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Tieu J, McPhee AJ, Crowther CA, Middleton P, Shepherd E

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[Intervention Review]

Screening for gestational diabetes mellitus based on different risk profiles and settings for improving maternal and infant health

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ABSTRACT

Background

Gestational diabetes mellitus (GDM) is a form of diabetes that occurs in pregnancy. Although GDM usually resolves following birth, it is associated with significant morbidities for mothers and their infants in the short and long term. There is strong evidence to support treatment for GDM. However, there is uncertainty as to whether or not screening all pregnant women for GDM will improve maternal and infant health and if so, the most appropriate setting for screening. This review updates a Cochrane Review, first published in 2010, and subsequently updated in 2014.

Objectives

To assess the effects of screening for gestational diabetes mellitus based on different risk profiles and settings on maternal and infant outcomes.

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register (31 January 2017), ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP) (14 June 2017), and reference lists of retrieved studies.

Selection criteria

We included randomised and quasi-randomised trials evaluating the effects of different protocols, guidelines or programmes for screening for GDM based on different risk profiles and settings, compared with the absence of screening, or compared with other protocols, guidelines or programmes for screening. We planned to include trials published as abstracts only and cluster-randomised trials, but we did not identify any. Cross-over trials are not eligible for inclusion in this review.

Data collection and analysis

Two review authors independently assessed study eligibility, extracted data and assessed the risk of bias of the included trials. We resolved disagreements through discussion or through consulting a third reviewer.

Main results

We included two trials that randomised 4523 women and their infants. Both trials were conducted in Ireland. One trial (which quasi-randomised 3742 women, and analysed 3152 women) compared universal screening versus risk factor-based screening, and one trial (which randomised 781 women, and analysed 690 women) compared primary care screening versus secondary care screening. We were not able to perform meta-analyses due to the different interventions and comparisons assessed.

Overall, there was moderate to high risk of bias due to one trial being quasi-randomised, inadequate blinding, and incomplete outcome data in both trials. We used GRADEpro GDT software to assess the quality of the evidence for selected outcomes for the mother and her child. Evidence was downgraded for study design limitations and imprecision of effect estimates.

Universal screening versus risk-factor screening (one trial)

Mother

More women were diagnosed with GDM in the universal screening group than in the risk-factor screening group (risk ratio (RR) 1.85, 95% confidence interval (CI) 1.12 to 3.04; participants = 3152; low-quality evidence). There were no data reported under this comparison for other maternal outcomes including hypertensive disorders of pregnancy, caesarean birth, perineal trauma, gestational weight gain, postnatal depression, and type 2 diabetes.

Child

Neonatal outcomes: large-for-gestational age, perinatal mortality, mortality or morbidity composite, hypoglycaemia; and childhood/adulthood outcomes: adiposity, type 2 diabetes, and neurosensory disability, were not reported under this comparison.

Primary care screening versus secondary care screening (one trial)

Mother

There was no clear difference between the primary care and secondary care screening groups for GDM (RR 0.91, 95% CI 0.50 to 1.66; participants = 690; low-quality evidence), hypertension (RR 1.41, 95% CI 0.77 to 2.59; participants = 690; low-quality evidence), pre-eclampsia (RR 0.80, 95% CI 0.36 to 1.78; participants = 690; low-quality evidence), or caesarean section birth (RR 1.00, 95% CI 0.80 to 1.27; participants = 690; low-quality evidence). There were no data reported for perineal trauma, gestational weight gain, postnatal depression, or type 2 diabetes.

Child

There was no clear difference between the primary care and secondary care screening groups for large-for-gestational age (RR 1.37, 95% CI 0.96 to 1.96; participants = 690; low-quality evidence), neonatal complications: composite outcome, including: hypoglycaemia, respiratory distress, need for phototherapy, birth trauma, shoulder dystocia, five minute Apgar less than seven at one or five minutes, prematurity (RR 0.99, 95% CI 0.57 to 1.71; participants = 690; low-quality evidence), or neonatal hypoglycaemia (RR 1.10, 95% CI 0.28 to 4.38; participants = 690; very low-quality evidence). There was one perinatal death in the primary care screening group and two in the secondary care screening group (RR 1.10, 95% CI 0.10 to 12.12; participants = 690; very low-quality evidence). There were no data for neurosensory disability, or childhood/adulthood adiposity or type 2 diabetes.

Authors' conclusions

There are insufficient randomised controlled trial data evaluating the effects of screening for GDM based on different risk profiles and settings on maternal and infant outcomes. Low-quality evidence suggests universal screening compared with risk factor-based screening leads to more women being diagnosed with GDM. Low to very low-quality evidence suggests no clear differences between primary care and secondary care screening, for outcomes: GDM, hypertension, pre-eclampsia, caesarean birth, large-for-gestational age, neonatal complications composite, and hypoglycaemia.

Further, high-quality randomised controlled trials are needed to assess the value of screening for GDM, which may compare different protocols, guidelines or programmes for screening (based on different risk profiles and settings), with the absence of screening, or with other protocols, guidelines or programmes. There is a need for future trials to be sufficiently powered to detect important differences in short- and long-term maternal and infant outcomes, such as those important outcomes pre-specified in this review. As only a proportion of women will be diagnosed with GDM in these trials, large sample sizes may be required.

PLAIN LANGUAGE SUMMARY

Screening women for gestational diabetes in pregnancy based on whether they are considered at risk, and in different settings

What is the issue?

What are the effects of screening all women for gestational diabetes mellitus (GDM), compared with only screening those who are 'at risk'? What are the effects of screening women for GDM in different settings (such as in the community versus the hospital)? This review updates a Cochrane Review, first published in 2010, and subsequently updated in 2014.

Why is this important?

GDM is a form of diabetes that can develop during pregnancy, and can increase the risk of complications for mothers and their babies. Women with GDM are more likely to develop pre-eclampsia (high blood pressure and protein in the urine) and require a caesarean section. For babies, potential problems include being large for gestational age (growing larger than they normally would), or having hypoglycaemia (low blood sugar) after birth. Although GDM usually resolves following birth, mothers and their babies are at risk of developing type 2 diabetes in the future.

Treating GDM can improve health outcomes. Women often do not know they have GDM. Screening to identify and treat GDM in pregnant women may therefore improve outcomes. The two main approaches are 'universal' where all women undergo screening; and 'selective' or 'risk factor'-based where only those women 'at risk' are screened. The risk factors for GDM include certain ethnicities, being older, overweight or obese, having had a previous large baby, or a family history of GDM or type 2 diabetes. It possible to screen for GDM in different settings, such as in the community (e.g. a general practice clinic) or in hospital. The ideal screening method for GDM that leads to the best health outcomes for mothers and their babies remains unclear.

What evidence did we find?

We searched for evidence (January 2017) and included two trials involving 4523 women and their babies. Both trials were conducted in Ireland and were at a moderate to high risk of bias. We could not combine the data from these trials because they looked at different interventions and comparisons. One compared 'universal' screening with 'risk factor'-based screening for GDM. The other compared screening women at their general practitioners' clinic (primary care) versus at the hospital (secondary care).

In one trial (with information available for 3152 women), more women were diagnosed with GDM in the group of women who received 'universal' screening, compared with the group of women with 'risk factor'-based screening (low-quality evidence). The trial did not report on outcomes relating to the mothers, including high blood pressure disorders of pregnancy, caesarean birth, perineal trauma, weight gain in pregnancy, postnatal depression, and type 2 diabetes. The trial did not report outcomes relating to the babies including being born large-for-gestational age, death (before or shortly after birth), death or a serious complication, hypoglycaemia, or adiposity, type 2 diabetes, and disability in childhood or adulthood.

In the second trial (with information available for 690 women), screening at the general practitioner's clinic versus the hospital did not make a clear difference to the number of women diagnosed with GDM (low-quality evidence), high blood pressure (low-quality evidence), pre-eclampsia (low-quality evidence), or the number who had a caesarean birth (low-quality evidence). This trial did not report perineal trauma, weight gain in pregnancy, postnatal depression, or type 2 diabetes. Screening at the general practitioner's clinic versus at the hospital did not make a clear difference to the number of babies born large-for-gestational age (low-quality evidence), death (before or shortly after birth), death or a serious complication (low-quality evidence), or hypoglycaemia (very low-quality evidence). Childhood or adulthood adiposity, type 2 diabetes, and disability were not reported in the trial.

What does this mean?

There is not enough evidence to guide us on effects of screening for GDM based on different risk profiles or settings on outcomes for women and their babies. Further large, well-designed, randomised controlled trials are required to assess important short- and long-term outcomes for mothers and their babies.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Universal screening versus risk-factor screening for gestational diabetes for improving maternal health

Universal screening versus risk-factor screening for gestational diabetes for improving maternal health

Patient or population: pregnant women, excluding women already diagnosed with GDM in this pregnancy and those with pre-existing diabetes mellitus

Setting: outpatient obstetric clinics at the National Maternity Hospital, Dublin, Ireland over a 24-month period (dates not specified)

Intervention: universal screening

Comparison: risk-factor screening

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with risk-factor screening	Risk with universal screening				
Gestational diabetes mellitus	Study population		RR 1.85 (1.12 to 3.04)	3152 (1 RCT)	⊕⊕○○ Low ^{1,2}	
	15 per 1000	27 per 1000 (16 to 44)				
Hypertensive disorders of pregnancy	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Caesarean birth	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Perineal trauma	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Gestational weight gain	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Postnatal depression	Study population		not estimable	(0 studies)	-	The included study did not report this outcome

	0 per 1000	0 per 1000 (0 to 0)				
Type 2 diabetes mellitus	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹Design limitations (-2): one study with serious design limitations.

²Imprecision (0): wide confidence interval but we did not downgrade the evidence due to the large sample size and high number of events.

Summary of findings 2. Universal screening versus risk-factor screening for gestational diabetes for improving infant health

Universal screening versus risk-factor screening for gestational diabetes for improving infant health

Patient or population: pregnant women, excluding women already diagnosed with GDM in this pregnancy and those with pre-existing diabetes mellitus

Setting: outpatient obstetric clinics at the National Maternity Hospital, Dublin, Ireland over a 24-month period (dates not specified)

Intervention: universal screening

Comparison: risk-factor screening

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with risk-factor screening	Risk with universal screening				
Large-for-gestational age	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Perinatal mortality	Study population		not estimable	(0 studies)	-	The included study did not report this outcome

	0 per 1000	0 per 1000 (0 to 0)				
Mortality or morbidity composite	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Hypoglycaemia	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Childhood/adulthood adiposity	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Childhood/adulthood type 2 diabetes mellitus	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Childhood/adulthood neurosensory disability	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Summary of findings 3. Primary care screening versus secondary care screening for gestational diabetes for improving maternal health

Primary care screening versus secondary care screening for gestational diabetes for improving maternal health

Patient or population: pregnant women, excluding women already diagnosed with GDM in this pregnancy and those with pre-existing diabetes mellitus

Setting: 3 public hospital sites in both rural and urban Ireland, between January 2013 and December 2013

Intervention: primary care screening

Comparison: secondary care screening

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with secondary care screening	Risk with primary care screening				
Gestational diabetes mellitus	Study population		RR 0.91 (0.50 to 1.66)	690 (1 RCT)	⊕⊕⊕⊖ Low ^{1,2}	
	72 per 1000	65 per 1000 (36 to 119)				
Hypertensive disorders of pregnancy: hypertension	Study population		RR 1.41 (0.77 to 2.59)	690 (1 RCT)	⊕⊕⊕⊖ Low ^{1,2}	
	53 per 1000	74 per 1000 (41 to 136)				
Hypertensive disorders of pregnancy: pre-eclampsia toxemia	Study population		RR 0.80 (0.36 to 1.78)	690 (1 RCT)	⊕⊕⊕⊖ Low ^{1,2}	
	46 per 1000	37 per 1000 (17 to 82)				
Caesarean birth	Study population		RR 1.00 (0.80 to 1.27)	690 (1 RCT)	⊕⊕⊕⊖ Low ^{1,2}	
	324 per 1000	324 per 1000 (259 to 412)				
Perineal trauma	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Gestational weight gain	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				

Postnatal depression	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Type 2 diabetes mellitus	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RCT:** randomised controlled trial; **RR:** Risk ratio

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹Design limitations (-1): one study with design limitations.

²Imprecision (-1): wide confidence interval crossing the line of no effect.

Summary of findings 4. Primary care screening versus secondary care screening for gestational diabetes for improving infant health

Primary care screening versus secondary care screening for gestational diabetes for improving infant health

Patient or population: pregnant women, excluding women already diagnosed with GDM in this pregnancy and those with pre-existing diabetes mellitus

Setting: 3 public hospital sites in both rural and urban Ireland, between January 2013 and December 2013

Intervention: primary care screening

Comparison: secondary care screening

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with secondary care screening	Risk with primary care screening				
Large-for-gestational age	Study population		RR 1.37 (0.96 to 1.96)	690 (1 RCT)	⊕⊕○○ Low ^{1,2}	
	139 per 1000	190 per 1000				

	(133 to 272)					
Perinatal mortality	Study population		RR 1.10 (0.10 to 12.12)	690 (1 RCT)	⊕⊕⊕⊕ Very low ^{1,3}	
	4 per 1000	5 per 1000 (0 to 51)				
Neonatal mortality or morbidity composite: neonatal complications	Study population		RR 0.99 (0.57 to 1.71)	690 (1 RCT)	⊕⊕⊕⊕ Low ^{1,2}	
	80 per 1000	79 per 1000 (46 to 137)				
Hypoglycaemia	Study population		RR 1.10 (0.28 to 4.38)	690 (1 RCT)	⊕⊕⊕⊕ Very low ^{1,3}	
	13 per 1000	14 per 1000 (4 to 55)				
Childhood/adulthood adiposity	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Childhood/adulthood type 2 diabetes mellitus	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				
Childhood/adulthood neurosensory disability	Study population		not estimable	(0 studies)	-	The included study did not report this outcome
	0 per 1000	0 per 1000 (0 to 0)				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence

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Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹ Design limitations (-1): one study with design limitations.

- 2 Imprecision (-1): wide confidence interval crossing the line of no effect.
- 3 Imprecision (-2): wide confidence interval crossing the line of no effect and few events.

BACKGROUND

Description of the condition

Gestational diabetes mellitus

Gestational diabetes mellitus (GDM) is defined as "carbohydrate intolerance of varying degrees of severity with onset or first recognition during pregnancy" (Metzger 1998). This definition includes women who first present with type 1 or type 2 diabetes during pregnancy, or where diabetes was previously undetected. GDM typically resolves following birth; however, these women are at risk for type 2 diabetes in the future (Kim 2002).

Epidemiology

The incidence of GDM varies between different populations and diagnostic criteria used, with rates of up to 28% estimated (Jiwani 2012). There is growing concern over the increasing incidence of GDM and its complications for individual mothers and infants along with its impact on public health (Ferrara 2007; Hunt 2007; Metzger 2007). GDM is associated with numerous risk factors. These include being of certain ethnicities (including African, Hispanic, South or East Asian, Native American and Pacific Islander), advanced maternal age, maternal high and low birthweight, high parity, a previous large (macrosomic) baby or stillborn, a family history or first-degree relative with GDM or type 2 diabetes (Petty 2010), a history of glucose intolerance or GDM (Kim 2007), maternal overweight or obesity (Torloni 2009) and polycystic ovarian syndrome (Toulis 2009).

Aetiology/pathophysiology

Normally, insulin is released by pancreatic beta cells in response to increasing blood glucose concentrations to achieve euglycaemia (normal blood glucose). This system can be disrupted in two ways. A problem with the release of insulin from beta cells can occur, such as in type 1 or insulin-dependent diabetes mellitus. Alternatively, insulin may not act as effectively in promoting glucose uptake. This is known as insulin resistance, and is seen in the development of type 2 or non insulin-dependent diabetes mellitus and GDM.

Placental hormones such as progesterone, cortisol, prolactin and human placental lactogen released mid-pregnancy contribute to decreased insulin action in pregnancy (Kuhl 1998). Physiologically, this ensures sufficient nutrient transport to the fetus as it develops, and promotes growth (Setji 2005). In a normal pregnancy, the action of these placental hormones is adequately compensated by increasing insulin release, creating an equilibrium between insulin supply and demand.

In pregnant women with abnormal glucose intolerance, the insulin resistance of pregnancy is not adequately compensated for, resulting in carbohydrate or glucose intolerance. It is suggested that women who develop GDM may also have an underlying insulin resistance, such as due to high maternal adiposity, or beta cell dysfunction that potentiates the insulin resistance of pregnancy (Buchanan 2005; Kuhl 1998; Richardson 2007). More recent theories relating to the pathogenesis of GDM include inflammation (Richardson 2007).

These effects culminate in a disruption of the action of insulin in maintaining glucose concentrations, resulting in maternal hyperglycaemia (high blood glucose). Glucose is transferred, via the placenta, to the fetus. Maternal hyperglycaemia therefore

stimulates fetal hyperinsulinaemia to counter the excess placental glucose transfer. There is strong evidence confirming the continuum of risk associated with increasing carbohydrate intolerance (Dodd 2007; HAPO 2008). The point at which this increasing carbohydrate intolerance becomes pathological remains uncertain (Hartling 2014).

Clinical features

Infant

Excess insulin due to maternal hyperglycaemia acts in two ways on the fetus. Firstly, insulin promotes fat deposition due to the state of nutrient excess (Pedersen 1954; Whitelaw 1977). Secondly, insulin acts as a growth factor, stimulating further growth of the infant in utero (Hunt 2007). Thus, fetal hyperinsulinaemia results in excessive growth of the fetus, leading to one of the major perinatal concerns in GDM, macrosomia (birthweight greater than 4000 g or 4500 g) or 'large-for-gestational age' (Wendland 2012). Macrosomia may lead to birth trauma including shoulder dystocia, nerve palsies and fractures (Reece 2009; Reece 2010). GDM is associated with respiratory distress syndrome, neonatal hypoglycaemia (low blood glucose), hyperbilirubinaemia (high blood bilirubin), polycythaemia (excess red blood cells), and hypocalcaemia (low calcium). In utero exposure to hyperglycaemia also has long-lasting effects on infants, increasing their risk of future obesity and type 2 diabetes (Reece 2009; Reece 2010).

Maternal

With the implementation of screening protocols, GDM is usually diagnosed before it becomes symptomatic during pregnancy. However, where GDM is undetected, the pregnant woman may experience polyuria (increased urinary frequency), polydipsia (excessive thirst) or fatigue. Macrosomia in utero or polyhydramnios (excess amniotic fluid volume) may also indicate GDM (Mack 2017).

In the mother, evidence supports an association between GDM and increased rates of caesarean birth and pre-eclampsia (Wendland 2012). As with their infants, the consequences of GDM for the mother extend beyond the perinatal period. There are strong links between GDM and future development of type 2 diabetes. Within 10 years of women developing GDM, half develop type 2 diabetes (Kim 2002), and there is increasing evidence that women with a history of GDM are at increased risk of cardiovascular disease and metabolic syndrome (Reece 2009; Reece 2010).

Diagnosis of GDM

Although diagnostic criteria vary (ACOG 2013; ADA 2013; CDA 2013; IADPSG 2010; Nankervis 2014; NICE 2015; WHO 2013), diagnostic testing commonly involves either a 75 g or 100 g oral glucose tolerance test (OGTT), with various diagnostic cut-offs used. Different testing strategies for diagnosing GDM are assessed in the Cochrane Review *Different strategies for diagnosing gestational diabetes to improve maternal and infant health* (Farrar 2015), which includes comparisons of a candy bar versus 50 g glucose monomer drink; a 50 g glucose polymer versus 50 g glucose monomer drink; 50 g glucose food versus a 50 g glucose drink; a 75 g OGTT versus 100 g OGTT; and a 75 g OGTT using World Health Organization criteria versus 75 g OGTT using American Diabetes Association criteria.

Management of GDM

The importance of management for women with GDM is now widely accepted (Alwan 2009; Crowther 2005; Landon 2009) and is the subject of several Cochrane Reviews, assessing different aspects of management, including lifestyle interventions (Brown 2017b), insulin (Brown 2016a), oral anti-diabetic therapies (Brown 2017a), exercise (Ceysens 2016), dietary supplementation with myo-inositol (Brown 2016b), different intensities of glycaemic control (Martis 2016), and elective birth (Boulvain 2001).

Description of the intervention

Screening

A screening tool establishes the risk of disease in an otherwise well person (UK National Screening Committee 2013). Ordinarily, the presentation of symptoms prompts testing for disease. However, screening aims to identify the illness earlier, before symptoms arise. Identification of an illness by screening allows for earlier management, which may result in better health outcomes. While screening can be beneficial, it can also cause unnecessary anxiety due to the testing process itself. This is further complicated by the occurrence of 'false positives', where screening has suggested an increased risk for the disease but the diagnostic test does not show evidence of the disease.

An accepted screening process must first meet certain criteria (UK National Screening Committee 2015). In addition to the illness being an important health problem, the screening process must benefit the individual. This includes the acceptability of the screening process clinically, socially and ethically, and the availability of an effective treatment. These benefits must outweigh any possible harms such as discomfort from any testing and costs of administering the screening process. From an economic perspective, the screening process must also be cost-effective. Screening does not always involve a clinical test, and may include, for example, a series of history questions.

While screening tools will identify those at risk of an illness, it is the subsequent management that ultimately affects health outcomes. 'Screening' can be used to refer to an individual screening tool or to a screening protocol, guideline or programme, which includes the screening tool and subsequent management such as diagnostic testing and treatment of any illness identified. By identifying individuals at high and low risk of a particular illness, a screening tool therefore identifies those who require diagnostic testing and those who do not. It follows that the implementation of a screening programme, which includes a combination of screening tool, subsequent diagnostic testing and management, is able to affect health outcomes.

How the intervention might work

Screening for GDM based on different risk profiles and settings

Whether to screen for GDM, and which strategies to use, remains controversial. This is compounded by the lack of consistency on testing methods and diagnostic criteria for GDM. However, without screening, the diagnosis of GDM, and therefore management, is potentially delayed. Screening for GDM is often implemented despite the uncertainty of its effectiveness and a wide variety of strategies have been employed. 'Universal' or routine screening, where all women are offered a test (often a 50 g oral glucose challenge test (OGCT)), commonly between 24 and 28 weeks'

gestation, and 'selective' or risk factor-based screening (by women's history) have been the most commonly used methods and combinations of these and others have been used.

Screening for GDM varies across the world, in regard to tests used and populations selected for screening. For example, a recent systematic review demonstrated inconsistencies in screening practices for GDM between and within countries in Europe through examination of the medical literature, clinical guidelines, health authority publications and online sources (Buckley 2012). Identified practices ranged from universal or routine screening, to testing on a case-by-case basis, according to clinician or patient decisions. Where systematic screening processes were in place, variations still existed, such as in the risk factors that were considered (Buckley 2012).

Observational studies have provided conflicting support for the use of universal screening compared with risk factor-based screening. For example, a study of 5235 women evaluated a screening model for GDM based on clinical risk indicators. The sensitivity of the model was reported to be comparable with universal screening by fasting glucose or a one-hour, 50 g OGCT. The authors concluded that screening and diagnostic testing could be avoided in two-thirds of all pregnant women with the use of such a model (Jensen 2003). Conversely, in another study comparing risk factor-based screening and universal screening for GDM, risk factor-based screening was shown to be associated with higher risks of risks of large-for-gestational age, preterm birth, jaundice and neonatal hospitalisation. The authors suggested that universal screening may improve outcomes through reducing delay of diagnosis and care (Cosson 2006).

Various barriers to screening for GDM have been identified, including a lack of evidence to support screening as an effective strategy for preventing adverse maternal or infant outcomes, or both; no consensus on diagnostic criteria for GDM; limited awareness or perceived importance of screening or diagnostic practices, or both among healthcare professionals; the potential to cause unnecessary anxiety for pregnant women (Buckley 2012; Hiéronimus 2010); and, particularly in low- and middle-income countries, scarcity of test consumables and lack of equipment (Nielsen 2014).

An additional barrier, which may influence screening uptake, relates to the chosen setting for GDM screening. Similar to variation in the use of universal and risk factor-based screening internationally, there is (though not well reported) variation in the settings or locations where GDM screening occurs, with some countries more commonly practicing general practitioner/community-based screening, and others, hospital-based screening. Studies have suggested that factors relating to settings, such as distance from home (Cullinan 2012), may serve as barriers or facilitators to screening uptake.

An evaluation of cost is imperative with screening strategies. While screening processes may affect detection and management, and therefore improve maternal and infant health, this must also be weighed against the costs of screening, any subsequent diagnostic tests and treatment for additional women diagnosed with GDM. An economic analysis of a systematic screening strategy for GDM suggested that, compared with a sequential screening strategy (an initial 50 g OGCT followed by, in those who screened positive, an OGTT), a no-screening strategy was more costly - proposed to be

associated with the additional costs associated with unrecognised cases of GDM (Nicholson 2005). Further economic analyses have revealed conflicting findings (Farrar 2016; Scott 2002).

Why it is important to do this review

The increasing incidence of GDM, adverse outcomes associated with GDM, and benefits of management suggest a need to consider a screening process. Given the lack of current consensus, an evaluation of different screening strategies based on different risk profiles and settings, on the detection of GDM and subsequent maternal and infant health outcomes is required.

This review updates a Cochrane Review on screening and subsequent management for GDM for improving maternal and infant health, which was first published in 2010 (Tieu 2010), and updated in 2014 (Tieu 2014). The last version of this review included four randomised trials and found that there was insufficient evidence to determine if screening for GDM, or what types of screening, can improve maternal and infant health; and concluded that high-quality, large trials are required in this area (Tieu 2014).

This update aims to evaluate the current evidence regarding the effects of screening for GDM, specifically based on different risk profiles and settings. The evaluation of different testing strategies for diagnosing GDM is no longer within the scope of this review, and is covered in the Cochrane Review *Different strategies for diagnosing gestational diabetes to improve maternal and infant health* (Farrar 2015). For further details, see [Differences between protocol and review](#).

OBJECTIVES

To assess the effects of screening for gestational diabetes mellitus based on different risk profiles and settings on maternal and infant outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials and quasi-randomised controlled trials. We planned to include cluster-randomised trials, however we did not identify any. We excluded cross-over trials. We planned to include studies published as abstracts provided there was sufficient information to assess study eligibility and risk of bias, however we did not identify any.

Types of participants

We included pregnant women, excluding those already diagnosed with gestational diabetes mellitus (GDM) in their current pregnancy and those with pre-existing (type 1 or 2) diabetes mellitus.

Types of interventions

Different protocols, guidelines or programmes for screening for GDM based on different risk profiles and settings, compared with the absence of screening, or compared with other protocols, guidelines or programmes for screening.

Types of outcome measures

Primary outcomes

Mother

- GDM
- Hypertensive disorders of pregnancy (including pre-eclampsia, eclampsia, pregnancy-induced hypertension)
- Caesarean birth

Child

- Large-for-gestational age
- Perinatal mortality (stillbirth and neonatal mortality)
- Mortality or morbidity composite (e.g. infant death, shoulder dystocia, bone fracture or nerve palsy)

Secondary outcomes

Mother

Perinatal

- Operative vaginal birth
- Induction of labour
- Perineal trauma
- Placental abruption
- Postpartum haemorrhage
- Postpartum infection
- Gestational weight gain
- Adherence to the intervention
- Behaviour changes associated with the intervention
- Use of pharmacotherapy to treat GDM
- Sense of well-being and quality of life
- Views/acceptance of screening
- Breastfeeding (e.g. at discharge, six weeks postpartum)

Long-term

- Postnatal depression
- Postnatal weight retention or return to pre-pregnancy weight
- Body mass index (BMI)
- GDM in a subsequent pregnancy
- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Impaired glucose tolerance
- Cardiovascular health (e.g. blood pressure (BP), hypertension, cardiovascular disease, metabolic syndrome)

Child

Neonatal

- Stillbirth
- Neonatal death
- Gestational age at birth
- Preterm birth (less than 37 weeks' gestation and less than 32 weeks' gestation)
- Apgar score (less than seven at five minutes)
- Macrosomia
- Small-for-gestational age
- Birthweight and z score

- Head circumference and z score
- Length and z score
- Ponderal index
- Adiposity
- Shoulder dystocia
- Bone fracture
- Nerve palsy
- Respiratory distress syndrome
- Hypoglycaemia
- Hyperbilirubinaemia or jaundice

Childhood

- Weight and z scores
- Height and z scores
- Head circumference and z scores
- Adiposity (e.g. as measured by BMI, skinfold thickness)
- BP
- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Impaired glucose tolerance
- Dyslipidaemia or metabolic syndrome
- Neurosensory disability
- Educational achievement

Adulthood

- Weight
- Height
- Adiposity (e.g. as measured by BMI, skinfold thickness)
- Cardiovascular health (e.g. BP, hypertension, cardiovascular disease, metabolic syndrome)
- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Impaired glucose tolerance
- Dyslipidaemia or metabolic syndrome
- Employment, education and social status/achievement

Health services

- Number of hospital or health professional visits (e.g. midwife, obstetrician, physician, dietitian, diabetic nurse)
- Number of antenatal visits or admissions
- Length of antenatal stay
- Neonatal intensive care unit (NICU) admission
- Length of postnatal stay (mother)
- Length of postnatal stay (baby)
- Costs to families associated with the management provided
- Costs associated with screening
- Cost of maternal care
- Cost of offspring care

Search methods for identification of studies

The following methods section of this review is based on a standard template used by Cochrane Pregnancy and Childbirth.

Electronic searches

We searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (31 January 2017).

The Register is a database containing over 23,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate Pregnancy and Childbirth's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the [Cochrane Pregnancy and Childbirth](#) in the Cochrane Library and select the '**Specialized Register**' section from the options on the left side of the screen.

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE (Ovid);
3. weekly searches of Embase (Ovid);
4. monthly searches of CINAHL (EBSCO);
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Two people screen search results and review the full text of all relevant trial reports identified through the searching activities described above. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set which has been fully accounted for in the relevant review sections ([Included studies](#); [Excluded studies](#); [Studies awaiting classification](#); [Ongoing studies](#))

In addition, we searched [ClinicalTrials.gov](#), the WHO International Clinical Trials Registry Platform (ICTRP) (14 June 2017) (see [Appendix 1](#)).

Searching other resources

We searched reference lists of retrieved studies.

We did not apply any language or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, see [Tieu 2014](#).

For this update, we used the following methods for assessing the 96 reports that were identified as a result of the updated search.

Selection of studies

Two reviewers independently assessed for inclusion all the potential studies identified as a result of the search strategy. We

resolved any disagreement through discussion or, if required, we consulted a third reviewer.

Data extraction and management

We designed a form to extract data. For eligible studies, two reviewers extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a third reviewer. We entered data into Review Manager 5 (RevMan 5) software and checked for accuracy ([RevMan 2014](#)).

When information regarding any of the above was unclear, we contacted authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two reviewers independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). Any disagreement was resolved by discussion or by involving a third reviewer.

(1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered, sealed, opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include missing data in the analyses which we undertook.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as-treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk of bias (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review were reported);
- high risk of bias (where not all the study's pre-specified outcomes were reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we had about other possible sources of bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane*

Handbook for Systematic Reviews of Interventions (Higgins 2011). With reference to (1) to (6) above, we planned to assess the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. In future updates, we will explore the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Assessment of the quality of the evidence using the GRADE approach

For this update the quality of the evidence was assessed using the GRADE approach as outlined in the [GRADE handbook](#) for the following outcomes (where possible) for both of our comparisons.

Mother

Perinatal

- GDM
- Hypertensive disorders of pregnancy (including pre-eclampsia, eclampsia, pregnancy-induced hypertension)
- Caesarean birth
- Perineal trauma
- Gestational weight gain

Long-term

- Postnatal depression
- Type 2 diabetes mellitus

Child

Neonatal

- Large-for-gestational age
- Perinatal mortality (stillbirth and neonatal mortality)
- Mortality or morbidity composite (e.g. infant death, shoulder dystocia, bone fracture or nerve palsy)
- Hypoglycaemia

Childhood/adulthood

- Adiposity (e.g. as measured by BMI, skinfold thickness)
- Type 2 diabetes mellitus
- Neurosensory disability

We used the GRADEpro Guideline Development Tool ([GRADEpro GDT](#)) to import data from RevMan 5 ([RevMan 2014](#)) in order to create 'Summary of findings' tables. We produced a summary of the intervention effect and a measure of quality for each of the above outcomes using the GRADE approach, which uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as risk ratios with 95% confidence intervals.

Continuous data

For continuous data, we presented results as mean differences with 95% confidence intervals. We were not able to conduct any meta-analyses. In future updates, if we conduct meta-analyses we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We planned to include cluster-randomised trials in the analyses along with individually-randomised trials, however we did not identify any. In future updates of this review, if we include cluster-randomised trials, we will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we will synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Cross-over trials

We considered cross-over trials inappropriate for this research question.

Dealing with missing data

For included studies, we noted levels of attrition. In future updates, if more eligible studies are included, we will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, that is, we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We planned to assess statistical heterogeneity in each meta-analysis using the τ^2 , I^2 (Higgins 2003) and χ^2 statistics, however we were not able to conduct any meta-analyses. In future updates, if we are able to conduct meta-analyses, we will regard heterogeneity as substantial if I^2 is greater than 30% and either τ^2 is greater than zero, or there is a low P value (less than 0.10) in the χ^2 test for heterogeneity. If we identify substantial heterogeneity (above 30%), we will explore it by pre-specified subgroup analysis (Deeks 2011).

Assessment of reporting biases

In future updates, if there are 10 or more studies in a meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analyses using the RevMan 5 software, however we were not able to conduct any meta-analyses (RevMan 2014). In future updates of this review, if we are able to conduct meta-analyses, we will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: that is, where trials are examining the same intervention, and we judge the trials' populations and methods to be sufficiently similar.

If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. We will treat the random-effects summary as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials. If we use random-effects analyses, we will present results as the average treatment effect with 95% confidence intervals, and the estimates of τ^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

We were not able to conduct any meta-analyses, and thus did not conduct subgroup analyses or investigate heterogeneity. In future updates of this review, if meta-analyses are possible and

we identify substantial heterogeneity, we will investigate it using subgroup analyses. We will consider whether an overall summary is meaningful, and if it is, we will use random-effects analysis to produce it.

We will carry out the following subgroup analyses for primary outcomes:

- High risk for GDM (variously defined) (we will explore risk factors individually if sufficient data are available).
- Gestational age at screening (less than 24 weeks, 24 to 30 weeks, 30 weeks or more).
- Number of stages in the screening protocol.
- Type of management protocol.

We will assess subgroup differences by interaction tests available within RevMan 5 (RevMan 2014). We will report the results of subgroup analyses quoting the χ^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We were not able to conduct any meta-analyses and thus did not conduct sensitivity analyses. In future updates of this review, if meta-analyses are possible, we will carry out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, high attrition rates, or both, with poor quality studies being excluded from the analyses in order to assess whether this makes any difference to the overall result.

RESULTS

Description of studies

Results of the search

See: Figure 1.

Figure 1. Study flow diagram

Figure 1. (Continued)

The updated search of Cochrane Pregnancy and Childbirth's Trials Register identified 16 new reports. We also searched [ClinicalTrials.gov](#) and the WHO International Clinical Trials Registry Platform (ICTRP), and identified 80 new reports. Following duplicate removal and title and abstract screening, we assessed 33 reports as full-texts (29 new reports; three reports for trials that we previously included ([Bergus 1992](#); [Martinez Collado 2003](#); [Murphy 1994](#)); and one report for a trial that was previously awaiting classification ([Bebbington 1999](#))).

From these 33 reports assessed, we included one trial (eight reports) ([O'Dea 2016](#)), excluded 18 trials (19 reports) ([Ahern 2014](#); [Bergus 1992](#); [IRCT138707081281N1](#); [Martinez Collado 2003](#); [Mirzamoradi 2015](#); [Murphy 1994](#); [NCT01026675](#); [NCT01552213](#); [NCT02036619](#); [NCT02266758](#); [NCT02309138](#); [NCT02610179](#); [NCT02708758](#); [NCT02979756](#); [NCT03073330](#); [Scifres 2015](#); [Sevket 2014](#); [Yeral 2014](#)), listed five trials (five reports) as ongoing ([ChiCTR-TRC-13003495](#); [NCT01864564](#); [NCT02183558](#); [NCT02377531](#); [NCT03116009](#)), and one trial (one report) awaits further classification ([Bebbington 1999](#)).

Therefore, overall, we have included two trials ([Griffin 2000](#); [O'Dea 2016](#)), excluded 44 trials ([Ahern 2014](#); [Bergus 1992](#); [Berkus 1995](#); [Brustman 1995](#); [Buhling 2004](#); [Cheng 1992](#); [Court 1984](#); [Court 1985](#); [Duenas-Garcia 2011](#); [Eslamian 2007](#); [Eslamian 2008](#); [Fung 1993](#); [Harlass 1991](#); [Helton 1989](#); [Hidar 2001](#); [IRCT138707081281N1](#); [Jones 1993](#); [Kjos 2001](#); [Lamar 1999](#); [Lewis 1993](#); [Martinez Collado 2003](#); [Meltzer 2010](#); [Mirzamoradi 2015](#); [Murphy 1994](#); [NCT01026675](#); [NCT01552213](#); [NCT02036619](#); [NCT02266758](#); [NCT02309138](#); [NCT02610179](#); [NCT02708758](#); [NCT02979756](#); [NCT03073330](#); [Olarinoye 2004](#); [Saijan 2011](#); [Sammarco 1993](#); [Scifres 2015](#); [Sevket 2014](#); [Soonthornpun 2003](#); [Soonthornpun 2008](#); [Stavrianos 2004](#); [Weiss 1998](#); [Yeral 2014](#); [Zhang 1995](#)), listed five as ongoing ([ChiCTR-TRC-13003495](#); [NCT01864564](#); [NCT02183558](#); [NCT02377531](#); [NCT03116009](#)), and one awaits further classification ([Bebbington 1999](#)).

Included studies

We have included two studies (involving 4523 women) in this updated review. One quasi-randomised controlled trial that assessed the effects of universal versus risk factor-based screening for gestational diabetes mellitus (GDM) ([Griffin 2000](#)), and one

randomised controlled trial that compared primary care versus secondary care screening for GDM ([O'Dea 2016](#)).

Participants and settings

Together the two trials randomised 4523 women; 3742 in the [Griffin 2000](#) trial, and 781 in the [O'Dea 2016](#) trial. Both trials were conducted in obstetrics clinics in hospitals in Ireland, one over a 24-month period (dates not specified) ([Griffin 2000](#)), and one from January to December 2013 ([O'Dea 2016](#)). [Griffin 2000](#) recruited women attending the outpatient obstetric clinics at the National Maternity Hospital, Dublin, and did not specify exclusion criteria, while [O'Dea 2016](#) recruited women 18 years or older attending their first obstetric appointment at one of three hospitals in Ireland, with or without GDM risk factors. Women with a diagnosis of established diabetes or GDM, and without a standard of English appropriate to provide informed consent were excluded.

Interventions

Universal versus risk factor versus universal screening

[Griffin 2000](#) compared universal and risk factor-based screening for GDM. Women in the universal screening group had a 50 g oral glucose challenge test (OGCT) at 26 to 28 weeks' gestation. A one-hour plasma glucose of greater than or equal to 7.8 mmol/L was considered positive. A positive screening test was an indication for a full 100 g oral glucose tolerance test (OGTT). The 50 g OGCT was repeated at 32 weeks' gestation for women with risk factors for GDM who had a negative OGCT (or a positive OGCT and negative OGTT). Women in the risk-factor screening group of [Griffin 2000](#) were screened using a 100 g OGTT at 32 weeks' gestation where they were found to have any of the following risk factors: a first-degree relative with diabetes mellitus, weighing more than 100 kg in the current pregnancy, having a previous baby greater than 4.5 kg, previous unexplained stillbirth or intrauterine death, previous major malformation, previous GDM, glycosuria in second fasting urine sample, macrosomia in the current pregnancy and polyhydramnios in the current pregnancy. For women in both groups in [Griffin 2000](#), GDM was diagnosed using the National Diabetes Data Group criteria, and women with GDM were referred to a combined care clinic and reviewed every two weeks until 36 weeks' gestation, and then weekly. Women received dietary advice, and insulin if required.

Primary care versus secondary care screening

O'Dea 2016 compared primary care and secondary care screening for GDM. Women in the primary care screening group were offered a screening appointment for GDM at their local general practitioner's (GP) clinic. GPs administered the test and samples were sent to the local laboratory for analysis; GPs were sent the results and informed women. GPs were directed to contact the local maternity unit to make appointments for women with positive test results at the diabetes antenatal service. Women in the secondary care screening group of O'Dea 2016 were offered a screening appointment for GDM at the hospital they attended for antenatal care; the samples were sent to the local laboratory for analysis, and results sent to the consulting obstetrician. Midwives made appointments for women with positive test results at the diabetes antenatal service. Women in both groups of O'Dea 2016 were screened using a two-hour 75 g OGTT between 24 and 28 weeks' gestation, and International Association of Diabetes and Pregnancy Study Groups Consensus Panel (IADPSG) criteria were used for GDM diagnosis. Women with GDM were offered treatment involving lifestyle intervention, self-monitoring of blood glucose, and insulin if required.

Outcomes

Griffin 2000 presented data according to GDM diagnosis (not group allocation), and thus we were only able to include data for two outcomes (GDM; gestational age at birth) in this review.

O'Dea 2016 reported data for a range of maternal and child outcomes, including: GDM; hypertensive disorders of pregnancy; caesarean birth; large-for-gestational age; perinatal mortality; neonatal morbidity composite; operative vaginal birth; postpartum haemorrhage; adherence to the intervention; stillbirth; neonatal death; gestational age at birth; preterm birth; birthweight;

shoulder dystocia; respiratory distress; hypoglycaemia; jaundice; and neonatal intensive care unit admission.

Funding and declarations of interest

Griffin 2000 reported support from grants from Bayer Diagnostics and National Maternity Hospital, Dublin; declarations of interest were not reported. O'Dea 2016 reported support from the Health Research Board of Ireland, and the authors declared no conflicts of interest.

Excluded studies

Thirty-seven studies assessed (or are assessing) strategies for diagnosing GDM (Ahern 2014; Bergus 1992; Berkus 1995; Brustman 1995; Buhling 2004; Cheng 1992; Court 1984; Court 1985; Duenas-Garcia 2011; Eslamian 2007; Eslamian 2008; Fung 1993; Harlass 1991; Helton 1989; Hidar 2001; IRCT138707081281N1; Jones 1993; Lamar 1999; Lewis 1993; Martinez Collado 2003; Meltzer 2010; Mirzamoradi 2015; Murphy 1994; NCT02266758; NCT02309138; NCT03073330; Olarinoye 2004; Saijan 2011; Sammarco 1993; Scifres 2015; Sevet 2014; Soonthornpun 2003; Soonthornpun 2008; Stavrianos 2004; Weiss 1998; Yeral 2014; Zhang 1995) and thus have been, or are likely to be considered for inclusion in the next update of the Farrar 2015 review (note: not all are randomised controlled trials). One study is non-randomised (NCT02610179), two are cohort studies (NCT01026675; NCT02036619), three included (or plan to include) women with GDM as the participants (Kjos 2001; NCT02708758; NCT02979756) and one is assessing an intervention for women with pre-diabetes for reducing impaired glucose tolerance later in pregnancy (NCT01552213).

Risk of bias in included studies

See Figure 2 and Figure 3 for summaries of all 'Risk of bias' assessments.

Figure 2. Risk of bias graph

Figure 3. Risk of bias summary

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Griffin 2000	⊖	⊖	⊖	?	⊖	⊖	?
O'Dea 2016	⊕	⊕	⊖	⊖	⊖	⊕	?

Allocation

[Griffin 2000](#) was quasi-randomised, allocating women to study group by the day of their clinic visit, and thus we judged it to be at high risk of selection bias. [O'Dea 2016](#) used a statistical software programme to generate the random sequence, and sealed envelopes were used for concealment of allocation, and thus we judged it to be at low risk of selection bias.

Blinding

[Griffin 2000](#) did not report on blinding of women, study personnel or outcome assessors; as it was not considered feasible for women and study personnel to have been blinded, we judged the trial to be at high risk of performance bias and unclear risk of detection bias. [O'Dea 2016](#) was reported to be 'unblinded', and thus we judged it at high risk of both performance and detection bias.

Incomplete outcome data

[Griffin 2000](#) reported that 590, or 31% of women in the universal screening group did not consent to the OGCT and were excluded from analysis. No women in the risk-factor screening group

were excluded. Though [Griffin 2000](#) reported that there were no significant differences between those that consented to the OGCT and those who did not, we judged the trial to be at high risk of attrition bias. [O'Dea 2016](#) was also judged to be at high risk of attrition bias, as a per-protocol analysis was performed for secondary outcomes "as the objective... was to investigate clinical outcomes based on actual screening location". While 391 women were allocated to the primary care screening group, 215 were analysed in this group (206 who received the allocated intervention, and nine who crossed over from secondary care); though 390 women were allocated to the secondary care screening group, 475 were analysed in this group (348 who received the allocated intervention, and 127 who crossed over from primary care); overall, 91, or 12% of women randomised were not analysed.

Selective reporting

We judged [Griffin 2000](#) to be at high risk of reporting bias, with outcome data analysed by GDM diagnosis rather than allocated group. We judged [O'Dea 2016](#) to be at low risk of reporting bias, reporting outcomes as pre-specified in the published protocol.

Other potential sources of bias

We judged both trials to be at unclear risk of other potential sources of bias, due to lack of methodological details provided in [Griffin 2000](#) and due to baseline imbalance in age between groups in [O'Dea 2016](#); women in the secondary care screening group were on average one year older, and the authors reported a significant relationship between uptake of screening and age.

Overall risk of bias

In general, assessment of the included trials for methodological quality revealed a moderate to high risk of bias ([Figure 2](#); [Figure 3](#)).

Effects of interventions

See: [Summary of findings for the main comparison Universal screening versus risk-factor screening for gestational diabetes for improving maternal health](#); [Summary of findings 2 Universal screening versus risk-factor screening for gestational diabetes for improving infant health](#); [Summary of findings 3 Primary care screening versus secondary care screening for gestational diabetes for improving maternal health](#); [Summary of findings 4 Primary care screening versus secondary care screening for gestational diabetes for improving infant health](#)

For this update we included two studies ([Griffin 2000](#); [O'Dea 2016](#)). We were not able to perform meta-analyses due to the different interventions and comparisons assessed. The [Griffin 2000](#) trial (which randomised 3742 women, and analysed 3152 women) compared universal screening versus risk factor-based screening, and the [O'Dea 2016](#) trial (which randomised 781 women, and analysed 690 women) compared primary care screening versus secondary care screening.

Universal screening versus risk-factor screening

Primary outcomes

Mother

GDM

More women were diagnosed with GDM in the universal screening group than in the risk-factor screening group ([Griffin 2000](#)). Thirty-five women were diagnosed with GDM in the universal screening group compared with 27 in the risk-factor screening group (risk ratio (RR) 1.85, 95% confidence interval (CI) 1.12 to 3.04; participants = 3152; low-quality evidence) ([Analysis 1.1](#)).

Hypertensive disorders of pregnancy (including pre-eclampsia, eclampsia, pregnancy-induced hypertension)

[Griffin 2000](#) did not report data that could be included for this outcome.

Caesarean birth

[Griffin 2000](#) did not report data that could be included for this outcome.

Child

Large-for-gestational age

[Griffin 2000](#) did not report data that could be included for this outcome.

Perinatal mortality (stillbirth and neonatal mortality)

[Griffin 2000](#) did not report data that could be included for this outcome.

Mortality or morbidity composite (e.g. infant death, shoulder dystocia, bone fracture or nerve palsy)

[Griffin 2000](#) did not report data that could be included for this outcome.

Secondary outcomes

Mother

[Griffin 2000](#) did not provide data that could be included for any of this review's secondary outcomes for the mother in the perinatal period (operative vaginal birth, induction of labour, perineal trauma, placental abruption, postpartum haemorrhage, postpartum infection, gestational weight gain, adherence to the intervention, behaviour changes associated with the intervention, user of pharmacotherapy to treat GDM, sense of well-being and quality of life, view/acceptance of screening, breastfeeding (e.g. at discharge, six weeks postpartum), or longer term (postnatal depression, postnatal weight retention or return to pre-pregnancy weight, body mass index, GDM in a subsequent pregnancy, type 1 diabetes mellitus, type 2 diabetes mellitus, impaired glucose intolerance, cardiovascular health (e.g. blood pressure (BP), hypertension, cardiovascular disease, metabolic syndrome).

Child

Gestational age at birth

Gestational age at birth was lower in the risk-factor screening group compared with the universal screening group (mean difference (MD) 0.15 weeks, 95% CI 0.03 to 0.27; participants = 3152) ([Analysis 1.2](#)).

[Griffin 2000](#) did not provide data that could be included for any of this review's other secondary outcomes for the child in the:

- neonatal period (stillbirth, neonatal death, preterm birth (less than 37 weeks' gestation and less than 32 weeks' gestation), Apgar score (less than seven at five minutes), macrosomia, small-for-gestational age, birthweight and z score, head circumference and z score, ponderal index, adiposity, shoulder dystocia, bone fracture, nerve palsy, respiratory distress syndrome, hypoglycaemia, hyperbilirubinaemia or jaundice;
- or in childhood (weight and z scores, height and z scores, head circumference and z scores, adiposity (e.g. as measured by BMI, skinfold thickness), BP, type 1 diabetes mellitus, type 2 diabetes mellitus, impaired glucose intolerance, dyslipidaemia or metabolic syndrome, neurosensory disability, educational achievement;
- or in adulthood (weight, height, adiposity (e.g. as measured by BMI, skinfold thickness), cardiovascular health (e.g. BP, hypertension, cardiovascular disease, metabolic syndrome), type 1 diabetes mellitus, type 2 diabetes mellitus, impaired glucose tolerance, dyslipidaemia or metabolic syndrome, employment, education and social status/achievement.

Health services

[Griffin 2000](#) did not provide data that could be included for any of this review's secondary outcomes relating to the use or costs

of health services (number of hospital or health professional visits (e.g. midwife, obstetrician, physician, dietitian, diabetic nurse), number of antenatal visits or admissions, length of antenatal stay, neonatal intensive care unit (NICU) admission, length of postnatal stay (mother), length of postnatal stay (baby), costs to families associated with the management provided, costs associated with screening, cost of maternal care, cost of offspring care.

Primary care screening versus secondary care screening

Primary outcomes

Mother

GDM

There was no clear difference in the proportion of women diagnosed with GDM between the primary care and secondary care screening groups (RR 0.91, 95% CI 0.50 to 1.66; participants = 690; low-quality evidence) ([Analysis 2.1](#)).

Hypertensive disorders of pregnancy

There was no clear difference between the primary care and secondary care screening groups for hypertension (RR 1.41, 95% CI 0.77 to 2.59; participants = 690; low-quality evidence) ([Analysis 2.2](#)) or pre-eclampsia toxemia (RR 0.80, 95% CI 0.36 to 1.78; participants = 690; low-quality evidence) ([Analysis 2.3](#)).

Caesarean birth

There was no clear difference between the primary care and secondary care screening groups for caesarean birth (RR 1.00, 95% CI 0.80 to 1.27; participants = 690; low-quality evidence) ([Analysis 2.4](#)).

Child

Large-for-gestational age

There was no clear difference between the primary care and secondary care screening groups for large-for-gestational age (RR 1.37, 95% CI 0.96 to 1.96; participants = 690; low-quality evidence) ([Analysis 2.5](#)).

Perinatal mortality

There was one perinatal death in the primary care screening group and two in the secondary care screening group (RR 1.10, 95% CI 0.10 to 12.12; participants = 690; very low-quality evidence) ([Analysis 2.6](#)).

Mortality or morbidity composite

[O'Dea 2016](#) reported on neonatal complications: composite perinatal score, including: hypoglycaemia, respiratory distress, need for phototherapy, birth trauma, shoulder dystocia, five minute Apgar less than seven at one or five minutes, prematurity, and there was no clear difference between the primary care and secondary care screening groups (RR 0.99, 95% CI 0.57 to 1.71; participants = 690; low-quality evidence) ([Analysis 2.7](#)).

Secondary outcomes

Mother

Operative vaginal birth

There was no clear difference between the primary care and secondary care screening groups for operative vaginal birth (RR 1.01, 95% CI 0.90 to 1.13; participants = 690) ([Analysis 2.8](#)).

Postpartum haemorrhage

There was no clear difference between the primary care and secondary care screening groups for postpartum haemorrhage (RR 1.25, 95% CI 0.75 to 2.09; participants = 690) ([Analysis 2.9](#)).

Adherence to the intervention

Uptake of the screening allocated was lower in the primary care screening group compared with the secondary care screening group (RR 0.59, 95% CI 0.53 to 0.65; participants = 781) ([Analysis 2.10](#)).

[O'Dea 2016](#) did not provide data that could be included for any of this review's secondary outcomes for the mother in the perinatal period (induction of labour, perineal trauma, placental abruption, postpartum infection, gestational weight gain, behaviour changes associated with the intervention, user of pharmacotherapy to treat GDM, sense of well-being and quality of life, view/acceptance of screening, breastfeeding (e.g. at discharge, six weeks postpartum), or longer term (postnatal depression, postnatal weight retention or return to pre-pregnancy weight, body mass index, GDM in a subsequent pregnancy, type 1 diabetes mellitus, type 2 diabetes mellitus, impaired glucose intolerance, cardiovascular health (e.g. blood pressure (BP), hypertension, cardiovascular disease, metabolic syndrome).

Child

Stillbirth

There was one stillbirth in the primary care screening group and two in the secondary care screening group (RR 1.10, 95% CI 0.10 to 12.12; participants = 690) ([Analysis 2.11](#)).

Neonatal death

There were no neonatal deaths in the primary care or secondary care screening groups ([Analysis 2.12](#)).

Gestational age at birth

Gestational age at birth was lower in the secondary care screening group compared with the primary care screening group (MD 0.41 weeks, 95% CI 0.14 to 0.68; participants = 690) ([Analysis 2.13](#)).

Preterm birth

There was no clear difference between the primary care and secondary care screening groups for preterm birth (RR 0.95, 95% CI 0.37 to 2.43; participants = 690) ([Analysis 2.14](#)).

Birthweight

There was no clear difference between the primary care and secondary care screening groups for birthweight (MD 0.00 kg, 95% CI -0.09 to 0.09; participants = 690) ([Analysis 2.15](#)).

Shoulder dystocia

There was no clear difference between the primary care and secondary care screening groups for shoulder dystocia (RR 6.61, 95% CI 0.27 to 161.63; participants = 690) ([Analysis 2.16](#)).

Respiratory distress syndrome

[O'Dea 2016](#) reported on respiratory distress (requiring ventilator support), and there was no clear difference between the primary care and secondary care screening groups (RR 0.74, 95% CI 0.24 to 2.26; participants = 690) ([Analysis 2.17](#)).

Hypoglycaemia

There was no clear difference between the primary care and secondary care screening groups for neonatal hypoglycaemia (RR 1.10, 95% CI 0.28 to 4.38; participants = 690; very low-quality evidence) ([Analysis 2.18](#)).

Hyperbilirubinaemia or jaundice

There was no clear difference between the primary care and secondary care screening groups for jaundice (need for phototherapy) (RR 2.21, 95% CI 0.14 to 35.16; participants = 690) ([Analysis 2.19](#)).

[O'Dea 2016](#) did not provide data that could be included for the following of this review's other secondary outcomes for the child in the:

- neonatal period (Apgar score (less than seven at five minutes), macrosomia, small-for-gestational age, head circumference and z score, ponderal index, adiposity, bone fracture, nerve palsy);
- or in childhood (weight and z scores, height and z scores, head circumference and z scores, adiposity (e.g. as measured by BMI, skinfold thickness), BP, type 1 diabetes mellitus, type 2 diabetes mellitus, impaired glucose intolerance, dyslipidaemia or metabolic syndrome, neurosensory disability, educational achievement);
- or in adulthood (weight, height, adiposity (e.g. as measured by BMI, skinfold thickness), cardiovascular health (e.g. BP, hypertension, cardiovascular disease, metabolic syndrome), type 1 diabetes mellitus, type 2 diabetes mellitus, impaired glucose tolerance, dyslipidaemia or metabolic syndrome, employment, education and social status/achievement).

Health services

[Griffin 2000](#) did not provide data that could be included for any of this review's secondary outcomes relating to the use or costs of health services (number of hospital or health professional visits (e.g. midwife, obstetrician, physician, dietitian, diabetic nurse), number of antenatal visits or admissions, length of antenatal stay, neonatal intensive care unit (NICU) admission, length of postnatal stay (mother), length of postnatal stay (baby), costs to families associated with the management provided, costs associated with screening, cost of maternal care, cost of offspring care).

Health services

Neonatal intensive care unit admission

There was no clear difference between the primary care and secondary care screening groups for neonatal intensive care unit admission (RR 0.99, 95% CI 0.58 to 1.69; participants = 690) ([Analysis 2.20](#)).

[O'Dea 2016](#) did not report on any of the other secondary outcomes in this review relating to the use or costs of health services (number of hospital or health professional visits (e.g. midwife, obstetrician, physician, dietitian, diabetic nurse), number of antenatal visits or admissions, length of antenatal stay, length of postnatal stay (mother), length of postnatal stay (baby), costs to families associated with the management provided, costs associated with screening, cost of maternal care, cost of offspring care).

Non pre-specified outcomes

[O'Dea 2016](#) reported on birth trauma (damage to tissues or organs as a result of childbirth) and there was no clear difference between the primary care and secondary care screening groups (RR 1.10, 95% CI 0.10 to 12.12; participants = 690) ([Analysis 2.21](#)).

[O'Dea 2016](#) reported on time to access antenatal diabetes care, and there was a suggestion of more time taken in the primary care screening group compared with the secondary care screening group (MD 4.70 days, 95% CI -0.39 to 9.79; participants = 48) ([Analysis 2.22](#)).

DISCUSSION

Summary of main results

In this updated review, we have included two trials involving 4523 women; one quasi-randomised controlled trial that assessed the effects of universal versus risk factor-based screening ([Griffin 2000](#)), and one randomised controlled trial that compared primary care versus secondary care screening for gestational diabetes mellitus (GDM) ([O'Dea 2016](#)). Overall, one trial had a high risk of bias ([Griffin 2000](#)), and one trial had a moderate risk of bias ([O'Dea 2016](#)). We were not able to perform meta-analyses due to the different interventions and comparisons assessed.

In [Griffin 2000](#), unsurprisingly, with more women offered screening and subsequent diagnostic testing for GDM in the universal screening group, compared with in the risk-factor screening group, more women were diagnosed with GDM (low-quality evidence). On average, infants born to mothers in the risk-factor screening group were born earlier (0.15 weeks); the clinical importance of this difference is uncertain. Based on their own analyses, [Griffin 2000](#) concluded that universal screening for GDM is superior to risk factor-based screening: detecting more cases, facilitating earlier diagnosis, and improving pregnancy outcomes (e.g. an increase in spontaneous vaginal birth at term; and reductions in pre-eclampsia, caesarean section, macrosomia, preterm birth, and admission to the neonatal intensive care unit). However, we could not include any other health outcomes (apart from gestational age at birth) from this trial in our review, as outcome data were presented/analysed by GDM diagnosis, rather than randomly allocated group.

In [O'Dea 2016](#), comparing primary care versus secondary care screening for GDM, no clear differences were found for GDM (low-quality evidence), hypertension (low-quality evidence), pre-eclampsia toxemia (low-quality evidence), or caesarean section birth (low-quality evidence). There were also no clear differences found for large-for-gestational age (low-quality evidence), perinatal death (very low-quality evidence), a composite outcome of neonatal complications (low-quality evidence), or neonatal hypoglycaemia (very low-quality evidence). We observed no other

differences for secondary outcomes, except for in regard to adherence - uptake of the screening as allocated was lower in the primary care screening group compared with the secondary care screening group; and gestational age at birth - on average, infants born to mothers in the secondary care screening group were born earlier (0.41 weeks). We also reported a non-pre-specified outcome 'time to access antenatal diabetes care', which, on average, was increased (4.7 days, $P = 0.07$) in the primary care screening group. Based on the 'trend' towards longer time to access diabetic care in the primary care screening group, and a reported 'trend' towards increased large-for-gestational-age infants in this group, O'Dea 2016 concluded that secondary care screening may be associated with potential benefits, however highlighted that further research is required to test the findings in other health systems.

Overall completeness and applicability of evidence

We were only able to include two trials in this review and we were unable to combine data in meta-analysis due to the different interventions and comparisons in these two trials. Both of the trials were conducted in a high-income country (Ireland), which limits the generalisability of the findings. It is also important to note that the trials used specific screening tests (Griffin 2000: 50 g OCGT at 26 to 28 weeks' gestation followed by 100 g OGTT if indicated in the universal screening group versus 100 g OGTT at 32 weeks' gestation in the risk-factor screening group; O'Dea 2016: 75 g OGTT at 24 to 28 weeks' gestation in both groups), diagnostic criteria (Griffin 2000: National Diabetes Data Group criteria; O'Dea 2016: IADPSG criteria), and subsequent management strategies for GDM, which may also limit applicability of their findings for countries/settings using varying approaches, and with different practicality and feasibility considerations.

In regard to our important outcomes selected for quality assessment using the GRADE approach, there were no data from either trial for outcomes for the mother: perineal trauma; gestational weight gain; postnatal depression; and type 2 diabetes; and for the infant: childhood/adulthood adiposity; type 2 diabetes; and neurosensory disability. Considering secondary outcomes, neither of the trials reported on any longer-term outcomes for the mother, or the infant in childhood or adulthood, or (excluding neonatal intensive care admission) on the use of health services, and associated costs.

Quality of the evidence

Overall, we assessed risk of bias to be moderate in one trial (O'Dea 2016), and high in the other trial (Griffin 2000). This was due to Griffin 2000 being quasi-randomised, and both trials displaying inadequate, or no blinding, and providing incomplete outcome data (see Figure 2; Figure 3).

For outcomes assessed using the GRADE approach, in the comparison of universal screening versus risk-factor screening (see Summary of findings for the main comparison; Summary of findings 2), evidence for GDM was low quality. We downgraded evidence for study design limitations in Griffin 2000. For the comparison of primary care screening versus secondary care screening (see Summary of findings 3; Summary of findings 4), evidence for maternal outcomes: GDM, hypertension, pre-eclampsia toxemia, and caesarean birth was low-quality; evidence for infant outcomes: large-for-gestational age, and neonatal morbidity composite was low-quality, and evidence for perinatal

mortality, and neonatal hypoglycaemia, was very low-quality. We downgraded evidence for study design limitations in Griffin 2000 and imprecision in effect estimates.

Potential biases in the review process

We took steps to minimise bias in the review process. Two reviewers independently carried out data extraction and checked all data. Two reviewers independently made the GRADE assessments and resolved any discrepancies by discussion.

Agreements and disagreements with other studies or reviews

Similar to the previous versions of this review (Tieu 2010; Tieu 2014), this update found little randomised controlled evidence on the effects of screening for GDM, based on different risk profiles and settings, on maternal and infant health outcomes. This is consistent with previous reviews addressing aspects of screening for GDM, which have commonly included analyses of observational data (Farrar 2016; Farrar 2017; Hollander 2007; Scott 2002).

We did not identify any additional studies or reviews specifically addressing screening based on different settings.

In regard to universal versus risk factor-based screening, a systematic review and economic analysis conducted over a decade ago (Scott 2002) concluded that "present evidence suggests that we should not have universal screening, but a highly selective policy, based on age and overweight". A more recent systematic review and meta-analysis similarly concluded that risk-factor screening methods are poor predictors of which women will be diagnosed with GDM, and that a simple approach, of offering an OGTT to women 25 years or older, and/or with a BMI of 25 kg/m² or higher is as good as more complex risk prediction models (Farrar 2017).

A review of literature and clinical guidelines highlighted that definitive answers to questions such as whether all pregnant women should be screened, or only those with risk factors, and whether it is, in fact, safe to screen at all, are not yet available (Hollander 2007). A further recent analysis of individual participant data, systematic reviews, meta-analyses and an economic evaluation concluded that current evidence suggests "it is not cost-effective to routinely identify pregnant women for treatment of hyperglycaemia", and suggested "Further research to reduce uncertainty around potential longer-term benefits for the mothers and offspring, find[ing] ways of improving the accuracy of identifying women with GDM, and reduc[ing] costs of identification and treatment would be worthwhile" (Farrar 2016).

The uncertainty regarding the effects of screening for GDM (including based on different risk profiles) continues to be evident through variation in clinical guidelines and practice, both between and within countries (Farrar 2016; Hollander 2007).

AUTHORS' CONCLUSIONS

Implications for practice

Although low-quality evidence suggests universal screening compared with risk factor-based screening leads to more women being diagnosed with gestational diabetes mellitus (GDM), the effects on maternal and infant short- and long-term outcomes are unclear. Low- to very low-quality evidence suggests no

clear differences between primary care and secondary care screening, for outcomes including GDM, hypertension, pre-eclampsia, caesarean birth, large-for-gestational age, neonatal complications composite, or hypoglycaemia. Consequently, there are insufficient randomised controlled trial data evaluating the effects of screening for GDM, including based on different risk profiles and settings on maternal and infant outcomes.

Implications for research

Further, high-quality randomised controlled trials are needed to assess the value of screening for GDM, which may compare different protocols, guidelines or programmes for screening (based on different risk profiles and settings), with the absence of screening, or with other protocols, guidelines or programmes. There is a need for future trials to be sufficiently powered to detect important differences in short- and long-term maternal and infant outcomes, such as those important outcomes pre-specified in this review. As only a proportion of women will be diagnosed with GDM in these trials, large sample sizes may be required.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Griffin 2000

Methods	Quasi-RCT
Participants	<p>3742 women were randomised.</p> <p>Setting: outpatient obstetric clinics at the National Maternity Hospital, Dublin, Ireland, over a 24-month period (dates not specified)</p> <p>Inclusion criteria: women attending the outpatient obstetric clinics at the National Maternity Hospital, Dublin</p> <p>Exclusion criteria: none specified</p>
Interventions	<p>Universal screening group (n = 1889)</p> <p>Women had a GCT (50 g glucose load with 1-h plasma glucose) at 26-28 weeks' gestation; if OGCT was positive (1 h post-load glucose ≥ 7.8 mmol/L) a 3-h 100 g OGTT was performed. If a woman had any risk factors, a repeat OGCT was performed at 32 weeks' gestation if either the first OGCT was negative, or had been positive, but with a negative OGTT.</p> <p>Risk-factor screening group (n = 1853)</p> <p>Women had a 100 g, 3-h OGTT performed at 32 weeks' gestation only if any of the risk factors were present: 1st-degree relative with diabetes; > 100 kg in current pregnancy; previous baby > 4.5 kg; previous unexplained stillbirth/intrauterine death; previous major malformation; previous GDM; glycosuria in second fasting urine sample; macrosomia in current pregnancy; polyhydramnios in current pregnancy.</p> <p>All women</p> <p>Positive OGTT was defined by the criteria of National Diabetes Data Group. Women with GDM were referred to a combined care clinic attended by an obstetrician and endocrinologist and reviewed every 2 weeks until 36 weeks and weekly until birth. All women were instructed in appropriate diabetic diet and intensive insulin treatment was instituted if fasting and postprandial glucose were not maintained at < 5.9 mmol/L or < 7.9 mmol/L respectively.</p>
Outcomes	<p>Review outcomes able to be reported: GDM; gestational age at birth</p> <p>Additional outcomes reported/analysed by GDM diagnosis rather than randomly allocated group; thus have not been included in the review</p>
Notes	<p>We have been in correspondence with trial authors for additional data.</p> <p>Funding: "Mr M. Griffin was supported by a grant from Bayer Diagnostics. M. Coffey was supported by a research grant from National Maternity Hospital, Holles Street, Dublin".</p> <p>Declarations of interest: not reported</p>

Risk of bias

Griffin 2000 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-randomised: "Randomization to group was performed on the basis of which day the clinic was held"
Allocation concealment (selection bias)	High risk	Quasi-randomised
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not specified. It was probably unfeasible for the study to blind participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessors was not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Of the 1889 women randomised to the universal screening group, 1299 consented to the OGCT (69%), and were compared to the 1853 randomised to the selective screening group
Selective reporting (reporting bias)	High risk	Outcome data for participants were not available by original group allocation by day of visit, and were analysed by GDM diagnosis rather than randomly allocated group, affecting interpretation of outcome data
Other bias	Unclear risk	Limited methodological detail provided to assess other bias

O'Dea 2016

Methods	RCT
Participants	<p>781 women were randomised.</p> <p>Setting: 3 public hospital sites in both rural and urban Ireland, between January 2013-December 2013</p> <p>Inclusion criteria: pregnant women (public and private patients), ≥ 18 years including those presenting/not presenting with GDM risk factors (overweight, older age, family history of diabetes) who attended for their 1st antenatal appointment at 1 of 3 hospitals (women were contacted by letter after their 1st antenatal appointment (typically between 12 and 18 weeks' gestation) and a follow-up telephone call)</p> <p>Exclusion criteria: women with a diagnosis of established diabetes or GDM; women < 18 years and without a standard of English deemed appropriate to provide informed consent</p>
Interventions	<p>Primary care screening group (n = 391)</p> <p>Women were offered a screening appointment for GDM at their local GP clinic. The materials required to perform the OGTT were sent to the woman's GP; the GP administered the test and test samples were sent to the local laboratory for analysis; the laboratory sent the results to the GPs who informed the women of their results. For women with positive test results, GPs were directed to contact the local maternity unit to make an appointment for the women to be seen at the diabetes antenatal service</p> <p>Secondary care screening group (n = 390)</p> <p>Women were offered a screening test appointment at the hospital that they attended for antenatal care; as per usual care, the samples were sent to the local laboratory for analysis; the results were sent directly to the consulting obstetrician who informed the women. For women with positive test results, midwives made an appointment for the women to be seen at the diabetes antenatal service</p>

O'Dea 2016 (Continued)

All women

Screening was performed with a 2-h, 75 g OGTT between 24-28 weeks' gestation using IADPSG criteria for GDM diagnosis. Women with GDM were offered treatment in secondary care, involving lifestyle intervention (consultations with a dietician and a diabetes nurse specialist), blood glucose self-monitoring (education and instruction to self-monitor) and, if required, insulin (if did not respond to lifestyle intervention after 2 weeks)

Outcomes	Review outcomes able to be reported: GDM; hypertension disorders of pregnancy; caesarean birth; large-for-gestational age; perinatal mortality; neonatal morbidity composite; operative vaginal birth; postpartum haemorrhage; adherence to the intervention; stillbirth; neonatal death; gestational age at birth; preterm birth; birthweight; shoulder dystocia; birth trauma; respiratory distress; hypoglycaemia; jaundice; neonatal intensive care unit admission
Notes	<p>Funding: "The trial was supported by a grant from the Health Research Board of Ireland (ICE/2011/3)".</p> <p>Declarations of interest: "The authors declare that there is no duality of interest associated with this manuscript"</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "an independent researcher was responsible for generating the allocation sequence using the NQuery statistical software programme (version 2.0)"
Allocation concealment (selection bias)	Low risk	Quote: "Sealed envelopes were used to assign participants to interventions groups. Thus the allocation sequence was concealed from all the study researchers until the interventions were assigned"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "unblinded parallel group randomised controlled trial"
Blinding of outcome assessment (detection bias) All outcomes	High risk	No detail specifically of blinded outcome assessment; assumed to be unblinded as above
Incomplete outcome data (attrition bias) All outcomes	High risk	<p>Published protocol outlined that the "main analysis will follow an intention to treat strategy"; however, a per-protocol analysis was performed for secondary outcomes "as the objective of this aspect of the trial was to investigate clinical outcomes based on actual screening location".</p> <p>391 women allocated to primary care screening; 206 received allocated intervention; 127 crossed over to secondary care; 58 were not screened; 215 were analysed</p> <p>390 allocated to secondary care screening; 348 received allocated intervention; 9 crossed over to primary care; 33 were not screened; 475 analysed</p> <p>In the data and analysis we used the per protocol denominators; ITT results were not reported.</p> <p>Denominators for infant outcomes were not clear. Some outcomes were reported for singletons only. For infant outcomes we used the number of women in each group (per protocol) as the denominator.</p>
Selective reporting (reporting bias)	Low risk	Published trial protocol available; minor difference: 2 recruitment hospitals mentioned in protocol; 3 in final manuscript. All expected outcomes reported

O'Dea 2016 (Continued)

as per published protocol (except economic outcomes, which have not as yet been reported).

Other bias	Unclear risk	On average, women in the secondary care group were 1 year older than those in the primary care group. Authors also reported that there was a significant relationship between uptake of screening and age; "For those that were randomised to the secondary care setting... The probability of uptake of screening was high and increased further with age".
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Abbreviations: GDM: gestational diabetes mellitus; GP: general practitioner; IADPSG: International Association of Diabetes and Pregnancy Study Groups; ITT: intention-to-treat; NICU: neonatal intensive care unit; OGCT: glucose challenge test; OGTT: oral glucose tolerance test; RCT: randomised controlled trial

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ahern 2014	This study compared a non-fasting 50 g OGCT and a fasting 75 g OGTT for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Bergus 1992	This study compared 50 g glucose monomer and glucose polymer OGCT beverages for GDM screening/diagnosis; it is included in the Farrar 2015 Cochrane Review.
Berkus 1995	This study compared a 50 g and 75 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded as "Outcomes data reported by whether or not the women had GDM, not by allocated group".
Brustman 1995	This study compared a 75 g and 100 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Not a randomised trial, cross-over design".
Buhling 2004	This study compared a low and high carbohydrate content diet preceding an OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial; no clinical outcomes reported".
Cheng 1992	This study compared a 50 g and 75 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial"
Court 1984	This study compared a 50 g OGTT and 50 g glucose polymer tolerance test for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial"
Court 1985	This study compared 100 g glucose polymer and glucose for GDM screening/diagnosis; it is included in the Farrar 2015 Cochrane Review
Duenas-Garcia 2011	This study compared a 75 g OGTT using WHO criteria with a 75 g OGTT using ADA criteria and a 100 g OGTT using ADA criteria for GDM screening/diagnosis; it is included in the Farrar 2015 Cochrane Review.
Eslamian 2007	This study compared breakfast containing 50 g simple glucose and a 50 g OGCT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".
Eslamian 2008	This study compared breakfast containing 50 g simple glucose and a 50 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".

Study	Reason for exclusion
Fung 1993	This study compared a 50 g OGTT and a 75 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".
Harlass 1991	This study assessed the use of a standard preparatory diet for a OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Quasi-randomised study using alternate allocations and a cross-over design".
Helton 1989	This study compared a 50 g glucose load and 100 g carbohydrate meal for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Quasi-randomised study using alternate allocations. Also, cross-over design and 42% lost to follow-up".
Hidar 2001	This study compared 1-h postprandial and 1-h, 50 g OGCT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".
IRCT138707081281N1	This ongoing study is comparing 5 different strategies for GDM screening/diagnosis (A: first trimester screening with fasting blood sugar; treatment of women with mild GDM; second trimester GDM screening by 1 step 75 g OGTT (diagnosis of GDM with 1 abnormal value); B: first trimester screening with fasting blood sugar; no treatment of women with mild GDM; second trimester screening by 1 step 75 g OGTT (diagnosis of GDM with 2 abnormal values); C: first trimester screening with fasting blood sugar; no treatment of women with mild GDM; second trimester screening by 1 step 75 g OGTT (diagnosis of GDM with 1 abnormal value); D: first trimester screening with fasting blood sugar; treatment of women with mild GDM; second trimester GDM screening by 2-step 100 g OGTT; E: not clearly reported in trial registration); it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Jones 1993	This study compared a '3-h standard' OGTT and an intravenous GTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".
Kjos 2001	This study included women with GDM; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Participants were women with a diagnosis of gestational diabetes."
Lamar 1999	This study compared 28 jelly beans (50 g simple carbohydrate) with a 50 g glucose drink screening for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".
Lewis 1993	This study assessed the effect of prior meal ingestion on response to 50 g OGCT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Not a randomised trial".
Martinez Collado 2003	This study compared a traditional 50 g OCGT with a diet of carbohydrates, protein and fats (including 50 g glucose) for GDM screening/diagnosis; it is included in the Farrar 2015 Cochrane Review.
Meltzer 2010	This study compared a 50 g OGCT plus a 100 g OGTT, with a 50 g OGCT plus a 75 g OGTT, and with a 75 g OGTT alone for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Outcomes reported as percentage rates".
Mirzamoradi 2015	This study compared a 1-step, 2-h, 75 g OGTT (IADPSG strategy) with a 2-step, 50 g OCGT and 3-h OGTT if indicated (ACOG strategy) for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Murphy 1994	This study compared a 50 g glucose polymer, candy bars, and a 50 g standard d-glucose for GDM screening/diagnosis; it is included in the Farrar 2015 Cochrane Review.
NCT01026675	This is an ongoing prospective cohort study.

Study	Reason for exclusion
NCT01552213	This ongoing study is assessing whether medical nutrition therapy for women with prediabetes decreases the rate and severity of impaired glucose tolerance later in pregnancy and improves perinatal outcomes.
NCT02036619	This is an ongoing prospective cohort study.
NCT02266758	This ongoing study is comparing a 1-step, 75 g approach and a 2-step approach for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
NCT02309138	This ongoing study is comparing a 2-h, 75 g OGTT (IADPSG criteria) with a 3-h, 100 g OGTT (Carpenter Coustan criteria) for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
NCT02610179	This is a non-randomised study comparing 10 Twizzlers with the 50 g glucola beverage for GDM screening/diagnosis.
NCT02708758	This ongoing study is comparing medical nutrition therapy plus self-monitoring of capillary glucose and if necessary drug therapy (metformin or insulin) when goals are not met, with prenatal routine care without medical nutrition therapy and without self-monitoring capillary glucose and drug therapy, in women diagnosed with GDM according to IADPSG criteria.
NCT02979756	This ongoing study plans to include women with GDM, comparing those identified via decentralised GDM screening and initial management with those identified via standard GDM screening and management practice.
NCT03073330	This ongoing study is comparing a 1-step, 2-h, 75 g OGTT approach, with a 2-step approach (50 g OGCT and if indicated, a 100 g OGTT) for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Olarinoye 2004	This study compared a 75 g and 100 g OGTT for GDM screening/diagnosis; it is included in the Farrar 2015 Cochrane Review.
Saijan 2011	This study compared a 50 g OGCT and OGTT with a 75 g OGCT alone for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Sammarco 1993	This study assessed a non-fasting OGTT and fasting OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".
Scifres 2015	This study compared a 2-h, 75 g OGTT using the IADPSG criteria, with a 3-h, 100 g OGTT using the Carpenter-Coustan criteria for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Sevket 2014	This study compared a 1-step (2-h OGTT) approach, with a 2-step (50 g OGCT and 100 g OGTT) approach for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Soonthornpun 2003	This study compared a 75 g OGTT and a 100 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over trial".
Soonthornpun 2008	This study compared a 75 g and 100 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Participants known to have normal glucose tolerance".

Study	Reason for exclusion
Stavrianos 2004	This study assessed fingertip versus forearm blood samples in women undergoing a 100 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Not a randomised trial: 2 groups matched for key characteristics".
Weiss 1998	This study compared a 75 g and a 100 g OGTT for GDM screening/diagnosis; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Cross-over study of response to different glucose loads in those with a diagnosis of GDM and those without".
Yeral 2014	This study compared a 1-step (2-h OGTT) approach, with a 2-step (50 g OGCT and 100 g OGTT) approach for GDM screening/diagnosis; it will likely be considered for inclusion in the next update of the Farrar 2015 Cochrane Review.
Zhang 1995	This study compared capillary and venous blood sampling following a 50 g OGTT; it was assessed for inclusion in the Farrar 2015 Cochrane Review and was excluded: "Not a randomised trial; women 'randomly selected' for a 50-gram oral GTT".

Abbreviations: ACOG: American College of Obstetricians and Gynecologists; ADA: American Diabetes Association; g: grams; GDM: gestational diabetes mellitus; IADPSG: International Association of the Diabetes and Pregnancy Study Groups; OGCT: oral glucose challenge test; OGTT: oral glucose tolerance test

Characteristics of studies awaiting assessment *[ordered by study ID]*

[Bebbington 1999](#)

Methods	Type of study: RCT Method of randomisation: unspecified Loss of participants to follow-up: 18 of 2401 women were lost to follow-up Intention-to-treat analysis: unspecified Blinding: unfeasible to blind participants or healthcare providers. "Blinded assessors collected outcomes postpartum." Funding: unspecified
Participants	Location: British Columbia Women's Hospital, British Columbia, Canada Inclusion criteria: low-risk pregnancy at British Columbia Women's Hospital Exclusion criteria: risk factors for GDM (specific risk factors not specified) 2401 women were enrolled into the study. 1197 women were allocated to the routine screening arm and 1204 women were allocated to the selected screening arm
Interventions	Routine testing group: received a 50 g OGCT and a full 100 g OGTT was performed in women whose 1-h glucose was > 7.8 mmol/L on 50-g screening Selected screening group: received glucose testing only for selected indications that arose during pregnancy
Outcomes	Maternal: none Infant: birthweight and macrosomia
Notes	The only publication of this trial is a conference abstract. We are in correspondence with the trial authors for additional data. No contact as at July 2013.

Abbreviations: g: grams; GDM: gestational diabetes mellitus; OGCT: oral glucose challenge test; OGTT: oral glucose tolerance test

Characteristics of ongoing studies [ordered by study ID]

ChiCTR-TRC-13003495

Trial name or title	A prospective study of the risk factors of gestational diabetes in patients with early screening and intensive insulin intervention
Methods	RCT
Participants	<p>Inclusion criteria: pregnant women aged > 30 years, BMI ≥ 25 kg/m², with polycystic ovary syndrome or irregular menstrual periods, a family history of diabetes, early pregnancy fasting urine positive, abnormal obstetric history (GDM, neonatal respiratory distress syndrome, stillbirth, macrosomia), suspicion of macrosomia or polyhydramnios.</p> <p>Exclusion criteria: women with diabetic ketosis or ketoacidosis, diabetic hyperosmolar state, diabetic lactic acidosis and other acute diabetes complications or serious chronic complications of diabetes, threatened abortion, pregnancy-induced hypertension, eclampsia, congestive heart failure, or other serious comorbidities</p>
Interventions	<p>Intervention: early screening group; with diet control and insulin</p> <p>Control: advanced screening group; with insulin</p>
Outcomes	<p>Primary outcome: HbA1c</p> <p>Secondary outcomes: oral glucose tolerance; C-peptide; LDL-C; triglycerides; insulin; HOMA-IR; mean glucose: MAGE; BMI; PPGE; SBP; DBP; Apgar at 5 minutes</p>
Starting date	January 2012
Contact information	Shaohua Wang: wshgyj@yahoo.com.cn
Notes	<p>Retrospective registration</p> <p>Estimated enrolment: 200</p>

NCT01864564

Trial name or title	Early Gestational diabetes screening in the Gravid Obese woman (EGGO)
Methods	RCT
Participants	<p>Inclusion criteria; pregnant women; ≥ 18 years; BMI ≥ 30 kg/m²; < 18 weeks' gestation at presentation for care</p> <p>Exclusion criteria: prior caesarean section; prior bariatric surgery; major maternal medical illness (cardiac disease, HIV, haemoglobinopathy; oxygen requirement); chronic prednisone use; known fetal anomalies; multiple gestation</p>
Interventions	<p>Intervention: early screening. Women will be randomised to be screened at 14-28 weeks' gestation for GDM using the standard US screening method of a 1-h, 50 g OGCT followed by a 3-h, 100 g OGTT if indicated. Women who do not have GDM will be re-screened at 24-28 weeks as per standard care</p> <p>Control: routine screening. Women will be screened at 24-28 weeks</p>

NCT01864564 (Continued)

Outcomes	<p>Primary outcome: composite perinatal outcome: macrosomia (birthweight > 4000 g), caesarean section, gestational hypertension, pre-eclampsia, shoulder dystocia, neonatal hyperbilirubinaemia, neonatal hypoglycaemia</p> <p>Secondary outcomes: macrosomia; caesarean section; pregnancy-induced hypertension; shoulder dystocia; neonatal hyperbilirubinaemia; preterm birth</p>
Starting date	June 2013
Contact information	Lorie M Harper: lmharper@uabmc.edu
Notes	Estimated enrolment: 1160

NCT02183558

Trial name or title	Glucose metabolism and screening for gestational diabetes mellitus according to different sets of criteria in women with polycystic ovary syndrome and controls
Methods	Unclear whether this is a cohort study or RCT
Participants	<p>Inclusion criteria: pregnancy during 2010-2012; residents of the municipality of Odense</p> <p>Exclusion criteria: moving from Odense during pregnancy</p>
Interventions	OGTT by randomisation; OGTT by indication
Outcomes	<p>Primary outcome: GDM</p> <p>Secondary outcomes: anthropometric measures in offspring</p>
Starting date	January 2010
Contact information	Marianne Andersen
Notes	Estimated enrolment: 2500

NCT02377531

Trial name or title	Early screen and treatment for gestational diabetes
Methods	RCT
Participants	<p>Inclusion criteria: pregnant women between 18-45 years, with risk factors for GDM: BMI > 30 kg/m²; history of GDM; history of macrosomic infant; 1st-degree relative with diabetes; multiple gestation</p> <p>Exclusion criteria: women with incomplete data; fetal malformations or aneuploidy; pre-gestational or overt diabetes; chronic medical conditions (hypertension, renal disease, autoimmune conditions); early diabetes screen prior to enrolment; medical contraindication to glucose tolerance test (bariatric surgery)</p>
Interventions	<p>Intervention: early glucose screen. Women will be screened with a 1-h, 50 g OGCT followed by a 3-h, 100 g OGTT if indicated (using the Carpenter-Coustan criteria for GDM diagnosis)</p> <p>Control: routine screening. Women will be screened at 24-28 weeks.</p>

NCT02377531 (Continued)

Outcomes	Primary outcome: composite perinatal morbidity (perinatal mortality (stillbirth or neonatal death), neonatal hypoglycaemia, hyperbilirubinaemia, birth trauma) Secondary outcomes: maternal weight gain
Starting date	March 2015
Contact information	Alejandro R Rodriguez: arodri24@health.usf.edu
Notes	Estimated enrolment: 1020

NCT03116009

Trial name or title	Randomization of early diabetes screening among obese pregnant women (REDSOAP)
Methods	RCT
Participants	Inclusion criteria: obese pregnant women with BMI > 30 kg/m ² ; 1st prenatal visit or subsequent visit < 20 weeks' gestation; maternal age > 18 years; willingness to participate in the study and give informed consent Exclusion criteria: pre-existing diabetes mellitus or pre-GDM; gestational age > 20 weeks at time of enrolment; unknown or inability to determine gestational age even with last menstrual period; previous medical history of GDM; known impaired glucose metabolism HbA1C > 6.5%
Interventions	Intervention: early diabetes screening. Women will receive a 1-h OGCT < 20 weeks' gestation. Those with positive test will undergo a 3-h OGTT. Diabetes will be diagnosed if they have 2 or more abnormal values out of the 4 values and they will be treated accordingly based on the institutional protocol. They will also have HbA1C done Control: standard diabetes screening. Women will only have HbA1C done < 20 weeks but will do the standard diabetes screening at 24-28 weeks. Those who have abnormal values will also be treated based on the institutional protocol
Outcomes	Primary outcome: large-for-gestational age or macrosomia Secondary outcomes: pre-eclampsia; 3rd- or 4th-degree perineal lacerations; normal vaginal birth; caesarean section; operative vaginal birth; glycaemic control during pregnancy and postpartum (HbA1c during pregnancy; OGCT result postpartum)
Starting date	March 2017
Contact information	Christopher A Enakpene: cenakpene@gmail.com Dimitrios Mastrogiannis: dmastro@uic.edu
Notes	Estimated enrolment: 600

Abbreviations: BMI: body mass index; DBP: diastolic blood pressure; g: grams; GDM: gestational diabetes mellitus; HbA1c: glycated haemoglobin; HOMAR-IR: homeostatic model assessment of insulin resistance; LDL-C: low-density lipoprotein cholesterol; MAGE: mean amplitude of glycaemic excursions; OGCT: oral glucose challenge test; OGTT: oral glucose tolerance test; PPGE: postprandial glucose excursion; RCT: randomised controlled trial; SBP: systolic blood pressure

DATA AND ANALYSES

Comparison 1. Universal screening versus risk-factor screening

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gestational diabetes mellitus	1	3152	Risk Ratio (M-H, Fixed, 95% CI)	1.85 [1.12, 3.04]
2 Gestational age at birth (weeks)	1	3152	Mean Difference (IV, Fixed, 95% CI)	0.15 [0.03, 0.27]

Analysis 1.1. Comparison 1 Universal screening versus risk-factor screening, Outcome 1 Gestational diabetes mellitus.

Analysis 1.2. Comparison 1 Universal screening versus risk-factor screening, Outcome 2 Gestational age at birth (weeks).

Comparison 2. Primary care screening versus secondary care screening

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gestational diabetes mellitus	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.50, 1.66]
2 Hypertensive disorders of pregnancy: hypertension	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.41 [0.77, 2.59]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Hypertensive disorders of pregnancy: pre-eclampsia toxemia	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.36, 1.78]
4 Caesarean birth	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.80, 1.27]
5 Large-for-gestational age	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.96, 1.96]
6 Perinatal mortality	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.10, 12.12]
7 Neonatal mortality or morbidity composite: neonatal complications	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.57, 1.71]
8 Operative vaginal birth	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.90, 1.13]
9 Postpartum haemorrhage	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.75, 2.09]
10 Adherence to the intervention: uptake of screening allocated	1	781	Risk Ratio (M-H, Fixed, 95% CI)	0.59 [0.53, 0.65]
11 Stillbirth	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.10, 12.12]
12 Neonatal death	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Gestational age at birth (weeks)	1	690	Mean Difference (IV, Fixed, 95% CI)	0.41 [0.14, 0.68]
14 Preterm birth	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.37, 2.43]
15 Birthweight (kg)	1	690	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.09, 0.09]
16 Shoulder dystocia	1	690	Risk Ratio (M-H, Fixed, 95% CI)	6.61 [0.27, 161.63]
17 Respiratory distress syndrome	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.24, 2.26]
18 Hypoglycaemia	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.28, 4.38]
19 Hyperbilirubinaemia or jaundice	1	690	Risk Ratio (M-H, Fixed, 95% CI)	2.21 [0.14, 35.16]
20 Neonatal intensive care unit admission	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.58, 1.69]
21 Not pre-specified: birth trauma	1	690	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.10, 12.12]
22 Not pre-specified: time to access antenatal diabetes care (days)	1	48	Mean Difference (IV, Fixed, 95% CI)	4.70 [-0.39, 9.79]

Analysis 2.1. Comparison 2 Primary care screening versus secondary care screening, Outcome 1 Gestational diabetes mellitus.

Analysis 2.2. Comparison 2 Primary care screening versus secondary care screening, Outcome 2 Hypertensive disorders of pregnancy: hypertension.

Analysis 2.3. Comparison 2 Primary care screening versus secondary care screening, Outcome 3 Hypertensive disorders of pregnancy: pre-eclampsia toxemia.

Analysis 2.4. Comparison 2 Primary care screening versus secondary care screening, Outcome 4 Caesarean birth.

Analysis 2.5. Comparison 2 Primary care screening versus secondary care screening, Outcome 5 Large-for-gestational age.

Analysis 2.6. Comparison 2 Primary care screening versus secondary care screening, Outcome 6 Perinatal mortality.

Analysis 2.7. Comparison 2 Primary care screening versus secondary care screening, Outcome 7 Neonatal mortality or morbidity composite: neonatal complications.

Analysis 2.8. Comparison 2 Primary care screening versus secondary care screening, Outcome 8 Operative vaginal birth.

Analysis 2.9. Comparison 2 Primary care screening versus secondary care screening, Outcome 9 Postpartum haemorrhage.

Analysis 2.10. Comparison 2 Primary care screening versus secondary care screening, Outcome 10 Adherence to the intervention: uptake of screening allocated.

Analysis 2.11. Comparison 2 Primary care screening versus secondary care screening, Outcome 11 Stillbirth.

Analysis 2.12. Comparison 2 Primary care screening versus secondary care screening, Outcome 12 Neonatal death.

Analysis 2.13. Comparison 2 Primary care screening versus secondary care screening, Outcome 13 Gestational age at birth (weeks).

Analysis 2.14. Comparison 2 Primary care screening versus secondary care screening, Outcome 14 Preterm birth.

Analysis 2.15. Comparison 2 Primary care screening versus secondary care screening, Outcome 15 Birthweight (kg).

Analysis 2.16. Comparison 2 Primary care screening versus secondary care screening, Outcome 16 Shoulder dystocia.

Analysis 2.17. Comparison 2 Primary care screening versus secondary care screening, Outcome 17 Respiratory distress syndrome.

Analysis 2.18. Comparison 2 Primary care screening versus secondary care screening, Outcome 18 Hypoglycaemia.

Analysis 2.19. Comparison 2 Primary care screening versus secondary care screening, Outcome 19 Hyperbilirubinaemia or jaundice.

Analysis 2.20. Comparison 2 Primary care screening versus secondary care screening, Outcome 20 Neonatal intensive care unit admission.

Analysis 2.21. Comparison 2 Primary care screening versus secondary care screening, Outcome 21 Not pre-specified: birth trauma.

Analysis 2.22. Comparison 2 Primary care screening versus secondary care screening, Outcome 22 Not pre-specified: time to access antenatal diabetes care (days).

APPENDICES

Appendix 1. Search terms for ClinicalTrials.gov and ICTRP

gestational AND diabetes AND screening

gdm AND screening

FEEDBACK

Oliveira, 9 March 2015

Summary

I'm a consumer and an activist for better health care practices. It seems that the famous HAPO¹ study was not included in this review. I would like to have your help to understand why.

Comment submitted by Sandra Oliveira, March 2015

References

1. Hyperglycemia and Adverse Pregnancy Outcomes. *New England Journal of Medicine* 2008;358:1991-2002.

Reply

Thank you for your feedback. The HAPO study was not a randomised controlled trial, and therefore was not eligible for inclusion in this review. The HAPO study was a cohort study which was conducted to clarify the risks of adverse outcomes associated with various degrees of maternal glucose intolerance less severe than that in overt diabetes mellitus.

Contributors

Emily Shepherd

WHAT'S NEW

Date	Event	Description
31 January 2017	New citation required and conclusions have changed	<p>We have included one new trial, excluded 15 new trials, and listed five new trials as ongoing. We have also excluded three trials which were previously included (due to clarification of the review's objective and thus inclusion criteria; see Differences between protocol and review).</p> <p>We now have two comparisons: 1) Universal screening versus risk-factor screening; and 2) Primary care screening versus secondary care screening.</p>
31 January 2017	Feedback has been incorporated	The authors have added a reply to Feedback 1 .
31 January 2017	New search has been performed	Search and methods updated. One new author joined the team.

HISTORY

Protocol first published: Issue 3, 2008

Review first published: Issue 7, 2010

Date	Event	Description
9 March 2015	Feedback has been incorporated	Feedback 1 submitted by Sandra Oliveira.
1 December 2013	New citation required but conclusions have not changed	New search. Three studies have been excluded (Duenas-Garcia 2011 ; Meltzer 2010 ; Saijan 2011); no new trials have been included.
1 December 2013	New search has been performed	Review updated.
10 January 2011	Amended	Contact details updated.

CONTRIBUTIONS OF AUTHORS

In this update of the review, Emily Shepherd assessed studies for eligibility, extracted data and drafted the first version of the update. All review authors made comments on subsequent drafts and contributed to the final version.

In the previous versions of this review Joanna Tieu and Philippa Middleton assessed studies for inclusion and extracted data. The first draft of the previous versions of this review were written by Joanna Tieu and Philippa Middleton, with Caroline Crowther and Andy McPhee making comments on subsequent drafts and contributing to the final versions.

Joanna Tieu researched and wrote the protocol with aid and regular feedback from Caroline Crowther, Philippa Middleton and Andy McPhee.

DECLARATIONS OF INTEREST

Joanna Tieu: is supported by an NHMRC postgraduate scholarship and Ken Muirden overseas fellowship, awarded by Arthritis Australia and jointly funded by the Australian Rheumatology Association and Roche.

Andrew J McPhee received a speaker's honorarium (from the Nestle Nutrition Institute) which was paid to his institution and used to fund undergraduate and postgraduate travel to attend conferences.

Caroline A Crowther: led the ACHOIS trial and is the principal investigator for the IDEAL trial assessing the effects of treatment for women with glucose intolerance not meeting current diagnostic thresholds for gestational diabetes. Both trials assessed treatment strategies, and would therefore not be assessed for inclusion in this review.

Philippa Middleton: none known.

Emily Shepherd: none known.

SOURCES OF SUPPORT

Internal sources

- ARCH: Australian Research Centre for Health of Women and Babies, Robinson Research Institute, The University of Adelaide, Australia.

External sources

- NHMRC: National Health and Medical Research Council, Australia.

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- NIHR: National Institute for Health Research, UK.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Prior to conduct of this update, a number of changes were made relating to the eligibility criteria of the first ([Tieu 2010](#)) and previous ([Tieu 2014](#)) versions of the review:

- We revised the title, which was previously: *Screening and subsequent management for gestational diabetes for improving maternal and infant health* ([Tieu 2010](#); [Tieu 2014](#)) to *Screening for gestational diabetes mellitus based on different risk profiles and settings for improving maternal and infant health*
- We also revised the objective, which was previously "To assess the effects of different methods of screening for gestational diabetes mellitus on maternal and infant outcomes" ([Tieu 2010](#); [Tieu 2014](#)) to "To assess the effects of screening for gestational diabetes mellitus based on different risk profiles and settings on maternal and infant outcomes."
- We explicitly stated under 'Types of interventions' that eligible screening protocols, guidelines or programmes for screening for GDM are those "based on different risk profiles and settings."

We have excluded three trials ([Bergus 1992](#); [Martinez Collado 2003](#); [Murphy 1994](#)) which were included in the previous versions of this review ([Tieu 2010](#); [Tieu 2014](#)).

The above changes were in recognition of the overlap between the eligibility criteria of the previous versions of this review ([Tieu 2010](#); [Tieu 2014](#)), and the [Farrar 2015](#) Cochrane Review: *Different strategies for diagnosing gestational diabetes to improve maternal and infant health*. The objective of the [Farrar 2015](#) review is "To evaluate and compare different testing strategies for diagnosis of gestational diabetes mellitus to improve maternal and infant health while assessing their impact on healthcare service costs;" and eligible interventions in the review are "all diagnostic tests for GDM, such as glycated haemoglobin, random and fasting blood sugar and oral glucose tolerance tests."

The [Farrar 2015](#) review thus includes the three trials that were previously included in this review (focused on GDM screening by different glucose loading methods) but are now excluded ([Bergus 1992](#); [Martinez Collado 2003](#); [Murphy 1994](#)). The [Farrar 2015](#) review recognises that the question of whether to offer universal or selective screening is the topic of this review, and therefore excludes the [Griffin 2000](#) trial (included in this review); and also excludes the [O'Dea 2016](#) trial (included in this review), which is focused on different settings for GDM screening.

Prior to conduct of this update, we also revised the review outcomes, using the standard outcome set agreed by consensus between review authors of Cochrane Pregnancy and Childbirth systematic reviews for prevention and treatment of GDM and pre-existing diabetes (please refer to [Tieu 2010](#) and [Tieu 2014](#) for the outcomes assessed in the previous versions of this review). We have also reported on two non pre-specified outcomes (birth trauma - damage to tissues or organs as a result of childbirth; and time to access antenatal diabetes care) as we believe they relate to our pre-specified outcomes and are of importance.

Prior to conducting this update, we also updated the methods to be in line with those in the standard template used by Cochrane Pregnancy and Childbirth. This now includes use of the GRADE approach to assess the quality of the body of evidence and the use of 'Summary of findings' tables, and an additional search of ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform ([ICTRP](#)).

INDEX TERMS

Medical Subject Headings (MeSH)

Diabetes, Gestational [*diagnosis] [therapy]; Glucose Tolerance Test [adverse effects] [*methods]; Infant Welfare; Mass Screening [*methods]; Maternal Welfare; Pregnancy Outcome; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Infant, Newborn; Pregnancy