.5 lower to 1.5 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf, g, h
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	112.0 (SD 4.1)	111.0 (SD 2.2)	NA	Mean difference 1.0 lower (3.1 lower to 1.1 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf, g
Diastolic blood pressure (mmHg)												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Baseline to 3 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	73.5 (SD 1.3)	72.5 (SD 5.5)	NA	Mean difference 1.0 lower (3.6 lower to 1.6 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessi	Serious imprecisionе	Yesf, g, h
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	74.5 (SD 5.1)	71.0 (SD 4.5)	NA	Mean difference 3.5 lower (6.6 lower to 0.4 lower)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessi	No serious imprecision	Yesf, g
Baseline to 6 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	73.5 (SD 1.3)	72.0 (SD 5.2)	NA	Mean difference 1.5 lower (3.9 lower to 0.9 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessi	Serious imprecisionе	Yesf, g, h
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Diab et al., 2000)	20	74.5 (SD 5.1)	69.0 (SD 2.2)	NA	Mean difference 5.5 lower (8.0 lower to 3.0 lower)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessi	No serious imprecision	Yesf, g
Baseline to 9 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	73.5 (SD 1.3)	71.5 (SD 5.9)	NA	Mean difference 2.0 lower (4.7 lower to 0.7 higher)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessi	Serious imprecisione	Yesf, g, h
Non-oral contraceptives – intrauterine contraceptive device												
Women with type 1 or type 2 diabetes												
1 (Diab et al., 2000)	20	74.5 (SD 5.1)	67.5 (SD 4.4)	NA	Mean difference 7.0 lower (10.1 lower to 3.9 lower)a	Very low	Observational	Serious limitationsb	No serious inconsistencyc	Serious indirectnessi	No serious imprecision	Yesf, g
Arterial blood pressure (mmHg)												
Baseline to 12 months												
Oral contraceptives – oestrogen and progestogen combined												
Women with type 1 diabetes												

Number of studies	Number of women	Mean Value		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
		At baseline	At N months	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Petersen et al., 1995)	22	Median 90.0 (IQR NR)	Median 92.0 (IQR NR)	NA	Median difference 2.0 higher (NC)a	Very low	Case-control	Serious limitations j	No serious inconsistency c	Serious indirectness k	NCl	Yesm, h
Non-oral contraceptives – unspecified non-hormonal contraceptives												
Women with type 1 diabetes												
1 (Petersen et al., 1995)	20	Median 97.0 (IQR NR)	Median 94.0 (IQR NR)	NA	Median difference 3.0 lower (NC)a	Very low	Case-control	Serious limitations j	No serious inconsistency c	Serious indirectness k	NCl	Yesm

IQR interquartile range, SD standard deviation, NA not applicable, NC not calculable

a Calculated by the NCC-WCH based on results reported in the paper

b No attempt was made within the design or analysis to balance the comparison groups for potential confounders. It is unclear whether clinicians were blinded to treatment exposure or to confounding prognostic factors.

c Single study analysis

d Systolic blood pressure is reported as a proxy for hypertension as there were no data reported for hypertension

e Confidence interval for the MD crosses the line of no effect (MD = 0) and the minimally important difference (50% of the combined standard deviation of the group at baseline and N months)

f 17/20 (85%) women in the combined oral contraceptives group had type 1 diabetes and 3/20 (15%) had type 2 diabetes. 15/20 (75%) of women in the intrauterine contraceptive device group had type 1 diabetes and 5/20 (25%) had type 2 diabetes.

g Conducted in Egypt. Ethnicity of the participants was not reported.

h Women received 30 micorgrams ethinyl estradiol and 75 micrograms gestodene

i Diastolic blood pressure is reported as a proxy for hypertension as there were no data reported for hypertension

j The main potential confounders were not identified or taken into account in the design and analysis of the study

k Arterial blood pressure is reported as a proxy for hypertension as there were no data reported for hypertension

l Confidence intervals for the median difference could not be calculated and so imprecision could not be calculated

m Conducted in Denmark. Ethnicity of the participants was not reported.

Table 20: GRADE profile for comparison of lower HbA_{1c} values with higher HbA_{1c} values before conception in women with type 1 diabetes mellitus and type 2 diabetes mellitus.

Number of studies	Number of children and young people		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Congenital malformations											
HbA_{1c} < 5.6% versus ≥ 5.6%											
1 (Suhonen et al., 2000)	1/47	25/616	RR 0.50 (0.07 to 3.61)a	20 fewer per 1000 (from 38 fewer to 106 more per 1000)	Very low	Retrospective cohort	No serious bias	No serious inconsistency 1	Very serious2,3	Very serious4	Yes5
HbA_{1c} > 6.3% versus ≤ 6.3%											
1 (Bell et al., 2012)	NR	NR	OR 5.22 (3.15 to 8.32)b	Not calculable	Very low	Retrospective cohort	No serious bias	No serious inconsistency 1	Very serious6,7	No serious imprecision	Yes8
HbA_{1c} < 6.9% versus ≥ 6.9%											
1 (Jensen et al., 2009)	11/284	34/649	RR 0.74 (0.38 to 1.44)a	14 fewer per 1000 (from 32 fewer to 23 more per 1000)	Very low	Retrospective cohort	Serious 9	No serious inconsistency 1	Serious6	Very serious10	Yes11
HbA_{1c} ≤ 8.0% versus > 8.0%											
1 (Diabetes and Pregnancy	8/315	10/120	RR 0.30 (0.12	58 fewer per 1000 (from 22 to	Very low	Cross-sectional	No serious bias	No serious inconsistency 1	Very serious12, 13	No serious imprecision	Yes14

Number of studies	Number of children and young people		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Group, France, 2008)			to 0.74)a	73 fewer per 1000)							
HbA_{1c} ≤ 8.4% versus > 8.4%c											
1 (Greene et al., 1989)	3/99	17/151	RR 0.27 (0.08 to 0.90)a	82 fewer per 1000 (from 11 to 104 fewer per 1000)	Very low	Retrospective cohort	Serious 15	No serious inconsistency 1	Very serious3,7 ,16	Serious17	Yes18
HbA_{1c} ≤ 8.5% versus > 8.5%											
1 (Miller et al., 1981)	2/58	13/58	RR 0.15 (0.04 to 0.64)a	191 fewer per 1000 (from 81 to 215 fewer per 1000)	Very low	Retrospective review	No serious bias	No serious inconsistency 1	Serious19	No serious imprecision	Yes20
Perinatal mortality											
HbA_{1c} < 6.6% versus ≥ 6.6%											
1 (Tennant et al., 2014)	NR	NR	OR 1.02 (1.00 to 1.04)d	NC	Very low	Retrospective cohort	No serious bias	No serious inconsitency1	Very serious21, 22	No serious imprecision	Yes23
HbA_{1c} < 6.9% versus ≥ 6.9%											
1 (Jensen et al., 2009)	6/284	25/649	RR 0.55 (0.23 to 1.33)a	17 fewer per 1000 (from 30 fewer to 13 more per 1000)	Very low	Retrospective cohort	Serious 9	No serious inconsistency 1	Serious6	Very serious10	Yes11
HbA_{1c} ≤ 8.0% versus > 8.0%											

Number of studies	Number of children and young people		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Diabetes and Pregnancy Group, France, 2008)	8/315	11/120	RR 0.28 (0.11 to 0.68)a	66 fewer per 1000 (from 29 to 82 fewer per 1000)	Very low	Cross-sectional	No serious bias	No serious inconsistency 1	Very serious12, 13	No serious imprecision	Yes14
Spontaneous miscarriage											
HbA_{1c} < 10.9% versus ≥ 10.9%e											
1 (Miodovnik et al., 1985)	14/89	12/27	RR 0.35 (0.18 to 0.66)a	289 fewer per 1000 (from 151 to 360 fewer per 1000)	Very low	Prospective cohort	No serious bias	No serious inconsistency 1	Very serious10, 24	No serious imprecision	Yes25

a Calculated by the NCC-WCH technical team.
b The OR for an HbA_{1c} threshold of 6.3% was calculated by the NCC-WCH technical team.
c Based on a reported HbA1 value of 9.3%. This value was converted to HbA_{1c} by the NCC-WCH technical team using a standard conversion formula ($HbA\neg_{1c}$ = 0.9 HbA1 + 0.05).
d Calculated by study authors based on the threshold for increased risk using locally weighted scatter plot smoothing.
e Based on a reported HbA1 value of 12.0%. This value was converted to HbA_{1c} by the NCC-WCH technical team using a standard conversion formula ($HbA\neg_{1c}$ = 0.9 HbA1 + 0.05).1 Single study analysis.
2 Participants were not treated to reach specific target values; thresholds for optimal blood glucose were applied post hoc.
3 HbA_{1c} measurements were taken at unspecified time points during the first trimester; it is possible that HbA_{1c} is representative of earl pregnancy rather than pre-pregnancy.
4 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25. Power calculations suggested a required sample size of 602 per group for cases (diabetes) and controls (euglycaemic). Data for control subjects were not analysed by the NCC-WCH technical team as these participants do not meet inclusion criteria for this review. The study is therefore likely underpowered to detect differences between women in HbA_{1c} groups used in analyses by the NCC-WCH technical team.
5 The study was carried out in Finland. Participants had type 1 diabetes. Ethnicity was 98% Finnish Caucasian.
6 Participants were not treated to reach specific target values; thresholds for optimal blood glucose were applied post hoc.
7 The use of mean first trimester HbA_{1c} makes the assumption that HbA_{1c} within three months of conception reflects levels around the time of conception; results may be biased towards HbA_{1c} values during pregnancy.
8 The study was carried out in the United Kingdom. Participants had both type 1 and type 2 diabetes. Ethnicity was Caucasian in 97.3% of participants. Other ethnicities are not defined.
9 Only 784 out of 933 (84%) women had complete data for pre-conception HbA_{1c}. First trimester measurements were used as a surrogate in 149 cases.

10 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.
11 The study was carried out in Denmark. Participants had type 1 diabetes. All women were Caucasian.
12 HbA_{1c} was measured in the first trimester but it is not clear when. Authors state HbA_{1c} reflects pre-pregnancy levels but this is not clear. Results may reflect early pregnancy.
13 Participants were not treated to reach specific target values; thresholds for optimal blood glucose were applied post hoc.
14 The study was carried out in France. Participants had both type 1 and type 2 diabetes. Ethnicity was not reported.
15 No explanation was provided for missing data for 31 women. Total sample size was reported as 303; 21 women were formally excluded at the outset and one was additional woman was excluded from analyses however outcome data were only reported for 250 women.
16 The study measured HbA1 rather than HbA_{1c}.
17 Confidence interval for the RR crosses RR = 0.75.
18 The study was carried out in the United States of America. Participants had type 1 diabetes. Ethnicity was not reported.
19 HbA_{1c} was measured in the first trimester. The mean gestational age and standard deviation for each group suggested that HbA_{1c} was measured at or before 12 weeks in most women however results may be biased towards HbA_{1c} values during pregnancy.
20 The study was carried out in the United States of America. Participants had type 1 diabetes. Ethnicity was not reported.
21 Peri-conception HbA_{1c} was used as a surrogate for pre-conception HbA_{1c}.
22 This outcome was defined as 'infant death' which comprised both 'neonatal deaths' (deaths, after live birth, within the first 28 days of life) and 'postnatal deaths' (deaths, after live birth, of an infant aged 28 days or more, but less than one year).
23 The study was carried out in the United Kingdom. Participants had both type 1 and type 2 diabetes. Ethnicity was not reported.
24 HbA1 was measured at study entry at approximately 7 to 10 weeks' gestation; results may be biased towards HbA_{1c} values during pregnancy.
25 The study was carried out in the United States of America. Participants had type 1 diabetes. Ethnicity was not reported.

J.2 Gestational diabetes

Table 21: GRADE profile for the incidence of gestational diabetes in the first trimester diagnosed using a 75g OGTT (World Health Organization 1999 diagnostic criteria for gestational diabetes: fasting plasma glucose ≥ 7.0 mmol/L and/or 2 hour plasma glucose ≥ 7.8 mmol/L). It also presents the proportion of women who were diagnosed as having gestational diabetes in the first trimester out of the total number of women who were diagnosed as having gestational diabetes in the first and second trimesters combined

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the first trimester in all women tested	Women diagnosed with gestational diabetes in the first trimester as a proportion of all women diagnosed in the first and second trimester	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
Screening and/or diagnosis in the first trimester using 75g OGTT as diagnostic test (WHO 1999)											

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the first trimester in all women tested	Women diagnosed with gestational diabetes in the first trimester as a proportion of all women diagnosed in the first and second trimester	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
1 (Agarwal et al., 2007)	760[a]	708 (93.2%)	79/708 (11.2%)	79/184 (42.9%)	Low	Prospective cohort	Serious[b],[c]	NA	No serious indirectness[d]	Serious[e]	Yes[f]
1 (Bito et al., 2005)	163g	163 (100%)	8/163 (4.9%)	8/40 (20.0%)	Very low	Prospective cohort	Serious[h]	NA	Serious[i]	Serious[e]	Yes[j]
1 (Kuti et al., 2011)	765k	69 (9.0%)	12/69 (17.4%)	12/47 (25.5%)	Very low	Retrospective cohort	Serioush	NA	Serious[l]	Serious[e]	Yes[m]

NA not applicable, OGTT oral glucose tolerance test, WHO World Health Organization

a Universal screening strategy using fasting plasma glucose (FPG) test in the first trimester, 52/760 women did not complete the diagnostic 2 hour 75g OGTT . Women with a screening FPG ≥ 5.3mmol/l underwent a diagnostic 2 hour 75g OGTT within 2 weeks of screening. Women with a screening FPG < 5.3mmol/l underwent a diagnostic 2 hour 75g OGTT diagnostic test between gestational weeks 24-28.

b Unclear whether index test results were interpreted without knowledge of the results of the reference standard

c Unclear whether reference standard results were interpreted without knowledge of the results of the index test

d Screening for gestational diabetes was usually performed in the first trimester (median and mean: gestational week 10) with the diagnostic test being performed 2 weeks later, although some women were screened and diagnosed in the second trimester (range: gestational weeks 5-18)

e Total number of events less than 300

f Country: United Arab Emirates. Ethnicity of population: Arab (92.2%), Indian subcontinent including India, Pakistan, Bangladesh, Sri Lanka (6.2%), other nationalities including Philippines, United Kingdom, Indonesia and Nigeria (1.6%)

g Risk factor based screening strategy with all participants undergoing at least one diagnostic 2 hour 75g OGTT. Participants did not have previous gestational diabetes nor any history of altered carbohydrate metabolism, but were referred to a specialist outpatient clinic and did have one or more of the following risk factors for gestational diabetes: any family history of type 2 diabetes, a history of a large neonate (≥4000g), a history of an adverse perinatal outcome (missed abortion, malformation, polyhydramnios, stillbirth or preterm delivery), obesity (pre-pregnant body mass index ≥ 30m2), age ≥ 35 years and glycosuria. Diagnostic 2 hour 75g OGTTs were performed at 3 time periods: ≤ gestational week 16, gestational weeks 24-28 and gestational weeks 32-34. 8 women diagnosed with gestational diabetes in the first trimester were excluded from the study. Incidence data from OGTTs performed in gestational weeks 32-34 were not included in this analysis

h No screening (index) test was used and diagnosis was made on the basis of a 75 gram oral glucose tolerance test (reference standard) in order to exclude women diagnosed with gestational diabetes ≤ gestational week 16 from the study

i The period when diagnosis was made (≤ gestational week 16) overlaps the first and second trimesters and no further details are given as to when the majority of diagnostic tests were actually performed

j Country: Hungary. Ethnicity of population: not reported

k Risk factor based screening strategy with all participants undergoing a diagnostic 2 hour 75g OGTT. Participants were women at high risk of gestational diabetes (based on a history of fetal macrosomia, maternal obesity, previous intrauterine fetal death, first degree relative with diabetes mellitus, glycosuria or history of gestational diabetes in a previous pregnancy) who were referred to a hospital research unit for a diagnostic 2 hour 75g OGTT. Women with OGTTs performed between gestational weeks 4 to 40 were included in the study. Results for 69, 276 and 420 women were available for the first, second and third trimesters respectively. Incidence data from OGTTs performed in the third trimester were not included in this analysis

l No definition of first trimester or second trimester is reported

m Country: Nigeria. Ethnicity of population: not reported

Table 22: GRADE profile for the diagnostic test accuracy of fasting plasma glucose test performed in the first trimester to detect gestational diabetes diagnosed using a 75g 2 hour OGTT (World Health Organization 1999 diagnostic criteria for gestational diabetes: fasting plasma glucose ≥ 7.0 mmol/L and/or 2 hour plasma glucose ≥ 7.8 mmol/L).

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
Fasting plasma glucose ≥ 3.89 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal et al., 2007)	708	99.5 (98.1 to 100)*	0.8 (0.3 to 0.9)*	1.00 (0.98 to 1.01)*	0.71 (0.03 to 6.65)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd
Fasting plasma glucose ≥ 4.17 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal et al., 2007)	708	98.4 (95.8 to 99.6)*	3.6 (2.7 to 4.0)*	1.02 (0.98 to 1.04)*	0.45 (0.11 to 1.57)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd
Fasting plasma glucose ≥ 4.44 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal et al., 2007)	708	94.0 (90.0 to 96.7)*	11.6 (10.2 to 12.6)*	1.06 (1.00 to 1.11)*	0.51 (0.26 to 0.98)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd
Fasting plasma glucose ≥ 4.72 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal	708	79.9	27.5	1.10	0.73	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious	Yesd

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
et al., 2007)		(74.2 to 84.9)*	(25.5 to 29.2)*	(1.00 to 1.20)*	(0.52 to 1.01)*						imprecision	
Fasting plasma glucose ≥ 5.00 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal et al., 2007)	708	60.9 (54.4 to 67.1)*	49.4 (47.2 to 51.6)*	1.20 (1.03 to 1.39)*	0.79 (0.64 to 0.97)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd
Fasting plasma glucose ≥ 5.28 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal et al., 2007)	708	39.1 (33.0 to 45.4)*	68.5 (66.4 to 70.7)*	1.24 (0.98 to 1.55)*	0.89 (0.77 to 1.01)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd
Fasting plasma glucose ≥ 5.56 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal et al., 2007)	708	21.7 (16.9 to 26.9)*	87.6 (85.9 to 89.4)*	1.75 (1.20 to 2.54)*	0.89 (0.82 to 0.97)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd
Fasting plasma glucose ≥ 5.83 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												
1 (Agarwal et al., 2007)	708	11.4 (7.9 to 15.2)*	94.7 (93.4 to 96.0)*	2.14 (1.20 to 3.79)*	0.94 (0.88 to 0.99)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd
Fasting plasma glucose ≥ 6.11 mmol/l in the first trimester for detecting gestational diabetes in the first or second trimester												

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Agarwal et al., 2007)	708	8.2 (5.4 to 10.3)*	98.5 (97.5 to 99.2)*	5.34 (2.17 to 13.59)*	0.93 (0.90 to 0.97)*	Moderate	Prospective cohort	Serious a,b	NA	No serious indirectness c	No serious imprecision	Yesd

a Unclear whether index test results were interpreted without knowledge of the results of the reference standard
b Unclear whether reference standard results were interpreted without knowledge of the results of the index test
c Screening for gestational diabetes was usually performed in the first trimester (median and mean: gestational week 10) with the diagnostic test being performed 2 weeks later, although some women were screened and diagnosed in the second trimester (range: gestational weeks 5-18)

d Country: United Arab Emirates. Ethnicity of population: Arab (92.2%), Indian subcontinent including India, Pakistan, Bangladesh, Sri Lanka (6.2%), other nationalities including Philippines, United Kingdom, Indonesia and Nigeria (1.6%)

Table 23: GRADE profile for the diagnostic test accuracy of random blood glucose test performed in the first trimester to detect overt diabetes in pregnancy diagnosed using a 75g 2 hour OGTT (World Health Organization 1999 diagnostic criteria for diabetes outside pregnancy: fasting plasma glucose ≥ 7.0 mmol/L and/or 2 hour plasma glucose ≥ 11.1 mmol/L).

Number of studies	Number of women with test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
Random blood glucose 7.31 – 7.40 mmol/l in the first trimester for detecting 'overt diabetes in pregnancy' (diagnosed with 75g OGTT WHO 1999 criteria)												
1 (Church et al., 2011)	17,852 [a,b]	78 (NC)	85 (NC)	5.20 (NC)	0.26 (NC)	Very low	Retrospective cohort	Very serious[c,d,e,f]	NA	Serious[g]	Very serious[h]	Yes[i]
Random blood glucose 7.51 – 7.59 mmol/l in the first trimester for detecting 'overt diabetes in pregnancy' (diagnosed with 75g OGTT WHO 1999 criteria or RBG ≥ 11.1mmol/l)												
1 (Church et al., 2011)	17,852 [a,j]	80 (NC)	85 (NC)	6.67 (NC)	0.23 (NC)	Very low	Retrospective cohort	Very serious[c,d,e,f]	NA	Seriousg	Very serious[h]	Yes[i]
Random blood glucose 8.60 – 8.70 mmol/l in the first trimester for detecting 'overt diabetes in pregnancy' (diagnosed with 75g OGTT WHO 1999 criteria)j												
1 (Church et al., 2011)	3007 [a,k]	60 (NC)	75 (NC)	2.40 (NC)	0.53 (NC)	Very low	Retrospective cohort	Very serious[c,d,e,f]	NA	Serious[g]	Very serious[h]	Yesi

NA not applicable, NC not calculable, OGTT oral glucose tolerance test, WHO World Health Organization

a Universal screening program where all women received plasma random blood glucose (RBG) measurement at antenatal booking (n=17,852). Women with a booking RBG test result >7.0 mmol/l or with a previous history of gestational diabetes were offered a diagnostic 2 hour 75g OGTT. Women diagnosed as not having gestational diabetes were screened again at 26–28 weeks using a 50g oral glucose challenge test (GCT). Those with a GCT result > 7.7 mmol/l were offered a diagnostic 2 hour 75g OGTT. Women with clinical indications were also offered OGTTs.
b This model uses all available random blood glucose data (n=17,852). It applies the assumption that women without a positive OGTT did not have 'overt diabetes in pregnancy' (n=17,785). 67 women had 'overt diabetes in pregnancy' (based on OGTT diagnosis) using this assumption.
c Unclear whether index test results were interpreted without knowledge of the results of the reference standard
d Unclear whether reference standard results were interpreted without knowledge of the results of the index test
e Capillary and venous blood samples taken for the OGTT were not analysed separately
f OGTTs performed at any time during gestation were included
g The period when screening tests were performed (between 0 and 20 weeks) overlaps the first and second trimesters and no further details are given as to when the majority of diagnostic tests were actually performed
h The data presented were insufficient to allow calculation of the confidence intervals for point estimates of sensitivity and specificity
i Country: United Kingdom. Ethnicity of population: Data is presented for 95.9% (17124/17852) of the study population. White British (71.3%), Asian (3.9%), African (0.7%), Caribbean (0.4%), Chinese (1.1%), other white backgrounds (18.5%)
j This model estimates the maximum diagnostic value of plasma RBG measurement by applying the assumption that those women with no or incomplete OGTT and RBG < 11.1mmol/l did not have 'overt diabetes in pregnancy' and by defining an additional 12 women who had RBG ≥ 11.1mmol/l, but who did not have a diagnostic OGTT performed, as having a diagnosis of 'overt diabetes in pregnancy'. This may overestimate the di as the authors also state that of 87 women with RBG ≥ 11.1mmol/l and who had an OGTT performed, only 30% had 'overt diabetes in pregnancy' diagnosed by OGTT.
k This model estimates the minimum diagnostic value of plasma RBG measurement using only data from those women who had both plasma RBG measurement and OGTT performed (n=3007). 67 women had 'overt diabetes in pregnancy' (based on OGTT diagnosis)

Table 24: GRADE profile for the incidence of gestational diabetes in the first trimester diagnosed using a 75g OGTT (International Association of the Diabetes and Pregnancy in Study Groups [IADPSG] diagnostic criteria for gestational diabetes: one or more plasma venous glucose values, fasting plasma glucose (FPG) ≥ 5.1mmol/l, 1 hour ≥10.0 mmol/l or 2 hour ≥ 8.5mmol/l). It also

presents the proportion of women who were diagnosed as having gestational diabetes in the first trimester out of the total number of women who were diagnosed as having gestational diabetes in the first and second trimesters combined.

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the first trimester in all women tested	Women diagnosed with gestational diabetes in the first trimester as a proportion of all women diagnosed in the first and second trimester	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
Screening and/or diagnosis in the first trimester using 75g OGTT as diagnostic test (IADPSG)											
1 (Corrado et al., 2012)	775[a]	738 (95.2%)	24/738 (3.25%)	24/88 (27.2%)	Very low	Retrospectivecohort	Seriousb,[c]	NA	Serious[d]	Serious[e]	Yes[f]
1 (Zhu et al., 2013)	17186[g]	17186 (100%)	1959/17186 (11.4%)	779/3002 (25.9%)	Very low	Retrospective cohort	Serious[c,h]	NA	Serious[i]	No serious imprecision	Yes[j]

NA not applicable, OGTT oral glucose tolerance test,

a Selective screening strategy as study population was all consecutive Caucasian women referred to a hospital department for a 75g OGTT at gestational weeks 24-28. Of 775 referred women, exclusions included 12 women with multiple pregnancy, 18 women with no first trimester FPG result, 6 women who had FPG tested after the first trimester, and 1 woman who was diagnosed to have pre-gestational diabetes (first trimester FPG ≥7.0mmol/L) No further details are provided.
b Selection criteria were unclear
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d No definition of first trimester or second trimester is reported.
e Total number of events less than 300

f Country: Italy. Ethnicity of population: Caucasian
g Universal screening strategy used for 1st trimester screening using FPG and diagnostic 2 hour 75g OGTT at 24-28 weeks gestation.
h Unclear whether index test results were interpreted without knowledge of the results of the reference standard
I No definition of first trimester or second trimester is reported The FPG was performed at the first prenatal visit at median = 13.4 gestational weeks (± SD = 3.5, Range 4-24 gestational weeks). 90% of FPG tests were performed before 18 weeks
i Country: China. Ethnicity of population: not reported

Table 25: GRADE profiles for the diagnostic test accuracy of fasting plasma glucose test performed in the first trimester to detect gestational diabetes diagnosed using a 75g 2 hour OGTT in the second trimester (International Association of the Diabetes and Pregnancy in Study Groups [IADPSG] diagnostic criteria for gestational diabetes: one or more plasma venous glucose values, fasting plasma glucose (FPG) ≥ 5.1mmol/L, 1 hour ≥10.0 mmol/L or 2 hour ≥ 8.5mmol/L).

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
Fasting plasma glucose < 4.1 mmol/l vs 4.1 to 6.99 mmol/l in the first trimester for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Zhu et al., 2013)	17,186	93.8 (92.9 - 94.6)*	12.4 (12.2 – 12.5)*	1.07 (1.06 – 1.08)*	0.50 (0.43 – 0.58)*	Very low	Retrospective cohort	Serious[a,b]	NA	Seriousc	No serious imprecision	Yesd
Fasting plasma glucose < 4.6 mmol/l vs 4.6 to 6.99 mmol/l in the first trimester for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Zhu et al., 2013)	17,186	64.8 (63.2 – 66.3)*	55.9 (55.6 – 56.3)*	1.47 (1.42 – 1.52)*	0.63 (0.60 – 0.66)*	Very low	Retrospective cohort	Serious[a,b]	NA	Serious[c]	No serious imprecision	Yes[d]

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
Fasting plasma glucose < 5.1 mmol/l vs 5.1 to 6.99 mmol/l in the first trimester for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Zhu et al., 2013)	17,186	25.9 (24.7 – 27.2)*	91.7 (91.4 – 92.0)*	3.12 (2.87 -3.38)*	0.81 (0.79 – 0.82)*	Very low	Retrospective cohort	Serious[a,b]	NA	Serious[c]	No serious imprecision	Yes[d]
Selected population												
1 (Corrado et al., 2012)	738	27.3 (19.7 - 35.0)*	95.5 (94.5 - 96.6)*	6.11 (3.59 - 10.25)*	0.76 (0.67 - 0.85)*	Very low	Retrospective cohort	Serious[b,e]	NA	Seriousf	Serious imprecisiong	Yes[h]
Fasting plasma glucose < 5.6 mmol/l vs 5.6 to 6.99 mmol/l in the first trimester for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Zhu et al., 2013)	17,186	5.4 (4.8 – 5.9)*:	99.1 (99.0 – 99.2)*	5.93 (4.7 - 7.5)*	0.955 (0.95 - 0.96)*	Very low	Retrospective cohort	Serious[a,b]	NA	Serious[c]	No serious imprecision	Yes[d]
Fasting plasma glucose < 6.1 mmol/l vs 6.1 to 6.99 mmol/l in the first trimester for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Zhu et al., 2013)	17,186	1.4 (1.2 – 1.6)*	99.9 (99.9 – 100)*	16.93 (8.65 – 33.83)*	0.987 (0.98 – 0.99)*	Very low	Retrospective cohort	Serious[a,b]	NA	Seriousc	No serious imprecision	Yes[d]

** Calculated by the NCC-WCH Team from data reported in the paper*

a Unclear whether index test results were interpreted without knowledge of the results of the reference standard

b Unclear whether reference standard results were interpreted without knowledge of the results of the index test
c No definition of first trimester or second trimester is reported The FPG was performed at the first prenatal visit at median = 13.4 gestational weeks (± SD = 3.5, Range 4-24 gestational weeks). 90% of FPG tests were performed before 18 weeks
d Country: China. Ethnicity of population: not reportede Selection criteria were unclear
f No definition of first trimester or second trimester is reported.
g Total number of events is under 300
h Country: Italy. Ethnicity of population: Caucasian

Table 26: GRADE profile for the incidence of gestational diabetes in the second trimester diagnosed using a 75g oral glucose tolerance test (OGTT) (World Health Organization 1999 diagnostic criteria for gestational diabetes: fasting plasma glucose (FPG) ≥ 7.0 mmol/l and/or 2 hour plasma glucose ≥ 7.8 mmol/l) in unselected and selected populations. Where possible, it also presents the proportion of women diagnosed as having gestational diabetes in the second trimester out of the total number of women diagnosed as having gestational diabetes in the first and second trimesters combined.

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the second trimester in all women tested	Women diagnosed with gestational diabetes in the second trimester as a proportion of all women diagnosed in the first and second trimester	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
Diagnosis in the second trimester using 75g OGTT as diagnostic test (WHO 1999) in an unselected study population											
1	1762 a	1685 (95.6%)	333/1685 (19.8%)	NC	High	Prospective cohort	No serious limitations	NA	No serious indirectnessb	No serious imprecision	Yesc

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the second trimester in all women tested	Women diagnosed with gestational diabetes in the second trimester as a proportion of all women diagnosed in the first and second trimester	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
(Agarwal et al., 2005a)											
1 (Agarwal et al., 2006)	4844d	4596 (94.9%)	979/4596 (21.3%)*	NC	High	Prospective cohort	No serious limitations	NA	No serious indirectnesse	No serious imprecision	Yesf
1 (Agarwal et al., 2005b)	454 g	442 (97.3%)	84/442 (19%)	NC	Low	Prospective cohort	Serioush	NA	No serious indirectnessh	Seriousi	Yesj
1 (van Leeuwen et al., 2009)	1301k	1266 (97.3%)	47/1266 (3.7%)	NC	Moderate	Prospective cohort	No serious limitations	NA	No serious indirectnessl	Seriousi	Yesm
Diagnosis in the second trimester using 75g OGTT as diagnostic test (WHO 1999) in a selected population											
1 (Bito et al., 2005)	163n	155 (95.1%)	32/155 (20.64%)*	32/40 (80%)	Moderate	Prospective cohort	No serious limitations	NA	No serious indirectnesso	Seriousi	Yesp

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the second trimester in all women tested	Women diagnosed with gestational diabetes in the second trimester as a proportion of all women diagnosed in the first and second trimester	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
1 (Kuti et al., 2011)	276q	276 (100%)	35/276 (12.6%)*	35/47 (74.5%)*	Very low	Retrospective cohort	Seriousr	NA	Seriouss	Seriousi	Yest
1 (Senanayake et al., 2006)	271u	271 (100%)	75/271 (27.7%)	NC	Low	Prospective cohort	Seriousr	NA	No serious indirectnessv	Seriousi	Yesw

NA not applicable, NC not calculable, OGTT oral glucose tolerance test, WHO World Health Organization

** Calculated by NCC-WCH*

a Universal screening strategy using FPG test results performed as part of a diagnostic 2 hour 75g OGTT in the second trimester. 41/1726 women did not complete the diagnostic OGTT

b Screening for gestational diabetes was scheduled between gestational weeks 24-28 (mean ±SD: 25.2 ± 6.14 and 24.9 ± 5.3 for women with and without gestational diabetes respectively) although it was performed when clinically warranted for some women (range, gestational weeks 7-40)

c Country: United Arab Emirates (UAE). Ethnicity of population: Expatriate and UAE Arab (92.2%), Indian subcontinent including India, Pakistan, Bangladesh, Sri Lanka (6.2%), other nationalities including Philippines, United Kingdom, Indonesia and Nigeria (1.6%)

d Universal screening strategy using FPG test results performed as part of a diagnostic 2 hour 75g OGTT in the second trimester. 242/4844 women did not complete the diagnostic OGTT

e Screening for gestational diabetes was scheduled between gestational weeks 24-28 (mean: 25.9 ± 6.3 gestational weeks, median: 26 weeks, range: 2-38 weeks)

f Country: UAE. Ethnicity of population: 3473 (75.5%) Arab, 932 (20.3%) South Asian (India, Pakistan, Bangladesh and Sri Lanka), 92 (2%) Other nationalities, 105 (2.3%) unavailable

g Universal screening strategy using HbA_{1c} screening test and a diagnostic 2 hour 75g OGTT in the second trimester. 12/454 women did not complete the diagnostic OGTT

h Screening for gestational diabetes was scheduled between gestational weeks 24-28 (mean ± SD: 27 ± 4.85 and 26 ± 4.5 for women with and without gestational diabetes respectively (p = 0.003), range: 16-40 gestational weeks)

i Total number of events less than 300

j Country: UAE. Ethnicity of population: UAE Arab (68.1%), Asian Arab (17.6%), Chami Arab (2.9%), East African Arab (1.1%), Indian subcontinent (1.6%), other nationalities (1.6%), unknown (7%)

k Universal screening strategy using a risk factor based clinical prediction rule and a random glucose test (RBG) threshold 6.8 mmol/l and/or 50g glucose challenge test (GCT) threshold 7.8mmol/l in the second trimester to select women requiring a diagnostic 2 hour 75g OGTT. The OGTT was performed in 322/1266 women. 146 of these women had at least one abnormal RBG or GCT result and 176 women had negative screening results but were randomly asked to undergo an OGTT to estimate the false negative fraction. A multiple imputation procedure was performed to correct for verification bias across the study population.

l Screening was performed between gestational weeks 24-28 and OGTTs were performed within one week of screening where indicated

m Country: The Netherlands. Ethnicity of population: Caucasian (89.4%), Black (2.5%), Asian (0.4%), Other (7.7%)

n Risk factor based screening strategy with all participants undergoing at least one diagnostic 2 hour 75g OGTT. Participants did not have previous gestational diabetes nor any history of altered carbohydrate metabolism, but were referred to a specialist outpatient clinic and did have one or more of the following risk factors for gestational diabetes: any family history of type 2 diabetes, a history of a large neonate (≥ 4000g), a history of an adverse perinatal outcome (missed abortion, malformation, polyhydramnios, stillbirth or preterm delivery), obesity (pre-pregnant body mass index ≥ 30m2), age ≥ 35 years and glycosuria. 8 women diagnosed with gestational diabetes in the first trimester were excluded from the study. Incidence data from OGTTs performed in gestational weeks 32-34 were not included in this analysis

o Diagnostic 2 hour 75g OGTTs were performed at 3 time periods: ≤ gestational week 16, gestational weeks 24-28 and gestational weeks 32-34.

p Country: Hungary. Ethnicity of population: not reported

q Risk factor based screening strategy with all participants undergoing a diagnostic 2 hour 75g OGTT. Participants were women at high risk of gestational diabetes (based on a history of fetal macrosomia, maternal obesity, previous intrauterine fetal death, first degree relative with diabetes, glycosuria or history of gestational diabetes in a previous pregnancy) who were referred to a hospital research unit for a diagnostic 2 hour 75g OGTT. Women with OGTTs performed between gestational weeks 4 to 40 were included in the study. Results for 69, 276 and 420 women were available for the first, second and third trimesters respectively.

r Selection criteria are unclear because no exclusion criteria are presented

s No definition of first trimester or second trimester is reported

t Country: Nigeria. Ethnicity of population: not reported

u Risk factor based screening strategy where women with at least one risk factor for gestational diabetes were referred for OGTT. Risk factors included having a first degree relative with diabetes, maternal BMI > 30kg/m2 at booking, maternal age > 35 years, previous birth weight > 3.5kg and previous unexplained stillbirth or fetal anomaly

v Mean gestational age at screening: 26.43 ± 5.46 gestational weeks

w Country: Sri Lanka. Ethnicity of population: not reported

Table 27: GRADE profile for diagnostic test accuracy of fasting plasma glucose test performed in the second trimester to detect gestational diabetes diagnosed using a 75g 2 hour oral glucose tolerance test (OGTT) (World Health Organization 1999 diagnostic criteria for gestational diabetes: fasting plasma glucose (FPG) ≥ 7.0 mmol/l and/or 2 hour plasma glucose ≥ 7.8 mmol/l) in selected and unselected populations

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
Fasting plasma glucose ≥ 3.9 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Agarwal et al., 2005a)	1685a	99.7 (98.9 to 100)*	0.3 (0.1 to 0.4)*	1.00 (0.99 to 1.00)*	1.02 (0.04 to 9.50)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnesse	No serious imprecision	Yesf
Fasting plasma glucose ≥ 4.2 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Agarwal et al., 2005a)	1685a	97.6 (95.6 to 98.8)*	3.3 (2.8 to 3.6)*	1.01 (0.98 to 1.03)*	0.74 (0.32 to 1.61)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
1 (Agarwal et al., 2006)	4602a	94.4 (92.9 to 95.7)*	10.4 (10.0 to 10.7)*	1.05 (1.03 to 1.07)*	0.54 (0.40 to 0.71)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnessg	No serious imprecision	Yesh
Selected population												
1 (Senanayake et al., 2006)	271i	97.3 (90.5 to 99.5)*	28.6 (26.0 to 29.4)*	1.36 (1.22 to 1.41)*	0.09 (0.02 to 0.36)*	Low	Prospective cohort	Very seriousb,c,d,i	NA	No serious indirectnessk	No serious imprecision	Yesl

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other conside ra-tions
Fasting plasma glucose ≥ 4.4 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Agarwal et al., 2005a)	1685a	93.4 (90.4 to 95.6)*	11.5 (10.8 to 12.1)*	1.06 (1.01 to 1.09)*	0.57 (0.36 to 0.89)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
1 (Agarwal et al., 2006)	4602a	87.0 (84.9 to 88.9)*	28.8 (28.3 to 29.3)*	1.22 (1.18 to 1.25)*	0.45 (0.38 to 0.54)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnessg	No serious imprecision	Yesh
Selected population												
1 (Senanayake et al., 2006)	271i	92.0 (83.7 to 96.6)*	48.5 (45.3 to 50.2)	1.78 (1.53 to 1.94)*	0.16 (0.07 to 0.36)*	Low	Prospective cohort	Very seriousb,c,d,i	NA	No serious indirectnessk	No serious imprecision	Yesl
Fasting plasma glucose ≥ 4.7 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Agarwal et al., 2005a)	1685a	78.1 (73.6 to 82.0)*	32.2 (31.1 to 33.2)*	1.15 (1.07 to 1.23)*	0.68 (0.54 to 0.85)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
1 (Agarwal et al., 2006)	4602a	71.7 (69.0 to 74.2)*	51.6 (50.8 to 52.3)*	1.48 (1.40 to 1.55)*	0.55 (0.49 to 0.61)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnessg	No serious imprecision	Yesh

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other conside ra-tions
Selected population												
1 (Senanayake et al., 2006)	271i	82.7 (73.3 to 89.7)*	66.8 (63.2 to 69.5)*	2.49 (1.99 to 2.94)*	0.26 (0.15 to 0.42)*	Low	Prospective cohort	Very seriousb,c,d,i	NA	No serious indirectnessk	No serious imprecision	Yesl
Fasting plasma glucose ≥ 5.0 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Agarwal et al., 2005a)	1685a	58.3 (53.3 to 63.0)*	63.1 (61.9 to 64.3)*	1.58 (1.34 to 1.76)*	0.66 (0.58 to 0.75)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
1 (Agarwal et al., 2006)	4602a	55.4 (52.6 to 58.1)*	73.3 (72.6 to 74.1)*	2.08 (1.92 to 2.24)*	0.61 (0.57 to 0.65)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnessg	No serious imprecision	Yesh
Selected population												
1 (Senanayake et al., 2006)	271i	69.3 (59.8 to 77.6)*	83.2 (79.5 to 86.3)*	4.12 (2.91 to 5.66)*	0.36 (0.26 to 0.51)*	Low	Prospective cohort	Very seriousb,c,d,i	NA	No serious indirectnessk	No serious imprecision	Yesl
Fasting plasma glucose ≥ 5.3 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1	1685a	37.5	83.5	2.28	0.75	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious	No serious imprecision	Yesf

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other conside ra-tions
(Agarwal et al., 2005a)		(33.1 to 42.1)*	(82.4 to 84.6)*	(1.88 to 2.74)*	(0.69 to 0.81)*					indirectnesse		
1 (Agarwal et al., 2006)	4602a	40.8 (38.3 to 43.3)*	86.6 (85.9 to 87.3)*	3.04 (2.72 to 3.40)*	0.68 (0.65 to 0.72)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnessg	No serious imprecision	Yesh
Selected population												
1 Senanayake et al., 2006)	271i	45.3 (36.7 to 52.7)*	91.8 (88.5 to 94.6)*	5.55 (3.20 to 9.82)*	0.60 (0.50 to 0.72)*	Low	Prospective cohort	Very seriousb, c,d,i	NA	No serious indirectnessk	No serious imprecision	Yesl
Fasting plasma glucose ≥ 5.6 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Agarwal et al., 2005a)	1685a	24.0 (20.4 to 27.7)*	93.1 (92.2 to 94.0)*	3.49 (2.63 to 4.63)*	0.82 (0.77 to 0.86)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
1 (Agarwal et al., 2006)	4602a	29.8 (27.7 to 31.8)*	94.3 (93.7 to 94.9)*	5.23 (4.43 to 6.18)*	0.74 (0.72 to 0.77)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnessg	No serious imprecision	Yesh
Fasting plasma glucose ≥ 5.8 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
1 (Agarwal et al., 2005a)	1685a	17.4 (14.4 to 20.2)*	96.7 (96.0 to 97.4)*	5.35 (3.63 to 7.92)*	0.85 (0.82 to 0.89)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
1 (Agarwal et al., 2006)	4602a	22.1 (20.5 to 23.6)*	97.4 (97.0 to 97.8)*	8.60 (6.78 to 10.92)*	0.80 (0.78 to 0.82)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnessg	No serious imprecision	Yesh
Fasting plasma glucose ≥ 6.1 mmol/l for detecting gestational diabetes in the second trimester												
Unselected population												
1 (Agarwal et al., 2005a)	1685a	9.0 (7.0 to 10.5)*	99.2 (98.7 to 99.5)*	11.07 (5.40 to 23.3)*	0.92 (0.90 to 0.94)*	Moderate	Prospective cohort	Seriousb,c,d	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
Fasting plasma glucose ≥ 7.0 mmol/l for detecting gestational diabetes in the second trimester												
Selected population												
1 (Senanayake et al., 2006)	271i	12.0 (7.3 to 13.3)*	99.5 (97.7 to 100)*	23.52 (3.18 to 495.46)*	0.88 (0.87 to 0.95)*	Low	Prospective cohort	Very seriousb,c,d,i	NA	No serious indirectnessk	No serious imprecision	Yesl

*NA not applicable, OGTT oral glucose tolerance test, * Calculated by NCC-WCH*

a Universal screening strategy using FPG test results performed as part of a diagnostic 2 hour 75g OGTT in the second trimester
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test

d The index test formed part of the reference standard
e Screening for gestational diabetes was scheduled between gestational weeks 24-28 (mean ±SD: 25.2 ± 6.14 and 24.9 ± 5.3 for women with and without gestational diabetes respectively) although it was performed when clinically warranted for some women (range, gestational weeks 7-40)
f Country: United Arab Emirates (UAE). Ethnicity of population: Expatriate and UAE Arab (92.2%), Indian subcontinent including India, Pakistan, Bangladesh, Sri Lanka (6.2%), other nationalities including Philippines, United Kingdom, Indonesia and Nigeria (1.6%)
g Screening for gestational diabetes was scheduled between gestational weeks 24-28 (mean: 25.9 ± 6.3 gestational weeks, median: 26 weeks, range: 2-38 weeks)
h Country: UAE. Ethnicity of population: 3473 (75.5%) Arab, 932 (20.3%) South Asian (India, Pakistan, Bangladesh and Sri Lanka), 92 (2%) Other nationalities, 105 (2.3%) unavailable
i Risk factor based screening strategy where women with at least one risk factor for gestational diabetes were referred for OGTT. Risk factors included having a first degree relative with diabetes, maternal BMI > 30kg/m2 at booking, maternal age > 35 years, previous birth weight > 3.5kg and previous unexplained stillbirth or fetal anomaly
j Selection criteria are unclear because no exclusion criteria are presented
k Mean gestational age at screening: 26.43 ± 5.46 gestational weeks
l Country: Sri Lanka. Ethnicity of population: not reported

Table 28: GRADE profile for diagnostic test accuracy of HbA_{1c} test performed in the second trimester to detect gestational diabetes diagnosed using a 75g 2 hour oral glucose tolerance test (OGTT) (World Health Organization 1999 diagnostic criteria for gestational diabetes: fasting plasma glucose ≥ 7.0 mmol/l and/or 2 hour plasma glucose ≥ 7.8 mmol/l) in an unselected population

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
HbA_{1c} ≥ 4.5% for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2005b)	442a	97.6 (94.2 to 99.6)*	1.4 (0.6 to 1.9)*	0.99 (0.95 to 1.02)*	1.70 (0.23 to 9.69)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnessd	No serious imprecision	Yese
HbA_{1c} ≥ 5% for detecting gestational diabetes in the second trimester												

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
1 (Agarwal et al., 2005b)	442a	97.6 (94.2 to 99.6)*	4.7 (3.5 to 5.2)*	1.02 (0.96 to 1.05)*	0.50 (0.08 to 2.17)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnessd	No serious imprecision	Yese
HbA_{1c} ≥ 5.5% for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2005b)	442a	82.1 (73.2 to 89.0)*	20.9 (18.9 to 22.6)*	1.04 (0.90 to 1.15)*	0.85 (0.49 to 1.42)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnessd	No serious imprecision	Yese
HbA_{1c} ≥ 6% for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2005b)	442a	48.8 (38.8 to 58.9)*	55.6 (53.2 to 57.9)*	1.10 (0.83 to 1.40)*	0.92 (0.71 to 1.15)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnessd	No serious imprecision	Yese
HbA_{1c} ≥ 6.5% for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2005b)	442a	21.4 (13.9 to 30.6)*	78.5 (76.7 to 80.6)*	1.00 (0.60 to 1.58)*	1.00 (0.86 to 1.12)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnessd	No serious imprecision	Yese
HbA_{1c} ≥ 7% for detecting gestational diabetes in the second trimester												
1 (Agarwal et	442a	10.7 (5.5 to 18.1)*	90.5 (89.3 to 92.2)*	1.13 (0.52 to 2.32)*	0.99 (0.89 to 1.06)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnessd	No serious imprecision	Yese

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
al., 2005b)												
HbA_{1c} ≥ 7.5% for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2005b)	442a	7.1 (3.1 to 12.9)*	95.8 (94.9 to 97.2)*	1.70 (0.60 to 4.51)*	0.97 (0.90 to 1.02)*	Moderate	Prospective cohort	Seriousb, c,d	NA	No serious indirectnessd	No serious imprecision	Yese
HbA_{1c} ≥ 8% for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2005b)	442a	3.6 (1.0 to 7.0)*	98.6 (98.0 to 99.4)*	2.56 (0.49 to 12.03)*	0.98 (0.94 to 1.01)*	Moderate	Prospective cohort	Seriousb, c,d	NA	No serious indirectnessd	No serious imprecision	Yese

NA not applicable, OGTT oral glucose tolerance test,

** Calculated by NCC-WCH*
a Universal screening strategy using HbA_{1c} screening test and a diagnostic 2 hour 75g OGTT in the second trimester
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d Screening for gestational diabetes was scheduled between gestational weeks 24-28 (mean ± SD: 27 ± 4.85 and 26 ± 4.5 for women with and without gestational diabetes respectively (p=0.003), range: 16-40 gestational weeks)
e Country: United Arab Emirates (UAE). Ethnicity of population: UAE Arab (68.1%), Asian Arab (17.6%), Chami Arab (2.9%), East African Arab (1.1%), Indian subcontinent (1.6%), other nationalities (1.6%), unknown (7%)

Table 29: GRADE profile for diagnostic test accuracy of 50g glucose challenge test (GCT) performed in the second trimester to detect gestational diabetes diagnosed using a 75g 2 hour oral glucose tolerance test (OGTT) (World Health Organization 1999 diagnostic criteria for gestational diabetes: fasting plasma glucose ≥ 7.0 mmol/l and/or 2 hour plasma glucose ≥ 7.8 mmol/l) in an unselected population

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
50g 1 hour GCT at 7.8 mmol/l threshold in an unselected population												
1 (van Leeuwen et al., 2009)	1266a	68.1 (53.4 to 80.2)*	89.2 (88.6 to 89.6)*	6.28 (4.69 to 7.74)*	0.36 (0.22 to 0.57)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnesse	No serious imprecision	Yesf
Determination of risk using a clinical prediction rule followed by 50g 1 hour GCT if indicated: no 50g 1 hour GCT (low risk n=311) or 50g 1 hour GCT at 7.8 mmol/l threshold (intermediate risk) or 50g 1 hour GCT at 7.1 mmol/l threshold (high risk)												
1 (van Leeuwen et al., 2009)	1266g	63.8 (49.0 to 76.6)*	87.4 (86.9 to 87.9)*	5.09 (3,74 to 6.35)*	0.41 (0.27 to 0.59)*	Moderate	Prospective cohort	Seriousb,c,d	NA	No serious indirectnesse	No serious imprecision	Yesf

*NA not applicable, OGTT oral glucose tolerance test, * Calculated by NCC-WCH*

a Universal screening strategy using a 1 hour 50g glucose challenge test and a diagnostic 2 hour 75g OGTT in the second trimester
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d The reference standard was not performed in the whole sample. The OGTT was performed in 322/1266 women. 146 of women had at least one abnormal random blood glucose (RBG) or glucose challenge test (GCT) result and 176 women had negative screening results but were randomly asked to undergo an OGTT to estimate the false negative fraction. A multiple imputation procedure was performed to correct for verification bias across the study population

e Screening was performed between gestational weeks 24-28 and OGTTs were performed within one week of screening where indicated. The OGTT was performed in 322/1266 women. 146 of women had at least one abnormal RBG or GCT result and 176 women had negative screening results but were randomly asked to undergo an OGTT to estimate the false negative fraction. A multiple imputation procedure was performed to correct for verification bias across the study population
f Country: The Netherlands. Ethnicity of population: Caucasian (89.4%), Black (2.5%), Asian (0.4%), Other (7.7%)
g Risk factor based clinical prediction rule (using age, BMI and ethnicity. Low risk = Clinical risk score 0 or 1, Intermediate risk = Clinical risk score 2 or 3, High risk = Clinical risk score higher than 3) and 1 hour 50g GCT as indicated in the second trimester.
Evidence profile for acceptability of the oral glucose tolerance test (OGTT)

Table 30: GRADE profile for acceptability of the oral glucose tolerance test (OGTT

Number of studies	Proportion of potential participants who did not complete an OGTT	Quality	Design	Limitations	Inconsist-ency	Indirect-ness	Imprecision	Other considera-tions
Acceptability of OGTT								
1 (Agarwal et al., 2005a)	12/454 (2.6%)a	High	Prospective cohort	No serious limitations	NA	No serious indirectness	NA	Yesb
1 (Agarwal et al., 2005b)	41/1726 (2.4%)c	High	Prospective cohort	No serious limitations	NA	No serious indirectness	NA	Yesd
1 (Agarwal et al., 2006)	242/4844 (5.0%)e	High	Prospective cohort	No serious limitations	NA	No serious indirectness	NA	Yesf

NA not applicable, OGTT oral glucose tolerance test

a 12 women did not complete the OGTT due to vomiting
b Country: United Arab Emirates (UAE). Ethnicity of population: Expatriate and UAE Arab (92.2%), Indian subcontinent including India, Pakistan, Bangladesh, Sri Lanka (6.2%), other nationalities including Philippines, United Kingdom, Indonesia and Nigeria (1.6%)
c 41 women did not complete the OGTT due to vomiting, refusal to undergo test, eating food during the test or due to other reasons
d Country: UAE. Ethnicity of population: UAE Arab (68.1%), Asian Arab (17.6%), Chami Arab (2.9%), East African Arab (1.1%), Indian subcontinent (1.6%), other nationalities (1.6%), unknown (7%)
e 242 women did not undergo the OGTT due to refusal to undergo the test (65), vomiting (110), eating food during the test or other reasons (67)
f Country: UAE. Ethnicity of population: 3473 (75.5%) Arab, 932 (20.3%) South Asian (India, Pakistan, Bangladesh and Sri Lanka), 92 (2%) Other nationalities, 105 (2.3%) unavailable
g Risk factor based clinical prediction rule (using age, BMI and ethnicity. Low risk = Clinical risk score 0 or 1, Intermediate risk = Clinical risk score 2 or 3, High risk = Clinical risk score higher than 3) and 1 hour 50g GCT as indicated in the second trimester.

h Country: The Netherlands. Ethnicity of population: Caucasian (89.4%), Black (2.5%), Asian (0.4%), Other (7.7%)

Table 31: GRADE profile for the incidence of gestational diabetes in the second trimester diagnosed using a 75g oral glucose tolerance test (OGTT) (International Association of the Diabetes and Pregnancy in Study Groups [IADPSG] diagnostic criteria for gestational diabetes: one or more plasma venous glucose values, fasting plasma glucose (FPG) ≥ 5.1mmol/l, 1 hour ≥10.0mmol/l or 2 hour ≥ 8.5mmol/l) in unselected populations. It also presents the proportion of women who were diagnosed as having gestational diabetes who were untreated

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the second trimester in all women tested	Women diagnosed with gestational diabetes in the second trimester as a proportion of all women diagnosed in the first and second trimester	Quality		Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
Diagnosis in the second trimester using 75g OGTT as diagnostic test (IADPSG) in an unselected population												
1 (Agarwal et al., 2010)	10283a	10283 (100%)	3875/10283 (37.7%)	NC	High		Prospective cohort	No serious limitations	NA	No serious indirectnesb	No serious imprecision	Yesc
1 (Huynh et al, 2011)	8486d	5473 (64.5%)	1022/5473 (19%)	NC	Moderate		Retrospective cohort	No serious limitations	NA	No serious indirectnesse	No serious imprecision	Yesf

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes diagnosed in the second trimester in all women tested	Women diagnosed with gestational diabetes in the second trimester as a proportion of all women diagnosed in the first and second trimester	Quality		Design	Limita-tions	Inconsistency	Indirect-ness	Imprecision	Other considera-tions
1 (Black et al., 2010)	9199g	9199 (100%)	2179/9199 (23.7%)	NC	Moderate		Retrospective cohort	No serious limitations	NA	No serious indirectnessh	No serious imprecision	Yesi
Diagnosis in the second trimester using 75g OGTT as diagnostic test (IADPSG) in an untreated population												
1 (Catalano et al., 2012)	53295j	25,505 (47.8%) j	3746/23267* (16.1%) j	NC	High		Prospective cohort	No serious limitations	NA	No serious indirectnessk	No serious imprecision	Yesl
1 (Black et al., 2010)	9199m	9199 (100%)	1691/8711 (19.4%)	NC	Moderate		Retrospective cohort	No serious limitations	NA	No serious indirectnessh	No serious imprecision	Yesi

NA not applicable, NC not calculable, OGTT oral glucose tolerance test, WHO World Health Organization

a Universal screening strategy using FPG test results performed as part of a diagnostic 2 hour 75g OGTT in the second trimester
b Screening for gestational diabetes was scheduled between gestational weeks 24-28 – no further details provided
c Country: United Arab Emirates. Ethnicity: 8233 (80.1%) were of Arab ethnicity and 1592 (15.5%) were of South Asian ethnicity
d Universal screening strategy using FPG test results performed as part of a diagnostic 2 hour 75g OGTT in the second trimester. 8486 women were included in the study of whom 5473 had diagnostic 2 hour 75g OGTT results available
e Screening for gestational diabetes was recommended between gestational weeks 26-28 – no further details provided

f Country: Australia. Ethnicity: not presented
g Universal testing with 2 hour 75g OGTT in the second trimester. Incidence of gestational diabetes pertains to the whole study population (treated and untreated women)
h Screening for gestational diabetes was performed between gestational weeks 24-28 (mean ± SD: 26.7 ± 2.9)
i Country: USA. Ethnicity: Non-Hispanic white 626 (7.2%), Hispanic 6484 (74.4%), Black 880 (10.1%), Asian 641 (6.4%), Other 80 (0.9%)
j 53,295 women from 15 international centres were eligible to participate. 28,562 (53.6%) agreed to participate and 25,505 women completed the OGTT. 746 (2.9%) were excluded because of glucose unblinding, 1,412 (5.5%) were excluded primarily because they had undergone glucose testing or delivery outside the context of the HAPO Study, and 31 (0.1%) were excluded owing to missing key data or improbable results. Data from 23,316 women were available for analysis although only results of only 23,267 women untreated for gestational diabetes contributed to incidence results.
k Universal diagnostic testing with 2 hour 75g OGTT was performed between gestational weeks 24 and 32, but as close to gestational week 28 as possible
l Countries: USA, Australia, UK and Israel Ethnicity: White, non-Hispanic 11,265 (48.3%), Black, non-Hispanic 2,696 (11.6%), Hispanic 1,984 (8.5%), Asian 6,757 (29.0%), Other 614 (2.6%)
m Universal testing with 2 hour 75g OGTT in the second trimester. Incidence of gestational diabetes pertains to the untreated women only within the study population

Table 32: GRADE profile for the diagnostic test accuracy of fasting plasma glucose test performed in the second trimester to detect gestational diabetes diagnosed using a 75g 2 hour oral glucose tolerance test (OGTT) (International Association of the Diabetes and Pregnancy in Study Groups [IADPSG] diagnostic criteria for gestational diabetes: one or more plasma venous glucose values, fasting plasma glucose (FPG) ≥ 5.1mmol/l, 1 hour ≥10.0 mmol/l or 2 hour ≥ 8.5mmol/l) in an unselected population

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
Fasting plasma glucose ≥ 4.2 mmol/l for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2010)	10,283 a	98.3 (97.9 to 98.7)*	11.5 (11.3 to 11.8)*	1.11 (1.10 to 1.12)*	0.15 (0.11 to 0.19)*	Low	Prospective cohort	Very seriousb,c,d,e	NA	No serious indirectnessf	No serious imprecision	Yesg
Fasting plasma glucose ≥ 4.4 mmol/l for detecting gestational diabetes in the second trimester												

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
1 (Agarwal et al., 2010)	10,283 a	95.4 (94.7 to 96.0)*	32.0 (31.6 to 32.4)*	1.40 (1.38 to 1.42)*	0.14 (0.12 to 0.17)*	Low	Prospective cohort	Very seriousb,c,d,e	NA	No serious indirectness	No serious imprecision	Yesg
Fasting plasma glucose ≥ 4.7 mmol/l for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2010)	10,283 a	88.9 (88.0 to 89.8)*	60.1 (59.6 to 60.7)*	2.23 (2.18 to 2.28)*	0.19 (0.17 to 0.20)*	Low	Prospective cohort	Very seriousb,c,d,e	NA	No serious indirectness	No serious imprecision	Yesg
Fasting plasma glucose ≥ 5.0 mmol/l for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2010)	10,283 a	80.5 (79.6 to 81.3)*	90.9 (90.4 to 91.4)*	8.86 (8.28 to 9.49)*	0.22 (0.20 to 0.23)*	Low	Prospective cohort	Very seriousb,c,d,e	NA	No serious indirectness	No serious imprecision	Yesg
Fasting plasma glucose ≥ 5.1 mmol/l for detecting gestational diabetes in the second trimester												
1 (Agarwal et al., 2010)	10,283 a	76.8 (75.4 to 78.1)*	99.99 (99.94 to 100)*	> 1000 (872 to > 1000)*	0.232 (0.232 to 0.234)*	Low	Prospective cohort	Very seriousb,c,d,e	NA	No serious indirectness	No serious imprecision	Yesg

Number of studies	Number of women with OGTT	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Impreci-sion	Other considera-tions
1 (Huynh et al., 2011)	5473h	51.17 (48.11 to 54.23)*	99.99 (99.29 to 100)*	> 1000 (404 to > 1000)*	0.488 (0.488 to 0.494)*	Low	Retrospective cohort	Seriousb, c,d	NA	No serious indirectnessi	No serious imprecision	Yesj

NA not applicable, OGTT oral glucose tolerance test, WHO World Health Organization

** Calculated by the NCC-WCH technical team*
a Universal screening strategy using FPG test results performed as part of a diagnostic 2 hour 75g OGTT in the second trimester
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d The index test formed part of the reference standard
e Selection criteria are unclear as no exclusion criteria are presented
f Screening for gestational diabetes was scheduled between gestational weeks 24-28 – no further details provided
g Country: United Arab Emirates. Ethnicity: 8233 (80.1%) were of Arab ethnicity and 1592 (15.5%) were of South Asian ethnicity
h Universal screening strategy using FPG test results performed as part of a diagnostic 2 hour 75g OGTT in the second trimester. 8486 women were included in the study of whom 5473 had diagnostic 2 hour 75g OGTT results available
i Screening for gestational diabetes was recommended between gestational weeks 26-28 – no further details provided
j Country: Australia. Ethnicity: not presented

Table 33: GRADE profile for maternal and neonatal outcomes following diagnosis using 75g 2 hour oral glucose tolerance test (OGTT) (International Association of the Diabetes and Pregnancy in Study Groups [IADPSG] diagnostic criteria for gestational

diabetes: one or more plasma venous glucose values fasting plasma glucose (FPG) ≥ 5.1mmol/l, 1 hour ≥ 10.0mmol/l or 2 hour ≥ 8.5mmol/l) in unselected untreated populations. Results are also presented for a subgroup analysis of obesity.

Number of studies	Number of babies/women		Effect		Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
	Gestational diabetes	No gestational diabetes	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Primary Caesarean Section: entire untreated unselected study population											
1 (Black et al., 2010)	336/1691 (19.9%)	1112/7020 (15.8%)	RR 1.25 (1.12 to 1.40)*	40 more per 1000 (from 19 more to 63 more)	Moderate	Retrospective cohort	No serious limitationsa	No serious inconsistency	No serious indirectnessb	No serious imprecision	Yesc
1 (Catalano et al., 2012)	779/3191 (24.4%)	2952/17541 (16.8%)	RR 1.45 (1.35 to 1.55)*	76 more per 1000 (from 59 more to 93 more)	High	Prospective cohort	No serious limitationsd	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
Primary Caesarean Section: subgroup of untreated women who were obeseg											
1 (Catalano et al., 2012)	215/749 28.7%)	430/1868 (23%)	RR 1.25 (1.08 to 1.43)*	58 more per 1000 (from 18 more to 99 more)	Moderate	Prospective cohort	No serious limitationsd	NA	No serious indirectnesse	Serious h	Yesf
Primary Caesarean Section: subgroup of untreated women who were not obeseg											
1 (Catalano et al., 2012)	564/2442 (23.1%)	2522/15673 (16.1%)	RR 1.44 (1.32 to 1.56)*	71 more per 1000 (from 51 more to 90 more)	High	Prospective cohort	No serious limitationsd	NA	No serious indirectnesse	No serious imprecision	Yesf
Large for gestational age: entire untreated unselected study population											

Number of studies	Number of babies/women		Effect		Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
	Gestational diabetes	No gestational diabetes	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Black et al., 2010)	264/1691 (15.6%)	528/7020 (7.5%)	RR 2.08 (1.81 to 2.38)*	81 more per 1000 (from 61 more to 104 more)	Moderate	Retrospective cohort	No serious limitationsi	NA	No serious indirectnessb	No serious imprecision	Yesc
Birthweight > 90th percentile: entire untreated unselected study population											
1 (Catalano et al., 2012)	604/3726 (16.2%)	1617/19491 (8.3%)	RR 1.95 (1.79 to 2.13)*	79 more per 1000 (from 66 more to 94 more)	High	Prospective cohort	No serious limitationsj	NA	No serious indirectnesse	No serious imprecision	Yesf
Birthweight > 90th percentile: subgroup of untreated women who were obeseg											
1 (Catalano et al., 2012)	203/935 (21.7%)	278/2247 (12.4%)	RR 1.75 (1.49 to 2.07)*	93 more per 1000 (from 61 more to 132 more)	High	Prospective cohort	No serious limitationsj	NA	No serious indirectnesse	No serious imprecision	Yesf
Birthweight > 90th percentile: subgroup of untreated women who were not obeseg											
1 (Catalano et al., 2012)	401/2791 (14.4%)	1339/17244 (7.8%)	RR 1.85 (1.67 to 2.05)*	66 more per 1000 (from 52 more to 82 more)	High	Prospective cohort	No serious limitationsj	NA	No serious indirectnesse	No serious imprecision	Yesf
Shoulder dystocia/birth injury: entire untreated unselected study population											

Number of studies	Number of babies/women		Effect		Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
	Gestational diabetes	No gestational diabetes	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Black et al., 2010)	96/1691 (5.7%)	268/7020 (3.8%)	RR 1.49 (1.19 to 1.87)*	19 more per 1000 (from 7 more to 33 more)	Moderate	Retrospective cohort	No serious limitationsk	No serious inconsistency	No serious indirectness	No serious imprecision	Yesc
1 (Catalano et al., 2012)	67/3728 (1.8%)	244/19499 (1.3%)	RR 1.44 (1.1 to 1.88)*	6 more per 1000 (from 1 more to 11 more)	High	Prospective cohort	No serious limitationsl	No serious inconsistency	No serious indirectnesse	No serious imprecision	Yesf
Shoulder dystocia/birth injury: subgroup of untreated women who were obese											
1 (Catalano et al., 2012)	26/936 (2.8%)	32/2252 (1.4%)	1.95 (1.17 to 3.26)*	13 more per 1000 (from 2 more to 32 more)	High	Prospective cohort	No serious limitationsl	NA	No serious indirectnesse	No serious imprecision	Yesf
Shoulder dystocia/birth injury: subgroup of untreated women who were not obeseg											
1 (Catalano et al., 2012)	41/2792 (1.5%)	212/17247 (1.2%)	RR 1.19 (0.86 to 1.67)*	2 more per 1000 (from 2 fewer to 8 more)	High	Prospective cohort	No serious limitationsl	NA	No serious indirectnesse	No serious imprecision	Yesf

NA not applicable, OGTT oral glucose tolerance test, Primary Caesarean Section : first Caesarean Section; RR relative risk

** Calculated by the NCC-WCH technical team from data reported in the article*
a Primary caesarean section confirmed from infant birth certificate
b Diagnostic testing for gestational diabetes was performed between gestational weeks 24-28 (mean ± SD: 26.7 ± 2.9)
c Country: USA. Ethnicity: Non-Hispanic white 626 (7.2%), Hispanic 6484 (74.4%), Black 880 (10.1%), Asian 641 (6.4%), Other 80 (0.9%)

d Primary caesarean section confirmed from infant birth certificate and defined as the need for the first caesarean delivery at the discretion of the subject's primary obstetrical care provider. Total caesarean deliveries was not used as an outcome because of the various policies regarding delivery at various HAPO Study sites
e Diagnostic testing was performed between gestational weeks 24 and 32, but as close to gestational week 28 as possible
f Countries: USA, Australia, UK and Israel. Ethnicity: White, non-Hispanic 11,265 (48.3%), Black, non-Hispanic 2696 (11.6%), Hispanic 1984 (8.5%), Asian 6757 (29.0%), Other 614 (2.6%)
g Obesity was defined at 28 weeks as a BMI ≥ 33.0 kg/m2, overweight at 28 weeks as a BMI of 28.5–32.9, and normal weight or underweight as a BMI ≤ 28.4. These cut points (from regression analyses) are equivalent to the WHO categories of (nonpregnant) class 1 obesity, BMI ≥ 30.0 kg/m2, overweight 25.0–29.9, and normal or underweight < 25.0, respectively
h The confidence intervals for the relative and absolute effect point estimates are wide
i Large for gestational age was defined as infants in whom sex-specific, race-specific and gestational age-specific birth weight > 90th percentile
j Birthweight > 90th percentile was defined as birth weight greater than the 90th percentile for the baby's sex, gestational age, ethnicity, field centre, and maternal parity with gestational ages of 30–44 weeks included
k Shoulder dystocia/birth injury was defined as presence of ICD-9 codes 653.4, 653.5, 660.4, 767.0 - 767.9 or 959.0 - 959.9 at delivery
l When either shoulder dystocia or birth injury was suspected, additional data were abstracted and were reviewed by two members of an outcome review committee (blinded to the mother's glycaemic status) to confirm whether either was present

Table 34: GRADE profile for the incidence of diagnosis of gestational diabetes using WHO and IADPSG criteria.

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes using WHO criteria	Incidence of gestational diabetes using IADPSG criteria	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Impreci-sion	Other considerations
Universal screening with 75g oral glucose tolerance tests											
1 (Dahanayaka et al., 2012)	NRa	405 (10%)	29/405 (7.2%)	36/405 (8.9%)	Low	Cross-sectional	Seriousb, c	NA	No serious indirectness	Seriousd	Yese
1 (Jenum et al., 2012)	823	759 (92.2%)	99/759 (13.0%)	239/759 (31.5%)	Low	Prospective cohort	Seriousb, c	NA	Seriousf	No serious imprecision	Yesg
1 (Kun et al., 2011)	2260	1835 (81.2%)	159/1835 (8.7%)	304/1835 (16.6%)	Low	Population based	Seriousb, c	NA	Seriousf	No serious imprecision	Yesh
Screening in a selected population											

Number of studies	Number of potential participants	Number of women who had test	Incidence of gestational diabetes using WHO criteria	Incidence of gestational diabetes using IADPSG criteria	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Impreci-sion	Other considerations
Nallaperuamal et al., 2013)	1351	1351	699/1351 women (51.7%)	699/1351 women (51.7%)	Very low	Retrospective cohort	Seriousb, c	NA	No serious indirectness	No serious imprecision	Yesi

a Annual births not reported, but would be approximately 4,000 because recruitment was performed to cover 10% of annual births (n = 400)
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d Total number of events less than 300
e Country: Sri Lanka. Ethnicity of population: not reported
f Incidence of gestational diabetes estimated using modified IADPSG criteria (fasting plasma glucose and 2 hour plasma glucose values only, no 1 hour plasma glucose values reported)
g Country: Norway. Ethnicity of population: 59% of women were of an ethnic minority, the largest groups being South Asians (25%) and Middle Easterners (15%)
h Country: Hungary. Ethnicity of population: not reported, although the study authors reported that most of the Hungarian population is Caucasian
I Country: Sri Lanka. Ethnicity of population: not reported, although the study authors make reference to the study being performed in an Asian Indian population

Table 35: GRADE profile for the diagnostic test accuracy of 2 hour 75g OGTT in the second trimester interpreted using IADPSG thresholds (FPG ≥ 5.1 mmol/l, 1 hour PG ≥ 10.0mmol/l or 2 hour PG ≥ 8.5 mmol/l for detecting gestational diabetes in the second trimester) compared with reference standard WHO 1999 criteria thresholds (FPG ≥7.0 or 2 hour PG ≥7.8 mmol/l)

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Impreci-sion	Other considerations
Fasting plasma glucose ≥ 5.1 mmol/l or 1 hour plasma glucose ≥ 10 mmol/l or 2 hour plasma glucose ≥ 8.5 mmol/l for detecting gestational diabetes in the second trimester												

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limita-tions	Inconsistency	Indirect-ness	Impreci-sion	Other considerations
1 (Dahanayaka et al., 2012)	405	60.8 (59.5 to 68.8)a	6.2 (0.32 to 36.9) a	0.65 (0.6 to 1.21)a	6.27 (0.72 to 3400786) a	Moderate	Cross-sectional	Serious b,c	NA	No serious indirectness	No serious imprecision	Yesd
1 (Jenum et al., 2012)	759	71.7 (62.4 to 79.7)	74.5 (73.2 to 75.7)	2.82 (2.32 to 3.28)	0.38 (0.27 to 0.51)	Low	Prospective cohort	Serious b,c	NA	Seriouse	No serious imprecision	Yesf
1 (Kun et al., 2011)	1835	65.4 (58.1 to 72.1)	88.1 (87.4 to 88.7)	5.48 (4.6 to 6.38)	0.39 (0.31 to 0.48)	Low	Population based	Serious b,c	NA	Seriouse	No serious imprecision	Yesg
Selected population												
1 (Nallaperumal et al., 2013)	1351	80 (77.7 to 82.0)*	78.5 (76.1 to 80.8)*	3.72 (3.26 to 4.26)*	0.26 (0.22 to 0.29)*	Very low	Retrospective cohort	Serious b,c	NA	No serious indirectness	No serious imprecision	Yesj
Fasting plasma glucose ≥ 5.1 mmol/l for detecting gestational diabetes in the first trimester												
1 (Dahanayaka et al., 2012)	16	12.5 (0.63 to 60.2)	82.1 (78.6 to 94.7)	0.7 (0.0 to 10.61)	1.07 (0.46 to 1.27)	Very low	Cross-sectional (retrospective data)	Serious b,c	NA	No serious indirectness	Serioush	Yesd,i

NA not applicable
a Calculated by the NCC-WCH technical team from data reported in the article
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d Country: Sri Lanka. Ethnicity of population: not reported

e Incidence of gestational diabetes estimated using modified IADPSG criteria (fasting plasma glucose and 2 hour plasma glucose values only, no 1 hour plasma glucose values reported
f Country: Norway. Ethnicity of population: 59% of women were of an ethnic minority, the largest groups being South Asians (25%) and Middle Easterners (15%)
g Country: Hungary. Ethnicity of population: not reported, although the study authors reported that most of the Hungarian population is Caucasian
h Confidence interval for sensitivity was wider than 40 percentage points
i Although the study was cross-sectional in design, retrospective methods were used to obtain the data and thus the initial quality rating in GRADE is moderate
j Country: Sri Lanka. Ethnicity of population: not reported, although the study authors make reference to the study being performed in an Asian Indian population

Table 36: GRADE profile of the incidence of clinical outcomes in untreated pregnant women with gestational diabetes diagnosed using the WHO compared with IADPSG criteria and their babies

Number of studies	Number of women who had test	Incidence in women with gestational diabetes diagnosed using WHO criteria and their babies	Incidence in women with gestational diabetes diagnosed using IADPSG criteria and their babies	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Imprecision	Other consider ations
Caesarean section										
1 (Wendland et al., 2012 [EBDG 2001])	4345	151/321 (47.0%)	309/801 (38.6%)	Moderate	Systematic review (prospective cohort study data)	Seriousa	NA	No serious indirectness	No serious imprecision	Yesb
1 (Wendland et al., 2012 [HAPO 2008])	20732	564/2314 (24.4%)	813/3338 (24.4%)	Low	Systematic review (prospective cohort study data)	Very seriousa,c	NA	No serious indirectness	No serious imprecision	Yesd
Large for gestational age (birthweight ≥ 90th centile)										

Number of studies	Number of women who had test	Incidence in women with gestational diabetes diagnosed using WHO criteria and their babies	Incidence in women with gestational diabetes diagnosed using IADPSG criteria and their babies	Quality	Design	Limita-tions	Inconsist-ency	Indirect-ness	Imprecision	Other consider ations
1 (Wendland et al., 2012 [EBDG 2001])	Variese	45/294 (15.3%)	87/772 (11.3%)	Very low	Systematic review (prospective cohort study data)	Very seriousa,f	NA	No serious indirectness	Seriousg	Yesb
1 (Wendland et al., 2012 [HAPO 2008])	Variesh	361/2642 (13.7%)	605/3738 (16.2%)	Low	Systematic review (prospective cohort study data)	Very seriousa,c, f	NA	No serious indirectness	No serious imprecision	Yesd
Perinatal mortality										
1 (Wendland et al., 2012 [EBDG 2001])	4431	12/330 (3.6%)	27/812 (3.3%)	Low	Systematic review (prospective cohort study data)	Seriousa	NA	No serious indirectness	Seriousg	Yesb

EBDG Brazilian Study of Gestational Diabetes, HAPO Hyperglycemia and Adverse Pregnancy Outcomes study, IADPSG International Association of Diabetes and Pregnancy Study Groups, NA not applicable, WHO World Health Organization

a The data presented in the systematic review did not allow calculation of the statistical significance of the results
b Country: Brazil. Ethnicity of population: white 44.9%, mixed 41.4%, black 13.6%, other 0.4%
c Unclear where the data presented in the systematic review for the HAPO 2008 study were sourced
d Country: multinational. Ethnicity of population: white 48.3%, black 11.6%, Hispanic 8.5%, Asian 29.0%, other 2.6%
e Total number of untreated women tested using WHO criteria 3,924, total number of untreated women tested using IADPSG criteria 3,974
f Unclear why the number of women tested for gestational diabetes using each criteria is different
g Total number of events less than 300
h Total number of untreated women tested using WHO criteria 23,027, total number of untreated women tested using IADPSG criteria 23,217

Table 37: GRADE profile for comparison of dietary strategy / advice with standard care

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (diet strategy or advice)	Comparator (no diet strategy or advice)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Maternal outcomes											
Caesarean1											
3 (Bevier et al., 1999; Crowther et al., 2005; Garner et al., 1997; Landon et al., 2009)	315/1166	358/1177	RR 0.89 (0.77 to 1.02)a,b	33 fewer per 1000 (from 70 fewer to 6 more per 1000)	Very low	Randomised controlled trial	Very serious2,3,4	Serious5	No serious indirectness	Serious6,7,8	Yes9,10,11,12,13
1 (Bonomo et al., 2005)	44/150	42/150	RR 1.05 (0.73 to 1.50)a	14 more per 1000 (from 76 fewer to 140 more per 1000)	Very low	Randomised controlled trial	Very serious14,15,16	No serious inconsistency17	No serious indirectness	Very serious18	Yes19,20
Vaginal delivery											
1 (Garner et al., 1997)	118/149	121/150	RR 0.98 (0.87 to 1.10)c	16 fewer per 1000 (from 105 fewer to	Low	Randomised controlled trial	Serious4	No serious inconsistency17	No serious indirectness	Serious6	Yes12,21

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (diet strategy or advice)	Comparator (no diet strategy or advice)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				81 more per 1000)							
Spontaneous vaginal delivery											
1 (Bevier et al., 1999)	22/35	30/48	RR 1.01 (0.72 to 1.41)	6 more per 1000 (from 175 fewer to 256 more per 1000)	Very low	Randomised controlled trial	Very serious2 2,23	No serious inconsistency 17	No serious indirectness	Very serious18	Yes10,24
Induction of labour1											
3 (Bevier et al., 1999; Crowther et al., 2005; Landon et al., 2009)	325/1017	272/1027	RR 1.20 (0.87 to 1.65)a,d	53 more per 1000 (from 34 fewer to 172 more per 1000)	Very low	Randomised controlled trial	Serious 25	Serious26	No serious indirectness	Serious8,27	Yes10,11,13,28
Treatment failure29,30,31											
1 (Garner et al., 1997)	36/149	NR	NC	NC	Moderate	Randomised controlled trial	Serious 4	No serious inconsistency 17	No serious indirectness	NA	Yes12,21
1 (Crowther et al., 2005)	100/490	17/510	RR 6.12 (3.72 to 10.08)c	171 more per 1000 (from 91 to 303 more per 1000)	High	Randomised controlled trial	No serious bias	No serious inconsistency 17	No serious indirectness	No serious imprecision	Yes11,32
1 (Landon et al., 2009)	37/476	2/455	RR 17.68	73 more per 1000 (from 14	Moderate	Randomised controlled trial	Serious 33	No serious inconsistency 17	No serious indirectness	No serious imprecision	Yes13,34

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (diet strategy or advice)	Comparator (no diet strategy or advice)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
			(4.29 to 72.93)c	to 316 more per 1000)							
Neonatal outcomes											
Large for gestational age1											
4 (Bevier et al., 1999; Crowther et al., 2005; Landon et al., 2009; Langer et al., 1989)	107/1081	208/1089	RR 0.49 (0.34 to 0.71)a,e	94 fewer per 1000 (from 55 fewer to 126 fewer per 1000)	Very low	Randomised controlled trial	Serious 35	Serious36	No serious indirectness	Serious6,8	Yes10,11,13,28,37,38
1 (Bonomo et al., 2005)	9/150	21/150	RR 0.43 (0.20 to 0.91)a	80 fewer per 1000 (from 13 to 112 fewer per 1000)	Very low	Randomised controlled trial	Very serious14,15,16	No serious inconsistency 17	No serious indirectness	Serious6	Yes19,20
Shoulder dystocia1,39											
3 (Bevier et al., 1999; Crowther et al., 2005; Landon et al., 2009)	15/1017	36/1027	RR 0.42 (0.23 to 0.77)a,f	20 fewer per 1000 (from 8 fewer to 27 fewer per 1000)	Very low	Randomised controlled trial	Serious 25	Very serious26,40	No serious indirectness	Serious6,8	Yes10,11,13,28
Serious perinatal complications41											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (diet strategy or advice)	Comparator (no diet strategy or advice)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Crowther et al., 2005)	7/506g	23/524g	RR 0.32 (0.14 to 0.73)h	30 fewer per 1000 (from 12 fewer to 38 fewer per 1000)	Moderate	Randomised controlled trial	No serious bias	No serious inconsistency 17	Serious42	No serious imprecision	Yes11,32
Admission to neonatal care											
1 (Crowther et al., 2005)	357/506g	321/524g	RR 1.15 (1.05 to 1.26)h	92 more per 1000 (from 31 more to 159 more per 1000)	Low	Randomised controlled trial	Serious 43	No serious inconsistency 17	Serious44	Serious27	Yes11,32
1 (Bonomo et al., 2005)	5/150	7/150	RR 0.71 (0.23 to 2.19)a	14 fewer per 1000 (from 36 fewer to 56 more per 1000)	Very low	Randomised controlled trial	Very serious14,15,16	No serious inconsistency 17	Serious44	Very serious18	Yes19,20
NICU stay > 24 hours											
1 (Langer et al., 1989)	4/63	7/63	RR 0.57 (0.17 to 1.87)a	48 fewer per 1000 (from 92 fewer to 97 more per 1000)	Very low	Randomised controlled trial	Serious 45	No serious inconsistency 17	Serious46	Very serious18	Yes37,38
Composite perinatal outcome47											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (diet strategy or advice)	Comparator (no diet strategy or advice)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Landon et al., 2009)	149/460	163/440	RR 0.87 (0.72 to 1.07)	48 fewer per 1000 (from 104 fewer to 26 more per 1000)	Very low	Randomised controlled trial	Very serious33,48	No serious inconsistency17	Serious49	Serious6	Yes13,34
Hyperinsulinaemia											
1 (Landon et al., 2009)	75/423	92/403	RR 0.78 (0.57 to 1.05)	50 fewer per 1000 (from 98 fewer to 11 more per 1000)	Low	Randomised controlled trial	Serious50	No serious inconsistency17	No serious indirectness	Serious6	Yes13,34
Hypoglycaemia (not defined)											
1 (Garner et al., 1997)	21/149	13/150	RR 1.63 (0.85 to 3.11)c	55 more per 1000 (from 13 fewer to 183 more per 1000)	Low	Randomised controlled trial	Very serious4,51	No serious inconsistency17	Serious52	Very serious7,27	Yes12,21
1 (Crowther et al., 2005)	35/506g	27/524g	RR 1.34 (0.82 to 2.18)a	18 more per 1000 (from 9 fewer to 61 more per 1000)	Low	Randomised controlled trial	Serious51	No serious inconsistency17	Serious52	Serious27	Yes11,32
Hypoglycaemia (< 1.7mmol/l)53											
1 (Bonomo et al., 2005)	5/150	6/150	RR 0.83 (0.26 to 2.66)a	7 fewer per 1000 (from 30	Very low	Randomised controlled trial	Very serious14,15,16	No serious inconsistency17	Serious52	Very serious18	Yes19,20

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (diet strategy or advice)	Comparator (no diet strategy or advice)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				fewer to 66 more per 1000)							
Hypoglycaemia (< 1.9mmol/l)											
1 (Langer et al., 1989)	1/63	8/63	RR 0.13 (0.02 to 1.01)a	110 fewer per 1000 (from 124 fewer to 1 more per 1000)	Very low	Randomised controlled trial	Very serious45	No serious inconsistency17	Serious46,52	Serious6	Yes37,38
Perinatal mortality											
1 (Garner et al., 1997)	0/149	0/150	NC	NC	Moderate	Randomised controlled trial	Serious 4	No serious inconsistency17	No serious indirectness	NA	Yes12,21
1 (Landon et al., 2009)	0/485	0/473	NC	NC	Low	Randomised controlled trial	Serious 33	No serious inconsistency17	No serious indirectness	NA	Yes13,34
1 (Crowther et al., 2005)	0/506g	5/524g	RR: 0.09 (0.005 to 1.62)c	9 fewer per 1000 (from 9 fewer to 6 more per 1000)	Low	Randomised controlled trial	No serious bias	No serious inconsistency17	No serious indirectness	Very serious18	Yes11,32

CI confidence interval, RR relative risk, NR not reported, NC not calculable, NA not applicable

a Data combined using Mantel-Haenszel random effects meta-analysis of study relative risks.

b RR = 1.08 (95% CI 0.68 to 1.71) for Garner et al., RR = 0.57 (95% CI 0.22 to 1.47) for Bevier et al., RR = 0.96 (95% CI 0.80 to 1.15) for Crowther et al., RR = 0.79 (95% CI 0.65 to 0.97) for Landon et al., heterogeneity I^2 = 13% overall.

c Calculated by the NCC-WCH technical team.

d RR = 17.69 (95% CI 1.03 to 304.09) for Bevier et al., RR = 1.30 (95% CI 1.09 to 1.56) for Crowther et al., RR = 1.02 (95% CI 0.82 to 1.26) for Landon et al., heterogeneity I^2 = 70%. The high I^2 value is due to there being no events in one study leading to a very wide CI around the RR; it was therefore judged to be acceptable not to split the meta-analysis into individual studies.

e RR = 0.11 (95% CI 0.02 to 0.84) for Bevier et al., RR = 0.61 (95% CI 0.47 to 0.81) for Crowther et al., RR = 0.49 (95% CI 0.33 to 0.73) for Landon et al., heterogeneity I^2 = 40%.
f RR = 0.69 (95% CI 0.06 to 7.27) for Bevier et al., RR = 0.45 (95% CI 0.19 to 1.09) for Crowther et al., RR = 0.37 (95% CI 0.16 to 0.88) for Landon et al., heterogeneity I^2 = 0%.
g Denominator represents the total number of births, not women.
h Unadjusted values are reported.
1 Different definitions of GDM and diagnostic criteria were used by each study.
2 All four studies did not completely specify whether allocation was concealed; three studies did not describe randomisation methods (Crowther et al., Garner et al. and Bevier et al.) and one study used minimisation to allocate participants (Landon et al.).
3 Data for Bevier et al. were combined for repeat and primary caesareans; data were missing for four controls for mode of birth.
4 It was not possible to determine how similar groups were at baseline for Garner et al. as not all relevant confounders were reported (ethnicity and parity were omitted).
5 Bevier et al. and Garner et al. applied a kcal limit for dietary intake in the intervention group in addition to counselling; the remaining two studies specified the use of counselling/advice only.
6 Confidence interval for the RR crosses RR = 0.75.
7 Small sample size for Garner et al. meant that the study was very underpowered and unable to detect significant differences for operative deliveries.
8 97% confidence intervals were used by Landon et al. due to adjustment of p-values to allow for changes in the type 1 error caused by the use of multiple testing. Meta-analyses were therefore performed which both included and excluded this study. It was deemed appropriate to present the results which include this study because 97% CIs are more conservative/wider than 95% CIs and, due to the large effect size, should therefore not have adversely affected the overall conclusions of the analysis.
9 The studies were carried out in Australia, the United Kingdom, Canada and the United States of America. Ethnicity was primarily Hispanic, followed by white, Asian, other and African-American. One study did not report ethnicity.
10 Interventjons for Bevier et al.: dietary counselling, instruction in self-monitoring of blood glucose and 30kcal/kg/day or 24kcal/kg/day if body weight was > 120% of ideal body weight.
11 Interventions for Crowther et al.: individualised dietary advice, instruction in self-monitoring of blood glucose (four times daily until within the recommended range for two weeks) and insulin if required.
12 Interventions for Garner et al.: standard obstetric care and strict glycaemic control which included counselling, 35kcal/kg/day dietary intake and instruction in self-monitoring of blood glucose.
13 Interventions for Landon et al.: dietary counselling and therapy, instruction in self-monitoring of blood glucose and insulin where appropriate.
14 Allocation was not concealed from investigators, clinicians or participants.
15 Groups were unbalanced with respect to attrition; 6 in the diet group left care versus none in the standard care group.
16 Performance bias is likely as participants in the diet group received more care than those in the standard care group.
17 Single study analysis.
18 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.
19 The study was carried out in Italy. All participants were Caucasian.
20 The intervention group received dietary advice to consume 24 to 30kcal/kg/day based on pre-pregnancy weight (50 to 50% carbohydrates, 25 to 30% protein, 20 to 25% fat). The control group received no special care, diet or pharmacological intervention.
21 The study was carried out in Canada. Ethnicity was not reported.
22 Attrition/missing data as only 83/103 participants were included in final analyses; the distribution between groups was not reported.
23 The method of randomisation was not described.
24 The study was carried out in the United States of America. Ethnicity was 4% white, 94% Hispanic and 2% African-American in the intervention group and 6% white and 94% Hispanic in controls.
25 All three studies did not completely specify whether allocation was concealed; two studies did not describe randomisation methods (Crowther et al. and Bevier et al.) and one study used minimisation to allocate participants (Landon et al.).
26 Bevier et al. applied a kcal limit for dietary intake in the intervention group in addition to counselling; the remaining two studies specified the use of counselling/advice only.
27 Confidence interval for the RR crosses RR = 1.25.

28 The studies were carried out in Australia, the United Kingdom, Canada and the United States of America. Ethnicity was primarily Hispanic, followed by white, Asian, other and African-American.
29 Garner et al. defined treatment failure as a requirement for insulin based on fasting plasma glucose > 4.4mmol/l or one hour post-prandial glucose > 7.8mmol/l.
30 Crowther et al. defined treatment failure as a requirement for insulin based on fasting plasma glucose > 5.5mmol/l or post-prandial glucose > 7.0mmol/l at ≤ 35 weeks' gestation, post-prandial glucose ≥ 8.0mmol/l > 35 weeks' gestation or one capillary blood glucose value ≥ 9.0mmol/l during two weeks of self-monitoring of blood glucose.
31 Landon et al. defined treatment failure as a requirement for insulin if the majority of fasting plasma glucose values > 5.3mmol/l or two hour post-prandial glucose values > 6.7mmol/l between clinic visits.
32 The study was carried out in Australia and the United Kingdom. Ethnicity was 73% white, 19% Asian and 9% other in the intervention group and 78% white, 14% Asian and 8% other in controls.
33 Minimisation was used as the randomisation technique which is not a truly random method of allocation.
34 The study was carried out in the United States of America. Ethnicity was 11.5% black, 25.4% white, 4.5% Asian, 57.9% Hispanic and 0.6% other in the intervention group and 11.4% black, 25.2% white, 5.9% Asian, 56.0% Hispanic and 1.5% other in controls.
35 All four studies did not completely specify whether allocation was concealed; three studies did not describe randomisation methods (Crowther et al., Bevier et al. and Langer et al.) and one study used minimisation to allocate participants (Landon et al.).
36 Bevier et al. and Langer et al. applied a kcal limit for dietary intake in the intervention group in addition to counselling; the remaining two studies specified the use of counselling/advice only.
37 Women in the intervention group received dietary advice to consume 25kcal/kg if pre-pregnancy BMI ≥ 27 or 30kcal/kg if pre-pregnancy BMI < 27. Women in the control group were advised to continue with their normal eating habits.
38 The study was carried out in the United States of America. Ethnicity was 30% black, 33% Hispanic and 36% white in the intervention group and 33% black, 33% Hispanic and 33% white in the control group.
39 Shoulder dystocia was assessed using a standardised checklist at birth (Crowther et al.), defined clinically (Landon et al.) or not defined (Bevier et al.).
40 Definitions were not given or not consistent across studies.
41 Serious perinatal complications comprised stillbirth, neonatal death, shoulder dystocia, bone fracture and nerve palsy.
42 Two of the composite outcome variables were not relevant to the GDG's priority outcomes specified in the protocol for this review (bone fracture and nerve palsy).
43 The term "neonatal nursery" was not defined.
44 No duration of admission was specified.
45 Randomisation methods were not described.
46 The ethnicity of women in the study is not comparable to the population in the United Kingdom therefore generalisability is poor.
47 The composite perinatal outcome comprised hypoglycaemia, hyperbilirubinaemia, elevated cord-blood C-peptide level, stillbirth or neonatal death and birth trauma.
48 There were substantial missing data for this outcome (25/485 intervention, 33/473 control overall; additional data were missing for individual components of this outcome).
49 Three of the composite outcome variables are not relevant to the GDG's priority outcomes specified in the protocol for this review (hypoglycaemia, hyperbilirubinaemia and birth trauma).
50 Data were missing for this outcome (62 intervention subjects, 70 control subjects).
51 Hypoglycaemia was not defined.
52 Hypoglycaemia is included as an outcome as a proxy for hyperinsulinaemia.
53 Hypoglycaemia was defined as any two blood glucose values < 1.7mmol/l.

Table 38: GRADE profile for comparison of diet plus insulin with diet alone.

Number of studies		Number of women		Effect		Quality	Design	Quality assessment				
		Intervention (diet + insulin)	Comparator (diet alone)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
	Maternal outcomes											
	Caesarean delivery											
1 (Coustan et al., 1978)		5/27	4/11	RR 0.51 (0.07 to 3.71)a	178 fewer per 1000 (from 338 fewer to 985 more per 1000)	Very lowb	Partially randomised trial	Very serious1, 2,3	No serious inconsistency4	No serious indirectness	Very serious5	Yes6,7
1 (Thompson et al., 1990)		14/45	16/50	RR 0.97 (0.54 to 1.76)a	10 fewer per 1000 (from 147 fewer to 243 more per 1000)	Low	Randomised controlled trial	No serious bias	No serious inconsistency4	No serious indirectness	Very serious5	Yes8,9
	Treatment failure[10,11]											
1 (Persson et al., 1985)		NR	15/105	NC	NC	Low	Randomised controlled trial	No serious bias	No serious inconsistency4	No serious indirectness	NA	Yes12,13

Number of studies		Number of women		Effect		Quality	Design	Quality assessment				
		Intervention (diet + insulin)	Comparator (diet alone)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Thompson et al., 1990)		9/45	16/50	RR 0.63 (0.04 to 9.90)a	118 fewer per 1000 (from 307 fewer to 1000 more per 1000)	Low	Randomised controlled trial	No serious bias	No serious inconsistency4	No serious indirectness	Very serious5	Yes8,9
	Neonatal outcomes											
	Large for gestational age (> 90th percentile)											
1 (Persson et al., 1985)		11/97	14/105	RR 0.85 (0.41 to 1.78)a	20 fewer per 1000 (from 79 fewer to 104 more per 1000)	Low	Randomised controlled trial	No serious bias	No serious inconsistency4	No serious indirectness	Very serious5	Yes12,13
	Hypoglycaemia (plasma glucose < 30mg/dl)											
1 (Thompson et al., 1990)		2/34	5/34	RR 0.40 (0.08 to 1.92)a	88 fewer per 1000 (from	Very low	Randomised controlled trial	No serious bias	No serious inconsistency4	Serious14	Very serious5	Yes8,9

Number of studies		Number of women		Effect		Quality	Design	Quality assessment				
		Intervention (diet + insulin)	Comparator (diet alone)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
					135 fewer to 135 more per 1000)							
Hypoglycaemia (not defined)												
1 (Persson et al., 1985)		20/97	13/105	RR 1.67 (0.88 to 3.17)a	83 more per 1000 (from 15 fewer to 269 more per 1000)	Very low	Randomised controlled trial	Serious15	No serious inconsistency4	Serious14	Serious5	Yes12,13
Shoulder dystocia												
1 (Coustan et al., 1978)		0/27	0/11	NC	NC	Very lowb	Partially randomised trial	Very serious1,2,3,16	No serious inconsistency4	No serious indirectness	NA	Yes6,7
1 (Thompson et al., 1990)		0/34	0/34	NC	NC	Moderate	Randomised controlled trial	No serious bias	No serious inconsistency 4	Serious17	NA	Yes8,9

Number of studies		Number of women		Effect		Quality	Design	Quality assessment				
		Intervention (diet + insulin)	Comparator (diet alone)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Perinatal mortality												
1 (Coustan et al., 1978)		0/27	0/11	NC	NC	Very lowb	Partially randomised trial	Very serious1,2,3	No serious inconsistency4	No serious indirectness	NA	Yes6,7
1 (Thompson et al., 1990)		0/34	0/34	NC	NC	High	Randomised controlled trial	No serious bias	No serious inconsistency4	No serious indirectness	NA	Yes8,9

CI confidence interval, RR relative risk, NC not calculable, NA not applicable
a Calculated by the NCC-WCH technical team.
b Starting point of moderate quality due to incomplete randomisation.
1 The first 20 participants that entered the study were allocated based on their gestational age at diagnosis of gestational diabetes rather than randomly.
2 The baseline comparability of patient characteristics is unclear: age is not reported and neither are p-values.
3 Follow-up was not the same for all participants; this was not accounted for in analyses.
4 Single study analysis.
5 Confidence interval for the relative risk crosses the line of no effect and RR = 0.75 and RR = 1.25.
6 The study was carried out in the United States of America. Ethnicity was not reported.
7 Interventions for Coustan et al.: The control group received instruction in a diet of 30-35kcal/kg ideal weight/day comprising 500kcal protein with the rest of the intake split equally between fat and carbohydrates. The intervention group received the same diet as controls plus 20 units NPH insulin and 10 units regular insulin 30 minutes before breakfast.
8 The study was carried out in the United States of America. Ethnicity was not reported.
9 Interventions for Thompson et al.: The control group received instruction in a diet of 35kcal/kg ideal body weight/day comprising 50% kcal as carbohydrate, 30% as fat and 20% as protein. The intervention group received the above diet plus 20 units of NPH insulin and 10 units of regular insulin 30 minutes before breakfast.
10 Thompson et al. defined treatment failure as requiring insulin in the diet alone group or an increase in insulin dosage in the diet plus insulin group. Thresholds for insulin therapy were fasting glucose > 5.8mmol/l on one occasion or two hour post-prandial glucose > 6.7mmol/l on two occasions.
11 Persson et al. defined treatment failure in the diet alone group as the requirement of insulin when fasting glucose exceeded 7.0mmol/l or one hour post-prandial values > 9.0mmol/l at least three times in one week.
12 The study was carried out in Sweden. Ethnicity was not reported.
13 Interventions for Persson et al.: The control group received instruction in a diet comprising 50% calories from carbohydrates, 20% from protein, 30% from fat. The intervention group received the same diet as controls plus an initial dose of 8 to 12IU/day of intermediate or fast-acting insulin.
14 Hypoglycaemia is included as an outcome as a proxy for hyperinsulinaemia.

Table 39: GRADE profile for comparison of two different diets

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Maternal outcomes											
Caesarean delivery											
1 (Cypryket al., 2007)	7/15	5/15	RR 1.40 (0.57 to 3.43)a	133 more per 1000 (from 143 fewer to 810 more per 1000)	Very low	Randomised controlled trial	Serious 1	No serious inconsistency2	Serious3	Very serious4	Yes5,6
1 (Coustan et al., 1978)	4/11	9/34	RR 1.37 (0.52 to 3.58)a	98 more per 1000 (from 127 fewer to 683 more per 1000)	Very low	Randomised controlled trial	Very serious 7,8,9	No serious inconsistency2	No serious indirectness	Very serious4	Yes10,11
1 (Rae et al., 2000)	26/65	19/56	RR 1.18 (0.74 to 1.89)a	61 more per 1000 (from 88 fewer to 302 more	Low	Randomised controlled trial	No serious bias	No serious inconsistency2	No serious indirectness	Very serious4	Yes12,13

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				per 1000)							
1 (Moreno-Castilla et al., 2013)	25/74	20/75	RR 1.27 (0.78 to 2.08)a	72 more per 1000 (from 59 fewer to 288 more per 1000)	Low	Randomised controlled trial	Serious 14	No serious inconsistency2	No serious indirectness	Serious15	Yes16,17
1 (Asemi et al., 2014)	12/26 (46.2%)	21/26 (80.8%)	RR 1.18 (0.74 to 1,89)	61 fewer per 1000 (from 88 fewer to 302 more per 1000)		Randomised controlled trial	Serious 28	No serious inconsistency2	No serious indirectness	Very serious4	Yes18,19
Emergency caesarean delivery											
1 (Louie et al., 2011)	9/44	5/44	RR 1.80 (0.64 to 1.85)a	91 more per 1000 (from 41 fewer to 97 more per 1000)	Very low	Randomised controlled trial	Serious 18	No serious inconsistency2	Serious19	Very serious4	Yes20,21
Vaginal delivery											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Cyprykt et al., 2007)	7/15	9/15	RR 0.77 (0.39 to 1.52)a	138 fewer per 1000 (from 366 fewer to 312 more per 1000)	Very low	Randomised controlled trial	Very serious 1,22	No serious inconsistency2	Serious3	Very serious4	Yes5,6
Spontaneous vaginal delivery											
1 (Rae et al., 2000)	31/65	30/56	RR 0.89 (0.63 to 1.27)a	59 fewer per 1000 (from 198 fewer to 145 more per 1000)	Low	Randomised controlled trial	No serious bias	No serious inconsistency2	No serious indirectness	Very serious4	Yes12,13
Induction of labour											
1 (Rae et al., 2000)	29/63	23/51	RR 1.02 (0.18 to 5.76)a	9 more per 1000 (from 370 fewer to 1000 more	Low	Randomised controlled trial	No serious bias	No serious inconsistency2	No serious indirectness	Very serious4	Yes12,13

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				per 1000)							
Treatment failure [23,24,25,26,27]											
1 (Moses et al., 2009)	9/31	19/32	RR 0.49 (0.26 to 0.91)a	303 fewer per 1000 (from 53 to 439 fewer per 1000)	Very low	Randomised controlled trial	Very serious 28	No serious inconsistency2	No serious indirectness	Serious29	Yes30,31
1 (Rae et al., 2000)	11/63	9/54	RR 1.05 (0.47 to 2.34)a	8 more per 1000 (from 88 fewer to 223 more per 1000)	Low	Randomised controlled trial	No serious bias	No serious inconsistency2	No serious indirectness	Very serious4	Yes12,13
1 (Louie et al., 2011)	25/47	29/45	RR 0.83 (0.59 to 1.17)a	110 fewer per 1000 (from 264 fewer to 100 more per 1000)	Low	Randomised controlled trial	Serious 18	No serious inconsistency2	No serious indirectness	Serious29	Yes20,21

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Moreno-Castilla et al., 2013)	41/75	41/75	RR 1.00 (0.75 to 1.34)a	0 fewer per 1000 (from 137 fewer to 186 more per 1000)	Low	Randomised controlled trial	Serious 14	No serious inconsistency2	No serious indirectness	Serious15	Yes16,17
1 (Grant et al., 2011)	13/18	12/20	RR 1.20 (0.75 to 1.93)a	120 more per 1000 (from 150 fewer to 558 more per 1000)	Low	Pilot study	Serious 35,36	No serious inconsistency2	No serious indirectness	Serious15	Yes37,38
Neonatal outcomes											
Large for gestational age (> 90th percentile)											
1 (Moses et al., 2009)	3/31	3/29	RR 1.03 (0.22 to 4.72)a	3 more per 1000 (from 81 fewer to 385 more per 1000)	Very low	Randomised controlled trial	Very serious 28,32	No serious inconsistency2	No serious indirectness	Very serious4	Yes30,31

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Louie et al., 2011)	6/47	2/43	RR 2.87 (0.97 to 8.46)a	87 more per 1000 (from 1 fewer to 347 more per 1000)	Very low	Randomised controlled trial	Serious 18	No serious inconsistency2	No serious indirectness	Very serious4	Yes20,21
1 (Moreno-Castilla et al., 2013)	3/74	6/75	RR 0.51 (0.13 to 1.96)a	39 fewer per 1000 (from 70 fewer to 77 more per 1000)	Very low	Randomised controlled trial	Serious 14	No serious inconsistency2	No serious indirectness	Very serious4	Yes16,17
1 (Grant et al., 2011)	2/18	3/20	RR 0.74 (0.13 to 4.18)a	39 fewer per 1000 (from 130 fewer to 477 more per 1000)	Very low	Pilot study	Serious 35,36	No serious inconsistency2	No serious indirectness	Very serious4	Yes37,38
Shoulder dystocia											
1 (Rae et al., 2000)	0/63	0/54	NC	NC	Moderate	Randomised controlled trial	Serious 33	No serious inconsistency2	No serious indirectness	NA	Yes12,13

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention	Comparator	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Coustan et al., 1978)	0/11	1/34	RR 0.97 (0.04 to 22.25)a	1 fewer per 1000 (from 28 fewer to 625 more per 1000)	Very low	Randomised controlled trial	Very serious 7,8,9,33	No serious inconsistency2	No serious indirectness	Very serious4	Yes20,21
Hypoglycaemia (< 30mg/100ml; <1.7mmol/L)											
1 (Coustan et al., 1978)	0/11	2/34	RR 0.58 (0.03 to 11.25)a	25 fewer per 1000 (from 57 fewer to 603 more per 1000)	Very low	Randomised controlled trial	Very serious 7,8,9	No serious inconsistency2	Serious34	Very serious4	Yes10,11
Hypoglycaemia (< 40mg/100ml; <2.2mmol/l)											
1 (Moreno-Castilla et al., 2013)	9/74	10/75	RR 0.91 (0.39 to 2.11)a	12 fewer per 1000 (from 81 fewer to 148 more per 1000)	Very low	Randomised controlled trial	Serious 14	No serious inconsistency2	Serious34	Very serious4	Yes16,17

CI confidence interval, RR relative risk, NC not calculable, NA not applicable
a Calculated by the NCC-WCH technical team.
1 No baseline characteristics were provided for each group and confounders were not adjusted for in analyses: it is unclear whether confounding may have affected the effect estimate.

2 Single study analysis.
3 Not clear whether an OGTT was performed to diagnose women with gestational diabetes: three-day diaries were reviewed to obtain 24 hour average estimates of glycaemia before diets were prescribed.
4 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.
5 The study was carried out in Poland. All women were Caucasian.
6 The intervention group received 45% of daily intake as carbohydrates, 25% protein and 30% fat. The control group received 60% of daily intake as carbohydrates, 25% protein and 15% fat.
7 The first 20 participants that entered the study were allocated based on their gestational age at diagnosis of gestational diabetes rather than randomly.
8 The baseline comparability of patient characteristics is unclear: age is not reported and neither are p-values.
9 Follow-up was not the same for all participants; this was not accounted for in analyses.
10 The study was carried out in the United States of America. Ethnicity was not reported.
11 The intervention was a diet of 30 to 35kcal/kg/day comprising 500kcal protein with the rest split equally between carbohydrate and fat. Control subjects received dietary counselling as per a standard prenatal care protocol aimed at 15 to 20lb weight gain.
12 The study was carried out in Australia. Ethnicity was not reported.
13 The intervention was a moderately energy-restricted diet comprising 1590 to 1776kcal per day. The control group received instruction in an unrestricted diet of between 2010 and 2220kcal per day.
14 Allocation was not concealed from clinicians responsible for providing care.
15 Confidence interval for the RR crosses RR = 1.25.
16 The study was carried out in Spain. Ethnicity was Caucasian in 92.0% of the control group and 98.7% of the intervention group. No other ethnicities were reported.
17 The intervention was a low carbohydrate diet comprising 40% carbohydrates, 40% fat and 20% protein. The control group received a diet comprising 55% carbohydrates, 25% fat and 20% protein. No changes to the carbohydrate content of each diet were allowed unless insulin therapy was initiated.
18 The study was carried out in Iran. Ethnicity was not reported
19 The control group received a diet base on 45-55% carbohydrates, 15-20% protein and 25-30% total fat. Th intervention group received the DASH diet which was similar to the control diet, but was rich in fruits, vegetables, whole grains and low-fat dairy products and low in saturated fats, cholesterol, refined grains and sweets
22 Possible attrition bias as 7 participants withdrew but the distribution between groups was not reported.
23 Does not include all Caesarean deliveries reported in the study.
24 The study was carried out in Australia. Ethnicity was 59.6% Asian, 31.9% Caucasian and 8.5% other in the low GI group, 55.6% Asian, 40.0% Caucasian and 4.4% other in the control group.
25 Both diets comprised 40 to 45% carbohydrate, 15 to 25% protein and 25 to 30% fat. Target GI levels were < 50 for the intervention group and < 60 for the control group.
26 Reported as "physiological delivery" but this was not defined.
23 Moses et al. defined treatment failure as a requirement for insulin based on fasting plasma glucose ≥ 5.5mmol/l or one hour post-prandial glucose ≥ 8.0mmol/l more than once in a week.
24 Rae et al. defined treatment failure as a requirement for insulin based on fasting plasma glucose > 5.5mmol/l or two hour post-prandial glucose > 7.0mmol/l on two or more occasions within 72 hours.
25 Louie et al. defined treatment failure as a requirement for insulin based on mean fasting plasma glucose > 5.2mmol/l or mean one hour post-prandial glucose > 7.5mmol/l during the preceding week.
26 Moreno-Castilla et al. defined treatment failure as at least two values exceeding fasting and preprandial blood glucose ≤ 5.3mmol/l and one hour postprandial glucose ≤ 7.8mmol/l within one week.
27 Grant et al. defined treatment failure as not meeting self-monitoring targets within two to three weeks of treatment starting. Targets were defined according to the Canadian Diabetes Association of fasting glucose between 3.8 and 5.2mmol/l and 2 hour postprandial between 5.0 and 6.6mmol/l.
28 Unclear whether participants and investigators were blinded to allocation.
29 Confidence interval for the RR crosses RR = 0.75.
30 The study was carried out in Australia. All women except one were Caucasian.

31 Both groups received 175g carbohydrate as part of their prescribed diets. The intervention group were advised to consume low GI foods including grain breads and unprocessed cereals with a high fibre content. Intervention participants were told to avoid white bread, processed cereals and potatoes. The control group were advised to follow a high fibre, low sugar diet comprising whole wheat bread and high fibre, high-to-moderate GI breakfast cereals.
32 19/32 (59%) of women in the control arm (high GI diet) required insulin therefore were switched to the low GI during the trial. This will have diluted the effect estimate towards the null.
33 Shoulder dystocia was not defined.
34 Hypoglycaemia is included as an outcome as a proxy for hyperinsulinaemia.
35 The method of randomisation was not described and it was unclear whether investigators were blinded to allocation.
36 Women in the study had either gestational diabetes or impaired glucose tolerance. Diagnostic criteria were not reported for either condition.
37 The study was carried out in Canada. Women had either gestational diabetes or impaired glucose tolerance. Ethnicity was 25% South East Asian, 21% Indian, 21% Caucasian, 11% East Asian, 9% Caribbean, 6% mixed and 6% Hispanic.
38 The intervention group were advised in a low glycaemic index diet where starchy foods were chosen from a list of low GI foods. The control group were advised in a diet where starchy foods were chosen from a list of intermediate and high GI foods.

Table 40: GRADE profile for comparison of exercise with no exercise in women with gestational diabetes mellitus.

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (exercise)	Comparator (no exercise)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Requirement for insulin											
1 (de Barros et al., 2010)	7/32	18/32	RR 0.38 (0.18 to 0.78)a	180 fewer per 1000 (from 124 to 461 fewer per 1000)	Very low	Randomised controlled trial	Very serious1,2,3	No serious inconsistency4	No serious indirectness	Serious5	Yes6,7,8
1 (Avery et al., 1997)	4/15	2/14	RR 1.86 (0.40 to 8.62)a	123 more per 1000 (from 86 fewer to 1000 more	Very low	Randomised controlled trial	Serious9,10	No serious inconsistency4	No serious indirectness	Very serious11	Yes12,13,14

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (exercise)	Comparator (no exercise)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				per 1000)							
Caesarean delivery											
1 (Avery et al., 1997)	3/15	3/14	RR 0.93 (0.22 to 3.87)a	15 fewer per 1000 (from 167 fewer to 615 more per 1000)	Very low	Randomised controlled trial	Serious9	No serious inconsistency4	No serious indirectness	Very serious11	Yes12,13,14
Macrosomia (> 4000g)											
1 (Avery et al., 1997)	3/15	3/14	RR 0.93 (0.22 to 3.87)a	15 fewer per 1000 (from 167 fewer to 615 more per 1000)	Very low	Randomised controlled trial	Serious9	No serious inconsistency4	No serious indirectness	Very serious11	Yes12,13,14
Neonatal hypoglycaemia (< 45mg/dl)											
1 (Avery et al., 1997)	0/15	0/14	Not calculable	Not calculable	Low	Randomised controlled trial	Serious9	No serious inconsistency4	No serious indirectness	NA	Yes12,13,14

CI confidence interval, RR relative risk, NA not applicable
a Calculated by the NCC-WCH technical team.
1 Possible selection bias as no baseline characteristics were reported.
2 Blinding was not clear and randomisation methods were not described.
3 Criteria for starting insulin therapy were not reported.

4 Single study analysis.
5 Confidence interval for the RR crosses RR = 0.75.
6 The study was carried out in Brazil. Ethnicity was not reported.
7 Intervention participants were instructed to perform eight circuit-based activities using a resistance band. Women performed 15 reps of each exercise three days per week and progressed from 2 circuits initially to 3 circuits after 3 weeks. Controls did not undertake an exercise programme.
8 No concurrent diet was reported. Women self-monitored their blood glucose before each exercise session. Glycaemia was also measured weekly by the clinic.
9 Participants were not blinded to allocation; blinding of study investigators and clinicians is not clear.
10 Blood glucose thresholds for initiation of insulin therapy were not reported.
11 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.
12 The study was carried out in the United States of America. All women in the intervention group were Caucasian. Two women in the control group were Japanese, the remainder were Caucasian.
13 Intervention participants undertook 30 minutes of exercise three to four times per week until delivery. Two exercise sessions per week were monitored by study staff. Controls maintained their usual physical activity level alongside dietary therapy.
14 Dietary therapy was provided for controls but not reported in the intervention group. Participants self-monitored blood glucose three days per week.

Table 41: GRADE profile for comparison of diet and exercise with diet alone in women with gestational diabetes mellitus.

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (diet + exercise)	Comparator (diet alone)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Requirement for insulin[1]											
1 (Branksto n et al., 2004)	7/16	9/16	RR 0.78 (0.39 to 1.58)a	124 fewer per 1000 (from 343 fewer to 326 more per 1000)	Very low	Randomis ed controlled trial	Serious2	No serious inconsistenc y	No serious indirectnes s	Very serious3	Yes[4,5,6]

CI confidence interval, RR relative risk
a Calculated by the NCC-WCH technical team.
1 Insulin therapy was initiated if: fasting blood glucose ≥ 5.3mmol/l, one hour post-prandial ≥ 7.8mmol/l or two hour post-prandial ≥ 6.7mmol/l consistently at any time during diet therapy.
2 Attrition is 16% overall but the split between groups is not reported; attrition bias is possible.
3 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.
4 The study was carried out in Canada. Ethnicity was not reported.

5 Intervention participants received a standard diabetic diet (40% carbohydrate, 40% protein, 20% fat) comprising 24 to 30kcal/kg/day of ideal pre-pregnancy body weight plus a progressive physical activity program of circuit-type exercise. Controls received instruction in the standard diabetic diet only.
6 All participants self-monitored blood glucose daily.

Table 42: GRADE profile for comparison of metformin and insulin in women with gestational diabetes

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mode of birth											
Spontaneous vaginal birth											
1 (Hague et al., 2003)	5/16 (31.3%)	11/14 (78.6%)	RR 0.4 (0.18 to 0.86)a	471 fewer per 1000 (from 110 fewer to 644 fewer)	Low	RCT	Serious 1	No serious inconsistency	No serious indirectness	Serious imprecision2	Yes3,4
1 (Ijas et al., 2010)	24/47 (51.1%)	26/50 (52%)	RR 0.98 (0.67 to 1.45) a	10 fewer per 1000 (from 172 fewer to 234 more)	Low	RCT	No serious bias5	No serious inconsistency	No serious indirectness	Very serious imprecision6	Yes7,8
Induction of labour											
3 (Hague et al., 2003; Ijas et al., 2010; Tertti et al., 2013)	69/172 (40.1%)	103/171 (60.2%)	RR 0.67 (0.54 to 0.83)a	199 fewer per 1000 (from 102 fewer to 277 fewer)	Low	RCT	Serious 1,5,9	No serious inconsistency	No serious indirectness	Serious imprecision2	Yes3,4,7,8,10,11
1 (Rowan et al., 2008)	196/363 (54%)	208/370 (56.2%)	RR 0.96 (0.84 to 1.09) a	22 fewer per 1000 (from 90 fewer to 51 more)	Moderate	RCT	Serious 12	No serious inconsistency	No serious indirectness	No serious imprecision	Yes13,14
Vacuum extraction											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Ijas et al., 2010)	7/47 (14.9%)	4/50 (8%)	RR 1.86 (0.58 to 5.95) a	69 more per 1000 (from 34 fewer to 396 more)	Low	RCT	No serious bias5	No serious inconsistency	No serious indirectness	Very serious imprecision6	Yes7,8
Caesarean section											
7 (Hague et al., 2003; Ijas et al. 2010; Moore et al., 2007; Nirmanesh et al., 2012; Rowan et al., 2008; Spaulonci et al., 2013; Tertti et al., 2013)	248/693 (35.8%)	250/698 (35.8%)	RR 1.00 (0.87 to 1.15) a	0 fewer per 1000 (from 47 fewer to 54 more per 1000)	Moderate	RCT	Serious 1,5,9,12,15,16,17	No serious inconsistency	No serious indirectness	No serious imprecision	Yes3,4,7,8,10,11,13,14,18,19,20,21,22,23
Elective Caesarean section											
1 (Hague et al., 2003)	8/16 (50%)	2/14 (14.3%)	RR 3.5 (0.89 to 13.82) a	357 more per 1000 (from 16 fewer to 1000 more)	Low	RCT	Serious 1	No serious inconsistency	No serious indirectness	Serious imprecision24	Yes3,4
1 (Rowan et al., 2008)	55/363 (15.2%)	63/370 (17%)	RR 0.89 (0.64 to 1.24) a	19 fewer per 1000 (from 61 fewer to 41 more)	Low	RCT	Serious 12	No serious inconsistency	No serious indirectness	Serious imprecision2	Yes13,14

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Emergency Caesarean section											
1 (Nirmanesh et al., 2012)	25/80 31.3%	16/80 20.0%	RR 1.6 (0.9 to 2.7)	120 more per 1000 (from 20 fewer to 340 more per 1000)	Low	RCT	Serious 16	No serious inconsistency	No serious indirectness	Serious24	Yes18,19
Assisted vaginal delivery											
1 (Tertti et al., 2013)	9/109 8.3%	8/107 7.5%	RR 1.10 (0.44 to 2.74) a	7 more per 1000 (from 42 fewer to 130 more per 1000)	Very low	RCT	Serious 9	No serious inconsistency	Serious25	Very serious6	Yes10,11
Need for additional insulin											
5 (Ijas et al., 2010; Moore et al., 2007; Nirmanesh et al., 2012; Spaulonci et al., 2013; Rowan et al., 2008)	206/568 (36.3%)	NC	NC	NC	Moderate	RCT	Serious 5,12,15, 16,17	No serious inconsistency	No serious indirectness	NC26	Yes7,8,13,14 ,18,19,20,21, 22,23
Acceptability											
How often did you forget to take your medication?											
1(Rowan et al., 2008)	Never/rarely: 231/333 (69.4%) 1–3 times/wk:	Never/rarely: 267/331 (80.7%) 1–3 times/wk:	p < 0.001	NC	Moderate	RCT	Serious 9	No serious inconsistency	No serious indirectness	NA	Yes10,11

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
	81/333 (24.3%) 4–6 times/wk: 12/333 (3.6%) >6 times/wk: 9/333 (2.7%)	52/331 (15.7%) 4–6 times/wk: 2/331 (0.6%) >6 times/wk: 10/331 (3.0%)									
Which medicine would you choose in another pregnancy?											
1(Rowan et al., 2008)	Metformin tablets: 256/334 (76.6%) Insulin injections: 42/334 (12.6%) Not sure: 36/334 (10.8%)	Metformin tablets: 127/331 (38.4%) Insulin injections: 90/331 (27.2%) Not sure: 114/331 (34.4%)	p < 0.001	NC	Moderate	RCT	Serious 9	No serious inconsistency	No serious indirectness	NA	Yes10,11
In another pregnancy, if you were told you were likely to need insulin injections to control the sugar levels but could try metformin first, what would you prefer?											
1(Rowan et al., 2008)	Start with metformin and add insulin if needed:	Start with metformin and add insulin if needed:	p < 0.001	NC	Moderate	RCT	Serious 9	No serious inconsistency	No serious indirectness	NA	Yes10,11

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
	270/334 (80.8%) Go straight to insulin injections: 36/334 (10.8%) Not sure: 28/334 (8.4%)	179/331 (54.1%) Go straight to insulin injections: 94/331 (28.4%) Not sure: 58/331(17.5%)									
Which part of your diabetes treatment was the easiest?											
1(Rowan et al., 2008)	Doing finger-prick tests: 74/334 (22.2%) Being careful with diet: 63/334 (18.9%) Taking medication : 197/334 (59.0%)	Doing finger-prick tests: 119/331 (36.0%) Being careful with diet: 95/331 (28.7%) Taking medication : 117/331 (35.3%)	p < 0.001	NC	Moderate	RCT	Serious 9	No serious inconsistency	No serious indirectness	NA	Yes10,11
Which part of your diabetes treatment was the hardest?											
1(Rowan et al., 2008)	Doing finger-prick tests: 123/334 (36.8%)	Doing finger-prick tests: 91/331 (27.5%)	p = 0.001	NC	Moderate	RCT	Serious 9	No serious inconsistency	No serious indirectness	NA	Yes10,11

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
	Being careful with diet: 176/334 (52.7%) Taking medication : 35/334 (10.5%)	Being careful with diet: 150/331 (45.3%) Taking medication : 90/331 (27.2%)									
Large for Gestational Age											
5 (Ijas et al., 2010; Mesdaghinia et al., 2013; Nirmanesh et al., 2012; Rowan et al., 2008; Tertti et al., 2013)	120/699 (17.2%)	143/707 (20.2%)	RR 0.85 (0.68 to 1.05) a	30 fewer per 1000 (from 65 fewer to 10 more)	Very low	RCT	Serious 5,9,12,16,27	Serious28	No serious indirectness	Serious2	Yes7,8,10,11,13,14,18,19,29,30
1 (Spaulonci et al., 2013)	0/46 (0.0%)	3/46 (6.5%)	RR 0.14 (0.007 to 2.64)a	56 fewer per 1000 (from 65 fewer to 107 more per 1000)	Very low	RCT	Serious 17	No serious inconsistency	Serious31	Very serious6	Yes20,21
>24 hours NICU stay											
1 (Rowan et al., 2008)	46/363 (12.7%)	45/370 (12.2%)	RR 1.04 (0.71 to 1.53) a	5 more per 1000 (from 35 fewer to 64 more)	Very low	RCT	Serious 12	No serious inconsistency	No serious indirectness	Very serious6	Yes,13,14

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Admission to NICU											
5 (Ijas et al., 2010; Nirmanesh et al., 2012; Mesdaghinia et al., 2013; Moore et al., 2007; Tertti et al., 2013)	62/368 (16.8%)	89/368 (24.2%)	RR 0.69 (0.52 to 0.92) a	75 fewer per 1000 (from 19 fewer to 116 fewer)	Very low	RCT	Serious 5,9,15,16,25	No serious inconsistency	No serious indirectness	Very serious6	Yes7,8,10,11,18,19,22,23.29,30
Composite neonatal outcomeb											
1 (Rowan et al., 2008)	116/363 (32%)	119/370 (32.2%)	RR 0.99 (0.8 to 1.23) a	3 fewer per 1000 (from 64 fewer to 74 more)	Moderate	RCT	Serious 12	No serious inconsistency	No serious indirectness	No serious imprecision	Yes13,14
Shoulder dystocia											
4 (Nirmanesh et al., 2012; Mesdaghinia et al., 2013; Moore et al., 2007; Rowan et al., 2008)	11/575 (1.9%)	15/581 (2.6%)	RR 0.76 (0.36 to 1.59) a	6 fewer per 1000 (from 17 fewer to 15 more)	Very low	RCT	Serious 12,15,16,27	No serious inconsistency	No serious indirectness	Very serious6	Yes13,14,18,19,22,23,29,30
Neonatal hypoglycaemia											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
6 (Ijas et al., 2010; Mesdaghinia et al., 2013; Moore et al., 2007; Nirmanesh et al., 2012; Spaulonci et al., 2013; Tertti et al., 2013)	38/414 (9.2%)	54/414 (13.0%)	RR 0.71 (0.48 to 1.04) a	38 fewer per 1000 (from 68 fewer to 5 more per 1000)	Very low	RCT	Serious 5,9,15,16,17,27	Serious32	No serious indirectness	Serious2	Yes7,8,10,11,18,19,20,21,22,23,29,30
Supplemental feeding											
1 (Rowan et al., 2008)	129/363 (35.5%)	145/370 (39.2%)	RR 0.91 (0.75 to 1.09) a	35 fewer per 1000 (from 98 fewer to 35 more)	Moderate	RCT	Serious 9	No serious inconsistency	No serious indirectness	No serious imprecision	Yes,10,11
Intravenous dextrose											
2 (Hague et al., 2003; Rowan et al., 2008)	29/379 (7.7%)	23/384 (6%)	RR 1.27 (0.75 to 2.15) a	16 more per 1000 (from 15 fewer to 69 more)	Low	RCT	Serious 1,9	No serious inconsistency	No serious indirectness	Serious24	Yes3,4,10,11
Fetal death											
1 (Rowan et al., 2008)	0/363 (0%)	1/370 (0.27%)	RR 0.34 (0.01 to 8.31) a	2 fewer per 1000 (from 3 fewer to 20 more)	Very low	RCT	Serious 9	No serious inconsistency	No serious indirectness	Very serious6	Yes,10,11

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Metformin	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Perinatal Mortality											
1 (Ijas et al., 2010)	0/47 (0%) -	0/50 (0%)	NC	NC	Low	RCT	No serious risk of bias1	No serious inconsistency	No serious indirectness	Very serious6	Yes7,8

NC not calculable, NR not reported, RCT randomised controlled trial, P probability, RR relative risk
a Calculated by the NCC-WCH technical team from data reported in the article
b The components of the composite neonatal outcome were hypoglycemia, respiratory distress, phototherapy, birth trauma, Apgar scores below 7, and preterm delivery. Infants could have one or more of the components
c No definitions were given in either RCT for shoulder dystocia

1 Hague et al., 2003: It is unclear if an appropriate randomisation method or adequate allocation concealment was used. It is unclear whether the treatment groups received the same care (apart from the intervention). Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions were not used for all outcomes. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
2 Confidence interval for the relative risk crosses RR = 0.75
3 Hague et al., 2003: Metformin and insulin were the treatments compared but no further details of these treatments were given. No details of any concurrent dietary interventions or monitoring techniques were presented
4 Hague et al., 2003: Ethnicity data is not presented
5 Ijas et al., 2010; Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors
6 Confidence interval for the relative risk crosses RR = 0.75 and RR = 1.25
7 Ijas et al., 2010: Metformin was started at 750mg once/day in the first week, 750mg twice/day in the second week and 750mg three times/day from the third week onwards. Medication was discontinued if significant side effects (eg diarrhoea) occurred. Supplemental insulin was added if normoglycaemia was not achieved in the 1-2 weeks using the maximum dose. Insulin treatment consisted of long acting insulin to normalise fasting glucose concentrations and rapid acting insulin to normalise postprandial glucose concentrations. Women continued to measure daily profiles of capillary glucose concentrations twice a week and reported values to the diabetes nurse.
8 Ijas et al., 2010: Ethnicity data is not presented
9 Tertti et al., 2013: Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions were not used for all outcomes. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
10 Tertti et al., 2013: All women attended the hospital for dietary counselling and were taught to measure overnight fasting and 1 hour postprandial glucose at least four times daily. Metformin was initiated at a dose of 500mg once daily for the first two days, increased to twice daily for the first week. The dose was increased to a maximum of 1g twice daily if required. Target values were < 5.5mmol/l after an overnight fast and < 7.8mmol/l 1 hour postprandial. Insulin was added if these targets were not met with metformin alone. Insulin treatment comprised NPH insulin and/or rapid acting insulin lispro or aspart.
11 Tertti et al., 2013: The study was carried out in Finland. Ethnicity data were not reported.

12 Rowan et al., 2008: It is unclear if adequate allocation concealment was used. There were no outcome data available for 10 women in the metformin group and 8 in the insulin group. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors. Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently.
13 Rowan et al., 2008: All women received lifestyle advice about diet and exercise prior to randomisation. All sites aimed for ADIPS 1998 recommendations for capillary glucose levels (fasting <5.5 mmol/l; 2-hour postprandial <7.0 mmol/l), several sites aimed for lower target levels. The initial dose of metformin was 500 mg once or twice daily with food and was typically increased over 1 to 2 weeks, to meet glycemic targets up to a maximum daily dose of 2500 mg. If the targets were not achieved with metformin alone, insulin was added. Metformin was stopped if maternal contraindications (such as liver or renal impairment or sepsis) or fetal growth restriction developed. Insulin was prescribed according to usual practice.
14 Rowan et al., 2008: Ethnicity data - Metformin group (n=363): European or white 175 (48.2%), Polynesian 73 (20.1%), Indian 38 (10.5%), Chinese or Southeast Asian 49 (13.5%), Other or mixed 28 (7.7%). Insulin group (n=370): European or white 168 (45.4%), Polynesian 83 (22.4%), Indian 55 (14.9%), Chinese or Southeast Asian 37 (10.0%), Other or mixed 27 (7.3%)
15 Moore et al., 2007: Groups were generally comparable at baseline except that women in the metformin group were significantly heavier than those in the insulin group. Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions were not used for all outcomes. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
16 Niromanesh et al., 2012: Participants were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions were not used for all outcomes. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
17 Spaulonci et al., 2013: No baseline characteristics were reported therefore comparability of the groups at baseline is unclear. Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions were not used for all outcomes. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
18 Niromanesh et al., 2012: All women were given counselling on diet and physical activity. Daily caloric intake was based on BMI. Carbohydrate intake was restricted to 45% of calories with remainder as protein (20%) and fat (35%). An exercise program of 30 minutes per day was recommended. Metformin was given as an initial dose of 500mg twice daily and increased by 500 to 1000mg up to a maximum dose of 2500mg divided dose with each meal and continued until delivery. Insulin was added if glucose control was not achieved with maximal metformin doses. Women in the insulin group were treated with NPH insulin at an initial dose of 0.2units/kg. If fasting glucose was high insulin was given before bedtime. If postprandial glucose was high, regular short-acting insulin was given before meals based on postprandial glucose levels (1 unit for every 10mg/dl glucose). If both fasting and postprandial values were high insulin was started at a dose of 0.7units/kg (two thirds NPH insulin before breakfast and bedtime, one third regular insulin as two or three preprandial injections).
19 Niromanesh et al., 2012: The study was carried out in Iran. Ethnicity data were not reported.
20 Spaulonci et al., 2013: Treatment information about dosages of metformin and insulin was not reported. Women who failed treatment with metformin were given supplemental insulin.
21 Spaulonci et al., 2013: The study was carried out in Brazil. Ethnicity data were not reported.
22 Moore et al., 2007: All women received dietary instruction by a registered dietician and also from a nurse educator. The diet was designed to provide 30kcal/kg body weight or 25kcal/kg body weight in women who were obese. The calories were split by source: 40% carbohydrates, 20% protein, 30 to 40% fat. The patient received 10% at breakfast, 20-30% for both lunch and dinner and 30% for snacks. All women were trained to use a portable glucose meter at home and tested their blood glucose x3/day: in the morning (fasting value) and 2 hours after each meal. The initial dose of metformin was 500mg/day and was increased as necessary to attain glucose control (maximum dose 1000mg x2/day. Women taking the maximum dose of metformin with 2 values that exceeded the goals for a measurement period for 2 consecutive weeks were considered metformin failures and were started on insulin. Insulin was started at a dosage of 0.7 units of insulin/kg actual body weight, and injected twice daily to maintain euglycaemia (fasting 60-90mg/dl; 2 hour postprandial <120mg/dl). The total daily dose was split; two thirds by subcutaneous injection in the morning and one third injected before the evening meal. A combination of regular insulin and NPH insulin was used.
23 Moore et al., 2007: Ethnicity data - Metformin group (n=32): African American 20 women, Native American 11 women and Caucasian 1 woman. Insulin group (n=32): African American 11 women, Native American 17 women and Caucasian 3 women.
24 Confidence interval for the relative risk crosses RR = 1.25
25 Tertti et al., 2013: Assisted vaginal delivery was not defined and is used as a proxy for operative vaginal delivery.
26 Confidence interval cannot be calculated.

27 Mesdaghinia et al., 2013: In the metformin group 22 out of 100 women randomised received supplemental insulin. These women were excluded and replaced by women who had not failed treatment. Participants were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions were not used for all outcomes.
28 Definitions of LGA varied across studies however meta-analysis was deemed appropriate due to a low level of heterogeneity (I2 = 32%) and the power gained by pooling data from multiple studies.
29 Mesdaghinia et al., 2013: Women were initially taught lifestyle modification and fasting and 2 hour postprandial blood glucose was measured for one week. If women obtained fasting values > 95mg/dl or 2 hour values > 120mg/dl pharmacological treatment was initiated. Women in the metformin group received an initial dose of 500mg per day. If necessary this dose was adjusted up to a maximum of 2500g per day. Women in the insulin group received an initial dose of 0.5IU/kg/day (two thirds in the morning, one third in the afternoon). Two thirds of the insulin dose was NPH and one third regular insulin. One IU of insulin was added to the dose per 10mg/dl increase in blood glucose above target values.
30 Mesdaghinia et al., 2013: The study was carried out in Iran. Ethnicity was not reported.
31 Spaulonci et al., 2013: Macrosomia is a proxy for large for gestational age.
32 Definitions of neonatal hypoglycaemia varied across studies however meta-analysis was deemed appropriate due to a low level of heterogeneity (I2 = 0%) and the power gained by pooling data from multiple studies.

Table 43: GRADE profile for comparison of glibenclamide and insulin in women with gestational diabetes

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Glibenclamide	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mode of birth											
Caesarean section											
2 (Bertini et al., 2005; Ogunyemi et al., 2007)	30/67 (44.8%)	37/72 (51.4%)	RR 0.87 (0.61 to 1.23) a	67 fewer per 1000 (from 200 fewer to 118 more)	Very low	RCT	Very serious risk of bias1,2	No serious inconsistency	No serious indirectness	Serious3	Yes4,5,6,7
Need for additional insulin											
4 (Bertini et al., 2005; Lain et al., 2009; Langer et al., 2000;Og	19/322 (5.9%)	NC	NC	NC	Low	RCT	Very serious risk of bias1,2,8,9	No serious inconsistency	No serious indirectness	NC	Yes4,5,6,7,10,11,12,13

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Glibenclamide	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
unyemi et al., 2007)											
Maternal hypoglycaemia											
1 (Ogunyemi et al., 2007)	18/48 (37.5%)	15/49 (30.6%)	RR 1.23 (0.7 to 2.14) a	70 more per 1000 (from 92 fewer to 349 more)	Very low	RCT	Very serious risk of bias2	No serious inconsistency	No serious indirectness	Very serious14	Yes6,7
Large for Gestational Age											
3 (Bertini et al., 2005; Lain et al., 2009; Mukhopadhyay et al., 2012)	22/95 (23.2%)	6/95 (6.3%)	RR 3.62 (1.54 to 8.49) a	165 more per 1000 (from 34 more to 473 more)	Low	RCT	Very serious risk of bias1,8,15	No serious inconsistency	No serious indirectness	No serious imprecision	Yes4,5,10,11,16,17
1 (Langer et al., 2000)	24/201 (11.9%)	26/203 (12.8%)	RR 0.93 (0.55 to 1.57) a	9 fewer per 1000 (from 58 fewer to 73 more)	Low	RCT	No serious risk of bias9	No serious inconsistency	No serious indirectness	Very serious14	Yes12,13
Admission to NICU											
3 (Bertini et al., 2005; Lain et al., 2009; Langer et al., 2000)	17/274 (6.2%)	14/280 (5%)	RR 1.22 (0.63 to 2.37) a	11 more per 1000 (from 19 fewer to 68 more)	Very low	RCT	Very serious risk of bias1,8,9	No serious inconsistency	No serious indirectness	Very serious14	Yes4,5,10,11,12,13

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Glibenclamide	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Shoulder dystocia											
1 (Lain et al., 2009)	1/49 (2%)	2/50 (4%)	RR 0.51 (0.05 to 5.45) a	20 fewer per 1000 (from 38 fewer to 178 more)	Very low	RCT	Very serious risk of bias8	No serious inconsistency	No serious indirectness	Very serious14	Yes10,11
Neonatal hypoglycaemia											
5 (Bertini et al., 2005; Lain et al., 2009; Langer et al., 2000; Ogunyemi et al., 2007; Mukhopadhyay et al., 2012)	46/347 (13.3%)	22/355 (6.2%)	RR 2.13 (1.32 to 3.43) a	70 more per 1000 (from 20 more to 151 more)	Low	RCT	Very serious risk of bias1,2,8,9, 15	No serious inconsistency	No serious indirectness	No serious imprecision	Yes4,5,6,7,10,11,12,13,16,17
IV glucose therapy											
1 (Langer et al., 2000)	28/201 (13.9%)	22/203 (10.8%)	RR 1.29 (0.76 to 2.17) a	31 more per 1000 (from 26 fewer to 127 more)	Moderate	RCT	No serious risk of bias9	No serious inconsistency	No serious indirectness	Serious18	Yes12,13
Intrauterine death											
1 (Lain et al., 2009)	1/40 (2.5%)	0/50 (0%)	RR 3.73 (0.16 to 89.21) a	-	Very low	RCT	Very serious risk of bias8	No serious inconsistency	No serious indirectness	Very serious14	Yes10,11,19
Stillbirth											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Glibenclamide	Insulin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Langer et al., 2000)	1/201 (0.5%)	1/203 (0.49%)	RR 1.01 (0.06 to 16.04) a	0 more per 1000 (from 5 fewer to 74 more)	Low	RCT	No serious risk of bias9	No serious inconsistency	No serious indirectness	Very serious14	Yes12,13
Neonatal death											
3 (Bertini et al., 2005; Lain et al., 2009; Langer et al., 2000)	1/274 (0.36%)	1/280 (0.36%)	RR 1.01 (0.06 to 16.04) a	0 more per 1000 (from 3 fewer to 54 more)		RCT	Very serious risk of bias1,8,9	No serious inconsistency	No serious indirectness	Very serious14	Yes4,5,10,11,12,13

NC not calculable, NR not reported, RCT randomised controlled trial, P probability, RR relative risk
a Calculated by the NCC-WCH technical team from data reported in the article

1 Bertini et al., 2005: Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. One woman from an unknown group did not complete treatment. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors
2 Ogunyemi et al., 2007: At baseline the treatment groups were similar at baseline for maternal age, parity, BMI, history of previous gestational diabetes and previous neonatal macrosomia. Results of blood glucose tests were significantly higher in the insulin group compared to the glibenclamide group and the gestational age at the time of recruitment was on average 4 weeks earlier. It is unclear whether the groups received the same care apart from the intervention. Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions were not reported. For some outcomes, there were no data available for up to 4 participants in the insulin group and 5 in the glibenclamide group. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
3 Confidence interval for the relative risk crosses RR = 0.75
4 Bertini et al., 2005: All women had three days of diet and physical activity and then their fasting and postprandial glucose levels were measured. No details of diet or exercise are given. Blood glucose was reviewed in clinic weekly. Women were tested in the fasting state and 2 hours after breakfast. If either test was abnormal, testing was performed after lunch and dinner to establish glucose profile and adjust doses as necessary. Glibenclamide group: An initial dose of 5mg in the morning was increased every week as necessary to a maximum dose of 20mg/day. Insulin group: Women were admitted to hospital for 24 hrs to learn how to use insulin and to receive guidance. Insulin was started at a dosage of 0.7 units of insulin/kg actual body weight, increasing by 0.1 IU/kg in each trimester. Rapid action and slow acting insulins were used in equal doses before main meals and at bedtime respectively. Treatment failure was defined taking the maximum dose without achieving glucose control. Oral medication was stopped in treatment failure and insulin therapy started.
5 Bertini et al., 2005: Ethnicity: no details are provided
6 Ogunyemi et al., 2007: No diet or monitoring details are presented. No details of dose for glibenclamide or insulin are presented
7 Ogunyemi et al., 2007: Ethnicity: 80% of participants were Hispanic and 15% were African American.

8 Lain et al., 2009: It is unclear whether an appropriate randomisation method or adequate allocation concealment was used. Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Depending on outcome, up to 13 participants were lost from the insulin group and up to 8 in the glibenclamide group. Precise outcome definition is available for two outcomes - large for gestational age and treatment failure. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
9 Langer et al., 2000: Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently. Precise outcome definitions are available for three outcomes - treatment failure, large for gestational age and neonatal hypoglycaemia. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
10 Lain et al., 2009: No details of diet, exercise or monitoring techniques are presented. Glibenclamide group: doses started at 2.5mg/day and were increased by 2.5-5mg weekly. Doses were taken once or twice daily. If a maximum dose of 20mg/day glibenclamide did not achieve goals, then women were transitioned to insulin. Insulin group: Insulin doses started at 0.8U/kg administered in multiple daily injections and were increased up to twice weekly as necessary. Women receiving glibenclamide were transitioned to insulin if the maximum dose of 20mg/day did not achieve targets.
11 Lain et al., 2009: Ethnicity: no details are provided
12 Langer et al., 2000: All women received dietary instruction for 3 meals and 4 snacks daily. Adherence was evaluated and reinforced at weekly clinic visits. The diet was designed to provide 30kcal/kg body weight for women of normal weight. Women who were obese (BMI>30) received a diet designed to deliver 25kcal/kg body weight. The calories were split by source with 40% from carbohydrates. All women were trained to use a portable glucose meter at home and tested their blood glucose x7/day: in the morning (fasting value), before and 2 hours after lunch and dinner, at bedtime. Targets were fasting 60-90mg/dl; preprandial 80-95 mg/dl; 2 hour postprandial <120mg/dl. Blood glucose was measured for comparison at weekly clinic. Glibenclamide group: An initial dose of 2.5mg in the morning was increased in the first week by 2.5mg and by 5mg weekly thereafter if necessary to a maximum dose of 20mg/day. Blood glucose was reviewed in clinic weekly. Insulin group: Insulin was started at a dosage of 0.7 units of insulin/kg actual body weight given subcutaneously, injected three times daily and increased as necessary to maintain targets. Treatment failure was defined taking the maximum dose without achieving glucose targets over a two week period. Oral medication was stopped in treatment failure and insulin therapy started.
13 Langer et al., 2000: Ethnicity: no details are provided
14 Confidence interval for the relative risk crosses RR = 0.75 and RR = 1.25
15 Mukhopadhyay et al., 2012: Participants and care givers were not kept 'blind' to allocation as this was not possible as the treatments were administered differently.
16 Mukhopadhyay et al., 2012: The initial dose of glibenclamide was 2.5mg/day orally in the morning. Doses were increased when necessary by 2.5mg per week up to a maximum of 20mg/week. Doses > 7.5mg were given as divided doses. If glycaemic control was not maintained for two weeks on the maximal dose then treatment was switched to insulin. Insulin treatment was initiated at 0.7units/kg/day, subcutaneously three times daily and increased weekly as necessary.
17 Mukhopadhyay et al., 2012: Ethnicity: no details are provided
18 Confidence interval for the relative risk crosses RR = 1.25
19 The intrauterine death was associated with trisomy 21

Table 44: GRADE profile for comparison of metformin and glibenclamide in women with gestational diabetes

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Glibenclamide	Metformin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mode of birth											
Non-elective Caesarean delivery											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Glibenclamide	Metformin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1(Moore et al., 2010)	2/74 (2.7%)	11/75 (14.7%)	RR 0.18 (0.04 to 0.8) a	120 fewer per 1000 (from 29 fewer to 141 fewer)	Moderate	RCT	No serious risk of bias1	No serious inconsistency	No serious indirectness	Serious2	Yes3,4
Need for additional insulin											
1(Moore et al., 2010)	12/74 (16.2%)	26/75 (34.7%)	RR 0.47 (0.26 to 0.86) a	184 fewer per 1000 (from 49 fewer to 257 fewer)	Moderate	RCT	No serious risk of bias1	No serious inconsistency	No serious indirectness	Serious2	Yes3,4
1(Silva et al., 2012)	28/96 (29.2%)	22/104 (21.2%)	RR 1.38 (0.85 to 2.24) a	80 more per 1000 (from 32 fewer to 262 more)	Moderate	RCT	No serious risk of bias6	No serious inconsistency	No serious indirectness	Serious7	Yes8,9
Maternal hypoglycaemia											
1(Moore et al., 2010)	1/74 (1.4%)	2/75 (2.7%)	RR 0.51 (0.05 to 5.47) a	13 fewer per 1000 (from 25 fewer to 119 more)	Low	RCT	No serious risk of bias1	No serious inconsistency	No serious indirectness	Very serious10	Yes3,4
Neonatal hypoglycaemia											
1(Moore et al., 2010)	0/74 (0%)	1/75 (1.3%)	RR 0.34 (0.01 to 8.16) a	9 fewer per 1000 (from 13 fewer to 95 more)	Low	RCT	No serious risk of bias1	No serious inconsistency	No serious indirectness	Very serious10	Yes3,4
1(Silva et al., 2012)	13/96 (13.5%)	11/104 (10.6%)	RR 1.28 (0.6 to 2.72) a	30 more per 1000 (from 42 fewer to 182 more)	Low	RCT	No serious risk of bias6	No serious inconsistency	No serious indirectness	Very serious10	Yes8,9
Shoulder dystocia											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Glibenclamide	Metformin	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1(Moore et al., 2010)	1/74 (1.4%)	0/75 (0%)	RR 3.04 (0.13 to 73.44) a	NC	Very low	RCT	Serious 1	No serious inconsistency	No serious indirectness	Very serious10	Yes3,4
Admission to NICU											
2 (Moore et al., 2010; Silva et al., 2012)	8/167 (4.8%)	13/179 (7.3%)	RR 0.66 (0.28 to 1.55) a	25 fewer per 1000 (from 52 fewer to 40 more)	Very low	RCT	Serious 1.6	No serious inconsistency	No serious indirectness	Very serious10	Yes3,4,8,9
Large for gestational age											
1(Silva et al., 2012)	19/96 (19.8%)	9/104 (8.7%)	RR 2.29 (1.09 to 4.81) a	112 more per 1000 (from 8 more to 330 more)	Low	RCT	Serious 6	No serious inconsistency	No serious indirectness	Serious7	Yes8,9
Death											
1(Silva et al., 2012)	1/96 (1%)	1/104 (0.96%)	RR 1.08 (0.07 to 17.08) a	1 more per 1000 (from 9 fewer to 155 more)	Very Low	RCT	Serious 6	No serious inconsistency	No serious indirectness	Very serious10	Yes8,9

NC not calculable, NR not reported, RCT randomised controlled trial, P probability, RR relative risk
** Calculated by the NCC-WCH technical team from data reported in the article*
1 Moore et al., 2010: Participants and care givers were not kept 'blind' to allocation. Precise outcome definitions were not used for all outcomes (shoulder dystocia and NICU admission). 6 women in the glibenclamide group and 8 women in the metformin group did not complete treatment. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
2 Confidence interval for the relative risk crosses RR = 0.75
3 Moore et al., 2010: All women were given instructions for a diet designed to provide 30kcals/kg at normal body weight and 25kcals/kg at obese body weight with 40% calories from carbohydrates, 20% from protein and 30-40% from fats.10% of calories were consumed at breakfast, 20-30% at lunch and dinner and 30% as snacks. The importance of exercise in controlling blood glucose was stressed and 30 minutes of walking per day was recommended to all women. All women were taught how to use memory based glucometers. Women performed testing in the fasting state and 2 hours post prandially. Glibenclamide group: An initial dose of glibenclamide 2.5mg twice per day was increased as necessary to a maximum dose of 20mg/day (10mg twice/day). Blood glucose was reviewed weekly. Metformin group: An initial dose of 500mg/day taken in divided doses was increased as necessary to a maximum dose of 2grams/day. Blood glucose was reviewed weekly.Treatment failures were defined as women taking the maximum dose with two or

more glucose values in the same meal exceeding target glucose values by 10mg/dl or more for 2 consecutive weeks. Oral medication was stopped in treatment failures and insulin therapy started.
4 Moore et al., 2010 : Glibenclamide group : Hispanic 66, Native American 3,White 5 and African American 0. Metformin group : Hispanic 66, Native American 2, White 6 and African American 1
5 Confidence interval for the relative risk crosses RR = 0.75
6 Silva et al., 2012: Participants and care givers were not kept 'blind' to allocation. Women in the glibenclamide group on average were heavier and had had fewer babies previously. Precise outcome definitions were not used for all outcomes (NICU admission or death). 6 women in the glibenclamide group and 8 women in the metformin group did not complete treatment. It is unclear whether the investigators were kept 'blind' to allocation and to other important confounding and prognostic factors.
7 Confidence interval for the relative risk crosses RR = 1.25
8 Silva et al., 2012: All women were given instructions for a diet designed to provide 35kcals/kg at normal body weight and 25kcals/kg at obese body weight, with 35-45% calories from carbohydrates and consisting of 3 full meals and four light meals. No details are given regarding any exercise regimen women were to follow. All women performed home glucose self-monitoring of fasting and postprandial capillary glucose testing to adjust dosage of medication. Glibenclamide group: An initial dose of 2.5mg before breakfast and dinner was increased as necessary by 2.5 - 5mg weekly until glucose control was acheived or until a maximum dose of 20mg/day was reached. Metformin group: An initial dose of 500mg before breakfast and dinner was increased as necessary by 500-1000 mg weekly until glucose control was acheived or until a maximum dose a maximum dose of 2500 mg/day was reached. Insulin therapy was started at 0.7 IU/kg/day regular insulin preprandial and neutral protamine hagedorn (NHP) insulin at bedtime when glycaemic goals were not met.
9 Silva et al., 2012: Ethnicity data was not provided
10 Confidence interval for the relative risk crosses RR = 0.75 and RR = 1.25

J.3 Antenatal care

Table 45: GRADE profile for monitoring of blood glucose vs. no monitoring of blood glucose

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Monitoring	No monitoring	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mode of birth											
Vaginal birth											

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Monitoring	No monitoring	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Bancroft, 2000)	22/32 (69%)	25/36 (69%)	RR 1.0 (0.7 to 1.4)a	7 fewer per 1000 (from 194 fewer to 250 more)a	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisiond	Yese
Caesarean section											
1 (Bancroft, 2000)	10/32 (31%)	11/36 (31%)	RR 1.0 (0.5 to 2.1)a	6 more per 1000 (from 153 fewer to 330 more)a	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisiond	Yese
HbA_{1c} (%)											
At 28 weeks											
1 (Bancroft, 2000)	8 women (mean 4.9 SD 0.7)	8 women (mean 5.5 SD 1.1)	NC	MD 0.6 lower (1.5 lower to 0.3 higher)a	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisionf	Yese
At 32 weeks											
1 (Bancroft, 2000)	20 women (mean 5.2 SD 0.8)	19 women (mean 5 SD 1.3)	NC	MD 0.2 higher (0.5 lower	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisionf	Yese

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Monitoring	No monitoring	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				to 0.9 higher)a							
At 36 weeks											
1 (Bancroft, 2000)	31 women (mean 5.3 SD 0.8)	32 women (mean 5.6 SD 1.3)	NC	MD 0.3 lower (0.8 lower to 0.2 higher)a	Moderate	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	No serious imprecision	Yese
At 38 weeks											
1 (Bancroft, 2000)	24 women (mean 5.3 SD 0.9)	27 women (mean 5.5 SD 0.9)	NC	MD 0.2 lower (0.7 lower to 0.3 higher)a	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisionf	Yese
At term											
1 (Bancroft, 2000)	10 women (mean 5.1 SD 0.8)	10 women (mean 5.5 SD 0.9)	NC	MD 0.4 lower (1.2 lower to 0.4 higher)a	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisionf	Yese
Large for gestational age											
> 90th percentile											
1 (Bancroft, 2000)	8/32 (25%)	7/36 (19%)	RR 1.3 (0.5 to 3.2)a	56 more per 1000 (from 91	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisiond	Yese

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Monitoring	No monitoring	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				fewer to 418 more)a							
1 (Esperse n, 1985)	12/61 (20%)	19/62 (31%)	RR 0.6 (0.3 to 1.2)a	110 fewer per 1000 (from 202 fewer to 64 more)a	Very low	Prospectiv e cohort	Serious limitationsg	No serious inconsistency c	Serious indirectness h	Serious imprecisiond	Yesi
Shoulder dystocia											
1 (Bancroft, 2000)	0/32 (0%)	1/36 (3%)	RR 0.4 (0.0 to 8.9)a	18 fewer per 1000 (from 27 fewer to 218 more)a	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisiond	Yese
Neonatal hypoglycaemia											
1 (Bancroft, 2000)	2/32 (6%)	6/36 (17%)	RR 0.4 (0.1 to 1.7)a	103 fewer per 1000 (from 153 fewer to 122 more)a	Low	RCT	Serious limitationsb	No serious inconsistency c	No serious indirectness	Serious imprecisiond	Yese

MD mean difference, NC not calculable, RCT randomised controlled trial, SD standard deviation, RR relative risk

a Calculated by the NCC-WCH technical team from data reported in the article

b Participants were not blinded to treatment allocation. It is not clear whether the groups were comparable at baseline. It is not clear whether investigators were blinded to the invention exposure.

c Single study analysis

d Confidence interval for the RR crosses the line of no effect (RR = 1) and RR = 0.75 and/or RR = 1.25

e The study was undertaken in the UK. Women with gestational diabetes (fasting blood glucose <7.0 mmol/l and 2 hour blood glucose 7.8-11.0 mmol/l) were included. 69% of the women were Caucasian and 31% were Asian. Both groups were given dietary advice regarding restriction of carbohydrates to 185g/day and a diet sheet listing calorific values of common foods were provided to both groups. HbA_{1c} was tested monthly in both groups although the results were not made known. The self monitoring group performed capillary glucose sampling one or two hours after meals five times per week. The control group did not perform capillary glucose self monitoring.

f The confidence interval for the mean difference crosses the line of no effect (MD = 0) and the minimally important difference (50% of the combined standard deviation of the two groups)

g No attempts were made to balance the comparison groups for potential confounders. Investigators were not blinded to participants' exposure to the intervention or to important confounding and prognostic factors. Participants were not blinded to treatment allocation. It is not clear whether groups were comparable at baseline. It is not clear whether the clinicians administering care were kept blind to treatment allocation. Controls were historical.

h This study used outdated self monitoring methods and a schedule of monitoring that was insufficiently intensive to be adequately reflective of current practice.

i The study was undertaken in Denmark. Women with insulin dependent diabetes mellitus were included. Ethnicity of the included women was not reported. For both groups, blood glucose and urine testing was performed in out patient clinic at one or two week intervals according to the woman's diabetological and obstetrical status. The monitoring group received tuition on self monitoring of blood glucose and tested their blood glucose at least twice weekly at 5 prespecified times throughout the day (7am, 10am, 1pm, 4pm and 8pm). The control group did not perform capillary glucose self monitoring.

Table 46: GRADE profile for daily monitoring vs. weekly testing of blood glucose

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Daily monitoring	Weekly testing	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mode of birth											
Vaginal birth (including vaginal birth with forceps)											
1 (Hawkins, 2009)	199/315 (63%)	453/675 (67%)	RR 0.94 (0.85 to 1.04)a	40 fewer per 1000 (from 101 fewer to 27 more)a	Very Low	Retrospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesd
1 (Varner, 1983)	7/14 (50%)	5/14 (36%)	RR 1.40 (0.56 to 3.50)a	143 more per 1000 (from 157 fewer to 893 more)a	Very low	Randomised controlled trial	Serious limitationse	No serious inconsistencyc	No serious indirectness	Very serious imprecisionf	Yesg
Vaginal birth (not including vaginal birth with forceps)											
1 (Goldberg, 1986)	27/58 (47%)	37/58 (64%)	OR 0.49 (0.24 to 1.04)a	175 fewer per 1000 (from 341 fewer to 9 more)a	Very low	Retrospective case control	Serious limitationsh	No serious inconsistencyc	No serious indirectness	Serious imprecisioni	Yesj
Vaginal birth with forceps											

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Daily monitoring	Weekly testing	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Goldberg, 1986)	12/58 (21%)	5/58 (9%)	OR 2.77 (0.9 to 8.4)a	121 more per 1000 (from 7 fewer to 357 more)a	Very low	Retrospective case control	Serious limitationsh	No serious inconsistencyc	No serious indirectness	Serious imprecisionk	Yesj
1 (Hawkins, 2009)	7/315 (2%)	25/675 (4%)	RR 0.6 (0.3 to 1.4)a	15 fewer per 1000 (from 27 fewer to 14 more)a	Very low	Retrospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Very serious imprecisionf	Yesd
Caesarean section											
1 (Goldberg, 1986)	18/58 (31%)	14/58 (24%)	OR 1.41 (0.6 to 3.2) a	68 more per 1000 (from 77 fewer to 264 more)a	Very low	Retrospective case control	Serious limitationsh	No serious inconsistencyc	No serious indirectness	Very serious imprecisionf	Yesg
1 (Hawkins, 2009)	116/315 (37%)	222/675 (33%)	RR 1.12 (0.9 to 1.3) a	39 more per 1000 (from 23 fewer to 112 more)a	Very low	Retrospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisionk	Yesd

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Daily monitoring	Weekly testing	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 Varner, 1983	7/14 (50%)	9/14 (64%)	RR 0.78 (0.39 to 1.54)a	141 fewer per 1000 (from 392 fewer to 347 more)a	Very low	Randomised controlled trial	Serious limitationse	No serious inconsistencyc	No serious indirectness	Very serious imprecisionf	Yesg
Large for gestational age											
≥90th percentile											
1 (Hawkins, 2009)	73/315 (23%)	232/675 (34%)	RR 0.7 (0.5 to 0.9)a	113 fewer per 1000 (from 52 fewer to 158 fewer)a	Very low	Retrospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesd
Not defined											
1 (Goldberg, 1986)	7/58 (12%)	24/58 (41%)	OR 0.19 (0.08 to 0.5)a	296 fewer per 1000 (from 153 fewer to 360 fewer)a	Very low	Retrospective case control	Serious limitationse	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesg
Shoulder dystocia											

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Daily monitoring	Weekly testing	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Hawkins, 2009)	5/315 (2%)	13/675 (2%)	RR 0.8 (0.3 to 2.3)a	3 fewer per 1000 (from 13 fewer to 25 more)a	Very low	Retrospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Very serious imprecisionf	Yesd
Neonatal hypoglycaemia											
1 (Hawkins, 2009)	23/315 (7%)	30/675 (4%)	RR 1.6 (1.0 to 2.8)a	28 more per 1000 (from 1 fewer to 79 more)a	Very low	Retrospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisionk	Yesd
1 (Varner, 1983)	4/14 (29%)	7/14 (50%)	RR 0.57 (0.20 to 1.59)a	215 fewer per 1000 (from 400 fewer to 295 more)a	Very low	Randomised controlled trial	Serious limitationse	No serious inconsistencyc	No serious indirectness	Very serious imprecisionf	Yesg

OR odds ratio, RR relative risk

a Calculated by the NCC-WCH technical team from data reported in the article

b The groups were not comparable at baseline. Participants were not kept blind to their treatment allocation. Individuals administering care were not kept blind to treatment exposure. Investigators were not kept blind to treatment exposure or other confounding and prognostic factors. It is not clear whether the participants received the same care (apart from the intervention studied).

c Single study analysis

d The study was undertaken in the USA. Included women had gestational diabetes. 81% of women were Hispanic, 10% of women were African American, 5% of women were white, and 4% of women were classified as 'other' ethnicity. Both groups received dietary counselling with instructions regarding daily caloric intake (35kcals/kg) and food types to avoid. Serum blood glucose tested weekly in clinic in both groups. In addition, the daily monitoring group performed self-monitoring of capillary blood glucose four times daily (preprandially, including a morning fasting value and before bedtime)

e It was unclear whether groups were comparable at baseline due to the very limited reporting of baseline characteristics.

f Confidence interval for the OR/RR crosses the line of no effect and OR/RR = 0.75 and OR/RR = 1.25.

g The study was undertaken in the USA. Women had type 1 diabetes. Ethnicity was not reported. Women in both groups were admitted at the first clinic visit for metabolic control and baseline evaluation. Women in the daily monitoring group self-monitored blood glucose after fasting and two hours postprandially in the morning, afternoon and evening. Women in the weekly monitoring group had serum glucose measured after fasting, two hours after breakfast and two hours after lunch on one day each week.

h The participation rate for each group was not reported. The participants and non-participants were not compared to establish similarities and differences. Measures were not taken to prevent knowledge of primary exposure from influencing case ascertainment.

i Confidence interval for the OR/RR crosses OR/RR = 0.75.

j The study was undertaken in the USA. Women in the study had gestational diabetes. 62% of women were Hispanic, and 34% were black. The ethnicity of the remaining women was not reported. Women in both groups were referred to the prenatal diabetes clinic and started on a diabetic diet. In the daily monitoring group a 1 hour post prandial capillary blood test was performed weekly in clinic and the women performed fasting and 1 hour post prandial capillary blood self-testing every day. In the weekly monitoring group, 2 hour post prandial capillary blood testing was performed weekly in clinic, but women did not perform capillary blood self-testing.

k Confidence interval for the OR/RR crosses OR/RR = 1.25.

Table 47: GRADE profile for pre-prandial monitoring vs. post-prandial monitoring of blood glucose

	Number of women/babies		Effect				Quality assessment				
Number of studies	**Pre-prandial monitoring**	**Post-prandial monitoring**	**Relative (95% CI)**	**Absolute (95% CI)**	**Quality**	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**
Mode of birth											
Caesarean section											
1 (Manderson, 2003)	21/31 (68%)	14/30 (47%)	RR 1.45 (0.9 to 2.3) a	210 more per 1000 (from 37 fewer to 597 more) a	Low	RCT	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yese
1 (de Veciana, 1995)	13/33 (39%)	8/33 (24%)	RR 1.63 (0.8 to 3.4) a	153 more per 1000 (from 53 fewer to 579 more) a	Low	RCT	Serious limitationsf	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yesg
HbA_{1c} (%)											
Final HbA_{1c} value											

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Pre-prandial monitoring	Post-prandial monitoring	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Manderson, 2003)	31 women (mean 6.3 SD 0.7)	30 women (mean 6.0 SD 0.8)	NC	MD 0.3 higher (0.1 lower to 0.7 higher)a	Moderate	RCT	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yese
Change in HbA_{1c} from booking											
1 (Manderson, 2003)	31 women (mean -1.3 SD 1)	30 women (mean -1.4 SD 1.3)	NC	MD 0.1 higher (0.5 lower to 0.7 higher)a	Moderate	RCT	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yese
Large for gestational age											
>90th percentile											
1 (Manderson, 2003)	18/31 (58%)	15/30 (50%)	RR 1.2 (0.7 to 1.9) a	80 more per 1000 (from 135 fewer to 425 more) a	Low	RCT	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yese
Not defined											
1 (de Veciana, 1995)	14/33 (42%)	4/33 (12%)	RR 3.5 (1.3 to 9.5)a	303 more per 1000 (from 35 more to 1000 more)a	Moderate	RCT	Serious limitationsf	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesg
Shoulder dystocia											
1 (de Veciana, 1995)	6/33 (18%)	1/33 (3%)	RR 6.0 (0.8 to 47.1)a	152 more per 1000 (from 7 fewer to	Low	RCT	Serious limitationsf	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yesg

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	Pre-prandial monitoring	Post-prandial monitoring	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
				1000 more)a							
Neonatal hypoglycaemia											
1 (Manderson, 2003)	9/31 (29%)	8/30 (27%)	RR 1.1 (0.5 to 2.5)a	24 more per 1000 (from 139 fewer to 387 more)a	Low	RCT	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yese
1 (de Veciana, 1995)	7/33 (21%)	1/33 (3%)	RR 7.0 (0.9 to 53.8)a	182 more per 1000 (from 3 fewer to 1000 more)a	Low	RCT	Serious limitationsf	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yesg
Neonatal/fetal mortality											
Stillbirth											
1 (Manderson, 2003)	1/32 (3%)	0/30 (0%)	RR 2.8 (0.1 to 66.6) a	NC	Low	RCT	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yese
1 (de Veciana, 1995)	1/33 (3%)	0/33 (0%)	RR 3 (0.1 to 71.1) a	NC	Low	RCT	Serious limitationsf	No serious inconsistencyc	No serious indirectness	Serious imprecisiond	Yesg

MD mean difference, NC not calculable, RCT randomised controlled trial, SD standard deviation, RR relative risk

a Calculated by the NCC-WCH technical team from data reported in the article

bThe groups were not comparable at baseline. Participants and clinicians were not blinded to treatment allocation. It is not clear whether an appropriate method of randomisation was used. 13 women were excluded from the analysis, but it is not clear which group they were in, so it is not possible to determine whether the groups were comparable for treatment completion or whether the groups were comparable with respect to the availability of outcome data. It is not clear whether investigators were blinded to participants' exposure to the intervention or to other important confounding factors.

c Single study analysis

d Confidence interval for the RR crosses the line of no effect and RR = 0.75 and/or RR = 1.25

e The study was undertaken in the UK. It included women with type 1 diabetes. All women were white. The daily preprandial capillary blood glucose monitoring group tested before breakfast and before meals whilst the daily postprandial capillary blood glucose monitoring group tested before breakfast and 1 hour after starting each meal.

f Participants were not blinded to treatment allocation. It is not clear whether allocation was adequately concealed. It is not clear whether clinicians giving care were blinded. It is not clear whether investigators were blinded to exposure to the intervention or to other confounding factors.
g The study was undertaken in the USA and included women with gestational diabetes. 85% of women were Hispanic, 11% of women were white, and 5% of women were black or Asian (adds up to more than 100% due to rounding errors). Women in both groups were evaluated in clinic on a weekly basis, started a diabetic diet and had HbA_{1c} measured at the start of the study and in the month before delivery. The daily preprandial monitoring group tested capillary blood fasting – before breakfast, preprandially and at bedtime. The daily postprandial monitoring group tested capillary blood fasting, and one hour after each meal.

Table 48: GRADE profile for 1 hour post-prandial monitoring vs. 2 hour post-prandial monitoring of blood glucose

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	1 hour post-prandial	2 hours post-prandial	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mode of birth											
Caesarean section											
1 (Weisz, 2005)	15/66 (23%)	14/46 (30%)	RR 0.8 (0.4 to 1.4)[a]	76 fewer per 1000 (from 183 fewer to 119 more)[a]	Very low	Prospective cohort	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness	Serious imprecision[d]	Yes[e]
Large for gestational age											
Not defined											
1 (Weisz, 2005)	5/66 (8%)	7/46 (15%)	RR 0.5 (0.2 to 1.5)[a]	76 fewer per 1000 (from 126 fewer to 72 more)[a]	Very low	Prospective cohort	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness	Serious imprecision[d]	Yes[e]

RR relative risk
a Calculated by the NCC-WCH technical team from data reported in the article
b The groups were not comparable at baseline. Participants and clinicians were not blinded to treatment allocation. 6 women were lost to follow up, but it is not clear which group they were in, therefore it is not possible to determine whether the groups were comparable for treatment completion or the availability of outcome data. It is not clear whether attempts were made to balance the comparison groups for potential confounders. It is not clear whether investigators were kept blind to participants' exposure or to other confounding factors.
c Single study analysis
d Confidence interval for the RR crosses the line of no effect and RR = 0.75 and/or RR = 1.25
e Study was undertaken in Israel. Included women had gestational diabetes. Ethnicity of the participants was not reported. All women received counselling and instructions from a dietician, were placed on the ADA diet and were "routinely seen in clinic". One group tested post-prandial capillary blood glucose monitoring after 1 hour and the other group tested after 2 hours

Table 49: GRADE profile for 4 daily measurements vs. 7 daily measurements of blood glucose

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	4 daily measurements	7 daily measurements	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mode of birth											
Caesarean section											
1 (Langer, 1994)	283/1316 (22%)	172/1145 (15%)	RR 1.4 (1.2 to 1.7)a	65 more per 1000 (from 32 more to 105 more)a	Very low	Prospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesd
Large for gestational age											
≥90th percentile											
1 (Langer, 1994)	265/1316 (20%)	150/1145 (13%)	RR 1.5 (1.3 to 1.9)a	71 more per 1000 (from 37 more to 111 more)a	Very low	Prospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesd
Neonatal intensive care unit length of stay (days)											
1 (Langer, 1994)	1316 babies (mean 4.4 SD 3)	1145 babies (mean 2.8 SD 2)	NC	MD 1.7 higher (1.5 higher to 1.9 higher)a	Very low	Prospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisione	Yesd
Shoulder dystocia											
1 (Langer, 1994)	18/1316 (1%)	5/1145 (<1%)	RR 3.1 (1.2 to 8.4)a	9 more per 1000 (from 1 more to 32 more)a	Very low	Prospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesd
Neonatal hypoglycaemia											

Number of studies	Number of women/babies		Effect		Quality	Design	Quality assessment				
	4 daily measurements	7 daily measurements	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Langer, 1994)	263/1316 (20%)	44/1145 (4%)	RR 5.2 (3.8 to 7.1)a	161 more per 1000 (from 108 more to 234 more)a	Very low	Prospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesd
Neonatal/fetal mortality											
Stillbirth rate (per 1000)											
1 (Langer, 1994)	4/1000 (<1%)	1/1000 (<1%)	RR 4 (0.5 to 35.7)a	3 more per 1000 (from 1 fewer to 35 more)a	Very low	Prospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisionf	Yesd
Neonatal death rate (per 1000)											
1 (Langer, 1994)	2/1000 (<1%)	3/1000 (<1%)	RR 0.7 (0.1 to 4.0)a	1 fewer per 1000 (from 3 fewer to 9 more)a	Very low	Prospective cohort	Serious limitationsb	No serious inconsistencyc	No serious indirectness	Serious imprecisionf	Yesd

MD mean difference, NC not calculable, RCT randomised controlled trial, RR relative risk, SD standard deviation

a Calculated by the NCC-WCH technical team from data reported in the article

b Participants and clinicians were not blinded to treatment allocation. It is not clear whether attempts were made to balance the comparison groups for potential confounders. 69 women were lost to follow up, but it is not clear which group they were in, and so it is unclear whether the groups were comparable for treatment completion and availability of outcome data. It is unclear whether investigators were kept blind to participants' exposure to interventions or to confounding factors.

c Single study analysis

d The study was undertaken in the USA. Included women had gestational diabetes. 80% were Hispanic, 15% were white, 4% of women were black, and 1% were classed as 'other'. Women in both groups were assigned to diet on basis of OGTT at diagnosis and mean blood glucose values since diagnosis and were assessed weekly for fasting and 2 hour post-prandial venous plasma glucose in clinic. The group that monitored 4 times a day followed a conventional strategy involving fasting, and 2 hour post prandial sampling after each meal. The group that monitored 7 times a day followed an intensified strategy involving fasting – before breakfast, pre-prandial, 2 hour post prandial and bedtime sampling.

e The confidence interval for the mean difference crosses the line of no effect (MD = 0) and the minimally important difference (50% of the combined standard deviation of the two groups)f Confidence interval for the RR crosses the line of no effect and RR = 0.75 and/or RR = 1.25

Table 50: GRADE profile for comparison of fasting blood glucose less than 5.3mmol/litre vs. greater than or equal to 5.3mmol in women with gestational diabetes

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (< 5.3mmol/litre)	Comparator (≥ 5.3mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Pre-eclampsia											
1 (Rowan et al., 2010)	57/486	59/238	RR 0.47 (0.27 to 0.83)[a]	51 fewer per 1000 (from 16 to 70 fewer per 1000)	Very low[b]	Secondary analysis of RCT data	Serious[1]	No serious inconsistency[2]	Very serious[3]	Serious imprecision[4]	Yes[5]
Large for gestational age											
1 (Rowan et al., 2010)	22/486	23/238	RR 0.48 (0.35 to 0.67)[a]	128 fewer per 1000 (from 81 to 160 fewer per 1000)	Very low[b,c]	Secondary analysis of RCT data	Serious[1]	No serious inconsistency[2]	Very serious[3]	No serious imprecision[6]	Yes[5]

Table 51: GRADE profile for comparison of fasting blood glucose less than 5.3mmol/litre vs. greater than or equal to 5.3mmol in women with White class diabetes B and C (type 1 diabetes)

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (< 5.6mmol/litre)	Comparator (≥ 5.6mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Maternal hypoglycaemia											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (< 5.6mmol/litre)	Comparator (≥ 5.6mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Farrag 1987)	7/16	0/44	RR 39.71 (2.26 to 697.01) b	Not calculable	Very low	Randomised controlled trial	Serious1	No serious inconsistency 2	Very serious3,4,5	No serious imprecision	Yes7,8
Pre-eclampsia											
1 (Farrag 1987)	1/16	3/44	RR 0.92 (0.10 to 8.59)[b]	5 fewer per 1000 (from 61 fewer to 518 more per 1000)	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency[2]	Very serious[3,4,5]	Very serious[6]	Yes[7,8]
Mode of delivery (Caesarean section)											
1 (Farrag 1987)	2/16	9/44	RR 0.62 (0.15 to 2.64)[b]	78 fewer per 1000 (from 174 fewer to 335 more per 1000)	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency[2]	Very serious[3,4,5]	Very serious[6]	Yes[7,8]
Large for gestational age											
1 (Farrag 1987)	0/16	13/44	RR 0.10 (0.006 to 1.68)[b]	266 fewer per 1000 (from 294 fewer to 201 more per 1000)	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency[2]	Very serious[3,4,5]	Very serious[6]	Yes[7,8]
Perinatal mortality											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (< 5.6mmol/litre)	Comparator (≥ 5.6mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Farrag 1987)	0/16	2/44	RR 0.53 (0.03 to 11.14)[b]	21 fewer per 1000 (from 44 fewer to 461 more per 1000)	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency[2]	Very serious[6]	Yes[7,8]	

CI confidence interval, RR relative risk

a Targets were assumed to be for fasting plasma glucose by the NCC-WCH technical team (see point 5).

b Calculated by the NCC-WCH technical team using the t-distribution due to a small sample size.

1 Randomisation methods are not described and group numbers were imbalanced (group A = 16, group B = 29, group C = 15).

2 Single study analysis.

3 Targets assigned to each group were < 5.6mmol/litre for group A, 5.6 to 6.7mmol/litre for group B and 6.7 to 8.9mmol/litre for group C. Numbers of women who achieved targets were not reported however mean blood glucose values were 5.0mmol/litre in group A, 6.1mmol/litre in group B and 8.4mmol/litre in group C.

4 Blood glucose measurements were determined in hospital rather than by self-monitoring by women.

5 It is not clear whether targets assigned were for fasting or post-prandial blood glucose. It was assumed by the NCC-WCH technical team that targets were for fasting blood glucose due to the use of low values. This is in line with the conclusion of the Cochrane review which included this study.

6 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.

7 The study was carried out in Saudi Arabia. Participants were White class B or C. Ethnicity was not explicitly reported however all women were Saudi.

8 Dichotomisation of target groups was performed by the NCC-WCH technical team.

Table 52: GRADE profile for comparison of mean capillary blood glucose[a] less than 6.1 mmol/litre[b] in women with White class diabetes B to D

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (lower target value)	Comparator (higher target value)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mean HbA_{1c} during 3rd trimester											
1 (Landon et al., 1987)	43 Mean = 5.9 ± 0.9c	32 Mean = 7.5 ± 1.1d	NA	MD -1.6 (-2.1 to -1.1)[e]	Very low	Retrospective chart review	Serious[1,2]	No serious inconsistency[3]	Very serious[4,5,6]	No serious imprecision[7]	Yes[8]
Mode of delivery (Caesarean section)											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (lower target value)	Comparator (higher target value)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Landon et al., 87)	20/43	16/32	RR 0.93 (0.58 to 1.49)[c]	35 fewer per 1000 (from 210 fewer to 245 more per 1000)	Very low	Retrospective chart review	Serious[1,2]	No serious inconsistency 3	Very serious[4,5,6]	Very serious[9]	Yes[8]
Large for gestational age											
1 (Landon et l., 1987)	4/43	11/32	RR 0.27 (0.09 to 0.77)[c]	251 fewer per 1000 (from 79 to 313 fewer per 1000)	Very low	Retrospective chart review	Serious[1,2]	No serious inconsistency[3]	Very serious[4,5,6]	Serious[10]	Yes[8]

CI confidence interval, NA not applicable, RR relative risk, MD mean difference

(a) Mean capillary blood glucose was calculated from a minimum of 16 weeks (>450 samples) of values from daily fasting and three pre-prandial (11am, before dinner and at bedtime) sampling throughout the second and third trimesters.

(b) The threshold for optimal glucose control was specified as < 110mg/dl or > 110mg/dl. It is unclear whether the value of 110mg/dl itself is included as optimal control or sub-optimal.

(c) Values quoted are for HbA_{1c}. Using the Michigan formula (HbA_{1c} = 0.9 HbA_1 + 0.05) mean HbA_{1c} is 5.4%. It was not possible to convert the standard deviation to HbA_{1c}.

(d) Values quoted are for HbA_{1c}. Using the Michigan formula (HbA_{1c} = 0.9 HbA_1 + 0.05) mean HbA_{1c} is 6.8%. It was not possible to convert the standard deviation to HbA_{1c}.

(e) Calculated by NCC-WCH technical team.

1 Selection bias as only two-thirds of admissions of pregnant diabetic women were included in the study; reasons for this were not provided.

2 The cut-off for optimal control of 110mg/dl using mean capillary glucose was specified post-hoc; possible misclassification bias.

3 Single study analysis.

4 Mean blood glucose, which included fasting plasma glucose measurements, was used as a proxy for postprandial glucose.

5 The study measured HbA1 rather than HbA_{1c}. Mean differences are calculated based on HbA1 values.

6 Participants were not treated to reach specific target values; thresholds for optimal blood glucose were applied post hoc.

7 Confidence interval does not span more than one zone. MID calculated by NCC-WCH technical team as 0.63 using sample means and standard deviations.

8 The study was carried out in the United States of America. Participants were White class B to D. Ethnicity was not reported.

9 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.

10 Confidence interval for the RR crosses RR = 0.75.

Table 53: GRADE profile for comparison of 2h post-prandial blood glucose less than 6.4mmol/litre vs. greater than or equal to 6.4mmol/litre in women with gestational diabetes

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (< 6.4mmol/litre)	Comparator (≥ 6.4mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Pre-eclampsia											
1 (Rowan et al., 2010)	19/486	26/238	RR 0.36 (0.30 to 0.43)a	70 fewer per 1000 (from 62 to 76 fewer per 1000)	Very low[b,c]	Secondary analysis of RCT data	Serious[1]	No serious inconsistency[2]	Very serious[3]	No serious imprecision [4]	Yes[5]
Large for gestational age											
1 (Rowan et l., 2010)	56/486	59/238	RR 0.46 (0.33 to 0.64)[a]	134 fewer per 1000 (from 89 to 166 fewer per 1000)	Very low[b,c]	Secondary analysis of RCT data	Serious[1]	No serious inconsistency[2]	Very serious[3]	No serious imprecision [4]	Yes[5]

CI confidence interval, NA not applicable, RR relative risk, MD mean difference

(a) Calculated by NCC-WCH technical team.

(b) Study quality started as moderate due to the use of secondary analysis of randomised controlled trial data.

(c) The study was rated up for large effect size however other serious bias and very serious indirectness in the study design meant that this did not impact on the overall study quality.

1 Selection bias as very strict inclusion/exclusion criteria were used in the original trial.

2 Single study analysis.

3 Participants were not treated to reach specific target values; thresholds for optimal blood glucose were applied post hoc. Dichotomisation to obtain a blood glucose threshold was applied by the NCC-WCH technical team as tertiles of blood glucose levels were used to group results.

4 Rated up for large effect size.

5 The study was carried out in the Australia and New Zealand. Participants had gestational diabetes. Ethnicity was 51% Caucasian, 21% Polynesian and 28% Asian or other.

Table 54: GRADE profile for comparison of strict control of 1.5h post-prandial blood glucose (< 6.7mmol/litre) vs. customary control (< 7.8mmol/litre) in women with type 1 diabetes (White class diabetes B to RT).

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (< 6.7mmol/litre)	Comparator (< 7.8mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Mean HbA_{1c} during 1st trimester											
1 (Demarini et al., 1994)	68 Mean = 9.4 ± 1.9[a]	69 Mean = 9.4 ± 1.8[a]	NA	MD 0.0 (-0.6 to 0.6)[b]	Very low	Randomised controlled trial	Very serious[1,2,3]	No serious inconsistency[4]	Serious[5]	Very serious[6]	Yes[7]
Mean HbA_{1c} during 2nd trimester											
1 (Demaini et al., 1994)	68 Mean = 7.8 ± 1.4[c]	69 Mean = 7.7 ± 1.4[d]	NA	MD 0.1 (-0.4 to 0.6)[b]	Very low	Randomised controlled trial	Very serious[1,2,3]	No serious inconsistency[4]	Serious[5]	Very serious[8]	Yes[7]
Mean HbA_{1c} during 3rd trimester											
1 (Demrini et al., 1994)	68 Mean = 7.5 ± 1.2[e]	69 Mean = 7.6 ± 1.1[f]	NA	MD -0.1 (-0.5 to 0.3)[b]	Very low	Randomised controlled trial	Very serious[1,2,3]	No serious inconsistency[4]	Serious[5]	Very serious[9]	Yes[7]

CI confidence interval, NA not applicable, MD mean difference

(a) Values quoted are for HbA_1. Using the Michigan formula (HbA_{1c} = 0.9 HbA_1 + 0.05) mean HbA_{1c} is 8.5%. It was not possible to convert the standard deviation to HbA_{1c}.

(b) Calculated by the NCC-WCH technical team.

(c) Values quoted are for HbA_1. Using the Michigan formula (HbA_{1c} = 0.9 HbA_1 + 0.05) mean HbA_{1c} is 7.1%. It was not possible to convert the standard deviation to HbA_{1c}

(d) Values quoted are for HbA_1. Using the Michigan formula (HbA_{1c} = 0.9 HbA_1 + 0.05) mean HbA_{1c} is 7.0%. It was not possible to convert the standard deviation to HbA_{1c}

(e) Values quoted are for HbA_1. Using the Michigan formula (HbA_{1c} = 0.9 HbA_1 + 0.05) mean HbA_{1c} is 6.8%. It was not possible to convert the standard deviation to HbA_{1c}

(f) Values quoted are for HbA_1. Using the Michigan formula (HbA_{1c} = 0.9 HbA_1 + 0.05) mean HbA_{1c} is 6.9%. It was not possible to convert the standard deviation to HbA_{1c}

1 Randomisation methods were not described and allocation concealment of participants, clinicians and investigators was not reported.

2 Women in the strict control (intervention) group received more frequent care during the study compared with the customary care (control) group.

3 The numbers of women who achieved the designated target values in each treatment group were not reported.

4 Single study analysis.

5 The study measured HbA1 rather than HbA_{1c}. Mean differences are calculated based on HbA1 values.

6 Confidence interval spans all three zones. MID calculated by NCC-WCH technical team as 0.92 using sample means and standard deviations.

7 The study was carried out in the United States of America. Women had type 1 diabetes with White classification ranging from B to RT. Ethnicity was not reported.

8 Confidence interval spans all three zones. MID calculated *by NCC-WCH technical team as 0.70 using sample means and standard deviations.*

9 Confidence interval spans all three zones. MID calculated by NCC-WCH technical team as 0.57 using sample means and standard deviations.

Table 55: GRADE profile for comparison of 1-2h post-prandial blood glucose less than or equal to 7.8mmol/litre vs. greater than 7.8mmol/litre in women with White class diabetes B to RF

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (≤ 7.8mmol/litre)	Comparator (> 7.8mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Macrosomia at 29 to 32 weeks' gestation											
1 (Combs et al., 1992)	14/66	18/45	RR 0.53 (0.29 to 0.95)[a]	188 fewer per 1000 (from 20 to 284 fewer per 1000)	Very low	Retrospective review (prospective data)	Serious1	No serious inconsistency[2]	Serious[3,4]	Serious[5]	Yes[6]

CI confidence interval, NA not applicable, RR relative risk, MD mean difference

a Calculated by NCC-WCH technical team.

1 Selection bias as deliveries before 36 weeks' gestation were excluded.

2 Single study analysis.

3 Participants were not treated to reach specific target values; thresholds for optimal blood glucose were applied post hoc. Results for the association between postprandial blood glucose and macrosomia were reported only at 29 to 32 weeks' gestation based on significance in a regression model were grouped into arbitrary categories. Dichotomisation to obtain a blood glucose threshold was applied by the NCC-WCH technical team based on optimal control as described in the study's methods section.

4 Macrosomia is a proxy for large for gestational age infants.

5 Confidence interval for the RR crosses RR = 0.75.

6 The study was carried out in the United States of America. Participants were White class B to RF. Ethnicity was not reported.

Table 56: GRADE profile for comparison of mean blood glucose[a] less than or equal to 7.8mmol/litre vs. less than or equal to 9.7mmol/litre in women with type 1 diabetes mellitus

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (≤ 7.8mmol/litre)	Comparator (≤ 9.7mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
HbA_{1c} levels											
1st trimester											

Number of studies	Number of women		Effect		Quality	Design	Quality assessment				
	Intervention (≤ 7.8mmol/litre)	Comparator (≤ 9.7mmol/litre)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Sacks et al., 2006)	13 Mean = 6.3 ± 0.7	9 Mean = 7.5 ± 1.5	NA	MD -1.2 (-2.32 to -0.08)[b]	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency[2]	Very serious[3,4,5]	Very serious[6,7]	Yes[8]
2nd trimester											
1 (Sacks et al., 2006)	13 Mean = 5.6 ± 0.8	9 Mean = 6.1 ± 0.6	NA	MD -0.5 (-1.12 to 0.12)[b]	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency[2]	Very serious[3,4,5]	Very serious[6,9]	Yes[8]
3rd trimester											
1 (Sacks et al., 2006)	13 Mean = 5.9 ± 0.6	9 Mean = 6.2 ± 0.8	NA	MD -0.3 (-0.95 to 0.35)[b]	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency 2	Very serious3,4,5	Very serious[6,10]	Yes[8]
Mode of delivery (caesarean)											
1 (Sacks et al., 2006)	8/13	6/9	RR: 0.92 (0.49 to 1.73)[b]	53 fewer per 1000 (from 340 fewer to 487 more per 1000)	Very low	Randomised controlled trial	Serious[1]	No serious inconsistency[2]	Very serious[3,4,5]	Very serious[6,11]	Yes[8]

CI confidence interval, NA not applicable, RR relative risk, MD mean difference

a Mean blood glucose values were derived from capillary plasma glucose self-monitoring results. Participants used memory based portable glucose meters to test capillary plasma glucose seven times a day, before *and 1 hour after the first bite of each meal and at bedtime. Data were downloaded every 1-2 weeks when patients visited the office and were electronically transmitted to a central collection site.*

b Calculated by NCC-WCH technical team.

1 Attrition bias as 31% (4 out of 13) of participants in the less rigid target group were lost to follow-up.

2 Single study analysis.

3 Mean blood glucose, which included fasting plasma glucose measurements, was used as a proxy for postprandial glucose.

4 Women were targeted to achieve blood glucose values within an optimal range therefore no optimal threshold value exists. Upper boundaries of the range are quoted in the GRADE profile.

5 The number of women who achieved the specified target values was not reported.

6 Power calculations required 84 participants per group however only 13 (rigid) and 9 (less rigid) were used. Power was therefore very inadequate and likely caused imprecision.

7 Confidence interval for the MD crosses MD = -0.61. MID calculated by NCC-WCH technical team as 0.61 using sample means and standard deviations.

8 The study was carried out in the United States of America. Participants had type 1 diabetes. Ethnicity was 77% Caucasian, 33% other.
9 Confidence interval for the MD crosses MD = -0.38. MID calculated by NCC-WCH technical team as 0.38 using sample means and standard deviations.
10 Confidence interval for the MD crosses the line of no effect and MD = -0.34 and MD = 0.34. MID calculated by NCC-WCH technical team as 0.34 using sample means and standard deviations.
11 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.

Table 57: GRADE profile for comparison of HbA_{1c} less than or equal to 37 mmol/mol (5.5%) with HbA_{1c} greater than 37 mmol/mol (5.5%) during pregnancy in women with gestational diabetes mellitus.

Number of studies	Number of women/infants		Effect		Quality	Design	Quality assessment				
	Intervention (≤ 5.5%)	Comparator (> 5.5%)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Large for gestational age (LGA)											
1 (Barnes et al., 2013)	NR	NR	OR 1.38 (1.01 to 1.90)[a]	NA	Very low	Retrospective audit	No serious bias	No serious inconsistency[1]	Serious[2]	Serious[3]	Yes[4,5]

CI confidence interval, NR not reported, OR odds ratio, NA not applicable
a Calculated by study authors using backward logistic regression to identify predictors of LGA.
1 Single study analysis.
2 Participants were not treated to reach specific target values; the threshold for optimal HbA_{1c} were applied based on the results of previous studies indicating the upper limit of normal HbA_{1c} during pregnancy.
3 Confidence interval for the OR crosses OR = 1.25.
4 The study was carried out in Australia. Women had gestational diabetes mellitus. Ethnicity was 36.7% South East Asian, 27.6% Middle Eastern, 22.4% European, 8.6% Indian and Pakistani, 1.9% 5 Samoan, 1.5% non-white African and 1.1% Maori.

Table 58: GRADE profile for comparison of HbA_{1c} less than or equal to 38 mmol/mol (5.6%) with HbA_{1c} greater than 38 mmol/mol (5.6%) during pregnancy in women with gestational diabetes mellitus.

Number of studies	Number of women/infants		Effect		Quality	Design	Quality assessment				
	Intervention (≤ 5.6%)	Comparator (> 5.6%)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Pre-eclampsia											
1 (Mikkelse	7/97	3/51	RR 1.23 (0.33 to 4.56)a	14 more per 1000 (from 39	Very low	Retrospective cohort	No serious bias	No serious inconsistency 1	No serious indirectness	Very serious2	Yes3,4

Number of studies	Number of women/infants		Effect		Quality	Design	Quality assessment				
	Intervention (≤ 5.6%)	Comparator (> 5.6%)	Relative (95% CI)	Absolute (95% CI)			Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
n et al., 2011)				fewer to 209 more per 1000)							
Mode of delivery (Caesarean section)											
1 (Mikkelsen et al., 2011)	32/97	16/51	RR 1.05 (0.47 to 1.72)a	16 more per 1000 (from 166 fewer to 226 more per 1000)	Very low	Retrospective cohort	No serious bias	No serious inconsistency 1	No serious indirectness	Very serious2	Yes3,4
Large for gestational age (LGA)											
1 (Mikkelsen et al., 2011)	18/97	20/51	RR 0.47 (0.27 to 0.81)a	208 fewer per 1000 (from 75 to 286 fewer per 1000)	Very low	Retrospective cohort	No serious bias	No serious inconsistency 1	No serious indirectness	Serious5	Yes3,4
Shoulder dystociab											
1 (Mikkelsen et al., 2011)	2/97	0/51	RR 2.65 (0.13 to 54.18)a	Not calculable	Very low	Retrospective cohort	No serious bias	No serious inconsistency 1	No serious indirectness	Very serious2	Yes3,4
Neonatal hypoglycaemia											
1 (Mikkelsen et al., 2011)	4/97	7/51	RR 0.30 (0.15 to 0.60)a	96 fewer per 1000 (from 55 to 117 fewer per 1000)	Moderatec	Retrospective cohort	No serious bias	No serious inconsistency 1	No serious indirectness	No serious imprecision	Yes3,4

CI confidence interval, RR relative risk

a Calculated by the NCC-WCH technical team.

b Shoulder dystocia was defined as shoulder delivery requiring obstetrical manoeuvres in addition to downward pressure, episiotomy or mild suprapubic pressure.

c Rated up for large effect size.

1 Single study analysis.

2 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.

3 The study was carried out in Denmark. Participants had gestational diabetes mellitus. Ethnicity was 57.4% Caucasian, 25.0% Middle Eastern, 7.4% Asian and 10.1% other.

4 97/148 (66%) of women achieved the target of having a last measured HbA_{1c} ≤5.6%.

5 Confidence interval for the RR crosses RR = 0.75.

Table 59: GRADE profile for comparison of HbA_{1c} less than or equal to 48 mmol/mol (6.5%) with HbA_{1c} greater than 48 mmol/mol (6.5%) during pregnancy in women with type 1 diabetes mellitus.

	Number of women/infants		Effect				Quality assessment				
Number of studies	Intervention (≤ 6.5%)	Comparator (> 6.5%)	Relative (95% CI)	Absolute (95% CI)	Quality	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Maternal hypoglycaemia											
1 (Ekbom et al., 2008)	22/131	11/82	RR 1.25 (0.65 to 2.44)[a]	34 more per 1000 (from 47 fewer to 193 more per 1000)	Very low	Prospective cohort	No serious bias	No serious inconsistency[1]	Serious[2]	Very serious[3]	Yes[4]

CI confidence interval, RR relative risk, NA not applicable

a Calculated by the NCC-WCH technical team.

1 Single study analysis.

2 Participants were not treated to reach specific target values; thresholds for optimal HbA_{1c} were applied post hoc. Dichotomisation of tertiles was performed by the NCC-WCH technical team.

3 Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25.

4 The study was carried out in Denmark. Participants had type 1 diabetes. Ethnicity was Caucasian.

Table 60: GRADE profile for comparison of HbA_{1c} between 20 and 42 mmol/mol (4.0% and 6.0%)r less than 56mmol/mol (7.3%) with HbA_{1c} greater than 42 mmol/mol (6.0%) or greater than or equal to 56mmol/mol 7.3% during pregnancy in women with White class diabetes B to R.

	Number of women/infants		Effect				Quality assessment				
Number of studies	Intervention (between 4.0% and 6.0% or < 7.3%)	Comparator (> 6.0% or ≥ 7.3%)	Relative (95% CI)	Absolute (95% CI)	Quality	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Stay in neonatal unit > 10 days											
1 (Vaarasmaki et al., 2000)	2/48	11/36	RR 0.14 (0.03 to 0.59)[b]	263 fewer per 1000 (from 125 to 296 fewer per 1000)	Very low	Retrospective cohort	Very serious[1,2]	No serious inconsistency[3]	Very serious[4,5,6]	No serious imprecision	Yes[7]

CI confidence interval, RR relative risk, NA not applicable

a Based on an assumed HbA1 value of 8.0%. This value was converted to HbA_{1c} by the NCC-WCH technical team using the Michigan formula (HbA_{1c} = 0.9HbA1 + 0.05).

b Calculated by the NCC-WCH technical team.

1 Substantial missing data; only 84/296 pregnancies had data available for glycaemic control determined by HbA_{1c}.

2 Optimal HbA_{1c} values changed across the time period of the study from < 7.3% to 4.0 to 6.0%; data for both thresholds were combined by study authors.

3 Single study analysis.

4 Participants were not treated to reach specific target values; thresholds for optimal HbA_{1c} were applied post hoc.

5 This outcome was used as a proxy for NICU stay greater than 24 hours, as specified in the review protocol.

6 The study measured HbA1 rather than HbA_{1c}.

7 The study was carried out in Finland. Participants were White class B to R. Ethnicity was not reported.

Table 61: GRADE profile for effectiveness of continuous glucose monitoring in pregnancy women with diabetes compared with intermittent capillary blood glucose monitoring

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Mode of birth											
Unassisted vaginal birth (including unspecified 'vaginal birth')											
1 (Kestila et al., 2007)	25/36 (69.4%)	26/37 (70.3%)	RR 0.99 (0.73 to 1.34)a	7 fewer per 1000 (from 190 fewer to 239 more)a	Very low	Randomised trial	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf
1 (Murphy et al., 2008)	11/38 (28.9%)	12/33 (36.4%)	RR 0.8 (0.41 to 1.56) a	73 fewer per 1000 (from 215 fewer to 204 more)a	Very low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesh
2 (Kestila et al., 2007 and Murphy et al., 2008)	36/74 (49%)	38/70 (54%)	RR 0.9 (0.7 to 1.2)a	43 fewer per 1000 (from 168 fewer to 130 more)a	Very Low	Randomised trials	Serious limitationsb,g	No serious inconsistency	Serious indirectnessd	Serious imprecisione	Yesf,h
Assisted vaginal birth											
1 (Kestila et al., 2007)	3/36 (8%)	3/37 (8%)	RR 1.0 (0.2 to 4.8)a	2 more per 1000 (from 63 fewer to 305 more)a	Very Low	Randomised trial	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf
Caesarean section											
1	8/36 (22.2%)	8/37 (21.6%)	RR 1.03 (0.43 to 2.44)a	6 more per 1000	Very Low	Randomised trial	Serious limitationsb	No serious	Serious indirectnessd	Serious imprecisione	Yesf

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Kestila et al., 2007)				(from 123 fewer to 311 more)a				inconsistencyc			
1 (Murphy et al., 2008)	27/38 (71.1%)	18/33 (54.5%)	RR 1.3 (0.9 to 1.89)a	164 more per 1000 (from 55 fewer to 485 more)a	Very Low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesh
1 (Secher et al., 2013)	28/79 (35.4%)	33/75 (44%)	RR 0.81 (0.54 to 1.19) a	84 fewer per 1000 (from 202 fewer to 84 more) a	Low	Randomised trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	Serious imprecisione	Yesj
2 (Murphy et al., 2008; Secher et al., 2013)	55/117 (47%)	51/108 (47.2%)	RR 0.99 (0.75 to 1.3)a,k	5 fewer per 1000 (from 118 fewer to 142 more)a	Very low	Randomised trials	Serious limitationsg,i	Very serious inconsistencyk	Serious indirectnessl	Serious imprecisione	Yesh,j
3 (Murphy et al., 2008; Kestila et al., 2007; and Secher et al., 2013)	63/153 (41%)	59/145 (41%)	RR 1.0 (0.8 to 1.3)a	4 fewer per 1000 (from 98 fewer to 118 more)a	Very Low	Randomised trials	Serious limitationsb,g,i	Serious inconsistencym	Serious indirectnessn	Serious imprecisione	Yesf,h,j
Pre-term birth											
Birth before 37 weeks											

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Kestila et al., 2007)	2/36 (5.6%)	2/37 (5.4%)	RR 1.03 (0.15 to 6.91)a	2 more per 1000 (from 46 fewer to 319 more)a	Very low	Randomised trial	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf
1 (Murphy et al., 2008)	6/38 (15.8%)	6/33 (18.2%)	RR 0.87 (0.31 to 2.43)a	24 fewer per 1000 (from 125 fewer to 260 more)a	Very low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesh
1 (Secher et al., 2013)	16/79 (20.3%)	12/75 (16%)	RR 1.27 (0.64 to 2.49)a	43 more per 1000 (from 58 fewer to 238 more)a	Low	Randomised trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	Serious imprecisione	Yesj
2 (Murphy et al., 2008; Secher et al., 2013)	22/117 (18.8%)	18/108 (16.7%)	RR 1.13 (0.64 to 1.99)a	22 more per 1000 (from 60 fewer to 165 more)a	Very low	Randomised trials	Serious limitationsg,i	No serious inconsistency	Serious indirectnessl	Serious imprecisione	Yesh,j
3 (Murphy et al., 2008; Kestila et al., 2007; and Secher et al., 2013)	24/153 (16%)	20/145 (14%)	RR 1.1 (0.7 to 1.9)a	17 more per 1000 (from 48 fewer to 128 more)a	Very Low	Randomised trials	Serious limitationsb,g,i	No serious inconsistency	Serious indirectnessn	Serious imprecisione	Yesf,h,j

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Gestational age at birth (weeks)											
1 (Kestila et al., 2007)	36 women (mean 39.3 weeks)	37 women (mean 39.7 weeks)	NA	MD 0.4 lower (1.0 lower to 0.2 higher)a	Low	Randomised trial	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	No serious imprecision	Yesf
Glycaemic control in pregnancy											
HbA_{1c} (%)											
At 8 weeks' gestation											
1 (Secher et al., 2013)	76 women (median 6.6, range 5.3 to 10.0)	73 women (median 6.8, range 5.3 to 10.7)	NA	MD 0.2 lowera (NC) (p= 0.72)	Moderate	Randomised trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesj
At 28 to 32 weeks' gestation											
1 (Murphy et al., 2008)	38 women (mean 6.1)	33 women (mean 6.4)	NA	MD 0.3 lower (0.6 lower to 0.03 higher)a	Low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	No serious imprecision	Yesh
At 32 to 36 weeks' gestation											
1 (Murphy et al., 2008)	38 women (mean 5.8)	33 women (mean 6.4)	NA	MD 0.6 lower (0.9 lower to 0.3 lower)a	Low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	No serious imprecision	Yesh
At 33 weeks' gestation											
1 (Secher et al., 2013)	76 women (median 6.1, range 5.1 to 7.8)	73 women (median 6.1, range 4.8 to 8.2)	NA	MD 0.0 a (NC) (p= 0.39)	Moderate	Randomised trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesj
At 36 weeks' gestation											

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Secher et al., 2013)	76 women (median 6.0, range 5.1 to 7.7)	73 women (median 6.1, range 4.7 to 8.4)	NA	MD 0.1 lowera (NC) (p= 0.63)	Moderate	Randomised trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	No serious imprecision	Yesj
Mean glucose level (mmol/l)											
1 (Yogev et al., 2003)	34 women (mean 6.7)	34 women (mean 5.6)	NA	MD 1.1 highera (0.8 higher to 1.5 higher)a	Very low	Within-participants	Serious limitationso	No serious inconsistencyc	Serious indirectnessd	No serious imprecision	Yesl
4 to 5 readings a day											
1 (Kerssen et al., 2006)	43 women (mean 6.9)	43 women (mean 6.8)	NA	MD 0.1 highera (NC) (p=NS)	Very low	Within-participants	Serious limitationso	No serious inconsistencyc	Serious indirectnessd	NCq	Yesr
6 to 9 readings a day											
1 (Kerssen et al., 2006)	43 women (mean 6.3)	43 women (mean 6.5)	NA	MD 0.2 lowera (NC) (p=NS)	Very low	Within-participants	Serious limitationso	No serious inconsistencyc	Serious indirectnessd	NCq	Yesr
10 or more readings a day											
1 (Kerssen et al., 2006)	43 women (mean 6.3)	43 women (mean 6.2)	NA	MD 0.1 highera (NC) (p=NS)	Very low	Within-participants	Serious limitationso	No serious inconsistencyc	Serious indirectnessd	NCq	Yesr
Severe hypoglycaemic episodes											
Severe hypoglycaemic episodes											
At least 1 episode											

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Secher et al., 2013)	13/79 (17%)	12/75 (16%)	RR 1.0 (0.5 to 2.1)a	5 more per 1000 (from 80 fewer to 178 more)a	Moderate	Randomized trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	Serious imprecisione	Yesl
Hypoglycaemic episodes											
4 to 5 readings a day											
1 (Kerssen et al., 2006)	43 women (mean 2.3)	43 women (mean0.6)	NA	MD 1.7 higherа (NC) (p=NS)	Very low	Within-participants	Serious limitationso	No serious inconsistencyc	Very serious indirectnessd,s	NCq	Yesr
6 to 9 readings a day											
1 (Kerssen et al., 2006)	43 women (mean 2.5)	43 women (mean 1.2)	NA	MD 1.3 higherа (NC) (p=NS)	Very low	Within-participants	Serious limitationso	No serious inconsistencyc	Very serious indirectnessd,s	NCq	Yesr
10 or more times a day											
1 (Kerssen et al., 2006)	43 women (mean 3.7)	43 women (mean 2.7)	NA	MD 1.0 higherа (NC) (p=NS)	Very low	Within-participants	Serious limitationso	No serious inconsistencyc	Very serious indirectnessd,s	NCq	Yesr
Perinatal and neonatal mortality											
Miscarriage											
1 (Secher et al., 2013)	3/79 (4%)	2/75 (3%)	RR 1.4 (0.2 to 8.3)a	11 more per 1000 (from 20 fewer to 194 more)a	Low	Randomized trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	Serious imprecisione	Yesj
Early neonatal deaths											

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Murphy et al., 2008)	1/39 (3%)	1/33 (3%)	RR 0.9 (0.1 to 13.0)a	5 fewer per 1000 (from 28 fewer to 364 more)a	Low	Randomised trial	Serious limitationsg	No serious inconsistencyf	Serious indirectnessd	Serious imprecisionc	Yesh
Large for gestational age											
Large for gestational age (≥ 90tn centile)											
1 (Kestila et al., 2007)	4/36 (11.1%)	3/37 (8.1%)	RR 1.37 (0.33 to 5.7)a	30 more per 1000 (from 54 fewer to 381 more)a	Very low	Randomised trial	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf
1 (Murphy et al., 2008)	13/39 (33.3%)	18/33 (54.5%)	RR 0.61 (0.36 to 1.05)a	213 fewer per 1000 (from 349 fewer to 27 more)a	Very low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesh
1 (Secher et al., 2013)	34/79 (43%)	25/75 (33.3%)	RR 1.29 (0.86 to 1.94)a	97 more per 1000 (from 47 fewer to 313 more)a	Low	Randomised trial	Serious limitationsi	No serious inconsistencyc	No serious indirectness	Serious imprecisione	Yesj
2 (Murphy et al., 2008; Secher et al., 2013)	47/118 (39.8%)	43/108 (39.8%)	RR 1.00 (0.72 to 1.38)a,t	0 fewer per 1000 (from 111 fewer to 151 more)a	Very low	Randomised trials	Serious limitationsg,i	Very serious inconsistencyt	Serious indirectnessl	Serious imprecisione	Yesh,j
3 (Murphy et al.,	51/154 (33%)	46/145 (32%)	RR 1.02 (0.74 to 1.40)a,u	6 more per 1000	Very Low	Randomised trials	Serious limitationsb,g,i	Very serious	Serious indirectnessn	Serious imprecisione	Yesf,h,j

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
2008; Kestila et al., 2007; and Secher et al., 2013)				(from 82 fewer to 127 more)a,				inconsistencyu			
Extremely large for gestational age (≥ 97.7tn centile)											
1 (Murphy et al., 2008)	5/39 (13%)	9/33 (27%)	RR 0.5 (0.2 to 1.3)a	145 fewer per 1000 (from 226 fewer to 74 more)a	Very low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesh
Neonatal intensive care unit stay											
Neonates transferred to NICU											
1 (Kestila et al., 2007)	7/36 (19.4%)	11/37 (29.7%)	RR 0.65 (0.29 to 1.5)a	104 fewer per 1000 (from 211 fewer to 149 more)a	Very low	Randomised trial	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesf
1 (Murphy et al., 2008)	9/39 (23.1%)	6/33 (18.2%)	RR 1.27 (0.5 to 3.19)a	49 more per 1000 (from 91 fewer to 398 more)a	Very low	Randomised trial	Serious limitationsg	No serious inconsistencyc	Serious indirectnessd	Serious imprecisione	Yesh
2 (Murphy, 2008 et al.and Kestila et al., 2007)	16/75 (21%)	17/70 (24%)	RR 0.9 (0.5 to 1.6)a	29 fewer per 1000 (from 126 fewer to 153 more)a	Very Low	Randomised trials	Serious limitationsv	No serious inconsistency	Serious indirectnessd	Serious imprecisione	Yesf,h
Days in NICU per treated neonate											

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Continuous monitoring	Intermittent monitoring	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Kestila et al., 2007)	36 women (mean 3 days)	37 women (mean 3.8 days)	NA	MD 0.8 lower (1.6 lower to 0.1 lower)a	Low	Randomised trial	Serious limitationsb	No serious inconsistencyc	Serious indirectnessd	No serious imprecision	Yesf

NA Not applicable, NC Not calculable, RR relative risk

a Calculated by the NCC-WCH based on results reported in the paper

b It is unclear whether an appropriate method of randomisation was used. It is unclear whether allocation was adequately concealed. Neither participants nor clinicians were blinded to treatment allocation (Kestila et al., 2007).

c Single study analysis

d Retrospective analysis of data from continuous glucose monitoring sensors

e Confidence intervals for the estimate of effect cross the line of no effect and either 0.75 and/or 1.25

f The study was conducted in Finland; 99% of participants were Finnish and 1% were Indonesian. All women had gestational diabetes (Kestila et al., 2007).

g It is unclear whether the two groups were comparable at baseline. Neither participants nor clinicians were blinded to treatment allocation (Murphy et al., 2008).

h The study was conducted in the UK; 89% of participants were white European, 9% were Asian, and 3% were 'other' (figures do not add up to 100% due to rounding); and 65% of the women had type 1 diabetes whilst 35% had type 2 diabetes (Murphy, 2008).

i Women receiving care, clinicians giving care, and investigators were not blinded to treatment allocation. It is unclear whether investigators were blinded to other important confounding factors (Secher et al., 2013).

j The study was conducted in Denmark; ethnicity of the women was not reported; and 80% of women had type 1 diabetes and 20% had type 2 diabetes (Secher et al., 2013).

k Evidence of substantial heterogeneity ($Chi^2 = 3.18$, $df = 1$ ($P = 0.07$); $I^2 = 69\%$). A random effects model was used as the I2 value is greater than 50%

l One study (Murphy et al., 2008) used retrospective data from continuous glucose monitoring sensors however the other study (Secher et al., 2013) used data from the sensors contemporaneously which reflects current clinical practice

m Some evidence of moderate heterogeneity ($Chi^2 = 3.16$, $df = 2$ ($P = 0.21$); $I^2 = 37\%$)

n Two studies (Kestila et al., 2007 and Murphy et al., 2008) used retrospective data from continuous glucose monitoring sensors however the other study (Secher et al., 2013) used data from the sensors contemporaneously which more closely reflects current clinical practice

o The people analysing the data were not blinded to the treatment condition the data came from.

p Study was conducted in Israel. Ethnicity of the participants was not reported. All women had type 1 diabetes.

q Standard deviation could not be calculated and therefore imprecision could not be determined

r Study was conducted in the Netherlands. Ethnicity of the participants was not reported. All women had type 1 diabetes.

s It is not clear whether these were severe hypoglycaemic episodes

t Evidence of substantial heterogeneity ($Chi^2 = 4.67$, $df = 1$ ($P = 0.03$); $I^2 = 79\%$) A random effects model was used as the I2 value is greater than 50%

u Evidence of substantial heterogeneity ($Chi^2 = 4.87$, $df = 2$ ($P = 0.09$); $I^2 = 59\%$). A random effects model was used as the I^2 value is greater than 50%

v It is unclear whether an appropriate method of randomisation was used. It is unclear whether allocation was adequately concealed. Neither participants nor clinicians were blinded to treatment allocation (Kestila et al., 2007). It is unclear whether the two groups were comparable at baseline. Neither participants nor clinicians were blinded to treatment allocation (Murphy et al., 2008).

Table 62: GRADE profile for effectiveness of multidisciplinary teams for pregnant women with diabetes

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Receiving care from a multidisciplinary team	Not receiving care from a multidisciplinary team	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Mode of birth											
Vaginal birth (not including assisted birth)											
1 (Wilson et al., 2009)	22/47 (47%)	21/49 (43%)	OR 1.2 (0.5 to 2.6)[a]	39 more per 1000 (from 148 fewer to 234 more)	Very low	Observational	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[e]	Yes[f]
Assisted/instrumental birth (including forceps and ventouse)											
1 (Wilson et al., 2009)	3/47 (6%)	4/49 (8%)	OR 0.8 (0.2 to 3.6)[a]	18 fewer per 1000 (from 68 fewer to 162 more)	Very low	Observational	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[e]	Yes[f]
Caesarean section											
2 (Owens et al., 2012 and Wilson et al., 2009)	135/262 (52%)	81/202 (40%)	OR 1.4 (0.9 to 2.2)a	85 more per 1000 (from 20 fewer to 191 more)	Very low	Observational	Serious limitations[g]	No serious inconsistency	No serious indirectness[d]	Serious imprecision[e]	Yes[h]
Glycaemic control in pregnancy											
HbA_{1C} in women with type 1 diabetes in the first trimester											
1 (Owens et al., 2012)	168	104	NA	MD 3 lower (4.5 lower to 1.5 lower)[a]	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[j]	Yes[k]
HbA_{1C} in women with type 2 diabetes in the first trimester											

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Receiving care from a multidisciplinary team	Not receiving care from a multidisciplinary team	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Owens et al., 2012)	168	104	NA	MD 7 lower (8.4 lower to 5.6 lower)[a]	Very low	Observational	Serious limitationsi	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[j]	Yes[k]
HbA_{1C} in women with type 1 and type 2 diabetes in the first trimester											
1 (Wilson et al., 2009)	47	49	NA	MD 0 higher (0.3 lower to 0.3 higher)[a]	Very low	Observational	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[l]	Yes[f]
HbA_{1C} in women with type 1 diabetes in the second trimester											
1 (Owens et al., 2012)	168	104	NA	MD 1 lower (1.3 lower to 0.7 lower)[a]	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[j]	Yes[k]
HbA_{1C} in women with type 2 diabetes in the second trimester											
1 (Owens et al., 2012)	168	104	NA	MD 5 lower (5.2 lower to 4.8 lower)[a]	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[j]	Yes[k]
HbA_{1C} in women type 1 and type 2 diabetes in the second trimester											
1 (Wilson et al., 2009)	47	49	NA	MD 0.2 lower (0.6 lower to 0.2 higher)[a]	Very low	Observational	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[l]	Yes[f]
HbA_{1C} in women with type 1 diabetes in the third trimester											
1	168	104	NA	MD 3 lower	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[j]	Yes[k]

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Receiving care from a multidisciplinary team	Not receiving care from a multidisciplinary team	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Owens et al., 2012)				(3.3 lower to 2.8 lower)[a]							
HbA_{1C} in women with type 2 diabetes in the third trimester											
1 (Owens et al., 2012)	168	104	NA	MD 1 higher (0.8 higher to 1.2 higher)[a]	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[j]	Yes[k]
HbA_{1C} in women with type 1 and type 2 diabetes in the third trimester											
1 (Wilson et al., 2009)	47	49	NA	MD 0.4 lower (0.7 lower to 0.1 lower)[a]	Very low	Observational	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[j]	Yes[f]
Fetal or neonatal mortality											
Perinatal death											
1 (Owens et al., 2012)	1/168 (< 1%)	5/104 (5%)	OR 0.1 (0.0 to 1.0)[a]	42 fewer per 1000 (from 48 fewer to 1 more)	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[e]	Yes[k]
Stillbirth											
1 (Owens et al., 2012)	2/168 (1%)	4/104 (4%)	OR 0.3 (0.1 to 1.7)[a]	27 fewer per 1000 (from 36 fewer to 24 more)	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[e]	Yes[k]
Miscarriage											

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Receiving care from a multidisciplinary team	Not receiving care from a multidisciplinary team	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Owens et al., 2012)	13/168 (8%)	23/104 (22%)	OR 0.3 (0.1 to 0.6)a	143 fewer per 1000 (from 74 fewer to 183 fewer)	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[m]	Yes[k]
Large for gestational age											
Large for gestational age babies in women with type 1 diabetes											
1 (Owens et al., 2012)	44/168 (26%)	31/104 (30%)	OR 0.8 (0.5 to 1.4)[a]	35 fewer per 1000 (from 126 fewer to 81 more)	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[e]	Yes[k]
Large for gestational age babies in women with type 2 diabetes											
1 (Owens et al., 2012)	42/168 (25%)	18/104 (17%)	OR 1.6 (0.9 to 3.0)[a]	77 more per 1000 (from 21 fewer to 209 more)	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[e]	Yes[k]
Neonatal intensive care unit stay											
Neonatal intensive care unit admission											
1 (Owens et al., 2012)	94/168 (56%)	63/104 (61%)	OR 0.8 (0.5 to 1.4)a	45 fewer per 1000 (from 171 fewer to 71 more)	Very low	Observational	Serious limitations[i]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[e]	Yes[k]
Special care baby unit admission											
1 (Wilson et al., 2009)	5/47 (11%)	16/49 (33%)	OR 0.3 (0.1 to 0.7)[a]	218 fewer per 1000	Very low	Observational	Serious limitations[b]	No serious inconsistency[c]	No serious indirectnessd	No serious imprecision[m]	Yes[f]

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Receiving care from a multidisciplinary team	Not receiving care from a multidisciplinary team	Relative (95% confidence interval)	Absolute (95% confidence interval)							
				(from 62 fewer to 289 fewer)							

MD mean difference, NA Not applicable, NC Not calculable, OR odds ratio
a Calculated by the NCC-WCH based on results reported in the paper
b It is not clear whether the groups had a comparable body mass index (BMI) at baseline (reported data were conflicting). It is unclear whether there are other potentially confounding factors present
c Single study analysis
d Study or studies met population and outcome criteria specified in the review protocol
e Confidence interval for the OR crosses the line of no effect (OR = 1) and OR = 0.75 and/or OR = 1.25
f This study was conducted in the UK. In the two groups, 42.6% and 51.0% of the women were white, 38.2% and 34.6% were South Asian. Other ethnicities were not reported. The average age at booking was 31.4 years in one group and 29.7 years in the other group.
g In one study it was unclear whether the groups had a comparable BMI at baseline (reported data were conflicting).It is unclear whether there are other potentially confounding factors present. In the other study, some of the data contradict what is published in another paper reporting the same study and it is unclear whether there are other potentially confounding factors present. In this study, the multidisciplinary team group also received pre-pregnancy advice, whilst the non-multidisciplinary team group did not.
h One study was conducted in the UK. In the two groups, 42.6% and 51.0% of the women were white, 38.2% and 34.6% were South Asian. Other ethnicities were not reported. The average age at booking was 31.4 years in one group and 29.7 years in the other group. The other study was conducted in Ireland. The number of women with type 1 diabetes was 52% and 77% in the two groups, and the number of women with type 2 diabetes was 48% and 25% in the two groups. The ethnicity of the women and their average age at booking or birth was not reported in the study.
i Some of the data contradict that which is published in another paper reporting on the same study. It is unclear whether there are other potentially confounding factors present. The multidisciplinary team group also received pre-pregnancy advice, whilst the non-multidisciplinary team group did not.
j The confidence interval for the mean difference does not cross the line of no effect
k Study was conducted in Ireland. In the two groups, 52% and 77% of the women had type 1 diabetes and 48% and 23% of the women had type 2 diabetes. The ethnicity of the women and the age at booking or birth were not reported.
l The confidence interval for the mean difference crosses the line of no effect (MD = 0) and the minimally important difference (50% of the combined standard deviation of the two groups)
m The confidence interval for the odds ratio does not cross the line of no effect (OR = 1)

Table 63: GRADE profile for effectiveness of centralised care for pregnant women with diabetes

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other consider
	Centralised care	Peripheral care	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Mode of birth											
Caesarean section											
1 (Traub et al., 1987)	26/60 (43%)	61/100 (61%)	OR 0.5 (0.3 to 0.9)[a]	176 fewer per 1000 (from 15 fewer to 321 fewer)	Very low	Observational	Serious limitations[b]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[e]	Yes[f]
Fetal or neonatal mortality											
Neonatal death											
2 (Hadden, 2009 and Traub et al., 1987)	3/446 (1%)	7/490 (1%)	OR 0.5 (0.1 to 2.0)[a]	7 fewer per 1000 (from 12 fewer to 14 more)	Very low	Observational	Serious limitations[g]	Serious inconsistency[h]	No serious indirectness[d]	Serious imprecision[i]	Yes[j]
Total fetal loss											
2 (Hadden, 2009 and Traub et al., 1987)	58/446 (13%)	53/490 (11%)	OR 1.2 (0.8 to 1.8)[a]	17 more per 1000 (from 21 fewer to 68 more)	Very low	Observational	Serious limitations[g]	No serious inconsistency	No serious indirectness[d]	Serious imprecision[i]	Yes[j]
Miscarriage											
2 (Dunne et al., 2009 and Traub et al., 1987)	10/91 (11%)	27/173 (16%)	OR 0.7 (0.3 to 1.6)[a]	39 fewer per 1000 (from 99 fewer to 71 more)	Very low	Observational	Serious limitations[k]	No serious inconsistency	No serious indirectness[d]	Serious imprecision[i]	Yes[l]
1 (Hadden	46/386 (12%)	32/390 (8%)	OR 1.5 (0.9 to 2.4)a	37 more per 1000 (from 5	Very low	Observational	Serious limitations[m]	No serious inconsistency[c]	Serious indirectness[n]	Serious imprecision[i]	Yes[o]

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other consider
	Centralised care	Peripheral care	Relative (95% confidence interval)	Absolute (95% confidence interval)							
et al., 2009)				fewer to 96 more)							
Stillbirth											
3 (Dunne et al., 2009; Hadden, 2009; Traub et al., 1987)	9/477 (2%)	15/563 (3%)	OR 0.7 (0.3 to 1.6)[a]	7 fewer per 1000 (from 18 fewer to 16 more)	Very low	Observational	Very serious limitations[p]	No serious inconsistency	No serious indirectness[d]	Serious imprecision[i]	Yes[q]
Perinatal deaths (calculated from neonatal death and stillbirth data reported above)											
3 (Dunne et al., 2009; Hadden 2009; and Traub et al., 1987)	12/477 (3%)	22/563 (4%)	OR 0.6 (0.3 to 1.3)[a]	14 fewer per 1000 (from 27 fewer to 11 more)	Very low	Observational	Very serious limitations[p]	No serious inconsistency	No serious indirectness[d]	Serious imprecision[i]	Yes[q]
Large for gestational age											
1 (Dunne et al., 2009)	5/31 (16%)	16/73 (22%)	OR 0.7 (0.2 to 2.1)[a]	57 fewer per 1000 (from 159 fewer to 148 more)	Very low	Observational	Serious limitations[r]	No serious inconsistency[c]	No serious indirectness[d]	Serious imprecision[i]	Yess
Neonatal intensive care unit stay											
Admission to neonatal unit											
1	5/31 (16%)	45/73 (62%)	OR 0.1 (0.0 to 0.4)[a]	455 fewer per 1000	Very low	Observational	Serious limitations[r]	No serious inconsistency[c]	No serious indirectness[d]	No serious imprecision[e]	Yes[s]

Number of studies	Number of women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other consider
	Centralised care	Peripheral care	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Dunne et al., 2009)				(from 256 fewer to 556 fewer)							

OR odds ratio

(a) Calculated by the NCC-WCH based on results reported in the paper.

(b) It is unclear whether the groups were comparable at baseline. It is unclear whether there are other potentially confounding factors present.

(c) Single study analysis

(d) The study/studies met the population and outcome criteria specified in the review protocol

(e) The confidence interval of the odds ratio does not cross the line of no effect (OR = 1)

(f) Study was undertaken in Northern Ireland. The ethnicity of the women was not reported. The average age in the two groups was 27.5 years and 26.7 years.

(g) In one study there are conflicting data reported in the paper, it is unclear if the groups were comparable at baseline, and it is unclear whether there are other potentially confounding factors present. In the other study it is unclear whether the groups were comparable at baseline. It is unclear whether there are other potentially confounding factors present.

(h) The I2 value was 33% or greater but less than 66%

(i) The confidence interval for the odds ratio crosses the line of no effect (OR = 1) and OR = 0.75 and/or OR = 1.25

(j) One study was undertaken in Northern Ireland. The ethnicity of the women was not reported. The average age in the two groups was 27.5 years and 26.7 years. The other study was conducted in Northern Ireland. The ethnicity of the women and their average age at booking or birth was not reported.

(k) In one study more women in the central care group received formal pre-pregnancy care and it was unclear whether there are other potentially confounding factors present. In the other study it is unclear whether the groups are comparable at baseline and it is unclear whether there are other potentially confounding factors present.

(l) One study was conducted in Northern Ireland. The ethnicity of the women was not reported. The average age of the women in the two groups was 27.5 and 26.7 years. The other study was conducted in Ireland. The ethnicity of the women was not reported. The average age of the women was 33 and 36 years.

(m) There are conflicting data reported in the paper, it is unclear if the groups were comparable at baseline, and it is unclear whether there are other potentially confounding factors present.

(n) The data was reported in this study as 'Abortion'. It is not clear whether this refers to terminations of pregnancy or spontaneous abortions (or both), however, the figures suggest that this is likely to include miscarriage data. Because of this ambiguity, it was not meta-analysed with the miscarriage data reported in other studies.

(o) The study was conducted in Northern Ireland. The ethnicity of the women and their average age at booking or birth was not reported.

(p) In one of the studies more women in the central care group received formal pre-pregnancy care than in the peripheral group and it is unclear whether there are other potentially confounding factors present. In another study there are conflicting data reported in the paper, it is unclear if the groups were comparable at baseline, and it is unclear whether there are other potentially confounding factors present. In the third study it was unclear if the groups were comparable at baseline and it is unclear whether there are other potentially confounding factors present.

(q) One study was conducted in Northern Ireland. The ethnicity of the women was not reported. The average age of the women in the two groups was 27.5 and 26.7 years. The second study was conducted in Ireland. The ethnicity of the women was not reported. The average age of the women was 33 and 36 years. The third study was conducted in Northern Ireland. The ethnicity of the women and their average age at booking or birth was not reported.

(r) More women in the central care group received pre-pregnancy care than in the peripheral group. It is unclear whether there are other potentially confounding factors present.

(s) The study was conducted in Ireland. The ethnicity of the women was not reported. The average age of the women was 33 and 36 years.

J.4 Intrapartum care

Table 64: GRADE profile for incidence of stillbirth by gestational age in pregnancies of women with gestational diabetes compared with women who do not have gestational diabetes

Number of studies	Total number of births in a given week Stillbirths/1,000 deliveries (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with gestational diabetes	In women without gestational diabetes	Relative (95% confidence interval)	Absolute							
Stillbirth[a]											
At gestational week 36											
1 (Rosenstein et al., 2012)	10445 6.13*	155597 5.43*	1.13 (0.88 – 1.45)*	0.7 more per 1000 deliveries*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision[c]	Yes [d]
At gestational week 37											
1 (Rosenstein et al., 2012)	22157 3.38*	340239 2.52*	1.34 (1.06 – 1.70)*	0.86 more per 1000 deliveries*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision[e]	Yes [d]
At gestational week 38											
1 (Rosenstein et al., 2012)	44487 1.51*	736413 1.37*	1.10 (0.86 – 1.41)*	0.14 more per 1000 deliveries*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision[c]	Yes [d]
At gestational week 39											

Number of studies	Total number of births in a given week Stillbirths/1,000 deliveries (95% CI) In women with gestational diabetes	In women without gestational diabetes	Effect Relative (95% confidence interval)	Absolute	Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Rosenstein et al., 2012)	56085 1.18*	1105279 0.91*	1.30 (1.01 – 1.66)*	0.27 more per 1000 deliveries*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision[e]	Yes [d]
At gestational week 40											
1 (Rosenstein et al., 2012)	37819 0.90*	981106 0.74*	1.21 (0.86 – 1.71)*	0.16 more per 1000 deliveries*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision[c]	Yes [d]
At gestational week 41											
1 (Rosenstein et al., 2012)	15739 1.21*	510292 0.85*	1.42 (0.90 – 2.25)*	0.36 more per 1000 deliveries*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision[c]	Yes [d]
At gestational week 42											
1 (Rosenstein et al., 2012)	6296 0.95*	168999 1.15*	0.83 (0.37 – 1.86)*	0.2 fewer per 1000 deliveries*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision[f]	Yes [d]

** Calculated by NCC from data provided by the author*

a Incidence of stillbirth at a given gestational age was defined as the number of stillbirths at that gestational age per 1000 delivieries

b The largest ethnic group within the study population was Latin American which is not directly applicable to the UK. The groups were significantly different at baseline for key characteristics. Women with and without gestational diabetes were of significantly different ethnicities and those with gestational diabetes were significantly more likely to have hypertensive disorders than those without gestational diabetes.

Gestational age was determined using the date of last menstrual period which is susceptible to inaccuracy as well as recall bias.
c Confidence interval for the RR crosses crosses the line of no effect and RR = 1.25

d Country: USA, Ethnicity of women with gestational diabetes N (%): White 52,498 (27.2%), African-American 7,548 (3.9%), Latino 94,682 (49.1%), Asian 35,295 (18.3%), Other 2,877 (1.5%). Ethnicity of women without gestational diabetes N (%): White 1,504,878 (37.7%), African-American 217,883 (5.5%), Latino 1,766,579 (44.2%), Asian 443,980 (11.1%), Other 59,816 (1.5%).

e Confidence interval for the RR crosses RR = 1.25

f Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25

Table 65: GRADE profile for incidence of neonatal death by gestational age in the babies of women with gestational diabetes compared with women who do not have gestational diabetes

Number of studies	Number of deliveries Neonatal deaths/10,000 live births (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with gestational diabetes	In women without gestational diabetes	Relative (95% confidence interval)	Absolute							
Neonatal deaths[a]											
At gestational week 36											
1 (Rosenstein et al., 2012)	10375† 10.6 (5.3 - 19.0)	154579† 9.1 (7.7 - 10.8)	1.16 (0.63 to 2.14)*	1.5 more per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 37											
1 (Rosenstein et al., 2012)	22074† 6.8 (3.8 - 11.2)	339187† 6.1 (5.3 - 7.0)	1.11 (0.66 to 1.88)*	0.7 more per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 38											
1 (Rosenstein et al., 2012)	44414† 3.6 (2.1 - 5.9)	735205† 3.9 (3.5 - 4.4)	0.92 (0.56 to 1.53)*	0.3 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 39											

Number of studies	Number of deliveries Neonatal deaths/10,000 live births (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with gestational diabetes	In women without gestational diabetes	Relative (95% confidence interval)	Absolute							
1 (Rosenstein et al., 2012)	56011† 3.4 (2.0 - 5.3)	1104127† 2.8 (2.5 - 3.1)	1.21 (0.76 to 1.92)*	0.6 more per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision [e]	Yes [d]
At gestational week 40											
1 (Rosenstein et al., 2012)	37779† 2.6 (1.3 - 4.9)	980203† 3.4 (3.1 - 3.8)	0.78 (0.41 to 1.46)*	0.8 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 41											
1 (Rosenstein et al., 2012)	15717† 3.2 (1.0 - 7.4)	509749† 3.6 (3.1 - 4.2)	0.88 (0.36 to 2.14)*	0.4 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias b	No serious inconsistency	No serious indirectness	Very serious imprecision c	Yes d
At gestational week 42											
1 (Rosenstein et al., 2012)	6285† 6.4 (1.7 - 16.3)	168769† 4.7 (3.7 - 5.8)	1.36 (0.50 to 3.72)*	1.7 more per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]

*† Data provided by author *Calculated by NCC-WCH*

a Incidence of neonatal death was defined as the number of infants born at this gestational age who die within 28 days of birth per 10,000 live births at that same gestational age.

b The largest ethnic group within the study population was Latin American which is not directly applicable to the UK. The groups were significantly different at baseline for key characteristics. Women with and without gestational diabetes were of significantly different ethnicities and those with gestational diabetes were significantly more likely to have hypertensive disorders than those without gestational diabetes. Gestational age was determined using the date of last menstrual period which is susceptible to inaccuracy as well as recall bias.
c Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25

d Country: USA, Ethnicity of women with gestational diabetes N (%): White 52,498 (27.2%), African-American 7,548 (3.9%), Latino 94,682 (49.1%), Asian 35,295 (18.3%), Other 2,877 (1.5%). Ethnicity of women without gestational diabetes N (%): White 1,504,878 (37.7%), African-American 217,883 (5.5%), Latino 1,766,579 (44.2%), Asian 443,980 (11.1%), Other 59,816 (1.5%).

e Confidence interval for the RR crosses the line of no effect and RR = 1.25

Table 66: GRADE profile for the incidence of infant death by gestational age in the babies of women with gestational diabetes compared with women who do not have gestational diabetes

Number of studies	Number of deliveries Infant deaths/10,000 live births (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with gestational diabetes	In women without gestational diabetes	Relative (95% confidence interval)	Absolute							
Infant deaths[a]											
At gestational week 36											
1 (Rosenstein et al., 2012)	10,445 19.3 (11.8 - 29.8)	155,597 22.9 (20.6 - 25.4)	0.84 (0.54 - 1.32)	3.6 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 37											
1 (Rosenstein et al., 2012)	22,157 14.0 (9.5 - 19.9)	340,239 18.4 (17.0 - 19.9)	0.76 (0.53 - 1.1)	4.4 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias b	No serious inconsistency	No serious indirectness	Serious imprecision [e]	Yes [d]
At gestational week 38											
1 (Rosenstein et al., 2012)	44,487 10.6 (7.8 - 14.1)	736,413 13.3 (12.5 - 14.2)	0.80 (0.59 - 1.06)	2.7 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision [e]	Yes [d]
At gestational week 39											
1 (Rosenstein et al., 2012)	56,085 8.7 (6.5 - 13.2)	1,105,279 10.7 (10.1 - 11.4)	0.82 (0.61 - 1.08)	2.0 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias b	No serious inconsistency	No serious indirectness	Serious imprecision e	Yes d
At gestational week 40											

Number of studies	Number of deliveries Infant deaths/10,000 live births (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with gestational diabetes	In women without gestational diabetes	Relative (95% confidence interval)	Absolute							
1 (Rosenstein et al., 2012)	37,819 9.5 (6.7 - 13.2)	981,106 11.6 (10.9 - 12.3)	0.82 (0.59 - 1.14)	2.1 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias b	No serious inconsistency	No serious indirectness	Serious imprecision e	Yes d
At gestational week 41											
1 (Rosenstein et al., 2012)	15,739 11.5 (6.8 - 18.1)	510,292 12.8 (11.9 - 13.9)	0.89 (0.56 - 1.43)	1.3 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias b	No serious inconsistency	No serious indirectness	Very serious imprecision c	Yes d
At gestational week 42											
1 (Rosenstein et al., 2012)	6,296 9.5 (3.5 - 20.8)	168,999 14.0 (12.3 - 15.9)	0.68 (0.30 - 1.52)	4.5 fewer per 10,000 live births*	Very low	Retrospective cohort	Serious risk of bias b	No serious inconsistency	No serious indirectness	Very serious imprecision c	Yes d

Table 67: GRADE profile for incidence of stillbirth in the babies of women with type 1 and type 2 diabetes compared with all women in England and Wales

Number of studies	Number of deliveries Stillbirth/1000 total births (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with type 1 diabetes	In all women in England and Wales	Relative (95% confidence interval)	Absolute							
Stillbirth [a]											

Number of studies	Number of deliveries Stillbirth/1000 total births (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with type 1 diabetes	In all women in England and Wales	Relative (95% confidence interval)	Absolute							
At gestational week 24-27											
1 (Holman et al., 2014)	20 250 (89.8-490.8)	16927† 264 (257.2 – 272.6)	0.95 (0.82 - 1.10)*	14 fewer per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	No serious imprecision	Yes [c]
At gestational week 28-31											
1 (Holman et al., 2014)	49 81.6 (29.5 – 194.6)	31894† 93.5 (90.2 – 96.9)	0.87 (0.66 - 1.16)*	11.9 fewer per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision [d]	Yes [c]
At gestational week 32-34											
1 (Holman et al., 2014)	161 43.5 (20.6 – 87.7)	69930† 34.8 (33.5 – 36.2)	1.25 (0.81 - 1.94)*	8.2 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Serious imprecision [e]	Yes [c]
At gestational week 35-36											
1 (Holman et al., 2014)	392 10.2 (3.9 – 26.0)	143609† 13.6 (13.0 – 14.2)	0.75 (0.33 - 1.68)*	3.4 fewer per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [f]	Yes [c]
At gestational week 37-38											
1 (Holman et al., 2014)	1185 5.1 (2.3 – 11.0)	670426† 3.5 (3.3 – 3.6)	1.46 (0.37 - 5.66)*	1.6 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [f]	Yes [c]
At gestational week ≥39											
1 (Holman	278 10.8 (3.6 – 31.3)	2590083† 1.5 (1.4 – 1.5)	7.2 (1.31 - 39.63)*	9.3 more per 1000*	Very low	Retrospective cohort	Serious risk of bias b	No serious	No serious	No serious	Yes c

Number of studies	Number of deliveries Stillbirth/1000 total births (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with type 1 diabetes	In all women in England and Wales	Relative (95% confidence interval)	Absolute							
et al., 2014)								inconsistency	indirectness	imprecision	

*† Data provided by author *Calculated by NCC-WCH*

A No *information* a Stillbirth was defined as an infant born after 24 completed weeks of gestation that did not show any signs of life after birth.
b *is provided regarding how gestational age was determined.*
c Country: England (and Wales) No ethnicity details were provided

d Confidence interval for the RR crosses the line of no effect and RR = 0.75

e Confidence interval for the RR crosses the line of no effect and RR = 1.25

f Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25

Evidence profile for incidence of perinatal mortality in the babies of women with type 1 diabetes compared with women who do not have type 1 diabetes

Number of studies	Number of deliveries Perinatal mortality/1000 (95% CI)		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	In women with type 1 diabetes	In women without type 1 diabetes	Relative (95% confidence interval)	Absolute							
Perinatal mortality [a]											
At gestational week 32-34											
1 (Eidem et al., 2011)	85 58.8 (19.4 - 132.0)†	19,594 50.3 (47.3 - 53.5)†	1.17 (0.50 - 2.74)*	8.5 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 35-36											

1 (Eidem et al., 2011)	190 15.8 (3.27 - 45.5)†	39,553 19.0 (17.7 - 20.4)†	0.83 (0.27 - 2.56)*	3.2 fewer per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 37											
1 (Eidem et al., 2011)	152 13.2 (1.60 - 46.7)†	47,517 9.28 (8.44 - 10.2)†	1.42 (0.36 - 5.63)*	3.92 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 38											
1 (Eidem et al., 2011)	225 8.89 (1.08 - 31.7)†	105,234 4.51 (4.12 - 4.94)†	1.97 (0.49 - 7.85)*	4.38 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision [c]	Yes [d]
At gestational week 39											
1 (Eidem et al., 2011)	245 12.2 (2.53 - 35.4)†	206,321 2.88 (2.66 - 3.12)†	4.25 (1.38 - 13.11)*	9.32 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	No serious imprecision	Yes [d]
At gestational week 40											
1 (Eidem et al., 2011)	159 6.29(0.16 - 34.5)†	281,805 2.08 (1.91 - 2.25)†	3.03 (0.43 - 21.41)*	4.82 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	Very serious imprecision c	Yes [d]
At gestational week 41-45											
1 (Eidem et al., 2011)	1071 29.7 (6.17 - 84.4)†	366,653 2.39 (2.24 - 2.56)†	12.42 (4.06 – 37.93)*	27.31 more per 1000*	Very low	Retrospective cohort	Serious risk of bias [b]	No serious inconsistency	No serious indirectness	No serious imprecision	Yes [d]

*† Data provided by author *Calculated by NCC-WCH*

a Perinatal death was defined as stillbirth (death of the fetus before or during labour) or early neonatal death (death during the first 7 days of life).
b Gestational age was primarily determined using the date of last menstrual period (LMP) which is susceptible to inaccuracy as well as recall bias. Where LMP information was not available, gestational age was estimated on the basis of ultrasound notes (which are more reliable) although fewer than a third of all births had this data recorded.
c Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25
d Country: Norway, Ethnicity of women with type 1 diabetes N (%): European origin 99.9%. Ethnicity of women without type 1 diabetes N (%): European origin 94.4%. European origin was defined as women who are not first or second generation immigrants from a country outside Europe, or from Turkey.

Table 68:GRADE profile for effectiveness of elective delivery in pregnant women with gestational diabetes compared with expectant management for maternal outcomes

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Elective Delivery	Expectant management	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Mode of birth											
Spontaneous vaginal birth											
Vaginal delivery											
1 (Kjos et al., 1993)	75/100 (75%)	69/100 (69%)	RR = 1.09 (0.91 to 1.29)*	62 more per 1000 (from 62 fewer to 200 more)	Low	Randomised trial	Serious limitations[a]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[c,d]
Spontaneous birth											
1 (Lurie et al., 1996)	69/96 (71.9%)	128/164 (75.6%)	RR = 0.92 (0.79 to 1.07)*	62 fewer per 1000 (from 164 fewer to 55 more)	Low	Prospective Cohort	Serious limitations[e]	No serious inconsistency	No serious indirectness	No serious imprecision	Yes[f,g]
1 (Alberico et al., 2010)	36/48 (75%)	39/51 (76%)	RR = 0.98 (0.78 to 1.23)*	15 fewer per 1000 (from 168 fewer to 176 more)	Very Low	Retrospective cohort	Serious limitations[h]	No serious inconsistency	No serious indirectness	No serious imprecision	Yes[i,j,k]
Operative delivery											
1 (Lurie et al., 1996)	5/96 (5.2%)	9/164 (5.5%)	RR = 0.95 (0.33 to 2.75)*	3 fewer per 1000 (from 37 fewer to 96 more)	Very Low	Prospective Cohort	Serious limitations[e]	No serious inconsistency	No serious indirectness	Very serious imprecision[l]	Yes[f,g]
1 (Alberico et al., 2010)	3/48 (6%)	1/51 (2%)	RR = 3.19 (0.34 to 29.60)	43 more per 1000	Very Low	Retrospective cohort	Serious limitations[h]	No serious inconsistency	No serious indirectness	Very serious imprecision[l]	Yes[i,k]

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Elective Delivery	Expectant management	Relative (95% confidence interval)	Absolute (95% confidence interval)							
				(from 13 fewer to 561 more)							
Caesarean section											
1 (Kjos et al., 1993)	20/89 (22.5%)	12/80 (17.5%)	RR = 1.28 (0.70 to 2.37)*	49 more per 1000 (from 53 fewer to 240 more)	Very Low	Randomised trial	Serious limitations[a]	No serious inconsistency	No serious indirectness	Very serious imprecision[l]	Yesc,[d,m]
1 (Lurie et al., 1996)	22/96 (22.9%)	31/164 (18.9%)	RR = 1.21 (0.75 to 1.97)*	40 more per 1000 (from 47 fewer to 183 more)	Very Low	Prospective Cohort	Serious limitations[d]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[f,g]
1 (Alberico et al., 2010)	9/48 (19%)	11/51 (22%)	RR = 0.87 (0.40 to 1.91)*	52 fewer per 1000 (from 125 fewer to 80 more)	Very Low	Retrospective cohort	Serious limitations[h]	No serious inconsistency	No serious indirectness	Very serious imprecision[l]	Yes[i,k,n,o]
Caesarean section - Subgroup of women with normal BMI (20-25)											
1 (Alberico et al., 2010)	14%	14%	OR = 0.99 (0.2 to 4.91)	NC	Very Low	Retrospective cohort	Serious limitations[h]	No serious inconsistency	No serious indirectness	Very serious imprecision[l]	Yes[i,k]
Caesarean section - Subgroup of women with obesity (BMI ≥30)											
1 (Alberico et al., 2010)	24%	50%	OR = 0.31 (0.04 - 2.14)	NC	Very Low	Retrospective cohort	Serious limitationsh	No serious inconsistency	No serious indirectness	Very serious imprecisionl	Yesi,k

**Calculated by NCC-WCH, NC Not calculable, RR relative risk*

a It is unclear whether an appropriate method of randomisation was used or if the method of allocation to treatment groups was unrelated to potential confounding factors.

b Confidence interval for the RR crosses the line of no effect and RR = 1.25

c Study conducted in USA. 187 were diagnosed with insulin dependent gestational diabetes. 13 women were diagnosed with pregestational non-insulin dependent diabetes before pregnancy - 9/13 in elective induction group, 4/13 in expectant management group. All women had no other medical or obstetric complications and were candidates for trial of vaginal delivery (had not had more than 2 previous caesarean sections). No details of ethnicity are given. Onset of labour: In the elective induction group, 22/100 had a spontaneous labour, 70/100 underwent induction of labour and 8/100 had a caesarean delivery without labour (no reasons for this are given). In the expectant management group, 44/100 had a spontaneous labour, 49/100 underwent induction of labour and 7/100 had a caesarean delivery without labour. (One additional woman presented in spontaneous labour with a transverse foetal lie and underwent caesarean section without allowing labour to proceed). The following indications were given for the 49 women who underwent induction of labour - abnormal antenatal testing: 19, ruptured membranes without labour: 8, 42 gestational weeks: 7, poor foetal growth: 4, pregnancy induced hypertension: 3, suspected macrosomia: 1, maternal insistence on delivery: 7

d Active induction of labour: In pregnancies where gestational age could not be determined with accuracy, amniocentesis was performed to assess foetal lung maturity. Women with 1) accurate estimation of gestational age or 2) evidence of foetal lung maturity (lecithin sphingomyelin ratio ≥ 2.0) were scheduled within 5 days for induction of labour. If foetal lung maturity was not confirmed, amniocentesis was performed again 1 week later. Women continued twice weekly antepartum surveillance and home insulin therapy. Labour was induced with intravenous oxytocin. Women with favourable Bishop scores (<4), unscarred uteri and normal amniotic fluid indices (>5.0cm), up to three applications of vaginal prostaglandin (3mg) were used for cervical ripening before treatment with oxytocin.

Expectant management: Expectant management was daily split-dose insulin treatment and home blood glucose monitoring, weekly antenatal clinic appointments and twice weekly antepartum testing until spontaneous labour occurred. Induction of labour was undertaken if 1) decelerations or nonstress testing or low amniotic fluid volume indicated suspected foetal distress 2) preeclampsia occurred, 3) maternal hyperglycaemia or ketonuria occurred 4) estimated foetal weight ≥ 4200g or 5) the pregnancy exceeded 42 gestational weeks. Gestational age in both groups determined by last menstrual period adjusted if ultrasonongraphic estimation (before 22 weeks) indicated a difference of ≥ 10 days.

e The study used a historic control group who received expectant management. No attempt was made within the design or analysis to balance the comparison groups for potential confounders.

f Study conducted in Israel. All women had class A2 gestational diabetes. No ethnicity details were given

g In the first period, unless foetal health was compromised, pregnancy was allowed to progress to spontaneous labour. If the woman was undelivered at 40 gestational weeks a nonstress test and evaluation of cervical status was performed twice weekly and biophysical score once a week. Induction of labour was attempted if one of the following was met. 1) Ultrasonography estimation of an excessively large foetus (>4000g) 2) Assessment of biophysical score or OCT indicating compromise of foetal health 3) a Bishop score of >6 was obtained Instrumental delivery or caesarean section was perfumed as usually indicated. Elective caesarean section was performed where foetal weight was estimated to be ≥4500g.

In the second period, an amniocentesis was performed to estimate lung maturity and the ratio of lecithin to sphingomyelin (L/S ratio) and phosphatidylglycerol presence were assessed from the amniotic fluid. If the lungs were assessed to be mature and the cervix was unfavourable (Bishop score <6), induction of labour was performed by either intracervical balloon catheter or placement of 0.5mg prostaglandin E2 gel. If the cervix was favourable, intravenous oxytocin was administered followed by amniotomy. If fetal weight was estimated to be ≥4500g by clinical or ultrasound examination, the mother was delivered by caesarean section.

h It is unclear whether the method of allocation to treatment groups was unrelated to potential confounding factors. There were significantly more very obese women in the elective delivery group compared to the expectant management group although for other major confounding and prognostic factors the groups were comparable at baseline.

i Study conducted in Italy. No ethnicity data presented. All women had gestational diabetes.

j 4/51 (8%) women in the expectant management group underwent Induction > 38 weeks for reasons not related to gestational diabetes; 3/4 spontaneous delivery following induction, 1/4 caesarean section

k Intervention: elective induction of labour was performed by administration of PGE2 gel every 6-8 hours until labour started. If induction did not succeed after 5 attempts then caesarean section was performed.

Control: women in the expectant management group were reassessed at 40-41 gestational weeks by ultrasound. If the estimated foetal weight was >4250g, then a caesarean section was performed, otherwise the patient was observed until spontaneous labour started. Induction was offered if there were any new emerging indications (oligohydramnios, PROM, post-term pregnancy).

For both groups, a caesarean section was performed if foetal distress was suspected.

l Confidence interval for the RR crosses the line of no effect and RR = 0.75 and RR = 1.25
m Data are corrected for Caesarean section rates in women who had not had a previous caesarean section
n 9/48 (19%)women in the elective induction group had a Caesarean section: 8/9 failed induction, 1/9 foetal distress. 11/51 (22%) women in the expectant management group had a Caesarean section:8/11 macrosomia, 2/11 foetal distress, 1/11 following induction>38 weeks
o A comparison of obese vs normal weight women across study groups demonstrated that obese women were significantly more likely to have a Caesarean section (33% vs 14%, p=0.03). A multivariate analysis of women with BMI ≥30 vs women with BMI <30 was performed and the resulting adjusted OR = 3.9 (95% CI 1.2 to 12.8) (adjusted for maternal age, parity, hypertensive disorders and induction of labour at 38 gestational weeks)

Table 69: GRADE profile for effectiveness of elective delivery in pregnant women with gestational diabetes compared with expectant management for foetal/neonatal outcomes

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Elective Delivery	Expectant management	Relative (95% confidence interval)	Absolute (95% confidence interval)							
Stillbirth											
1 (Alberico et al., 2010)	0/48 (0%)	1/51 (2%)	RR = 0.35 (0.01 to 8.48)*	13 fewer per 1000 (from 19 fewer to 147 more)	Very low	Retrospective cohort	Serious limitations[a]	No serious inconsistency	No serious indirectness	Very serious imprecision[b]	Yes[c,d]
Perinatal death											
1 (Kjos et al., 1993)	0/100 (0%)	0/100 (0%)	NC	NC	Low	Randomised trial	Serious limitations[e]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[f,g]
1 (Lurie et al., 1996)	1/96 (1%)	0/164 (0%)	NC	NC	Very low	Prospective Cohort	Serious limitations[h]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[i,j,k]
Macrosomia											
Birth weight >4000g											
1 (Kjos et al., 1993)	15/100 (15%)	27/100 (27%)	RR = 0.56 (0.32 to 0.98)*	119 fewer per 1000 (from 5 fewer to 184 fewer)	Low	Randomised trial	Serious limitations[e]	No serious inconsistency	No serious indirectness	Serious imprecision	Yes[f,g]
1 (Lurie et al., 1996)	9/96 (9.4%)	30/164 (18.3%)	RR = 0.51 (0.25 to 1.03)*	90 fewer per 1000 (from 137 fewer to 5 more)	Low	Prospective Cohort	Serious limitations[h]	No serious inconsistency	No serious indirectness	Serious imprecision	Yes[i,j,k,l]

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Elective Delivery	Expectant management	Relative (95% confidence interval)	Absolute (95% confidence interval)							
1 (Alberico et al., 2010)	6/48 (13%)	11/51 (22%)	RR = 0.58 (0.23 to 1.44)*	91 fewer per 1000 (from 166 fewer to 95 more)	Very low	Retrospective cohort	Serious limitations[a]	No serious inconsistency	No serious indirectness	Very serious imprecision[b]	Yes[c,d]
Birth weight >4500g											
1 (Kjos et al., 1993)	0/100 (0%)	2/100 (2%)	RR = 0.2 (0.01 to 4.11)*	16 fewer per 1000 (from 20 fewer to 62 more)	Low	Randomised trial	Serious limitations[e]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[f,g]
Shoulder dystocia (with and without consequences for the baby such as trauma, neuromuscular injury)											
1 (Kjos et al., 1993)	0/100 (0%)	3/100 (3%)	RR = 0.14 (0.01 to 2.73)*	26 fewer per 1000 (from 30 fewer to 52 more)	Very Low	Randomised trial	Serious limitations[e,m,n]	No serious inconsistency	No serious indirectness	Very serious imprecision b	Yes[f,g]
1 (Lurie et al., 1996)	1/74 (1.4%)	7/133 (5.3%)	RR = 0.26 (0.03 to 2.05)*	39 fewer per 1000 (from 51 fewer to 55 more)	Very low	Prospective Cohort	Serious limitations[h]	No serious inconsistency	No serious indirectness	Very serious imprecision[b]	Yes[i,k,o]
1 (Alberico et al., 2010)	0/48 (0%)	0/51 (0%)	NC	NC	Very low	Retrospective cohort	Serious limitations[a,n,p]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[c,d]
Admission to NICU											
1	1/48	6/51 (12%)	RR = 0.18 (0.02 to 1.42)*	96 fewer per 1000	Very low	Retrospective cohort	Serious limitations[a,n,q]	No serious inconsistency	No serious indirectness	Very serious imprecision[b]	Yes[c,d]

Number of studies	Number of events/women		Effect		Quality	Design	Limitations (risk of bias)	Inconsistency	Indirectness	Imprecision	Other considerations
	Elective Delivery	Expectant management	Relative (95% confidence interval)	Absolute (95% confidence interval)							
(Alberico et al., 2010)	(2%)			(from 115 fewer to 49 more)							
Respiratory disease (including respiratory distress syndrome and transient tachypnoea of the newborn)											
1 (Lurie et al., 1996)	0/96 (0%)	0/164 (0%)	NC	NC	Very low	Prospective Cohort	Serious limitations[h,r]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[i,k]
Neonatal hypoglycaemia											
1 (Kjos et al., 1993)	0/100 (0%)	0/100 (0%)	NC	NC	Low	Randomised trial	Serious limitations [e,s]	No serious inconsistency	No serious indirectness	Serious imprecision[b]	Yes[f,g]

**Calculated by NCC-WCH, NA Not applicable, NC Not calculable, RR relative risk*

a It is unclear whether the method of allocation to treatment groups was unrelated to potential confounding factors. There were significantly more very obese women in the elective delivery group compared to the expectant management group although for other major confounding and prognostic factors the groups were comparable at baseline.

b Confidence intervals for the estimate of effect cross the line of no effect and either 0.75 and/or 1.25

c Study conducted in Italy. No ethnicity data presented. All women had gestational diabetes

d Intervention: elective induction of labour was performed by administration of PGE2 gel every 6-8 hours until labour started. If induction did not succeed after 5 attempts then caesarean section was performed.

Control: women in the expectant management group were reassessed at 40-41 gestational weeks by ultrasound. If the estimated foetal weight was >4250g, then a caesarean section was performed, otherwise the patient was observed until spontaneous labour started. Induction was offered if there were any new emerging indications (oligohydramnios, PROM, post-term pregnancy).

For both groups, a caesarean section was performed if foetal distress was suspected.

e It is unclear whether an appropriate method of randomisation was used or if the method of allocation to treatment groups was unrelated to potential confounding factors.

f Study conducted in USA. 187 were diagnosed with insulin dependent gestational diabetes. 13 women were diagnosed with pregestational non-insulin dependent diabetes before pregnancy - 9/13 in elective induction group, 4/13 in expectant management group. No details of ethnicity are given.

g Active induction of labour: In pregnancies where gestational age could not be determined with accuracy, amniocentesis was performed to assess foetal lung maturity. Women with 1) accurate estimation of gestational age or 2) evidence of foetal lung maturity (lecithin sphingomyelin ratio ≥ 2.0) were scheduled within 5 days for induction of labour. If foetal lung maturity was not confirmed, amniocentesis was performed again 1 week later. Women continued twice weekly antepartum surveillance and home insulin therapy. Labour was induced with intravenous oxytocin. Women with favourable Bishop scores (<4), unscarred uteri and normal amniotic fluid indices (>5.0cm), up to three applications of vaginal prostaglandin (3mg) were used for cervical ripening before treatment with oxytocin.

Expectant management: Expectant management was daily split-dose insulin treatment and home blood glucose monitoring, weekly antenatal clinic appointments and twice weekly antepartum testing until spontaneous labour occurred. Induction of labour was undertaken if 1) decelerations or nonstress testing or low amniotic fluid volume indicated suspected foetal distress 2) preeclampsia occurred, 3) maternal hyperglycaemia or ketonuria occurred 4) estimated foetal weight ≥ 4200g or 5) the pregnancy exceeded 42 gestational weeks. Gestational age in both groups determined by last menstrual period adjusted if ultrasononographic estimation (before 22 weeks) indicated a difference of ≥ 10 days.

h The study used a historic control group who received expectant management. No attempt was made within the design or analysis to balance the comparison groups for potential confounders.

i Study conducted in Israel. All women had class A2 gestational diabetes. No ethnicity details were given

j One neonate died of severe asphyxia

k In the first period, unless foetal health was compromised, pregnancy was allowed to progress to spontaneous labour. If the woman was undelivered at 40 gestational weeks a nonstress test and evaluation of cervical status were performed twice weekly and biophysical score once a week. Induction of labour was attempted if one of the following was met. 1) Ultrasonographic estimation of an excessively large foetus (>4000g) 2) Assessment of biophysical score or OCT indicating compromise of foetal health 3) a Bishop score of >6 was obtained Instrumental delivery or caesarean section was performed as usually indicated. Elective caesarean section was performed where foetal weight was estimated to be ≥4500g.

In the second period, an amniocentesis was performed to estimate lung maturity and the ratio of lecithin to sphingomyelin (L/S ratio) and phosphatidylglycerol presence were assessed from the amniotic fluid. If the lungs were assessed to be mature and the cervix was unfavourable (Bishop score <6), induction of labour was performed by either intracervical balloon catheter or placement of 0.5mg prostaglandin E2 gel. If the cervix was favourable, intravenous oxytocin was administered followed by amniotomy. If foetal weight was estimated to be ≥4500g by clinical or ultrasound examination, the mother was delivered by caesarean section.

l In expectant management group: 15/30 delivered after 40 weeks

m The outcome is described as mild shoulder dystocia but no definition is given. No incidences of birth trauma - Erg's palsy or bone fracture - in either group

n It is unclear whether a valid and reliable method was used to determine the outcome

o The denominators exclude caesarean section deliveries. Definition: failure of the shoulder to be delivered spontaneously after the head due to impaction of the anterior shoulder against the symphysis pubis, as judged by the clinician delivering the foetus. In the expectant management group 5/7 delivered after 40 weeks. 2/7 Erb's palsy, 1/7 clavicular fracture

p No definition of shoulder dystocia is given

q No definition of admission to NICU is given

r The outcome was respiratory distress syndrome, but no definition was given

s No definition of neonatal hypoglycaemia was given

J.5 Postnatal care

Table 70: GRADE profile for diagnostic test accuracy of fasting plasma glucose at various thresholds between 5.0mmol/l and 7.0mmol/l to detect impaired glucose tolerance postnatally in women who have had gestational diabetes, compared to the 75g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
Fasting plasma glucose ≤ 5.0 mmol/l for detecting IGT												
1 (McClean 2010)	985	14.9 (9.3 to 22.7)a	52.4 (51.6 to 53.4)a	0.31 (0.19 to 0.49)a	1.63 (1.45 to 1.76)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg
Fasting plasma glucose ≤ 5.5 mmol/l for detecting IGT												
1 (McClean 2010)	985	31.6 (23.8 to 40.4)a	28.7 (27.7 to 29.9)a	0.44 (0.33 to 0.58)a	2.38 (2.00 to 2.76)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg
Fasting plasma glucose < 6.0 mmol/l for detecting IGT												
1 (Holt 2003)	122	12.5 (0 to 68.5) a	6.3 (5.8 to 8.1) a	0.13 (0 to 0.75) a	14.00 (3.88 to 17.14) a	Very low	Retrospective cohort	Very seriousb,c,d,e,h	NA	Seriousf	Seriousi	Yesj
Fasting plasma glucose ≤ 6.0 mmol/l for detecting IGT												
1 (McClean 2010)	985	54.4 (45.8 to 62.9)a	16.9 (15.7 to 18)a	0.65 (0.54 to 0.77)a	2.70 (2.06 to 3.45)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg
Fasting plasma glucose < 6.1 mmol/l for detecting IGT												
1 (Agarwal 2004)	549	82.1 (73.2 to 89.0) a	15.5 (13.9 to 16.7) a	0.97 (0.85 to 1.07)a	1.15 (0.66 to 1.93)a	Very low	Retrospective cohort	Very seriousb,c,d,e,h	NA	Seriousf	No serious	Yesk

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Reichelt 2002)	117	76.9 (66.1to 87.2)a	14.1 (8.7to 19.2)a	0.90 (0.72 to 1.08)a	1.64 (0.67 to 3.91)a	Very low	Prospective cohort (case-cohort)	Very seriousb,c,d,e,h	NA	Seriousf	No serious	Yesl
Fasting plasma glucose < 7.0 mmol/l for detecting IGT												
1 (McClean 2010)	985	99.6 (95.4 to 100)a	9.7 (9.1 to 9.7)a	1.10 (1.05 to 1.11)a	0.05 (0 to 0.50)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg
1 (Holt 2003)	122	87.5 (43.3 to 100) a	2.1 (0.6 to 2.5) a	0.89 (0.44 to 1.03) a	6.00 (0 to 92.85) a	Very low	Retrospective cohort	Very seriousb,c,d,e,h	NA	Seriousf	Seriousi	Yesj
1 (Agarwal 2004)	549	99.4 (94.2 to 100) a	7.8 (6.9 to 7.9) a	1.08 (1.01 to 1.09)a	0.08 (0 to 0.84)a	Very low	Retrospective cohort	Very seriousb,c,d,e,h	NA	Seriousf	No serious	Yesk
1 (Reichelt 2002)	117	98.8 (90.6 to 100)a	10.8 (6.6 to 11.4)a	1.11 (0.97 to 1.13)a	0.12 (0.00 to 1.43)a	Very low	Prospective cohort (case-cohort)	Very seriousb,c,d,e,h	NA	Seriousf	No serious	Yesl

IGT impaired glucose tolerance, NA not applicable, NC not calculable

a Calculated by the NCC-WCH technical team from data reported in the article
b The selection criteria were not clearly reported
c The reference standard was not independent of the index test
d Unclear whether index test results were interpreted without knowledge of the results of the reference standard
e Unclear whether reference standard results were interpreted without knowledge of the results of the index test
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Country: UK, Ethnicity of population: South Asian-Pakistani, Bangladeshi or Indian (71%), White European (26%), not reported (4%)
h Some clinical data available when the test is used in practice were not available when test results were interpreted
I Confidence interval for sensitivity was wider than 40 percentage points
j Country: UK, Ethnicity of population: Caucasian (86%), Asian (14%)
k Country: United Arab Emirates (UAE), Ethnicity of population: Arabs (78.8%), Indian National (20.5%)
l Country: Brazil, Ethnicity of population: not reported

Table 71: GRADE profile for diagnostic test accuracy of fasting plasma glucose at various thresholds between 5.1mmol/l and 7.0mmol/l to detect diabetes postnatally in women who have had gestational diabetes, compared to the 75 g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
Fasting plasma glucose ≥ 5.1 mmol/l for detecting diabetes												
1 (McClean 2010)	985	99.1 (94.3 to 100)a	49.2 (48.6 to 49.3)a	1.95 (1.84 to 1.97)a	0.02 (0.00 to 0.12)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg
Fasting plasma glucose ≥ 5.6 mmol/l for detecting diabetes												
1 (McClean 2010)	985	97.2 (91.7 to 99.3)a	74.7 (74.0 to 74.9)a	3.84 (3.53 to 3.96)a	0.04 (0.01 to 0.11)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg
1 (Myers 2014)	629	76	91	3.8 a	0.03 a	Very low	Retrospective cohort	Very serious,c,d,e	NA	Seriousf	Serioust	Yesh
Fasting plasma glucose ≥ 6.0 mmol/l for detecting diabetes												
1 (Holt 2003)	122	87.5 (31.5 to 100)a	93.8 (91.9 to 94.2)a	14.00 (3.88 to 17.14)a	0.13 (0 to 0.75)a	Very low	Retrospective cohort	Very seriousb,c,d,e,i	NA	Seriousf	Seriousij	Yesk
1 (Joseph 2013)	148	94.4	90.4	9.8 a	0.06 a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	Serioust	Yesl
Fasting plasma glucose ≥ 6.1 mmol/l for detecting diabetes												
1 (McClean 2010)	985	89.9 (82.9 to 94.5)a	88.5 (87.6 to 89.0)a	7.80 (6.68 to 8.63)a	0.11 (0.06 to 0.20)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Reichelt 2002)	117	88.9 (53.2 to 99.4)a	88.9 (85.9 to 89.8)a	8.00 (3.78 to 9.71)a	0.13 (0.01 to 0.55)a	Very low	Prospective cohort (case-cohort)	Very seriousb,c,d,e,h	NA	Seriousf	Seriousi	Yesm
1 (Myers 2014)	629	90	91	10.4 a	0.11 a	Very low	Retrospective cohort	Very serious,c,d,e	NA	Seriousf	Serioust	Yesh
1 (Agarwal 2004)	549	84.0 (71.7 to 92.1)a	91.0 (89.7 to 91.8)a	9.32 (7.00 to 11.23)a	0.18 (0.09 to 0.32)a	Very low	Retrospective cohort	Very serious b,c,d,e,h	NA	Seriousf	No serious	Yesn
Fasting plasma glucose ≥ 7.0 mmol/l for detecting diabetes												
1 (Ferrara 2009)	5524	25.0 (7.3 to 52.4)a	NC	NC	NC	Very low	Retrospective cohort	Very serious,c,d,e,o	NA	Seriousf	Very serious p	Yesq
1 (Conway 1999)	179	85.7 (57.2 to 98.2)a	NC	NC	NC	Very low	Retrospective cohort	Very serious b,c,d,e,h	NA	Seriousf	Very serious p	Yesr
1 (Agarwal 2004)	549	72.0 (64.4 to 72.0)a	100 (NC)s	> 1000 (NC)	0.28 (0.28 to 0.36)a	Very low	Retrospective cohort	Very seriousb,c,d,e,h	NA	Seriousf	Serioust	Yesn
1 (Hunt 2008)	400	30.8 (12.7 to 30.8)a	100 (NC)q	> 1000 (NC)	0.69 (0.69 to 0.88)a	Very low	Prospective cohort	Very seriousb,c,d,e,o	NA	Seriousf	Serioust	Yesu
1 (Kitzmiller 2007)	527	16.0 (6.5 to 16.0)a	100 (NC)q	> 1000 (NC)	0.84 (0.84 to 0.94)a	Very low	Retrospective cohort	Very serious b,c,d,e	NA	Seriousf	Serioust	Yesv
1 (Reinblatt 2006)	275	46.2 (33.3 to 46.2)a	100 (NC)q	> 1000 (NC)	0.54 (0.54 to 0.68)a	Very low	Retrospective cohort	Very seriousb,c,d,e,w	NA	Seriousf	Seriousr	Yesx

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (McClean 2010)	985	76.8 (72.8 to 77.3)a	99.9 (99.4 to 100)a	> 1000 (129.87 to > 1000)a	0.23 (0.23 to 0.27)a	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	No serious	Yesg
1 (Reichelt 2002)	117	88.9 (59.8 to 88.9)a	100 (NC)q	> 1000 (NC)	0.11 (0.11 to 0.41)a	Very low	Prospective cohort (case-cohort)	Very seriousb,c,d,e,h	NA	Seriousf	Seriousj	Yesm
1 (Kousta 1999)	165	75.0 (61.4 to 76.9)a	99.6 (97.1 to 100)a	211.50 (21.47 to > 1000)a	0.25 (0.23 to 0.40)a	Very low	Retrospective cohort	Very seriousc,d,e	NA	Seriousf	No serious	Yesy
1 (Holt 2003)	122	62.5 (17.0 to 75.0)a	99.6 (98.1 to 100)a	150.00 (8.81 to > 1000)a	0.38 (0.25 to 0.85)a	Very low	Retrospective cohort	Very seriousb,c,d,e,h	NA	Seriousf	Seriousj	Yesk
1 (Megia 2012)	364	58.3 (27.7 to 84.8)a	NC	NC	NC	Very low	Prospective cohort	Very serious b,c,d,e	NA	Seriousf	Very serious p	Yesx
1 (Myers 2014)	629	76	91	8.4	0.26	Very low	Retrospective cohort	Very serious,c,d,e	NA	Seriousf	Serioust	Yesh

NA not applicable, NC not calculable

a Calculated by the NCC-WCH technical team from data reported in the article
b The selection criteria were not clearly reported
c The reference standard was not independent of the index test
d Unclear whether index test results were interpreted without knowledge of the results of the reference standard
e Unclear whether reference standard results were interpreted without knowledge of the results of the index test
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Country: UK, Ethnicity of population: South Asian-Pakistani, Bangladeshi or Indian (71%), White European (26%), not reported (4%)
h Country: UK, Ethnicity of population: White (17%), Black (16.1%), Asian (40.7%), Other (26.3%)
I Some clinical data available when the test is used in practice were not available when test results were interpreted
j Confidence interval for sensitivity was wider than 40 percentage points
k Country: UK, Ethnicity of population: Caucasian (86%), Asian (14%)
l Country: UK, Ethnicity of population: Caucasian (90%), Asian (6%), Afro-Caribbean (2%), Southeast Asian (2%)

m Country: Brazil, Ethnicity of population: not reported
n Country: United Arab Emirates (UAE), Ethnicity of population: Arabs (78.8%), Indian National (20.5%)
o The whole sample or a random selection of the sample did not receive verification using the reference standard
p The difference between the upper and lower confidence limits is greater than 40 percentage points for sensitivity and the confidence interval for specificity could not be calculated
q Country: USA, Ethnicity of population: Non-Hispanic white (28%), African American (3.2%), Asian (31.3%), Hispanic (27.1%), Other (5.6%), Unknown (4.8%)
r Country: USA, Ethnicity of population: not reported
s The specificity was fixed at 100% as all the 2 hour 75g oral glucose tolerance tests (OGTTs) with negative test results (fasting plasma glucose (FPG) < 7.0mmol/l and 2 hour plasma glucose < 11.1mmol/l) will necessarily have an FPG < 7.0mmol/l which means it is not possible to have a false positive result. Specificity treated as 99.999% instead of 100% to calculate LR+
t Confidence interval for sensitivity and/or specificity could not be calculated
u Country: USA, Ethnicity of population: Mexican American (94%)
v Country: USA, Ethnicity of population: Asian Indian (15%), Far East Asian (18%), Southeast Asian (29%), Hispanic (18%), Non-Hispanic white-Caucasian: European, Russian or middle eastern origin (20%)
w The spectrum of participants was not representative of the women who will receive the test in practice
x Country: Canada, Ethnicity of population: not reported
y Country: UK, Ethnicity of population: European (35%), South Asian from India, Sri Lanka or Bangladesh (29%), Afro-Caribbean (17%), Other/mixed origin (19%)
z Country: Spain, Ethnicity of population: European (91.5%), Arabic (5.5%), Hispanic (1.6%), Others (1.4%)

Table 72: GRADE profile for diagnostic test accuracy of HbA1C at thresholds from 5.3% to 6.5% to detect diabetes postnatally in women who have had gestational diabetes, compared to the 75g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
HbA1C ≥ 5.3% for detecting diabetes												
1 (Megia 2012)	364	91.7 (NC)	72.4 (NC)	3.33 (NC)	0.11 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 5.4% for detecting diabetes												
1 (Megia 2012)	364	75.0 (NC)	82.7 (NC)	4.33 (NC)	0.30 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 5.5% for detecting diabetes												

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Megia 2012)	364	66.7 (NC)	88.1 (NC)	5.59 (NC)	0.38 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 5.6% for detecting diabetes												
1 (Megia 2012)	364	41.7 (NC)	92.1 (NC)	5.24 (NC)	0.63 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 5.7% for detecting diabetes												
1 (Megia 2012)	364	41.7 (NC)	96.3 (NC)	11.29 (NC)	0.61 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 5.8% for detecting diabetes												
1 (Megia 2012)	364	41.7 (NC)	98.9 (NC)	36.55 (NC)	0.59 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 5.9% for detecting diabetes												
1 (Megia 2012)	364	33.3 (NC)	100 (NC)	> 1000h (NC)	0.67 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 6.0% for detecting diabetes												
1 (Megia 2012)	364	25.0 (NC)	100 (NC)	> 1000h (NC)	0.75 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg
HbA1C ≥ 6.5% for detecting diabetes												

Number of studies	Number of women with postnatal test	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)	Positive likelihood ratio (95% confidence interval)	Negative likelihood ratio (95% confidence interval)	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Megia 2012)	364	16.7 (NC)	100 (NC)	> 1000h (NC)	0.83 (NC)	Very low	Prospective	Very seriousa,b,c,d	NA	Serious e	Very seriousf	Yesg

NA not applicable, NC not calculable

a The reference standard was not independent of the index test
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d The selection criteria were not clearly reported
e Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
f Confidence interval for both sensitivity and specificity could not be calculated
g Country: Spain, Ethnicity of population: European (91.5%), Arabic (5.5%), Hispanic (1.6%), Others (1.4%)
h Specificity treated as 99.999% instead of 100% to calculate LR+

Table 73: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a 75 g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – testing performed at 0-13 weeks

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Hunt 2008)	707	288	4-6 weeks	4.5% (13/288)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Holt 2003)	152	122	6 weeks	2.5% (3/122)	2.5% (3/122)	3.3% (4/122)	Very low	Retrospective cohort	Very seriousa,c,d,e,i	NA	Seriousf	Seriousg	Yesj
1 (McClean 2010)	1189	985	6 weeks	11.1% (109/985)	11.6% (114/985) [IGT and IFG: 5.3% (52/985)]	10.3% (101/985)	Very low	Retrospective cohort	Very seriousa,b,d,e	NA	Seriousf	Seriousg	Yesk
1 (Rivero 2008)	125	109	6 weeks	17.4% (19/109)	NR	NR	Very low	Prospective cohort	Very seriousc,d,e	NA	Seriousf	Seriousg	Yesl
1 (Saucedo 2012)	100	52	6 weeks	17.3% (9/52)	NR	NR	Very low	Prospective cohort	Very seriousc,d,e	NA	Seriousf	Seriousg	Yesm
1 (Joseph 2013)	258	147	6 weeks	5.4% (8/147)	14.2% (21/147)	15.6% (23/147)	Very low	Retrospective cohort	Very seriousa,c,d,e	NA	Seriousf	Seriousg	Yesn
1 (Katreddy)	408	203	6 weeks	3.5% (7/203)	NR	5.4% (11/203)	Very low	Retrospective cohort	Very seriousc,d,e	NA	Seriousf	Seriousg	Yeso
1 (Myers 2014)	NR	629	median 44 days (IQR 42-50)	4.8% (30/629)	NR	NR	Very low	Retrospective cohort	Very seriousc,d,e	NA	Seriousf	Seriousg	Yesp
1 (Agarwal 2004)	1641	549	4-8 weeks	9.1% (50/549)	15.3% (84/549)	5.5% (30/549)	Very low	Retrospective cohort	Very seriousa,c,d,e,i	NA	Seriousf	Seriousg	Yesq
1 (Jang 2003)	392	311	6-8 weeks	15.1% (47/311)	NR	NR	Very low	Prospective cohort	Very seriousc,d,e	NA	Seriousf	Seriousg	Yesr

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Lauenborg 2004)	753	481	2 months	35.6% (171/481)	IGT/IFG: 27.0% (130/481)	NR	Very low	Retrospective cohort	Very seriousc,d,e,i	NA	Seriousf	Seriousg	Yess
1 (Kwak 2013)	NR	843	2 months	12.5% (105/843)	NR	NR	Very low	Prospective cohort	Very seriousc,d,e	NA	Seriousf	Seriousg	Yest
1 (Ogonowski 2009)	855	318	5-9 weeks	1.3% (4/318)	NR	NR	Very low	Prospective cohort	Very seriousa,c,d,e	NA	Seriousf	Seriousg	Yesu
1 (Kerimoglu 2010)	78	10	6-12 weeks	50.0% (5/10)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,e,i	NA	Seriousf	Seriousg	Yesv
1 (Retnakaran 2009)	NR	284	3 months	3.2% (9/284)	NR	1.1% (3/284)	Very low	Prospective cohort	Very seriousa,c,d,e,i	NA	Seriousf	Seriousg	Yesw
1 (Conway 1999)	1017	179	4-13 weeks	7.8% (14/179)	NR	NR	Very low	Retrospective cohort	Very seriousa,c,d,e,i	NA	Seriousf	Seriousg	Yesx

NA not applicable, NR not reported, IFG impaired fasting glucose, IGT impaired glucose tolerance

a The selection criteria were not clearly reported
b The whole sample or a random selection of the sample did not receive verification using the reference standard
c The reference standard was not independent of the index test
d Unclear whether index test results were interpreted without knowledge of the results of the reference standard
e Unclear whether reference standard results were interpreted without knowledge of the results of the index test
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Total number of events less than 300 for each form of glucose intolerance
h Other considerations: Country: USA, Ethnicity of population: Mexican American (94%)
I Some clinical data available when the test is used in practice was not available when test results were interpreted
j Country: UK, Ethnicity of population: Caucasian (86%), Asian (14%)
k Country: UK, Ethnicity of population: South Asian-Pakistani, Bangladeshi or Indian (71%), White European (26%), not reported (4%)
l Country: Brazil, Ethnicity of population: NR

m Country: Mexico, Ethnicity of population: NR
n Country: UK Ethnicity of population: Caucasian (90%), Asian (6%), Afro-Caribbean (2%), Southeast Asian (2%)
o Country: UK Ethnicity of population: Caucasians (70%) and Other racial groups (Asian: 50, Afro-Caribbean: 2, others: 9)(30%)
p Country: UK Ethnicity of population: White (17%), Black (16.1%), Asian (40.7%), Other (26.3%)
q Country: United Arab Emirates (UAE), Ethnicity of population: Arabs (78.8%), Indian National (20.5%)
r Country: Korea, Ethnicity of population: Korean women
s Country: Denmark, Ethnicity of population: Danish population
t Country: Korea Ethnicity of population: Not reported
u Country: Poland, Ethnicity of population: Caucasian (100%)
v Country: Turkey, Ethnicity of population: NR
w Country: Canada, Ethnicity of population: White- In those with IGT by ADA only (85.7%), In those with GDM by ADA only (74.5%). Asian-In those with IGT by ADA only (6.1%), In those with GDM by ADA only (17.6%). Other-In those with IGT by ADA only (8.2%), In those with GDM by ADA only (7.8%)
x Country: USA, Ethnicity of population: NR

Table 74: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a fasting plasma glucose test applied using the World Health Organization 1999 diagnostic criteria – testing performed at 0-13 weeks

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Hunt 2008)	707	112	4-6 weeks	4.5% (5/112)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh
1 (Holt 2003)	152	122	6 weeks	1.6% (2/122)	NR	NR	Very low	Retrospective cohort	Very seriousa,c,d,e,i	NA	Seriousf	Seriousg	Yesj
1 (Lee 2008)	868	620	6 weeks	11.5% (71/620)	NR	NR	Very low	Retrospective case control	Very seriousa,c,d,e,k	NA	Seriousf	Seriousg	Yesl
1 (Agarwal 2004)	1641	549	4-8 weeks	6.6% (36/549)	NR	9.3% (51/549)	Very low	Retrospective cohort	Very seriousa,c,d,e,i	NA	Seriousf	Seriousg	Yesm

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Hossein-nezhad 2009)	114	98	6-12 weeks	8.1% (8/98)	NR	NR	Very low	Prospective cohort	Very seriousa,c,d,e	NA	Seriousf	Seriousg	Yesn
1 (Kerimoglu 2010)	78	27	6-12 weeks	7.4% (2/27)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,e,i	NA	Seriousf	Seriousg	Yeso

NA not applicable, NR not reported

a The selection criteria were not clearly reported
b The whole or random selection of the sample did not receive verification using the reference standard
c The reference standard was not independent of the index test
d Unclear whether index test results were interpreted without knowledge of the results of the reference standard
e Unclear whether reference standard results were interpreted without knowledge of the results of the index test
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Total number of events less than 300 for each form of glucose intolerance
h Country: USA, Ethnicity of population: Mexican American (94%)
I Some clinical data available when the test is used in practice was not available when test results were interpreted
j Country: UK, Ethnicity of population: Caucasian (86%), Asian (14%)
k Unclear whether all clinical data available when the test is used in practice was available when test results were interpreted
l Country: Korea Ethnicity of population: NR
m Country: United Arab Emirates (UAE), Ethnicity of population: Arabs (78.8%), Indian National (20.5%)
n Country: Iran Ethnicity of population: NR
o Country: Turkey, Ethnicity of population: NR

Table 75: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a fasting plasma glucose test or oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – testing performed at 0-13 weeks

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Lawrence 2010)	11825	2596	7 days to <6 weeks	0.6% (16/2596)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh
1 (Lawrence 2010)	11825	2728	6-12 weeks	1.0% (27/2728)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh

NA not applicable, NR not reported
a The whole sample or a random selection of the sample did not receive verification using the reference standard
b The reference standard was not independent of the index test
c Unclear whether index test results were interpreted without knowledge of the results of the reference standard
d Unclear whether reference standard results were interpreted without knowledge of the results of the index test
e Uninterpretable, indeterminate or intermediate test results were not reported
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Total number of events less than 300 for each form of glucose intolerance
h Country: USA Ethnicity of population: Hispanic (53%), Black (4%), Asian/Pacific Islander (22%), Other/unknown (1%), Non-Hispanic white (20%)

Table 76: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a 75 g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – testing performed at more than 13 weeks and up to 1 year

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Sauce	100	52	6 months	Cumulative incidence:32.7% (17/52)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesf

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
do 2012)													
1 (Aberg 2002)	315	229	1 year	9.2% (21/229)	NR	NR	Very low	Retrospective cohort	Very seriousa,c,g,h	NA	Seriousd	Seriouse	Yesi
1 (Saucedo 2012)	100	52	1 year	Cumulative incidence:48.1% (25/52)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesf
1 (Ekelund 2010)	174	123	1 year	12.2% (15/123)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesj

NA not applicable, NR not reported

a The reference standard was not independent of the index test
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
e Total number of events less than 300 for each form of glucose intolerance
f Country: Mexico, Ethnicity of population: NR
g The selection criteria were not clearly reported
h Some clinical data available when the test is used in practice was not available when test results were interpreted
I Country: Sweden, Ethnicity of population: NR
j Country: Sweden, Ethnicity of population: In those with NGT at 5 years postpartum 59% Swedish, in those with IGT-IFG at 5 years postpartum 26% Swedish, in those with Diabetes at 5 years postpartum 42% Swedish

Table 77: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a 75 g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – testing performed at more than 1 year

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Anderberg 2011)	298	160	1-2 years	10.6% (17/160)	23.8% (38/160)	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Seriouse	Seriousf	Yesg
1 (Ekelund 2010)	159	85	2 year	8.2% (7/85)	NR	NR	Very low	Prospective cohort	Very seriousb,c,d	NA	Seriouse	Seriousf	Yesh
1 (Xiang 2010)	NR	72	15-30 months	At a median follow-up of 72 (12-142) months: 43.1% (31/72)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d,i	NA	Seriouse	Seriousf	Yesj
1 Gingras 2013	215	178	At a mean 3.5 ± 1.9 years	18% (32/182)	NR	NR	Very low	Prospective cohort	Very seriousb,c,d	NA	Seriouse	Seriousf	Yesk
1 Kwak 2013	738	370	At a Median 49 months (IQR 30-82)	23.8% (88/370)	NR	NR	Very low	Prospective cohort	Very seriousb,c,d	NA	Seriousf	Seriousg	Yesm
1 (Krishnaveni 2007)	41	35	5 years	37.1% (13/35)	IGT/IFG: 31.4% (11/35)	NR	Very low	Prospective cohort	Very seriousb,c,d	NA	Seriouse	Seriousf	Yesm
1 (Ekelund 2010)	152	112	5 years	12.5% (14/112)	24.1% (27/112)	3.6% (4/112)	Very low	Prospective cohort	Very seriousb,c,d	NA	Seriouse	Seriousf	Yesh
1 (Vambergue 2008)	466	209	6 years	NR	13.4% (28/209)	NR	Very low	Prospective cohort	Very seriousa,b,c,d,o	NA	Seriouse	Seriousf	Yesp

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Jacob Reichelt 2002)	159	117	4-8 years	7.7% (9/117)	NR	NR	Very low	Prospective cohort (case-cohort)	Very seriousa,b,c,d,i	NA	Seriouse	Seriousf	Yesq
1 (Tam 2007)	134	67	7-10 years	9.0% (6/67)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d	NA	Seriouse	Seriousf	Yesr

NA not applicable, NR not reported, IFG impaired fasting glucose, IGT impaired glucose tolerance

a The selection criteria were not clearly reported
b The reference standard was not independent of the index test
c Unclear whether index test results were interpreted without knowledge of the results of the reference standard
d Unclear whether reference standard results were interpreted without knowledge of the results of the index test
e Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
f Total number of events less than 300 for each form of glucose intolerance
g Country: Sweden, Ethnicity of population: Swedish (58%), European except Swedish (16%), Non-European (27%)
h Country: Sweden, Ethnicity of population: In those with NGT at 5 years postpartum 59% Swedish, in those with IGT-IFG at 5 years postpartum 26% Swedish, in those with Diabetes at 5 years postpartum 42% Swedish.
I Some clinical data available when the test is used in practice was not available when test results were interpreted
j Country: USA, Ethnicity of population: All Hispanic women
k Country: Canada, Ethnicity of population: Non-Hispanic white (94.6%), Other (5.4%)
l Country: Korea Ethnicity of population: Not reported
m Country: India Ethnicity of population: NR
o The whole sample or a random selection of the sample did not receive verification using the reference standard
p Country: France, Ethnicity of population: In subjects with normal glucose tolerance at follow-up 95.4% French, in subjects with IFG at follow-up 85.7% French, in sujects with IGT at follow-up 72.1% French, in subjects with Diabetes at follow-up 75.8% French.
q Country: Brazil, Ethnicity of population: NR
r Country: Hong Kong, Ethnicity of population: All Chinese women

Table 78: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a fasting plasma glucose test applied using the World Health Organization 1999 diagnostic criteria – testing performed at more than 1 year

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Vambergue 2008)	466	295	6 years	18.0% (53/295)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh
1 (Jacob Reichelt 2002)	159	117	4-8 years	6.8% (8/117)	NR	NR	Very low	Prospective cohort	Very seriousa,c,d,e,i	NA	Seriousf	Seriousg	Yesj

NA not applicable, NR not reported
a The selection criteria were not clearly reported
b The whole sample or a random selection of the sample did not receive verification using the reference standard
c The reference standard was not independent of the index test
d Unclear whether index test results were interpreted without knowledge of the results of the reference standard
e Unclear whether reference standard results were interpreted without knowledge of the results of the index test
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Total number of events less than 300 for each form of glucose intolerance
h Country: France, Ethnicity of population: In subjects with normal glucose tolerance at follow-up 95.4% French, in subjects with IFG at follow-up 85.7% French, in subjects with IGT at follow-up 72.1% French, in subjects with Diabetes at follow-up 75.8% French
I Some clinical data available when the test is used in practice was not available when test results were interpreted
j Country: Brazil, Ethnicity of population: NR

Table 79: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a 75 g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – testing performed at more than one time interval

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limita-tions	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Saucedo 2012)	100	52	6 weeks	17.3% (9/52)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesf

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Saucedo 2012)	100	52	6 months	Cumulative incidence:32.7% (17/52)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesf
1 (Saucedo 2012)	100	52	1 year	Cumulative incidence:48.1% (25/52)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesf
1 (Ekelund 2010)	174	123	1 year	12.2% (15/123)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesg
1 (Ekelund 2010)	159	85	2 year	8.2% (7/85)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesg
1 (Ekelund 2010)	152	112	5 years	12.5% (14/112)	24.1% (27/112)	3.6% (4/112)	Very low	Prospective cohort	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesg
1 (Chew 2012)	342	170	1-5 years	8.8% (15/170)	15.9% (27/170)	NR	Very low	Cross sectional	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesh
1 (Chew 2012)	342	94	6-10 years	22.3% (21/94)	7.5% (7/94)	NR	Very low	Cross sectional	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesh
1 (Chew 2012)	342	78	11-15 years	21.8% (17/78)	10.3% (8/78)	NR	Very low	Cross sectional	Very seriousa,b,c	NA	Seriousd	Seriouse	Yesh

a The reference standard was not independent of the index test
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
d Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
eTotal number of events less than 300 for each form of glucose intolerance
f Country: Mexico, Ethnicity of population: NR
gCountry: Sweden, Ethnicity of population: NR

h Country: Malaysia Ethnicity of population: Not reported

Table 80: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a fasting plasma glucose or 75 g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – testing performed at more than one time interval

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Lawrence 2010)	11825	2596	7 days to <6 weeks	0.6% (16/2596)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh
1 (Lawrence 2010)	11825	2728	6-12 weeks	1.0% (27/2728)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh
1 (Lawrence 2010)	11825	533	>12 weeks to 6 months	4.3% (23/533)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh

a The reference standard was not independent of the index test
b Unclear whether index test results were interpreted without knowledge of the results of the reference standard
c Unclear whether reference standard results were interpreted without knowledge of the results of the index test
dThe whole sample or a random selection of the sample did not receive verification using the reference standard
e Uninterpretable, indeterminate or intermediate test results were not reported
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Total number of events less than 300 for each form of glucose intolerance
h Country: USA Ethnicity of population: Hispanic (53%), Black (4%), Asian/Pacific Islander (22%), Other/unknown (1%), Non-Hispanic white (20%)

Table 81: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a using a 75 g oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – timing of testing overlaps the predefined categories

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Schaefer-Graf 2002)	4041	1636	1-4 months	14.1% (230/1636)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d	NA	Serious e	Diabetes:Seriousf IGT/IFG: No serious	Yesg
1 (Rivas 2007)	169	117	2-4 months	18.8% (22/117)	NR	11.97% (14/117)	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Serious e	Seriousf	Yesh
1 (Kitzmiller 2007)	NR	527	6-21 weeks	4.7% (25/527)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d	NA	Serious e	Seriousf	YesI
1 (Buchanan 1998)	233	122	1-6 months	9.8% (12/122)	NR	NR	Very low	Prospective cohort	Very seriousb,c,d	NA	Serious e	Seriousf	Yesj
1 (Reinblatt 2006)	1350	275	6 weeks to 6 months	9.5% (26/275)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d,k	NA	Serious e	Seriousf	Yesl
1 (Albareda 2003)	982	696	6 weeks or after cessation of breast feeding, whichever occurred later.	At 6 years: 5.6% (39/696)	At 6 years: 8.8% (61/696)	At 6 years: 3.6% (25/696)	Very low	Retrospective cohort	Very seriousa,b,c,d	NA	Serious e	Seriousf	Yesm

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
				At 11 years: 13.8% (NR/NR)	NR	NR	Very low	Retrospective cohort	Very seriousa,b,c,d	NA	Serious e	Seriousf	Yesm
1 (Pallardo 2003)	1350	838	3-6 months	3.6% (30/838)	NR	7.8% (65/838)	Very low	Prospective cohort	Very seriousa,b,c,d,n	NA	Serious e	Seriousf	Yeso
1 (Noussitou 2005)	159	74	6.4-45 weeks	10.8% (8/74)	16.2% (12/74)	NR	Very low	Retrospective cohort	Very seriousb,c,d	NA	Serious e	Seriousf	Yesp
1 (Schaefer-Graf 2009)	1184	605	13 weeks (median), within 1 year	5.5% (33/605)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Serious e	Seriousf	Yesq
1 (Megia 2012)	NR	364	Within 1 year, 6 weeks-3 months n=260 (71%) 4-6 months n=69 (19%) 7 months	3.3% (12/364)	NR [IGT, IFG or both: 24.5% (89/364)]	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Serious e	Seriousf	Yesr

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
			-1 year n=35 (10%)										
1 (Lin 2005)	235	127	1-19 months	13.4% (17/127)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Serious	Seriousf	Yess
1 (Katon 2012)	536	277	3-111 weeks	5.4% (15/277)	NR	NR	Very low	Retrospective cohort	Very seriousb,c,d	NA	Serious	Seriousf	Yest
1 (Kim 2011)	NR	54	6 weeks-36 months	9.3% (5/54)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Serious	Seriousf	Yesu
1 (Kousta 1999)	192	165	1-86 months	15.2% (25/165)	29.7% (49/165)	4.2% (7/165)	Very low	Retrospective cohort	Very seriousb,c,d	NA	Serious	Seriousf	Yesv
1 (Malinowska-Polubiec 2012)	NR	155	6 months-10 years	14.8% (23/155)	30.0% (31/155)	18.1% (28/155)	Very low	Retrospective case control	Very seriousb,c,d,n	NA	Serious	Seriousf	Yesw
1 (Lobner 2006)	NR	302x	9 months, 2, 5, 8 and 11 years	At 8 years: 52.7% (55/105)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	No serious	Seriousf	Yesy

NA not applicable, NR not reported, IFG impaired fasting glucose, IGT impaired glucose tolerance

a The selection criteria were not clearly reported
b The reference standard was not independent of the index test
c Unclear whether index test results were interpreted without knowledge of the results of the reference standard
d Unclear whether reference standard results were interpreted without knowledge of the results of the index test

e Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
f Total number of events less than 300 for each form of glucose intolerance.
g Country: USA, Ethnicity of population: NR
h Country: Venezuela, Ethnicity of population: NR
i Country: USA, Ethnicity of population: Asian Indian (15%), Far East Asian (18%), Southeast Asian (29%), Hispanic (18%), Non-Hispanic white, Caucasian: european, russian or middle eastern origin (20%)
j Country: USA, Ethnicity of population: All Latino women
k The spectrum of participants was not representative of the patients who will receive the test in practice
l Country: Canada, Ethnicity of population: NR
m Country: Spain, Ethnicity of population: All Spanish women
n Some clinical data available when the test is used in practice was not available when test results were interpreted
o Country: Spain, Ethnicity of population: All Caucasian women
p Country: Switzerland, Ethnicity of population: Caucasian (51%)
q Country: Germany, Ethnicity of population: Caucasian (100%)
r Country: Spain, Ethnicity of population: European (91.5%), Arabic (5.5%), Hispanic (1.6%), Others: 1.4%
s Country: Taiwan, Ethnicity of population: NR
t Country: USA, Ethnicity of population: White (38%), African-American (18%), Hispanic (32%), Asian Indian (10%), Other (2%)
u Country: USA, Ethnicity of population: Non-Hispanic white (73%), Asian (11%), African American (11%)
v Country: UK, Ethnicity of population: European (35%), South Asian from India, Pakistan, Sri Lanka or Bangladesh (29%), Afro-Caribbean (17%), Other/mixed origin (19%)
w Country: Poland, Ethnicity of population: White 100%
x 302 women participated in follow-up, cumulative drop-out rate was 21% by 5 years
yCountry: Germany, Ethnicity of population: NR

Table 82: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a fasting plasma glucose test applied using the World Health Organization 1999 diagnostic criteria – timing of testing overlaps the predefined categories

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Reinblatt 2006)	1350	275	6 weeks-6 months	4.4% (12/275)	NR	2.5% (7/275)	Very low	Retrospective cohort	Very seriousa,b,c,d,e	NA	Seriousf	Seriousg	Yesh

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Ferrara 2009)	14448	5524 (screened 1995-2006)	6 weeks-1 year	3.5% (191/5524)	NR	NR	Very low	Retrospective cohort	Very seriousc,d,e,i	NA	Serious f	Serious g	Yesj
1 (Ferrara 2009)	14448	564 (screened 1995-1997)	6 weeks-1 year	5.7% (32/564)	NR	NR	Very low	Retrospective cohort	Very seriousc,d,e,i	NA	Serious f	Serious g	Yesj
1 (Ferrara 2009)	14448	2381 (screened 2004-2006)	6 weeks-1 year	3.4% (80/2381)	NR	NR	Very low	Retrospective cohort	Very seriousc,d,e,i	NA	Serious f	Serious g	Yesj
1 (Costa 2000)	NR	120	2-12 months	NR	NR	3.3% (4/120)	Very low	Retrospective cohort	Very seriousb,c,d,e,k	NA	Serious f	Serious g	Yesl
1 (Megia 2012)	NR	364	Within the first year 6 weeks-3 months n=260 (71%) 4-6 months n=69 (19%) 7 months-1 year	1.9% (7/364)	NR	NR	Very low	Prospective cohort	Very seriousb,c,d,e	NA	Serious f	Serious g	Yesm

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
			n=35 (10%)										
1 (Kousta 1999)	192	165	1-86 months	11.5% (19/165)	NR	10.9% (18/165)	Very low	Retrospective cohort	Very seriousc,d,e	NA	Seriousf	Seriousg	Yesn

NA not applicable, NR not reported
a The spectrum of participants was not representative of the patients who will receive the test in practice
b The selection criteria were not clearly reported
c The reference standard was not independent of the index test
d Unclear whether index test results were interpreted without knowledge of the results of the reference standard
e Unclear whether reference standard results were interpreted without knowledge of the results of the index test
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Total number of events less than 300 for each form of glucose intolerance
h Country: Canada, Ethnicity of population: NR
i The whole or random selection of the sample did not receive verification using the reference standard
j Country: USA, Ethnicity of population: Non-Hispanic white (28%), African-American (3.2%), Asian (31.3%), Hispanic (27.1%), Other (5.6%), Unknown (4.8%)
k Some clinical data available when the test is used in practice was not available when test results were interpreted
l Country: Spain, Ethnicity of population: Caucasian (100%)
m Country: Spain, Ethnicity of population: European (91.5%), Arabic (5.5%), Hispanic (1.6%), Others (1.4)
n Country: UK, Ethnicity of population: European (35%), South Asian from India, Pakistan, Sri Lanka or Bangladesh (29%), Afro-Caribbean (17%), Other/mixed origin (19%)

Table 83: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a fasting plasma glucose test or oral glucose tolerance test applied using the World Health Organization 1999 diagnostic criteria – timing of testing overlaps the predefined categories

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
1 (Kwong 2009)	909	438a	6 weeks-6 months	3.2% (14/438)	NR	NR	Very low	Retrospective cohort	Very seriousb,c,d,e	NA	Seriousf	Seriousg	Yesh
1 (Lawrence 2010)	11825	533	>12 weeks to 6 months	4.3% (23/533)	NR	NR	Very low	Retrospective cohort	Very seriousc,d,e,l,j	NA	Seriousf	Seriousg	Yesk
1 (Stasenko 2010)	745	251	<=6 months	2.0% (5/251)	NR	NR	Very low	Retrospective cohort	Very seriousb,c,d,e,l	NA	Seriousf	Seriousg	Yesm

NA not applicable, NR not reported
a 95% OGTT, 5% FPG
b The selection criteria were not clearly reported.
c The reference standard was not independent of the index test.
d Unclear whether index test results were interpreted without knowledge of the results of the reference standard.
e Unclear whether reference standard results were interpreted without knowledge of the results of the index test.
f Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
g Total number of events less than 300 for each form of glucose intolerance
h Country: Canada, Ethnicity of population: Caucasian (56.4%), Non-Caucasian (43.4%)
i The whole sample or a random selection of the sample did not receive verification using the reference standard
j Uninterpretable, indeterminate or intermediate test results were not reported
k Country: USA Ethnicity of population: Hispanic (53%), Black (4%), Asian/Pacific Islander (22%), Other/unknown (1%), Non-Hispanic white (20%)
l Unclear if the whole sample or a random selection of the sample received verification using the reference standard
m Country: USA Ethnicity of population: White (27%), African-American (7%), Latina (7%), Asian (59%)

Table 84: GRADE profile for incidence of glucose intolerance (diabetes, impaired glucose tolerance or impaired fasting glucose) detected postnatally in women who have had gestational diabetes using a HbA_{1C} test applied using the World Health Organization 1999 diagnostic criteria – timing of testing overlaps the predefined categories

Number of studies	Number of potential participants	Number of women with postnatal test	Timing of postnatal test	Incidence of diabetes	Incidence of impaired glucose tolerance	Incidence of impaired fasting glucose	Quality	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations
HbA_{1C} ≥5.6%													
1 (Megia 2012)	NR	364	Within the first year 6 weeks-3 months n=260 (71%) 4-6 months n=69 (19%) 7 months-1 year n=35 (10%)	0.5% (2/364)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Serious e	Serious f	Yesg
HbA_{1C} ≥5.7%													
1 (Kim 2011)	NR	54	6 weeks-36 months	46.3% (25/54)	NR	NR	Very low	Prospective cohort	Very seriousa,b,c,d	NA	Serious e	Serious f	Yesh

NA not applicable, NR not reported

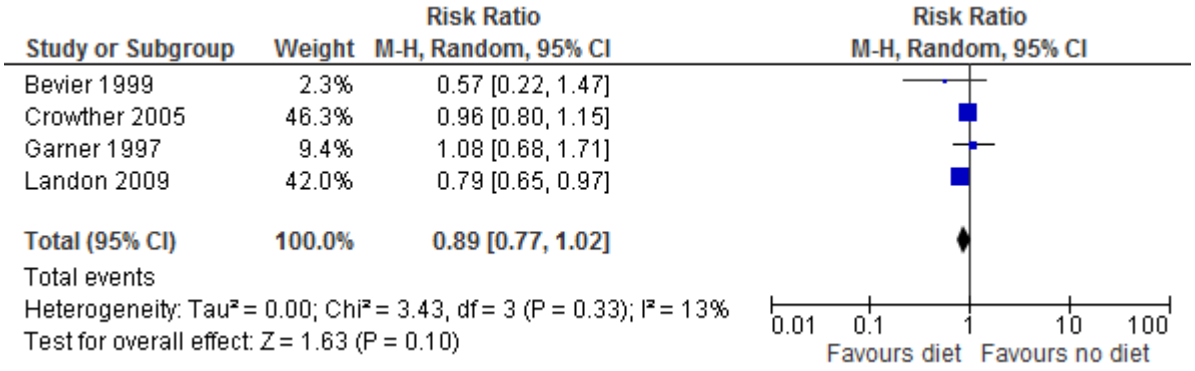
a The selection criteria were not clearly reported
b The reference standard was not independent of the index test
c Unclear whether index test results were interpreted without knowledge of the results of the reference standard
d Unclear whether reference standard results were interpreted without knowledge of the results of the index test
e Study did not document a return to euglycaemia in the immediate days following birth and before transfer to community care
f Total number of events less than 300 for each form of glucose intolerance
g Country: Spain, Ethnicity of population: European (91.5%), Arabic (5.5%), Hispanic (1.6%), Others (1.4%)
h Country: USA, Ethnicity of population: Non-Hispanic white (73%), Asian (11%), African American (11%

Appendix K: Compiled forest plots

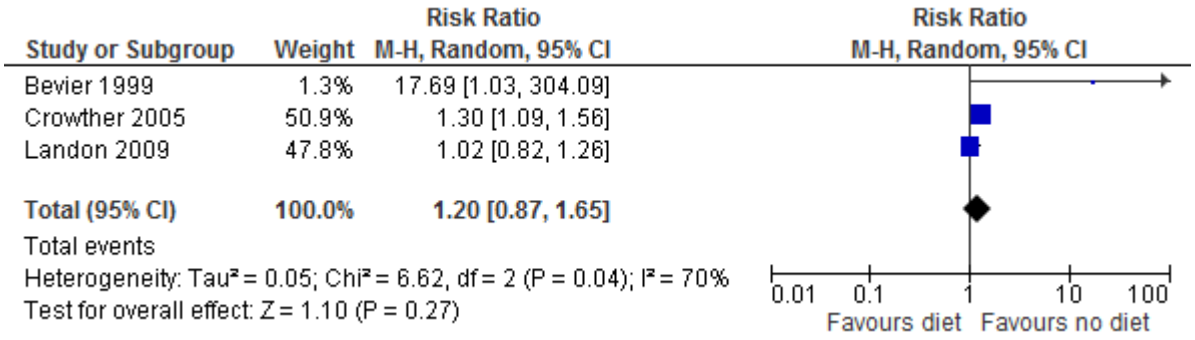
K.1 Interventions for gestational diabetes

K.1.1 Comparison: Diet versus standard care

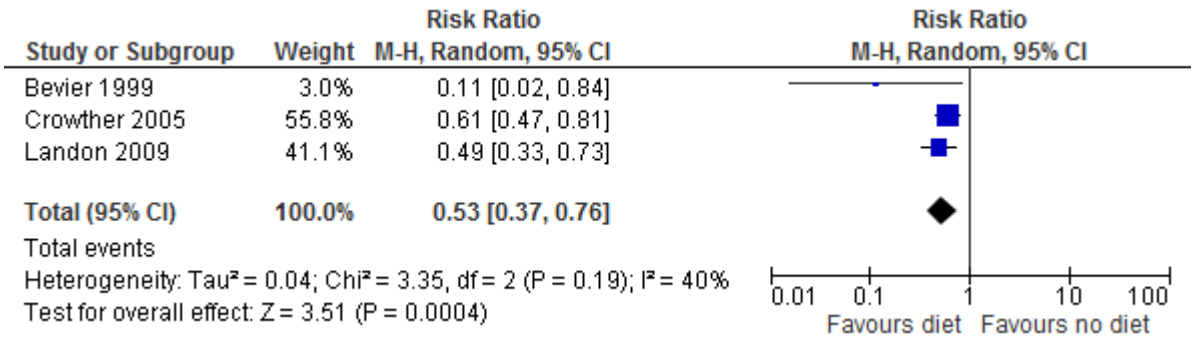
Outcome: Caesarean section



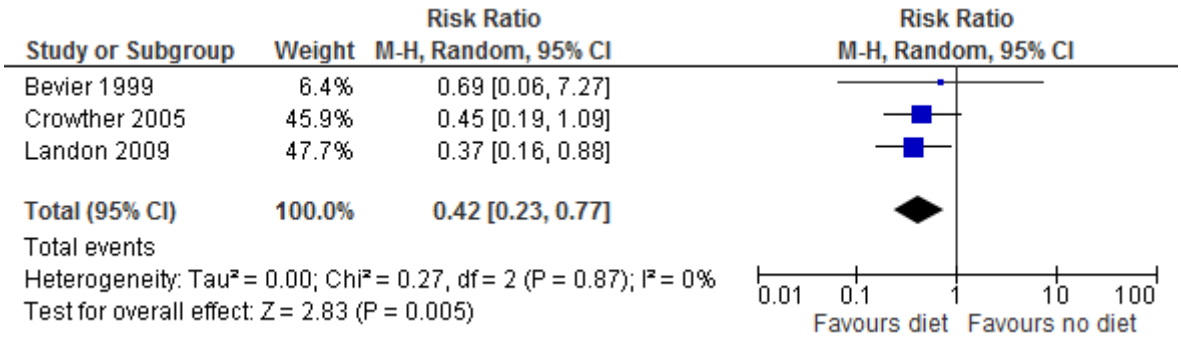
Outcome: Induction of labour



Outcome: Large for gestational age births

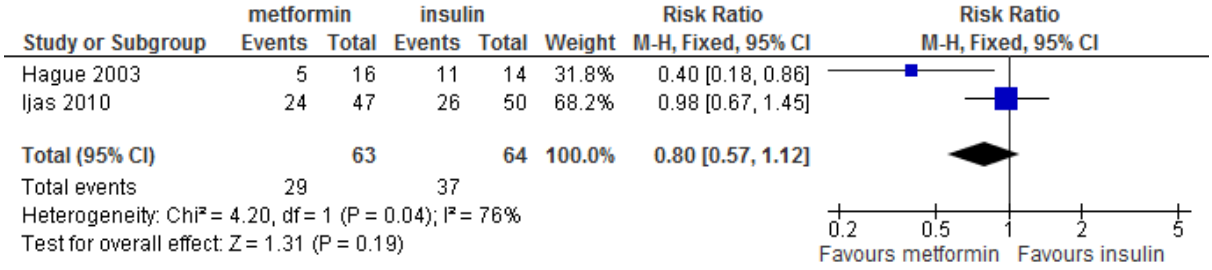


Outcome: Shoulder dystocia

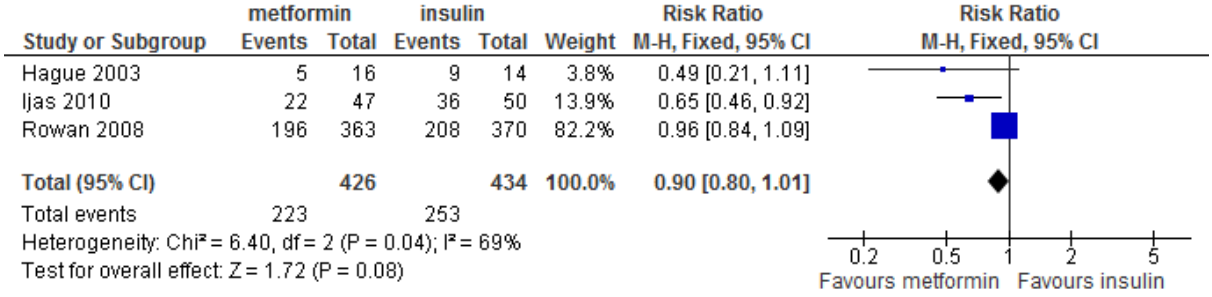


K.1.2 Comparison: Metformin versus insulin

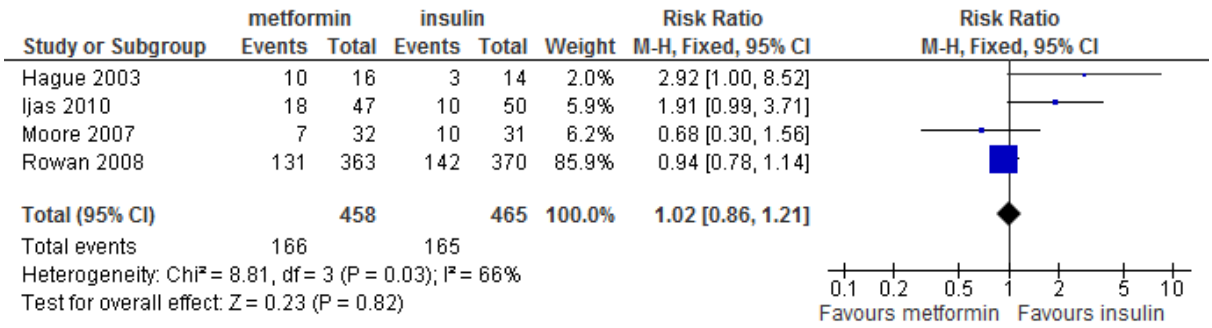
Outcome: Spontaneous vaginal birth



Outcome: Induction of labour



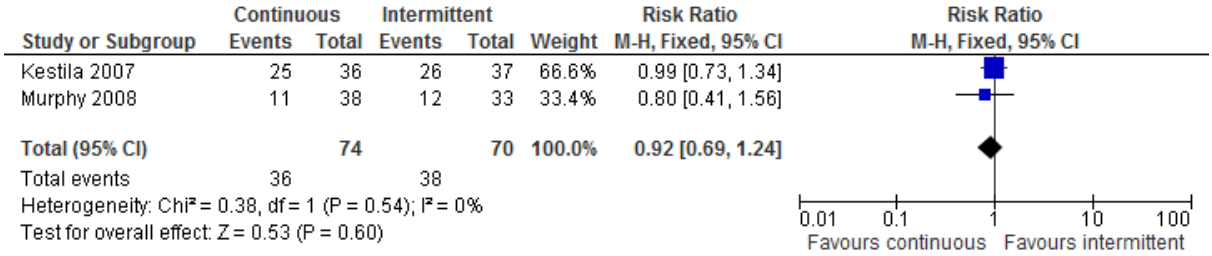
Outcome: Caesarean section



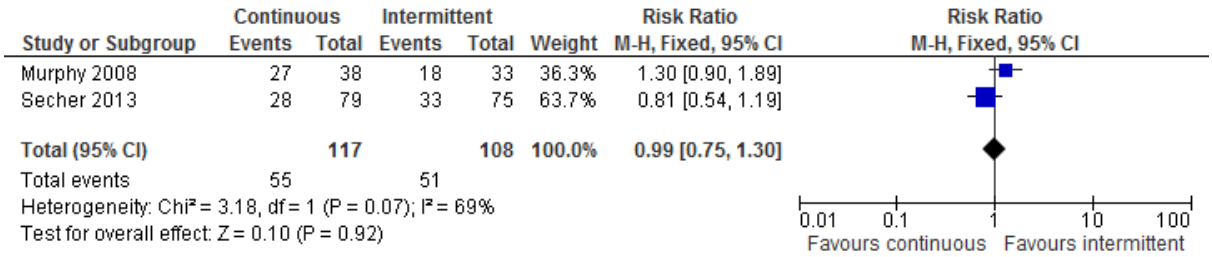
K.2 Continuous glucose monitoring

K.2.1 Comparison: Continuous versus intermittent monitoring

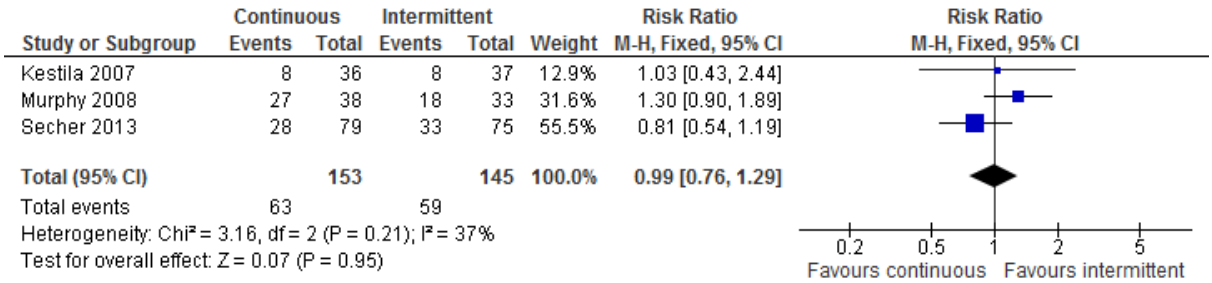
Outcome: Vaginal (unassisted/non-instrumental) birth



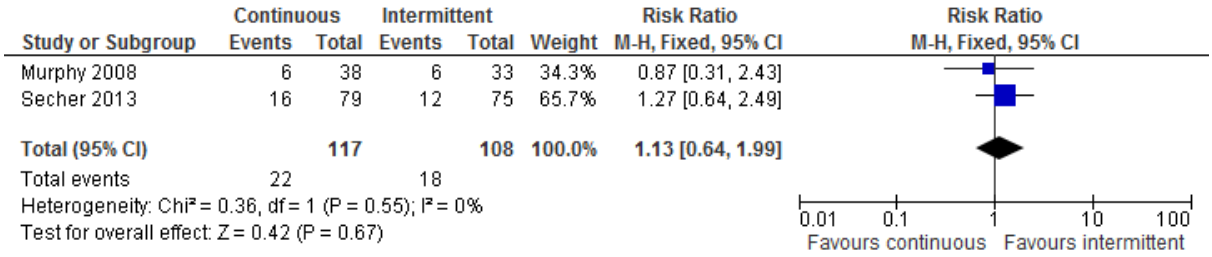
Outcome: Caesarean section



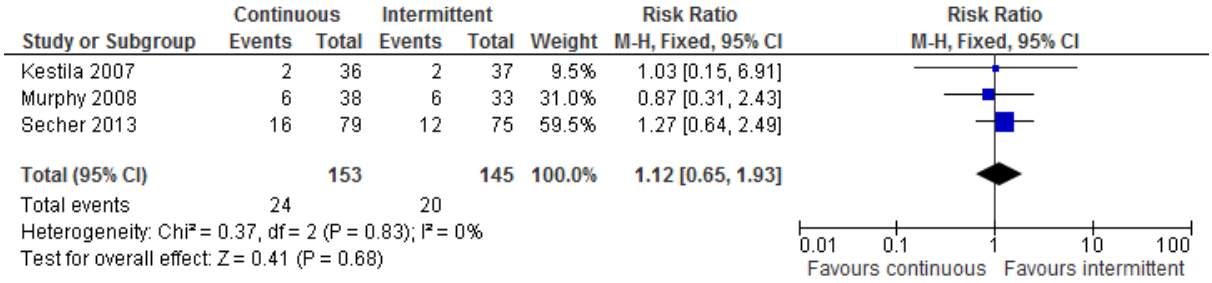
Outcome: Caesarean section



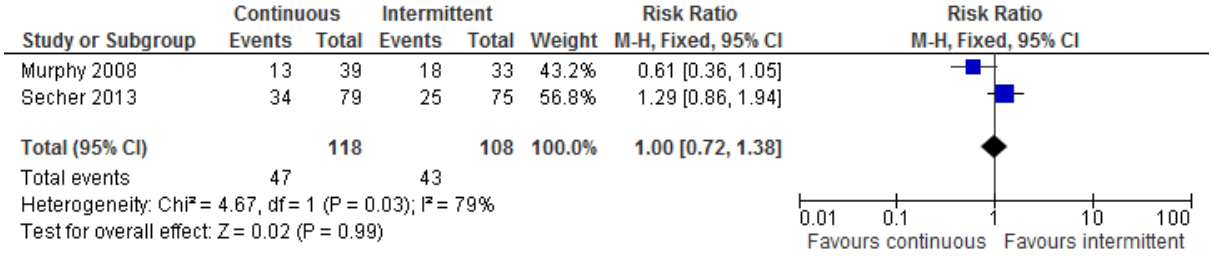
Outcome: Preterm birth (<37 weeks)



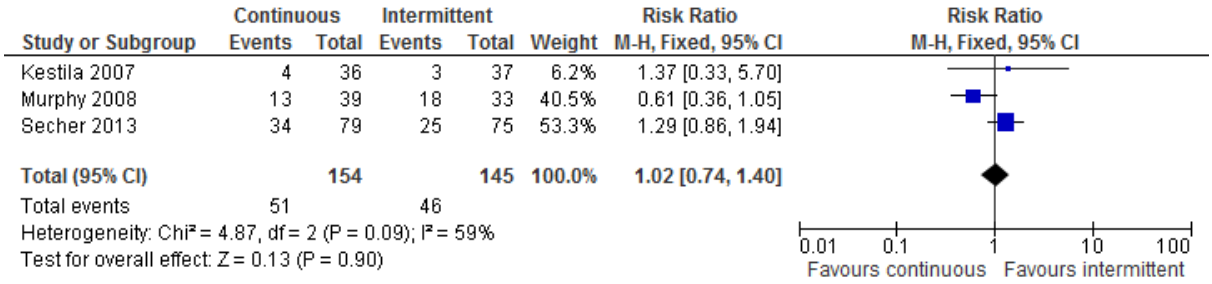
Outcome: Preterm birth (<37 weeks)



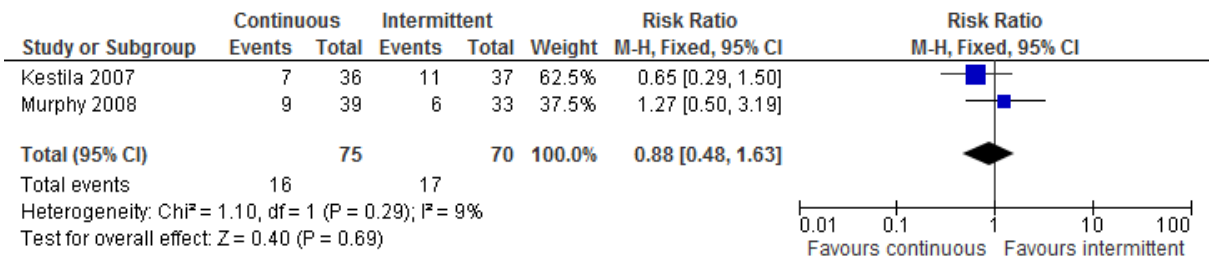
Outcome: Large for gestational age (≥ 90th Centile)



Outcome: : Large for gestational age (≥ 90th Centile)



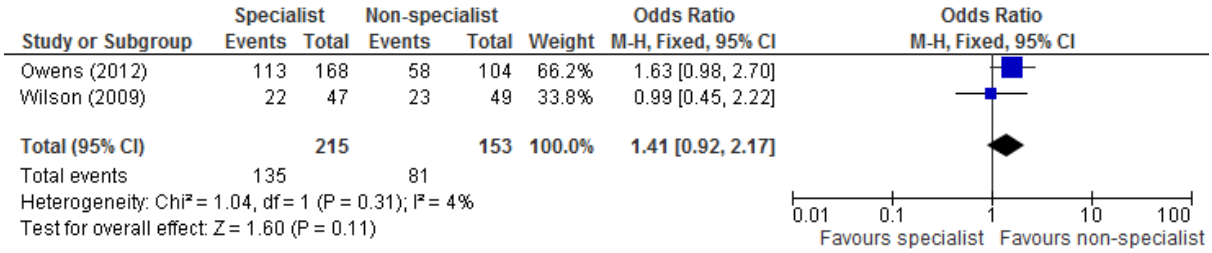
Outcome: Neonates transferred to NICU



K.3 Specialist Teams

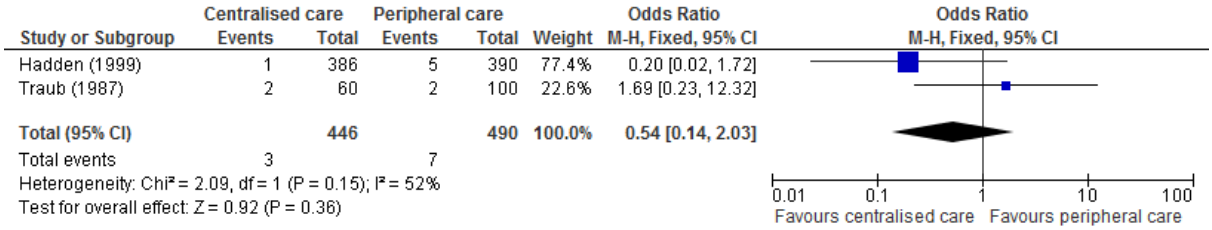
K.3.1 Comparison: Specialist team versus non-specialist team

Outcome: Vaginal (unassisted/non-instrumental) birth

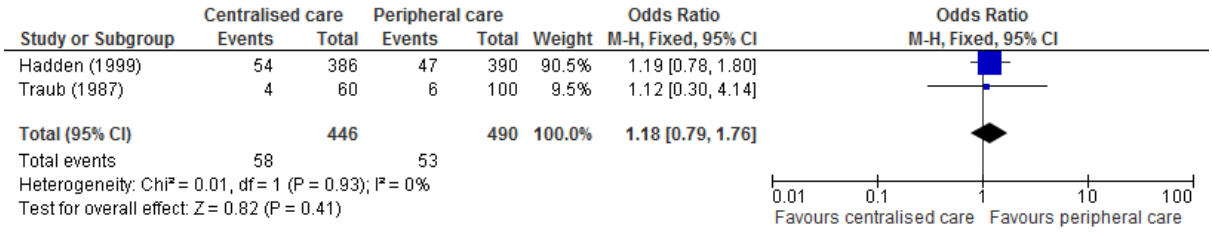


K.3.2 Comparison: Centralised vs peripheral care

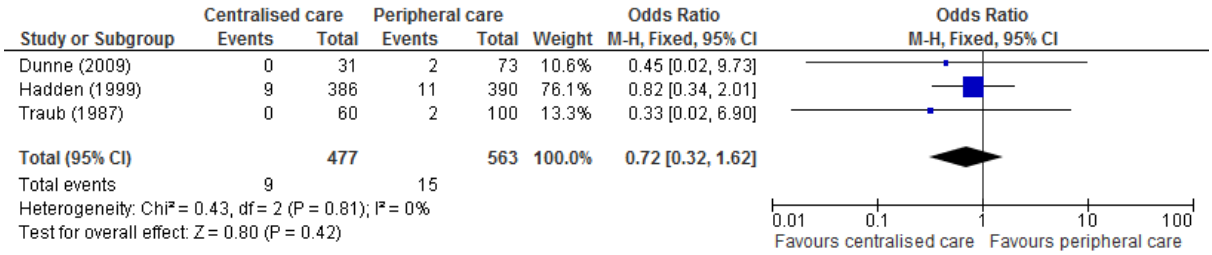
Outcome: Neonatal deaths



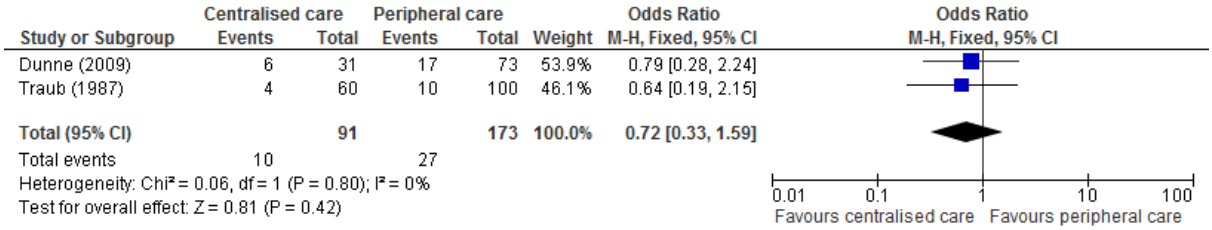
Outcome: Total fetal loss



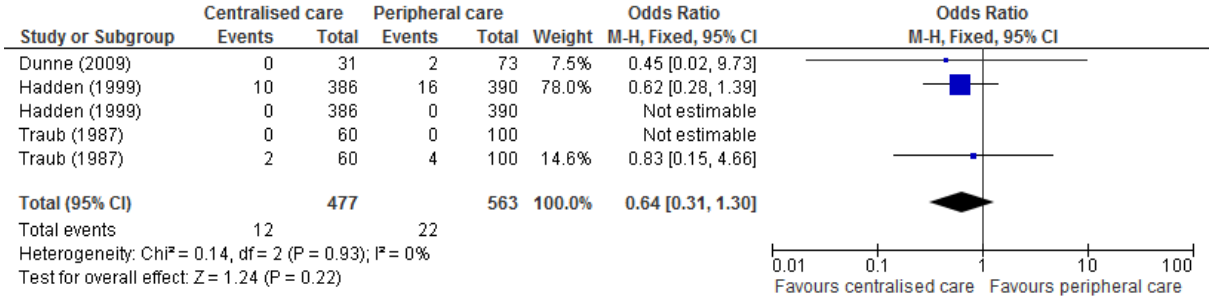
Outcome: Stillbirth



Outcome: Miscarriage



Outcome: Perinatal deaths (stillbirth and neonatal data)



Appendix L:Heath economics: List of studies excluded from the review of the literature

Excluded studies - 0. HEALTH ECONOMIC POPULATION (ONLY) SEARCH	
Study	**Reason for Exclusion**
Ali,F.M., Farah,N., O'Dwyer,V., O'Connor,C., Kennelly,M.M., Turner,M.J., The impact of new national guidelines on screening for gestational diabetes mellitus, Irish Medical Journal, 106, 57-59, 2013	Short-term resource impact on new screening guidelines for gestational diabetes mellitus in Ireland. No econ evaluation undertaken.
Banerjee,S., Tran,K., Li,H., Cimon,K., Daneman,D., Simpson,S., Campbell,K., Short-acting insulin analogues for diabetes mellitus: meta-analysis of clinical outcomes and assessment of cost-effectiveness (Structured abstract), Health Technology Assessment Database, -, 2014	Two CBAs and two cost comparisons identified, but not for gestational diabetes patients. No CUA identified in review.
Coster,S., Gulliford,M.C., Seed,P.T., Powrie,J.K., Swaminathan,R., Monitoring blood glucose control in diabetes mellitus: A systematic review, Health Technology Assessment, 4, i-84, 2000	No CEA/CUA
Cummins,E., Royle,P., Snaith,A., Greene,A., Robertson,L., McIntyre,L., Waugh,N., Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation (Structured abstract), Health Technology Assessment Database, -, 2014	Not population of interest
Franklin,B.E., Farland,M.Z., Thomas,J., McFarland,M.S., Ray,S.M., Byrd,D.C., Pharmacoeconomic Analysis of the Diabetes Initiative Program: A Pharmacist-Physician Collaborative Care Model, Annals of Pharmacotherapy, 47, 1627-1634, 2013	Pregnant patients excluded from study
Fryer,A.A., Shelley-Hitchin,A., Duff,C., Hodgson,E., Stirling,K., Hanna,F.W.F., Does HbA_{1c} have a role as a diagnostic tool in gestational diabetes mellitus (GDM)?, Practical Diabetes, 29, 124a-, 2012	No economic evaluation
Gillespie,P., O'Neill,C., Cullinan,J., Dunne,F., The effect of Gestational Diabetes Mellitus (GDM) on maternity care and costs in Ireland, Diabetologia, 55, S449-, 2012	Effect of GDM on mode of delivery
Gobl,C.S., Bozkurt,L., Rivic,P., Schernthaner,G., Weitgasser,R., Pacini,G., Mittlbock,M., Bancher-Todesca,D., Lechleitner,M., Kautzky-Willer,A., A two-step screening algorithm including fasting plasma glucose measurement and a risk estimation model is an accurate strategy for detecting gestational diabetes mellitus, Diabetologia, 55, 3173-3181, 2012	Clinical study, efficacy of screening; no cost analysis.
Health,Technology Assessment, A clinical and economic evaluation of screening and diagnostic tests to identify and treat women with gestational diabetes: association between maternal risk factors, glucose levels, and adverse outcomes (Project record), Health Technology Assessment Database, -, 2014	Work in progress. Due for publication December 2015

Excluded studies - 0. HEALTH ECONOMIC POPULATION (ONLY) SEARCH	
Lenoir-Wijnkoop,I., Nuijten,M., Uauy,R., Health economic model for assessing the impact of high birth weight on public health, Annals of Nutrition and Metabolism, 63, 399-, 2013	Conference abstract
Luoto,R., Kolu,P., Raitanen,J., Rissanen,P., Cost-effectiveness of lifestyle counselling in primary prevention of gestational diabetes, European Journal of Epidemiology, 28, S186-S187, 2013	Conference abstract
May,C.J., Nayak,U.A., Dawidziak,M., Churchill,D., Baskar,V., Viswanath,A.K., Additional utility of HbA_{1c} in postnatal glycaemic assessment in women with gestational diabetes, Diabetic Medicine, 28, 172-, 2011	Clinical study, screening for GDM; no cost analysis.
McIntyre,H.D., Diagnosing gestational diabetes mellitus: Rationed or rationally related to risk?, Diabetes Care, 36, 2879-2880, 2013	No economic evaluation undertaken
Murphy,A., Guilar,A., Donat,D., Nutrition education for women with newly diagnosed gestational diabetes mellitus: Small-group vs. individual counselling, Canadian Journal of Diabetes, 28, 147-151, 2004	No costs/cost effectiveness model
Myagerimath,R., Albert,S., Nwosu,E.C., Outcome of glucose tolerance test in a district general hospital, BJOG: An International Journal of Obstetrics and Gynaecology, 120, 134-, 2013	Conference presentation. No costs data presented
Noctor,E., Crowe,C., Avalos,G., Carmody,L., Wickham,B., O'Shea,P., Gaffney,G., Dunne,F., Comparison of fasting plasma glucose and HbA_{1c} for follow-up of women with previous gestational diabetes, Irish Journal of Medical Science, 181, S350-, 2012	No costs
Noctor,E., Crowe,C., Carmody,L.A., Wickham,B., Avalos,G., Gaffney,G., O'Shea,P., Dunne,F., ATLANTIC DIP: The prevalence of pre-diabetes/diabetes up to 5 years post partum in women with previous gestational diabetes along the Atlantic coast, Diabetologia, 55, S442-, 2012	No costs/economic analysis
Oostdam,N., Bosmans,J., Wouters,M.G.A.J., Eekhoff,E.M.W., van,MechelenW, van,PoppelM, Cost-effectiveness of an exercise program during pregnancy to prevent gestational diabetes: Results of an economic evaluation alongside a randomised controlled trial, BMC Pregnancy and Childbirth, 12 , 2012. Article Number, -, 2012	Wrong PICO.
Pelaez-Crisologo,Ma, Castillo-Torralba,M.G.A.G., Festin,M.R., Different techniques of blood glucose monitoring in women with gestational diabetes for improving maternal and infant health, Cochrane Database of Systematic Reviews, 2009. Article Number, -, 2009	Protocol; no CEA/CUA
Pereira Gray,D.J., Evans,P.H., Wright,C., Langley,P., The cost of diagnosing Type 2 diabetes mellitus by clinical opportunistic screening in general practice, Diabetic Medicine, 29, 863-868, 2012	Pregnant women excluded from study
Phaloprakarn,C., Tangjitgamol,S., Diagnosis of gestational diabetes mellitus using a modified 100 g oral glucose tolerance test, Journal of Perinatology, 28, 7-11, 2008	No analysis of costs
Racusin,D., Andrabi,S., Crawford,N., Sangi-Haghpeykar,H., Showalter,L., Sharma,S., Haymond,M., Aagaard,K., Twizzlers as a cost effective and a equivalent alternative to the glucola beverage in screening for	Conference abstract and not an economic evaluation

Excluded studies - 0. HEALTH ECONOMIC POPULATION (ONLY) SEARCH	
gestational diabetes (GDM), Reproductive Sciences, 19, 307A-, 2012	
Racusin,D., Antony,K., Showalter,L., Sharma,S., Haymond,M., Aagaard,K., Twizzlers as a cost effective and equivalent alternative to the glucola beverage in diabetes screening, American Journal of Obstetrics and Gynecology, 210, S131-, 2014	Conference abstract and not an economic evaluation
Racusin,D.A., Crawford,N.S., Andrabi,S., Suter,M.A., Sangi-Haghpeykar,H., Showalter,L., Sharma,S., Haymond,M., Aagaard,K.M., Twizzlers as a cost-effective and equivalent alternative to the glucola beverage in diabetes screening, Diabetes Care, 36, e169-e170, 2013	Not a full economic evaluation
Reel,M., Werner,E., Pettker,C., Funai,E., Thung,S., Screening for gestational diabetes with a 1 hour glucose challenge test: Is a 130mg/dL threshold more cost-effective than a 140mg/dL threshold?, American Journal of Obstetrics and Gynecology, 204, S117-S118, 2011	Cost-effectiveness for different thresholds of blood glucose levels, but thresholds not comparator of interest/relevant to question.
Salemi,J.L., Comins,M.M., Chandler,K., Mogos,M.F., Salihu,H.M., A practical approach for calculating reliable cost estimates from observational data: application to cost analyses in maternal and child health, Applied Health Economics and Health Policy, 11, 343-357, 2013	Costing of US healthcare for maternal and child health
Scott,D.A., Loveman,E., McIntyre,L., Waugh,N., Screening for gestational diabetes: a systematic review and economic evaluation. [256 refs], Health Technology Assessment (Winchester, England), 6, 1-161, 2002	Already included in previous guideline (2008).
Shivanath,M., Nayar,R., Emmerson,C., Loughney,A., Purvis,A., Fairs,A., Smart,J., Forbister,R., Will 'simple telehealth' help in the management of women with gestational diabetes?, BJOG: An International Journal of Obstetrics and Gynaecology, 120, 111-, 2013	Conference abstract
Todorova,K., Palaveev,O., Petkova,V.B., Stefanova,M., Dimitrova,Z., A pharmacoeconomical model for choice of a treatment for pregnant women with gestational diabetes, Acta Diabetologica, 44, 144-148, 2007	Cost analysis (Bulgaria) only
Uy,J., Fogelfeld,L., Guerra,Y., Cumulative clinical experience with use of insulin lispro: Critical appraisal, role in therapy, and patient considerations, Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy, 5, 1-10, 2012	Reviews previous cost-effectiveness studies
Waugh,N., Royle,P., Clar,C., Henderson,R., Cummins,E., Hadden,D., Lindsay,R., Pearson,D., Screening for hyperglycaemia in pregnancy: a rapid update for the National Screening Committee, Health Technology Assessment (Winchester, England), 14, 1-183, 2010	No economic evaluation; none of the identified studies were published after 2008, should have been/were included in previous guideline.
Zacharieva,S.Z., Todorova-Ananieva,K.N., Konova,E.I., Petkova,V.B., Guerguiev,S.R., Dimitrova,Z.D., Pharmacoeconomic analysis for the future treatment of diabetes mellitus after gestational diabetes, Diabetologia, 52, S409-, 2009	"prophylactic method/preventive programme": no details on test used

Appendix M: Health economics: List of studies included in the review of the literature

Avalos GE, Owens LA, Dunne F for the ATLANTIC DIP Collaborators. Applying current screening tools for gestational diabetes mellitus to a European population: is it time for change? Diabetes Care 2013;36: 3040–3044

Berger, H and Sermer, M. Counterpoint: selective screening for gestational diabetes mellitus. Diabetes Care 2009; 32: 1352-1354

Cavassini,A.C., Lima,S.A., Calderon,I.M., Rudge,M.V. Cost-benefit of hospitalization compared with outpatient care for pregnant women with pregestational and gestational diabetes or with mild hyperglycemia, in Brazi.l Sao Paulo Medical Journal; Revista Paulista de Medicina 2012 130:17-26

Culligan, PJ, Myers, JA, Goldberg, RP, Blackwell, L, Gohmann, SF and Abell TD. Elective cesarean section to prevent anal incontinence and brachial plexus injuries associated with macrosomia – a decision analysis. Int Urogynecol J Pelvic Floor Dysfunc 2005; 16: 19–28

Cundy, T, Ackermann, E and Ryan, EA. Gestational diabetes: new criteria may triple the prevalence but effect on outcome is unclear. BMJ 2014; 348: g1567

Gillespie, P, Cullinan, J, O'Neill, C, and Dunne, F for ATLANTIC DIP Collaborators. Modeling the independent effects of gestational diabetes mellitus on maternity care and costs. Diabetes Care 2013; 36: 1111-1116

Gillespie, P, O'Neill, C, Avalos,G, and Dunne, FP for ATLANTIC DIP Collaborators. New estimates of the costs of universal screening for gestational diabetes mellitus in Ireland. Irish Medical Journal 2012; 105: 15-18

Holt, RI, Coleman, MA and McCance, DR. The implications of the new International Association of Diabetes and Pregnancy Study Groups (IADPSG) diagnostic criteria for gestational diabetes. Diabet. Med. 2011: 28, 382–385

Kim,C, Herman,WH and Vijan,S. Efficacy and cost of postpartum screening strategies for diabetes among women with histories of gestational diabetes mellitus. Diabetes Care 2007; 30: 1102-1106

Kolu, P, Raitanen, J, Rissanen, P and Luoto, R. Cost-Effectiveness of lifestyle counselling as primary revention of gestational diabetes mellitus: findings from a cluster-randomised trial PLoS ONE 2013; 10:1371/journal.pone.0056392

Kolu,P, Raitanen, J, Rissanen, P and Luoto, R. Health care costs associated with gestational diabetes mellitus among high-risk women--results from a randomised trial. BMC Pregnancy and Childbirth 2012, 12:71

Marseille, E, Lohse, N, Jiwani, A, et al. The cost-effectiveness of gestational diabetes screening including prevention of type 2 diabetes: Application of a new model in India and Israel. Journal of Maternal-Fetal and Neonatal Medicine 2013; 26: 802-810

Metzger BE, Gabbe SG, Persson B, et al. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 2010; 33: 676-82.

Mission, J, Ohno, M, Cheng, Y and Caughey, A. Treating patients in HAPO glucose category 4 to improve maternal and neonatal outcomes: a cost effectiveness analysis. American Journal of Obstetrics and Gynecology 2013; 208: p.S122

Mission, J, Ohno, M, Yanit, K, Cheng, Y and Caughey, A. Gestational diabetes screening with the new IADPSG 2 hour glucose tolerance test vs the 1 hour glucose challenge test: a cost-effectiveness analysis. American Journal of Obstetrics and Gynecology 2012; 206: p.S126

Mission, J, Ohno, M, Yanit, K, Pilliod, R, Cheng, Y, and Caughey, AB. Treating patients in HAPO glucose category 5 to improve maternal and neonatal outcomes: a cost effectiveness analysis. American Journal of Obstetrics and Gynecology 2012; 206: p.S126

Mission, JF, Ohno, MS, Cheng, YW and Caughey, AB. Gestational diabetes screening with the new IADPSG guidelines: a cost-effectiveness analysis American Journal of Obstetrics and Gynecology 2012; 207: 326-326

Moses, RG and Cheung, NW. Point: Universal screening for gestational diabetes mellitus. Diabetes Care 2009; 32: 1349-1351

Moses, RG. New consensus criteria for GDM: problem solved or Pandora's box. Diabetes Care 2010; 33: 690-691

Moss, JR, Crowther, CA, Hiller, JE, Willson, KJ and Robinson, JS, the Australian Carbohydrate Intolerance Study in Pregnant Women Group. Costs and consequences of treatment for mild gestational diabetes mellitus - evaluation from the ACHOIS randomised trial. BMC Pregnancy and Childbirth 2007, 7:27

Munigoti, SP, Davies, R and Peters,J. Impact of adopting the IADPSG criteria for diagnosing gestationa;l diabetes. Diabetic Medicine 2011; 28:170-

Nayeri, U, Tabbah, S, Werner, E. et al. Labor induction at 38 weeks versus expectant management of insulin-requiring diabetics in pregnancy: a cost effective analysis. American Journal of Obstetrics and Gynecology 2014; 210: p.S230

Neuhauser D and Lewicki AM. What do we gain from the sixth stool guaiac? N Engl J Med. 1975; 293: 226-8.

Nguyen, N, Allen, A, Gorman, M. et al. Group prenatal care for women with pre-gestational type II diabetes mellitus: a cost-effectiveness analysis. American Journal of Obstetrics and Gynecology 2014; 210: p.S190

Ohno, MS, Sparks, TN, Cheng, YW and Caughey, AB. Treating mild gestational diabetes mellitus: a cost-effectiveness analysis. American Journal of Obstetrics and Gynecology 2011; 205: 282-287

Oostdam, N, Bosmans, J, Wouters, MG, et al. Cost-effectiveness of an exercise program during pregnancy to prevent gestational diabetes: results of an economic evaluation alongside a randomised controlled trial. BMC Pregnancy and Childbirth 2012, 12:64

O'Sullivan JB snd Mahan C. Criteria for oral glucose tolerance test in pregnancy. Diabetes 1964;13: 278-85.

Ratner RE. Prevention of Type 2 diabetes in women with previous gestational diabetes. Diabetes Care 2007; 30: S242-S245.

Round,JA, Jacklin, P, Fraser, RB, et al. Screening for gestational diabetes mellitus: cost-utility of different screening strategies based on a woman's individual risk of disease. Diabetologia 2011; 54: p.256-263

van Leeuwen, M, Vijgen, S, Opmeer, BC et al. Cost-effectiveness analysis of screening for GDM. American Journal of Obstetrics and Gynecology 2009; 201: p.S109

van Leeuwen, M, Louwerse, M, Opmeer, B et al. Glucose challenge test for detecting gestational diabetes: a systematic review. BJOG 2012; 119: 393–401.

Waugh, N, Pearson, D and Royle, P. Screening for hyperglycaemia in pregnancy: consensus and controversy. Best Practice & Research Clinical Endocrinology & Metabolism 2010; 24: 553–571

Werner, EF, Pettker, CM, Zuckerwise, L et al. Screening for gestational diabetes mellitus: are the criteria proposed by the international association of the Diabetes and Pregnancy Study Groups cost-effective? Diabetes Care 2012; 35: 529-535

Appendix N: Reference list for 2015 update

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Aberg,A.E., Jonsson,E.K., Eskilsson,I., Landin-Olsson,M., Frid,A.H., Predictive factors of developing diabetes mellitus in women with gestational diabetes, Acta Obstetricia et Gynecologica Scandinavica, 81, 11-16, 2002

Agarwal et al., 2004a

Agarwal,M.M., Punnose,J., Dhatt,G.S., Gestational diabetes: implications of variation in post-partum follow-up criteria, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 113, 149-153, 2004

Agarwal et al., 2005

Agarwal,M.M., Dhatt,G.S., Punnose,J., Koster,G., Gestational diabetes in a high-risk population: using the fasting plasma glucose to simplify the diagnostic algorithm, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 120, 39-44, 2005

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Agarwal,M.M., Dhatt,G.S., Punnose,J., Koster,G., Gestational diabetes: a reappraisal of HBA1c as a screening test, Acta Obstetricia et Gynecologica Scandinavica, 84, 1159-1163, 2005

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Agarwal,M.M., Dhatt,G.S., Punnose,J., Gestational diabetes: utility of fasting plasma glucose as a screening test depends on the diagnostic criteria, Diabetic Medicine, 23, 1319-1326, 2006

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Agarwal,M.M., Dhatt,G.S., Shah,S.M., Gestational diabetes mellitus: simplifying the international association of diabetes and pregnancy diagnostic algorithm using fasting plasma glucose, Diabetes Care, 33, 2018-2020, 2010

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Ahmed,S.B., Hovind,P., Parving,H.H., Rossing,P., Price,D.A., Laffel,L.M., Lansang,M.C., Stevanovic,R., Fisher,N.D., Hollenberg,N.K., Oral contraceptives, angiotensin-dependent renal vasoconstriction, and risk of diabetic nephropathy, Diabetes Care, 28, 1988-1994, 2005

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Albareda,M., de,Leiva A., Corcoy,R., Reproducibility of diabetes mellitus diagnosis (WHO 1999 criteria) in women, Acta Diabetologica, 41, 14-17, 2004

Alberico et al., 2010

Alberico,S., Businelli,C., Wiesenfeld,U., Erenbourg,A., Maso,G., Piccoli,M., Ronfani,L., Gestational diabetes and fetal growth acceleration: induction of labour versus expectant management, Minerva Ginecologica, 62, 533-539, 2010

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Anderberg,E., Landin-Olsson,M., Kalen,J., Frid,A., Ursing,D., Berntorp,K., Prevalence of impaired glucose tolerance and diabetes after gestational diabetes mellitus comparing different cut-off criteria for abnormal glucose tolerance during pregnancy, Acta Obstetricia et Gynecologica Scandinavica, 90, 1252-1258, 2011

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Asemi,Z., Samimi,M., Tabassi,Z., Esmaillzadeh,A., The effect of DASH diet on pregnancy outcomes in gestational diabetes: A randomized controlled clinical trial, European Journal of Clinical Nutrition, 68, 490-495, 2014

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Avalos,G.E., Owens,L.A., Dunne,F., Tlantic,D.I.P., Applying current screening tools for gestational diabetes mellitus to a European population: is it time for change?, Diabetes Care, 36, 3040-3044, 2013

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Avery,M.D., Leon,A.S., Kopher,R.A., Effects of a partially home-based exercise program for women with gestational diabetes, Obstetrics and Gynecology, 89, 10-15, 1997

Bancroft et al., 2000

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Barnes et al., 2013

Barnes,R.A., Edghill,N., Mackenzie,J., Holters,G., Ross,G.P., Jalaludin,B.B., Flack,J.R., Predictors of large and small for gestational age birthweight in offspring of women with gestational diabetes mellitus, Diabetic Medicine, 30, 1040-1046, 2013

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Bell,R., Glinianaia,S.V., Tennant,P.W.G., Bilous,R.W., Rankin,J., Peri-conception hyperglycaemia and nephropathy are associated with risk of congenital anomaly in women with pre-existing diabetes: A population-based cohort study, Diabetologia, 55, 936-947, 2012

Berger & Sermer, 2009

Berger,H., Sermer,M., Counterpoint: Selective screening for gestational diabetes mellitus, Diabetes Care, 32, 1352-1354, 2009

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Bertini,A.M., Silva,J.C., Taborda,W., Becker,F., Lemos Bebber,F.R., Zucco Viesi,J.M., Aquim,G., Engel,Ribeiro T., Perinatal outcomes and the use of oral hypoglycemic agents, Journal of Perinatal Medicine, 33, 519-523, 2005

Bevier et al., 1999

Bevier,W.C., Fischer,R., Jovanovic,L., Treatment of women with an abnormal glucose challenge test (but a normal oral glucose tolerance test) decreases the prevalence of macrosomia, American Journal of Perinatology, 16, 269-275, 1999

Bito et al., 2005

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Black et al., 2010

Black,M.H., Sacks,D.A., Xiang,A.H., Lawrence,J.M., Clinical outcomes of pregnancies complicated by mild gestational diabetes mellitus differ by combinations of abnormal oral glucose tolerance test values, Diabetes Care, 33, 2524-2530, 2010

Bonomo et al., 2005

Bonomo,M., Corica,D., Mion,E., Goncalves,D., Mottat,G., Merati,R., Ragusa,A., Morabito,A., Evaluating the therapeutic approach in pregnancies complicated by borderline glucose intolerance: A randomized clinical trial, Diabetic Medicine, 22, 1536-1541, 2005

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Buchanan,T.A., Xiang,A., Kjos,S.L., Lee,W.P., Trigo,E., Nader,I., Bergner,E.A., Palmer,J.P., Peters,R.K., Gestational diabetes: antepartum characteristics that predict postpartum glucose intolerance and type 2 diabetes in Latino women, Diabetes, 47, 1302-1310, 1998

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Cavassini et al., 2012

Cavassini,A.C., Lima,S.A., Calderon,I.M., Rudge,M.V., Cost-benefit of hospitalization compared with outpatient care for pregnant women with pregestational and gestational diabetes or with mild hyperglycemia, in Brazil, Sao Paulo Medical Journal = Revista Paulista de Medicina, 130, 17-26, 2012

Chew et al., 2012

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Appendix P: Deleted text from previous guideline

Antenatal care

5.3 Monitoring blood glucose and ketones during pregnancy

Description of the evidence

Two RCTs were identified that investigated preprandial versus postprandial monitoring of blood glucose during pregnancy.

The first study consisted of 61 women with type 1 diabetes who were randomly assigned at 16 weeks of gestation to either preprandial or postprandial blood glucose monitoring.[202] All women were on a four-times-daily basal bolus insulin regimen. The preprandial group was asked to monitor before breakfast and preprandially. The postprandial group was asked to monitor before breakfast and 1 hour after meals. CBG readings were measured by using a memory-based glucose reflectance meter. Insulin doses and glucose readings were also recorded by diary and brought to the clinic. The postprandial monitoring group had a significantly reduced incidence of pre-eclampsia (3% versus 21%, $P < 0.05$), greater success in achieving glycaemic control targets (55% versus 30%, $P < 0.001$) and smaller neonatal triceps skinfold thickness (4.5 ± 0.9 versus

5.1 ± 1.3, $P = 0.05$). [EL = 1++]

The second study consisted of 66 women with gestational diabetes who required insulin therapy.[155] The ethnic background of the sample was 85% Hispanic, 11% white and 4% black or Asian. Women were randomly assigned to monitor either preprandial or 1 hour postprandial blood glucose levels. The preprandial monitoring protocol required daily monitoring of fasting, preprandial and bedtime CBG concentrations. The postprandial protocol required daily monitoring of blood glucose concentrations before breakfast (fasting) and 1 hour after each meal. The women measured their blood glucose concentration using memory-based reflectance glucometers. All blood glucose values as well as insulin doses and dietary intake were recorded. There were 3/33 (9%) macrosomic babies in the postprandial monitoring group compared with 12/33 (36%) in the preprandial monitoring group ($P = 0.01$). Women in the postprandial group were significantly less likely to have a caesarean section for cephalopelvic disproportion (12% versus 36%, $P = 0.04$) or a baby with neonatal hypoglycaemia (3% versus 21%, $P =$

0.05). There were also fewer instances of shoulder dystocia (3% versus 18%) and third- or fourth-degree perineal laceration (9% versus 24%). [EL = 1++]

The ACHOIS trial randomly assigned 1000 women with gestational diabetes to either an intervention group or routine care.[153] The intervention was a package of care that included instructions on self-monitoring of blood glucose four times daily until blood glucose levels had been in the recommended range for 2 weeks (fasting glucose levels more than 3.5 mmol/litre and 5.5 mmol/litre or less, preprandial levels 5.5 mmol/litre or less and 2 hour postprandial levels

7.0 mmol/litre or less) followed by daily monitoring at rotating times. The package of care also included insulin therapy with the dose adjusted on the basis of glucose levels and individualised dietary advice from a qualified dietitian. The rate of serious perinatal outcomes among babieswas significantly lower in the intervention group (1% versus 4%, P = 0.01). The number needed to treat to prevent a serious outcome in a baby was 34. There was no significant difference between groups in maternal quality of life. [EL = 1++]

Three studies were identified that reported on the use of continuous blood glucose monitoring in women with diabetes. Two cohort studies were in women with type 1 diabetes[209,210] [EL = 2+] and one case series was in women with gestational diabetes.[211] [EL = 3] All three studies reported hyperglycaemic episodes undetected by self-monitoring of blood glucose. These episodes were usually due to the consumption of high carbohydrate food between meals and were undetected by self-monitoring protocols that required testing only after main meals. The three studies showed that examining 72 hour glucose profiles can help to identify patterns of glucose control, better target insulin treatment, assist in patient education and improve dietary adherence.

A retrospective study[120] examined the effect of an intensive diabetes management programme during pregnancy on women's long-term self-management behaviours and glycaemic control. There was a significant improvement in all diabetes self-management behaviours, including frequency of self-monitoring of blood glucose, frequency of insulin injections, and frequency and complexity of insulin dose adjustment from entry to the programme to the baby's birth. There was also a significant improvement in HbA_{1c} from entry to the baby's birth. [EL = 2−]

An RCT[212] investigated whether glycaemic control achieved by women using telephone modems for the transmission of self-monitored blood glucose data was better than that achieved by women managed in a similar fashion without modem connection. The study showed that telemedicine is a practical way of providing specialist care to pregnant women. [EL = 1+]

A systematic review of observational studies[213] investigated the risk of adverse pregnancy outcomes in pregnant women with diabetes in relation to glycaemic control. The review showed that an increase in adverse pregnancy outcomes in women with diabetes who had poor glycaemic control (congenital malformations, pooled OR 3.44, 95% CI 2.30 to 5.15; risk reduction of congenital malformation 0.39–0.59 for each 1% decrease in HbA_{1c}; miscarriage, pooled OR 3.23, 95% CI 1.64 to 6.36; perinatal mortality, pooled OR 3.03, 95% CI 1.87 to 4.92). [EL = 3]

No studies were identified that assessed how ketones should be monitored during pregnancy.

Existing guidance

The NSF for diabetes[20] recommends that 'women should be supported and encouraged to monitor their blood glucose regularly'.

Evidence statement

Two high quality RCTs have found better pregnancy outcomes for women with diabetes when blood glucose is monitored 1 hour after meals than when it is monitored before meals. One RCT found that a treatment package that included self-monitoring of blood glucose improved outcomes in women with gestational diabetes compared with routine obstetric care. Two cohort studies and a case series showed that self-monitoring of blood glucose undertaken only after main meals may not detect hyperglycaemia following the consumption of food between meals.

No studies were found on monitoring for ketones during pregnancy.

From evidence to recommendations

The evidence regarding the effectiveness of self-monitoring of blood glucose 1 hour after meals for improving pregnancy outcomes suggests that postprandial monitoring should not be restricted to main meals. The effectiveness of monitoring using meters supports the provision of such meters (see Section 3.5).

The GDG's view is that women with insulin-treated diabetes are vulnerable to nocturnal hypoglycaemia during pregnancy and that it is good clinical practice to undertake an additional test before going to bed at night.

Intrapartum care

Timing and mode of birth

Optimal timing of birth

An RCT (n = 200) from the USA compared the outcomes of birth after 38 weeks of gestation in women with insulin-requiring diabetes.[323] Those enrolled had gestational diabetes (n = 187) or pre-existing diabetes (n = 13). In women with pre-existing diabetes, the expectant management of pregnancy after 38 weeks of gestation did not reduce the incidence of caesarean section, but rather led to an increased prevalence of LGA babies (23% versus 10%) and shoulder dystocia (3% versus 0%). Given the risk associated with birth after 38 weeks of gestation, the study suggested that active induction of labour at 38 weeks of gestation should be considered in women with insulin-requiring diabetes, but if this is not pursued careful monitoring of fetal growth should be performed. [EL = 1+]

A case–control study (n = 260) from Israel compared inducing labour at 38–39 weeks of gestation with allowing pregnancy to continue naturally in women with type 1 diabetes.[331] There were no differences between the two groups at baseline. The rate of shoulder dystocia was 1.4% in the induction of labour group compared with 10.2% in the non-induced group who gave birth beyond 40 weeks of gestation (P < 0.05). No differences in caesarean section rates or birthweights of babies were found. The rate of shoulder dystocia was lower in the babies of women who had induction of labour at 38–39 weeks of gestation than in those without induction (1.4% versus 10.2%, P < 0.05). The study recommended elective induction of labour for women with insulin- requiring diabetes in order to reduce the rate of shoulder dystocia. [EL = 2−]

A case–control study (n = 3778) from Canada examined the relationship between gestational glucose intolerance (3 hour 100 g OGGT) and fetal outcomes.[318] The study identified four groups: negative gestational diabetes (n = 2940), false-positive gestational diabetes (n = 580), untreated borderline gestational diabetes (n = 115) and known

treated gestational diabetes (n = 143). There were no significant differences in gestational age at birth (39.8 ± 1.8 weeks for women without diabetes, 39.8 ± 1.8 for women with borderline diabetes and 39.3 ± 1.6, P > 0.20 for women with gestational diabetes). There were no differences among the groups in the rates of fetal distress or shoulder dystocia. [EL = 2+]

A cohort study (n = 317) from Israel conducted between 1993 and 1995 examined the effect of intensive management of gestational diabetes with diet in relation to birth timing and outcomes and compared the effect with that for women without diabetes.[324] The gestational age at birth for women with gestational diabetes was 39 ± 2.5 weeks and that of women without diabetes was 39 ± 1.5 weeks. [EL = 2+]

A case–control study (n = 428) from the USA examined the mean gestational ages at birth of babies of women with gestational diabetes and those in a control group without maternal diabetes.[332] The study found no significant difference between women with diabetes and the controls in gestational age at birth (38. 4 ± 2.8 weeks versus 39 ± 2.9 weeks), shoulder dystocia, Apgar scores, neonatal death or prolonged hospital stay after birth. The study suggests that if pregnancy is not interrupted then the gestational age at birth is similar between women with diabetes and those without diabetes, and neonatal outcomes do not differ between the two groups. [EL = 2−]

Current practice

The CEMACH enquiry reported that women with pre-existing diabetes had high rates of obstetric intervention with a 39% induction of labour rate compared with 21% in the general maternity population. The reasons given for induction of labour were that it was routine for women with diabetes (48.4%), general obstetric complications (13.9%), presumed fetal compromise (9.4%), large baby or polyhydramnios (8.5%) and diabetes complications (2.1%), and the remainder were other clinical reasons, preterm rupture of membranes, maternal request, or unknown or inadequately described.[2] [EL = 3–4]

The caesarean section rate was 67%, which is three times higher than the general maternity population (24%). The indications for elective and emergency caesarean section were presumed fetal compromise (28.3%), previous caesarean section (24.9%), general obstetric complication (14.2%), failure to progress in labour (13.9%), large baby (3.7%), diabetes complications (2.5%) and routine for diabetes (1.9%), and the remainder were due to other clinical reasons, maternal request, reason unknown or inadequately described. [EL = 3–4]

The preterm birth rate was 35.8% compared with 7.4% in the general maternity population. Of the total births 26.4% were iatrogenic and 9.4% were spontaneous preterm births (including preterm rupture of the membranes requiring induction) which is higher than in the general maternity population. The majority of iatrogenic preterm births were due to preterm caesarean sections, 21.9% of which were for previous caesarean section, large baby, maternal request or routine for maternal diabetes. [EL = 3–4]

The enquiry case–control study found that 8% (15/178) of women with poor pregnancy outcomes and 2% (4/202) of women with good pregnancy outcome had no details of discussion about timing and mode of birth in their medical records.[33] A lack of discussion was associated with poor pregnancy outcome (OR 4.0, 95% CI 1.2 to 12.7, adjusted for maternal age and deprivation). Additional case–control analysis showed an association with fetal or neonatal death, but not with fetal congenital anomaly, although it is important to note that women who did not have a discussion also gave birth at an earlier gestational age. The majority of women (65% of 382 women) were assessed as having optimal care during labour and birth and there was no association of sub-optimal care and pregnancy outcome. The most frequent issues

noted were poor management of maternal risks, inappropriate decisions relating to birth and inadequate fetal surveillance during labour or delay in acting on signs of fetal compromise. [EL = 3–4]

The condition of the baby at birth was reported by the CEMACH enquiry: 2.6% of live births had an Apgar score of less than 7 at 5 minutes. The corresponding figure for the general maternity population is 0.76%. [EL = 3–4]

The enquiry found that 6.9% (261/3808) of pregnancies led to *in utero* losses (there were also two early neonatal deaths, twins born live at 20 weeks of gestation who both died within 1 hour of birth). This is thought to be an underestimate of the actual number of pregnancies that ended.

Evidence statements

Five studies were considered in relation to optimal timing of birth in women with diabetes. An RCT involving women with insulin-requiring diabetes and a case–control study involving women with type 1 diabetes compared elective induction of labour at 38–39 weeks of gestation with expectant management. There were more LGA babies and cases of shoulder dystocia in the expectant management groups. Routine induction of labour at 38–39 weeks of gestation did not increase the rate of caesarean section. The remaining studies allowed comparison of gestational ages at birth between babies of women with diabetes and those of women without diabetes, but these none of these studies was specifically designed to address the optimal timing of birth in women with diabetes.

From evidence to recommendations

Routine induction of labour for women with diabetes at 38–39 weeks of gestation reduces the risk of stillbirth and shoulder dystocia without increasing the risk of caesarean section. However, there was insufficient evidence to determine the precise gestational age at which elective induction of labour should be offered. The GDG's discussions highlighted the need to balance the risk of fetal lung immaturity which may be associated with induction at 36–37 weeks of gestation against the risk of stillbirth associated with later induction. In the absence of evidence to determine whether elective birth through induction of labour, or elective caesarean section if indicated, should be offered before 38 weeks of gestation, the GDG's view was that elective birth should be offered after 38 completed weeks of gestation. No evidence was identified to suggest that the indications for elective caesarean section in preference to induction of labour in women with diabetes would be any different to those in women without diabetes.

Evidence shows that diabetes should not be considered a contraindication to attempting VBAC.

Postnatal care

Information and follow-up after birth

Follow up screening

A retrospective diagnostic study (n = 152) from the UK examined whether an FPG test at 6 weeks postpartum could be used to determine which women needed an OGTT.[408] The study compared FPG with OGTT (as the gold standard). A total of 122 women had results available for analysis. Using a cut-off for FPG of 6.0 mmol/litre, the sensitivity was 100% and the specificity was 94% for identifying those who had diabetes

compared to OGTT. The study concluded that FPG could be used to determine who should undergo an OGTT. [EL = 2]

A retrospective diagnostic study (n = 298) from Singapore examined whether the results of an antenatal OGTT could be used to predict which of those women who had been diagnosed with gestational diabetes would go on to develop diabetes, the aim being to avoid the need for a 6 week follow-up OGTT.[409] The study compared the antenatal OGTT results with the postnatal OGTT results. At a cut-off of 4.5 mmol/litre the sensitivity was 73.9% and specificity was 70.3%. For a 2 hour OGTT the cut-off was 10.5 mmol/litre with a sensitivity of 55.1% and a specificity of 84.7%. The authors concluded that antenatal OGTT results could not be used reliably to predict postnatal OGTT results. [EL = 3]

Existing guidance

The NSF for diabetes[20] recommends that services should be in place for women with pre-existing diabetes and those who have been diagnosed with gestational diabetes.

'Pregestational diabetes: Following delivery, all women should be offered the opportunity to be reviewed by the multidisciplinary team and to discuss the future self-management of their diabetes and the implications of breastfeeding. They should all be offered contraceptive advice and should all receive a six-week postpartum check.

Gestational diabetes: Six weeks after delivery, a 75 g oral glucose tolerance test should be undertaken to determine whether the woman:

- still has diabetes; or
- now has impaired glucose tolerance; or
- has returned to normal.

Women who are found still to have diabetes should be managed accordingly.

Those who are found still to have impaired glucose regulation and those who have returned to normal should be advised that they have an increased risk of developing:

- gestational diabetes in subsequent pregnancies; and
- type 2 diabetes later in life, a risk that can be reduced by eating a balanced diet, maintaining a healthy weight and increasing their physical activity levels. They should also be given advice about the symptoms and signs of diabetes.

Those who are found still to have impaired glucose regulation should also be offered a full assessment of their cardiovascular risk and appropriate follow-up.'

Evidence statement

Two diagnostic studies showed that follow-up of women with gestational diabetes was required to accurately identify ongoing disruption of glucose metabolism, suggesting a clinical need for postnatal testing of women who have been diagnosed with gestational diabetes.

There is evidence from a diagnostic study that FPG measurements have high sensitivity and specificity compared with OGTTs (the gold standard). They are also less costly than OGTTs and it is the GDG's view that using OGTTs instead of FPG measurements would not affect outcomes. Women who have been diagnosed with gestational diabetes should, therefore, be offered blood glucose testing using FPG, rather than an OGTT. This represents a change in clinical practice that will bring a cost saving to the NHS.

Research recommendations for information and follow-up after birth

Are there suitable long-term pharmacological interventions to be recommended postnatally for women who have been diagnosed with gestational diabetes to prevent the onset of type 2 diabetes?

Why this is important

Oral hypoglycaemic agents such rosiglitazone and metformin offer the possibility of pharmacological treatment for prevention of progression to type 2 diabetes in women who have been diagnosed with gestational diabetes. As yet there have been no clinical studies to investigate the effectiveness of oral hypoglycaemic agents in this context. Randomised controlled trials are needed to determine the clinical and cost-effectiveness of such treatments compared to diet and exercise.