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Screening for Gestational Diabetes Mellitus: A Systematic Review to Update the 2014 U.S. Preventive Services Task Force Recommendation

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Structured Abstract

Background: Gestational diabetes mellitus (GDM) is largely asymptomatic; screening for GDM during pregnancy could identify women who could benefit from treatments to reduce adverse consequences of GDM.

Purpose: To systematically update the 2012 evidence review used to inform United States Preventive Services Task Force (USPSTF) recommendations on benefits and harms of screening for GDM.

Data Sources: MEDLINE, Embase, and CINAHL (2010 to May 2020), ClinicalTrials.gov, reference lists of primary studies and systematic reviews; with surveillance through December 2020. All previously reviewed studies were re-assessed for eligibility.

Study Selection: Two investigators independently reviewed abstracts and full-text articles against a set of a priori inclusion criteria. Disagreements were resolved through discussion. We included English-language controlled trials for effectiveness of screening and treatment; observational studies on screening effectiveness, harms, and association between GDM and outcomes; and prospective studies on diagnostic accuracy of screening tests.

Data Extraction: One investigator abstracted data and a second investigator checked data abstraction for completeness and accuracy. Two investigators independently rated quality of the included studies using design-specific criteria.

Data Synthesis (Results): Eighteen trials (different screening strategies [N=2,483]; treatment benefits and harms [N=4,235]) and 87 observational studies (screening benefits [N=4,336] and harms [N=166,082]; diagnostic accuracy [N=91,260]; outcome associations [N=105,492]) were included.

Four observational studies (N=4,336) of screening versus no screening suggested that screening may be associated with reduced risk of some pregnancy and neonatal outcomes, but findings for each outcome were based on single studies with methodological limitations. Undergoing screening or receiving a false positive result may not be associated with anxiety; GDM may be associated with unnecessary cesarean delivery.

Three small trials (N=1,059) found screening using a 1-step International Association of Diabetes and Pregnancy Study Group (IADPSG), versus 2-step Carpenter-Coustan (CC), strategy associated with decreased risk of primary cesarean deliveries (RR, 0.73 [95% CI, 0.55 to 0.97; absolute risk reduction [ARD], 6.3%), large-for-gestational age [LGA] infants (RR, 0.46 [95% CI, 0.25 to 0.83]; ARD, 3.2%), NICU admissions (RR, 0.49 [95% CI, 0.29 to 0.84]; ARD, 3.7%) and neonatal hypoglycemia (RR, 0.52 [95% CI, 0.28 to 0.95]; ARD, 2.7%), with no differences or limited data for other pregnancy and neonatal outcomes. Inconsistency was present in analyses, there were study quality concerns, and two additional large trials are pending. One trial (N=922) suggested that early versus usual timing of 2-step CC screening may not improve outcomes in obese women.

Forty-five studies (N=91,260) evaluated diagnostic accuracy. At 24 to 28 weeks' gestation, the oral glucose challenge test using 135 or 140 mg/dL thresholds, against CC and National Diabetes Data Group (NDDG) criteria, and a fasting plasma glucose of 85 mg/dL or 90 mg/dL against CC GDM, had reasonable accuracy (sensitivities ≥81% and specificities ≥73%). Fasting glucose at or below 80 mg/dL appears useful for ruling out CC or IADPSG GDM. Screening with the glucose challenge test against IADPSG criteria had low sensitivity.

Being diagnosed with GDM based on more (e.g., 1-step IADPSG) versus less (e.g., 2-step CC) inclusive criteria, but not treated, associated with increased risk of preeclampsia, cesarean deliveries, preterm deliveries, macrosomia, LGA, neonatal hypoglycemia, and hyperbilirubinemia. No association was found for NICU admissions.

From nine trials (N=3,982), treatment for mild GDM at or after 24 weeks' gestation associated with decreased risk of primary cesarean deliveries (RR, 0.70 [95% CI, 0.54 to 0.91]; ARD, 5.3%), preterm deliveries (RR, 0.75 [95% CI, 0.56 to 1.01]; ARD 2.3%), preeclampsia (RR, 0.60 [95% CI, 0.35 to 1.01]; ARD, 1%; after excluding one outlier trial), shoulder dystocia (RR, 0.42 [95% CI, 0.23 to 0.77]; ARD, 1.3%), macrosomia by 8.9% (RR, 0.53 [95% CI, 0.41 to 0.68]; ARD, 8.9%), LGA (RR, 0.56 [95% CI, 0.47 to 0.66]; ARD, 8.4%), birth injuries (e.g., fracture or nerve palsies) (OR, 0.33 [95% CI, 0.11 to 0.99]; ARD, 0.2%) and NICU admissions (RR, 0.73 [95% CI, 0.53 to 0.99; ARD, 2.0%). There was no association with risk of neonatal hypoglycemia or total cesarean deliveries, or for the potential harm of small-for-gestational age. There was limited evidence on long-term health outcomes.

Limitations: Evidence on screening versus no screening was observational; very limited evidence on early treatment; restricted to English language studies; unable to formally assess for publication bias; limited evidence for some comparisons and outcomes, and most subgroups; heterogeneity present in some analyses.

Conclusions: While direct evidence on outcomes of screening remains very limited, screening tests can identify with gestational diabetes at or after 24 weeks' gestation and treatment is associated with improvement in various maternal and neonatal outcomes without serious harms. More research is needed to determine the impacts of screening and treatment earlier or based on more inclusive criteria.

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Chapter 1. Introduction and Background

Purpose

This report updates a 2012 systematic review on screening for gestational diabetes mellitus (GDM) conducted by the Agency of Healthcare Research and Quality (AHRQ).[1-4] It will be used by the United States Preventive Services Task Force (USPSTF) to update their 2014 recommendations.[5]

In 2014, the USPSTF recommended screening for GDM in asymptomatic pregnant women after 24 weeks of gestation.[5] (B recommendation) This recommendation was based on the USPSTF assessment of adequate evidence that primary care providers could accurately detect GDM and that treatment of screen-detected GDM can significantly reduce maternal and fetal complications (preeclampsia, macrosomia, and shoulder dystocia), with small or no harm. The USPSTF concluded that the evidence was insufficient to assess the balance of benefits and harms of screening for GDM in asymptomatic pregnant women before 24 weeks of gestation. (I statement).

Condition Background

Condition Definition

GDM was originally defined as glucose intolerance first discovered in pregnancy.[6] Because this definition does not clearly distinguish between GDM and women with preexisting, overt diabetes (unknown until pregnancy), GDM is now defined by the development of diabetes during pregnancy.[7-9] The latter definition will be used for this report, recognizing that it can be difficult to distinguish between GDM and preexisting diabetes. Pregnant women with preexisting diabetes (type 1 or 2) have more complex care needs and risks for serious complications (e.g., exacerbation of diabetes-related complications, such as retinopathy and nephropathy; congenital malformations; stillbirth) compared with women having GDM;[10-13] detection and management of preexisting diabetes during pregnancy is beyond the scope of this report.

Prevalence and Burden of Disease/Illness

The prevalence of GDM in the United States has been in the past estimated at 5.6 to 9.2 percent.[14-17] These estimates are largely based on use of the widely adopted "two-step" screening approach, which refers to the application of a screening test and, if indicated, a diagnostic test using either Carpenter Coustan (CC)[18] or National Diabetes Data Group (NDDG)[19] criteria. Prevalence varies depending on which criterion is used, as NDDG leads to about 30-50% fewer diagnoses than CC criteria.[20] Comparing the U.S. prevalence to that in other countries is difficult, due to population characteristics (e.g., race/ethnicity, maternal age) and/or different screening approaches. Prevalence may be lower if selective/risk-based approaches are used rather than universal screening; they will be higher when "one-step" screening with a diagnostic test is

applied without an initial screening test, and/or more inclusive diagnostic criteria (i.e., lower threshold to diagnose GDM) are used. In 2010, the International Association of Diabetes and Pregnancy Study Group (IADPSG) Consensus Panel released recommendations for a new one-step screening approach using "outcome-based" criteria,[21] informed by data from the landmark, international Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study of glucose-outcome associations.[9] Across the study centers of the HAPO study, applying the IADPSG criteria resulted in a prevalence of GDM of 17.8 percent.[22] Data from other studies in countries that previously used two-step approaches with the CC or NDDG criteria indicate that the absolute rates of GDM increase by 8 to 33 percent (1.03 to 3.78-fold rise) when using the IADPSG criteria.[23]

A large cohort of over 125 million pregnancies in the United States found that the prevalence of GDM increased from 0.3 to 5.8 percent during the period between 1979-1980 and 2008-2010.[16] This increase is likely related to increased awareness and screening for GDM, some diagnoses being based on lower thresholds (e.g., changing from NDDG to CC criteria), and a true increase in prevalence, largely from increasing maternal age and body mass index (BMI). Between 2006 and 2016, there was an absolute increase in GDM of 3.6 percent from National Health Interview Survey data; changes were most marked in groups categorized as overweight, low income, ages 45 to 64 years, not white or Hispanic, and having insufficient physical activity.[17]

Etiology and Natural History

GDM usually arises after 20 weeks' gestation when placental hormones with the opposite effect of insulin increase substantially. Women with adequate insulin secreting capacity overcome this insulin resistance of pregnancy by secreting more insulin in order to maintain normal blood glucose. Women with less pancreatic reserve are unable to produce adequate insulin to overcome the increase in insulin resistance, and glucose intolerance results.

Evidence from the HAPO and other studies has demonstrated a continuous linear association between (untreated) plasma serum glucose levels—both fasting and postload—and adverse perinatal outcomes including large for gestational age (LGA) neonates, shoulder dystocia, primary cesarean delivery, preeclampsia, neonatal hypoglycemia.[2,4,9,24] Reviews examining associations based on differing diagnostic thresholds have generally found a GDM diagnosis associated with poorer perinatal outcomes, though most included studies did not use the newest, more inclusive IADPSG criteria.[2,4,25] GDM has also been associated with increased risk of several long-term intermediate (e.g., obesity) and health outcomes (e.g., development of T2DM, neurodevelopment in childhood) in both women and their offspring. In some analyses, confounding from factors such as parental BMI, gestational age at birth, lifestyle, and socioeconomic status could have impacted the findings.[26-28] For some outcomes, such as perinatal death, previous syntheses have found that studies were generally underpowered to determine accurate effects.[2,4,9] The associations between GDM and long-term health outcomes are addressed in more detail in both a Key Question (related to different criteria for GDM) and Contextual Question 3.

Risk Factors

Risk factors for GDM include greater maternal age (e.g., 35 years or older), elevated BMI, member of an ethnic group at increased risk for development of type 2 diabetes mellitus (T2DM), past history of GDM, macrosomia in a previous pregnancy, history of unexplained stillbirth, T2DM in a first degree relative, polycystic ovary syndrome, and metabolic syndrome.[29-31] There is some variation between U.S. reports on the prevalence of GDM by race/ethnicity, although American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, and Hispanic women are at higher risk for GDM than non-Hispanic white women.[14,32,33] Much of the risk in different ethnic groups is attenuated when accounting for overweight, obesity, and low socioeconomic status, with the exception of Asian American women, who may have higher GDM prevalence despite normal BMI.[34,35] Factors associated with decreased risk of GDM include young age (25 or 30 years and younger), non-Hispanic white ethnicity, normal BMI (25 kg/m^2 or less [with the exception of Asian women]), no history of previous glucose intolerance or adverse pregnancy outcomes associated with GDM, and no first degree relative with known diabetes.[31,36]

Rationale for Screening/Screening Strategies

GDM is usually asymptomatic and preventing consequences by detecting and treating GDM during pregnancy could improve pregnancy and neonatal outcomes. Identification and treatment of GDM during pregnancy may also improve long-term maternal or childhood outcomes and facilitate other preventive interventions after delivery.

Screening women for GDM involves either a two- or one-step approach (**Table 1**). In two-step screening, the screening test is often a 50 g oral glucose challenge test (OGCT) administered in a nonfasting state, and patients who meet or exceed a screening threshold (usually 130 mg/dL or 140 mg/dL) at one hour receive the diagnostic oral glucose tolerance test (OGTT) in which a 75 g or 100 g oral glucose load is administered in a fasting state and plasma glucose levels are evaluated at fasting and after 1, 2, and sometimes 3 hours. A diagnosis of GDM is made when one or two glucose values fall at or above the specified glucose thresholds, depending on the diagnostic criteria. Alternatives to the OGCT as the first step in some two-step screening strategies include assessment of risk factors (e.g., the National Institute for Health and Care Excellence in the United Kingdom) for targeted, or selective, screening, or testing of fasting plasma glucose (FPG). Risk-factor based approaches may also be used to determine who receives a two-step strategy, using for example applying an OGCT and then an OGTT, when indicated, only in select populations. A one-step screening method does not use a screening test, but administers the OGTT in all patients.

While a universal two-step method using an OGCT is widely performed in the United States, much of the rest of the world utilizes targeted two-step screening or a one-step screening method.[23] The potential advantages of a two-step over a one-step screening approach are the ease of use and lower resources required,[37] but its utility depends on the ability of a negative screen to accurately rule out GDM and on adherence to the second step of the screening. One-step approaches reduce false negative and positive screening results since only the reference standard is used; these approaches may appear desirable for a high-risk population, but may be limited by

requiring a fasting state for all women. With either approach, using more inclusive criteria (e.g., lower glucose threshold or requiring one rather than two glucose values above the threshold) could result in overdiagnosis and associated overtreatment and other potential harms. Different countries and ethnicities have been shown to have differences in whether GDM diagnostic criteria are more likely to be met on the fasting or post-glucose load measurement (e.g., majority of diagnoses based on fasting glucose in South African, Latino and Middle Eastern populations but on post-glucose load measurements in Chinese and Thai populations).[22,38] At this time it is not clear if this is a result of racial differences in glucose handling or reflective of per/kg body weight differences of the glucose load used for testing and if this should impact which criteria and approach used for a given population.

The first two-step screening approach (a 50 g 1-hour OGCT then a 100g 3-hour OGTT with two abnormal OGTT values required for diagnosis) was proposed in 1964 by O'Sullivan and Mahan, after validation against the development of future T2DM (up to 60% cumulative increase after 16 years) in the mother.[39,40] The NDDG modified the diagnostic criteria in 1979, for measuring glucose in plasma rather than whole blood,[19,23] and in 1982 Carpenter and Coustan (CC) further modified the criteria in order to incorporate considerations related to use of more modern analytic methods.[18] For over three decades it has been common globally to use a two-step procedure with the OGTT criteria of NDDG (i.e., 2 abnormal values with thresholds at fasting 105 mg/dL [5.8 mmol/L], and/or postglucose load at 1 hour 190 mg/dL [10.5 mmol/L], 2 hours 165 mg/dL [9.1 mmol/L], or 3 hours 145 mg/dL [8.0 mmol/L]), or of CC (i.e., 2 abnormal values at fasting 95 mg/dL [5.3 mmol/L], and/or post-glucose load at 1 hour 180 mg/dL [10 mmol/L], 2 hours 155 mg/dL [8.6 mmol/L], or 3 hours 140 mg/dL [7.8 mmol/L]) (**Table 1**). Because of evidence that elevated glucose levels that do not meet NDDG or CC thresholds for GDM are also associated with adverse health outcomes (e.g. HAPO study),[9] and that treatment for women with lesser degrees of dysglycemia appears to improve outcomes,[41,42] alternative two-step and one-step approaches and criteria have been developed over the years by professional, national, or international organizations. Most of these two- and one-step approaches are more inclusive (i.e., result in diagnosis of more women with GDM), requiring one rather than two abnormal values on the OGTT for diagnosis. The one-step IADPSG criteria which has lower glucose thresholds and uses one abnormal value (75 g 2-hour OGTT with fasting 92 mg/dL [5.1 mmol/L], or postglucose load at 1 hour 180 mg/dL [10 mmol/L] or 2 hours 153 mg/dL [8.5 mmol/L]) is currently endorsed internationally by several societies and guideline communities as the recommended diagnostic test or as a diagnostic option (**Table 1**).

Interest has grown about the usefulness of FPG as an alternative to the OGCT in two-step screening for GDM for a number of reasons. First, the IADPSG has proposed the use of a high-threshold FPG of 126 mg/dL (7.0 mmol/L) as soon as pregnancy is confirmed in women at high risk of T2DM as a means of identifying women with preexisting (overt) diabetes. It has been proposed that lesser degrees of fasting glucose elevation could be used to screen for GDM if this test is already being done to rule out preexisting diabetes. Second, the reproducibility of fasting glucose measurement is superior to postglucose load measurements.[43] Third, some women do not tolerate the oral glucose drinks. Apart from FPG, a glycated hemoglobin (HbA1c) concentration greater than 6.5 percent (as used in the non-pregnant population) is also applied for detecting T2DM in early pregnancy. Research is emerging about whether FPG and HbA1c values in early

pregnancy indicating hyperglycemia, but below thresholds used for diagnosis of T2DM, can predict later GDM or lead to interventions that improve outcomes.

Without a universally accepted "gold standard" for GDM diagnosis, and because of alternatives that apply diagnostic tests alone for screening, decisionmaking about screening involves understanding whether a screening test can predict GDM in a two-step approach, as well as about which diagnostic criteria to apply, based on the magnitude of their associations with poor outcomes and of effects after treatment. The most appropriate timing for screening is also uncertain; waiting too long may miss the window of opportunity to provide beneficial treatment, but whether screening early in pregnancy provides more benefit than harm is being actively investigated.

Interventions/Treatment

The treatment of GDM during pregnancy aims to lower and stabilize blood glucose levels, in order to reduce complications during pregnancy, delivery, and postpartum for the mother and neonate. Risk identification for prevention and surveillance of longer-term maternal outcomes, such as development of T2DM or cardiovascular disease, is often a secondary goal, with the potential for interventions to prevent or delay the development of these associated conditions. Preventing the development of T2DM before subsequent pregnancies may offer significant benefit for future offspring. Contextual Questions 3 and 4 address the long-term development of T2DM and the effects from postpartum interventions in women with previous GDM, respectively.

Initial treatment for GDM typically involves medical nutrition therapy, glucose monitoring, physical activity, and weight management depending on pregestational weight.[44] When this treatment does not achieve desired glucose targets, insulin or oral glucose lowering medications may be used. The American Diabetes Association currently recommends insulin over metformin and glyburide as first-line treatment.[45] Women diagnosed with GDM may also undergo increased prenatal surveillance or changes in delivery management, depending on fetal size and the effectiveness of measures to control glucose.

Current Clinical Practice/Recommendations of Other Groups

Major guidelines from the United States generally recommend universal, rather than selective/risk-based screening at 24 to 28 weeks' gestation (**Table 2**). Guidelines differ with respect to the number of tests and the diagnostic criteria applied. The Endocrine Society[46] recommends a one-step approach using the IAPSG thresholds[21] (also adopted by the World Health Organization in 2013[47]), while the American Diabetes Association[8] recommends either one-step (using IADPSG criteria) or two-step (using CC criteria) screening, and the American College of Obstetricians and Gynecologists[7] and National Institutes of Health[48] recommend a two-step approach using the CC or NDDG thresholds. The American College of Obstetricians and Gynecologists has stated that one rather than two abnormal values on the OGTT may be used with the CC or NDDG criteria.

A 2014-15 survey of members of the Society for Maternal-Fetal Medicine found that 90.6 percent of respondents recommend a two-step screening approach, with the most common screening test the 140 mg/dL OGCT (39% vs. 24% and 37% using 130 and 135 mg/dL, respectively), and the most common diagnostic test the OGTT (83%) based on two abnormal values using CC criteria.[49] Practitioners in the Western United States were more likely to use a one-step approach (24% vs. 4-6% in other regions). These figures differ somewhat from a previous (2004) survey, which found that nearly 60 percent of American College of Obstetricians and Gynecologists fellows used the NDDG criteria.[50] Data on current practices are limited, but several U.S. studies have evaluated outcomes before and after adoption of the IADPSG one-step screening criteria, suggesting that this approach is being considered in various regions of the country.[51-54] During a very large (n = 23,792) recently completed multicenter trial in the United States comparing screening with one-step IADPSG vs. two-step CC strategies (but allowing for providers and patients to "opt out" of one to receive an alternative test), a greater proportion of women and their care providers preferred the two-step approach.[55]

Chapter 2. Methods

Considerations for This Update

The previous USPSTF recommendation mainly focused on the use of two-step screening approaches, and recognized the importance of accurate screening tests (e.g., 50 g OGCT, FPG) within these approaches. For this report, the complexity and variability in current practice and recommendations required additional examination related to one vs. two-step screening approaches as well as which diagnostic criteria to apply within these approaches. To address more inclusive screening approaches (e.g., one-step IADPSG, one vs. two abnormal values in two-step screening using CC or NDDG criteria), this report (i) focused its question on outcome associations to examine health outcomes for the additional women who would be diagnosed with GDM—without treatment and vs. women with normal glucose tolerance—using these more inclusive screening approaches (i.e., indicating less severe hyperglycemia) rather than those most commonly used in the past (two-step CC or NDDG with two abnormal values), and (ii) added a question about outcomes from different screening approaches (one- vs. two-step, using IADSPG vs. CC criteria, timing in pregnancy [after or being 24 weeks' gestation]). Further, for screening test accuracy within two-step screening approaches, this report focuses on the main screening tests (i.e., OGCT, FPG, HbA1c, risk factors) and diagnostic criteria currently considered for use in the United States.

Key Questions and Analytic Framework

Using the methods developed by the USPSTF,[56] the Evidence-based Practice Centers developed the scope and Key Questions in collaboration with the USPSTF and AHRQ. The investigators created an analytic framework depicting the Key Questions and the patient populations, interventions, and outcomes reviewed (**Figure 1**). The research plan was externally reviewed and modified prior to finalization.

Key Questions

1. a. Does screening for GDM reduce poor health outcomes?
   b. Does screening for GDM reduce poor intermediate outcomes?
   c. Does the effectiveness of screening for GDM vary according to maternal subgroup characteristics, including timing during pregnancy, previous GDM diagnosis, family history of type 2 diabetes mellitus, body mass index, age, or race/ethnicity?
2. What are the harms of screening for and diagnosis of GDM to the mother, fetus, or neonate?
3. a. What is the comparative effectiveness of different screening strategies for GDM on health outcomes?
   b. What is the comparative effectiveness of different screening strategies for GDM on intermediate outcomes?

c. Does the comparative effectiveness of different screening strategies vary according to maternal subgroup characteristics, including timing during pregnancy, previous GDM diagnosis, family history of type 2 diabetes mellitus, body mass index, age, or race/ethnicity?

4. a. What is the diagnostic accuracy of commonly used screening tests for GDM?
   b. Does the accuracy of commonly used screening tests for GDM vary according to maternal subgroup characteristics, including timing during pregnancy, body mass index, age, race/ethnicity, or prevalence of GDM?
5. What is the association between diagnosis of GDM and outcomes in women meeting more inclusive but not less inclusive diagnostic criteria for GDM?
6. a. Does treatment of GDM during pregnancy reduce poor health outcomes?
   b. Does treatment of GDM during pregnancy reduce poor intermediate outcomes?
   c. Does the effectiveness of treatment of GDM vary according to maternal subgroup characteristics, including timing and criteria used for diagnosis during pregnancy, severity of hyperglycemia, body mass index, age, or race/ethnicity?
7. What are the harms of treatment of GDM, including severe maternal and fetal/neonatal hypoglycemia, delivery of neonates who are small for gestational age, and poor long-term growth and development outcomes in the child?

Contextual Questions

Four Contextual Questions were also requested by the USPSTF to help inform the report. Contextual Questions are not reviewed using systematic review methodology.

1. What is the association between measures of serum glucose (e.g., fasting and postload glucose concentrations, percent hemoglobin A1c) and outcomes, and does it differ based on timing of measurement?
2. What is the association between GDM diagnosed before 24 weeks of gestation and outcomes, and does it differ based on screening strategy, timing of diagnosis, and severity of risk factors?
3. What are the long-term health consequences, for the mother from a diagnosis of GDM, and for the child from their mother's GDM diagnosis, neonatal hypoglycemia, shoulder dystocia, or fetal overgrowth?
4. Are postpartum interventions effective for reducing incidence of long-term health outcomes in women previously diagnosed with GDM or their children?

Search Strategies

We searched MEDLINE (via Ovid), Embase (via Ovid) and CINAHL (via EBSCOhost) from 2010 to May 22, 2020. Searches were restricted by language to include full texts published in English.[57,58] We also searched ClincialTrials.gov (2017 to 2019), and reviewed reference lists of included studies and of systematic reviews. Search strategies are available in **Appendix A1.** All studies included in the 2012 report[2] were screened for eligibility for this review. We also reviewed the 2012 review's excluded studies list and scanned reference lists for relevance to the Key Questions and scope addressed in this review. Ongoing surveillance was conducted to

identify major studies published since May 2020 that may affect the conclusions or understanding of the evidence and the related USPSTF recommendation. The last surveillance was conducted in December 2020 and identified no studies published in full text affecting review conclusions.

All results of the database searches were imported into an EndNote® database (Thomson Reuters, New York, NY) for reference citation, and, after duplicate removal, into DistillerSR (Evidence Partners Inc., Ottawa, Canada) for screening and selection procedures.

Study Selection

All titles and abstracts identified through the database searches were independently reviewed by two trained members of the research team using broad criteria. Studies marked for possible inclusion by either reviewer and all studies from the previous report underwent full-text review. Each full-text article possibly relevant to a Key Question was independently reviewed by two trained members of the research team for inclusion or exclusion on the basis of the eligibility criteria, organized by PICOTS (population, intervention, comparator, outcome, timing, study design) (**Appendix A2**). Conflicts were resolved by discussion and consensus or by consulting another member of the team including the clinical lead. Results of the full-text review were tracked in EndNote®, including the reason for exclusion for excluded full-text publications. The selection of literature is summarized in the literature flow diagram (**Appendix A3**). **Appendix A4** lists the included studies, and **Appendix A5** lists the excluded studies with reasons for exclusion.

Appendix A2 contains detailed eligibility criteria. For screening effectiveness and test accuracy (Key Questions 1, 3 and 4), we included studies of pregnant women without known preexisting diabetes mellitus. The term GDM was defined as hyperglycemia not meeting criteria for overt diabetes at any time point during pregnancy. For studies on harms from screening or a GDM diagnosis (Key Question 2), outcome associations (Key Question 5), or treatment of GDM (Key Questions 6 and 7), studies could enroll some or only women with GDM or known hyperglycemia.

For the benefits and harms of screening, comparative effectiveness of screening approaches, and screening test accuracy (Key Questions 1 to 4), we included studies using one- or two-step screening strategies at any time during pregnancy. In two-step strategies, the screening test needed to be one of the following: FPG, a 50 g OGCT, a risk factor–based tool (clinical or historical using one or more factors), or HbA1c. For benefits and harms of screening (Key Questions 1 and 2) the comparison was no screening. When assessing the harms of screening or a GDM diagnosis, we also included studies that compared women with GDM aware of their diagnosis vs. those unaware and studies comparing outcomes before and after a GDM diagnosis. To further evaluate potential harms related to labeling (i.e., from the diagnosis of GDM rather than its consequences), we also included studies comparing women diagnosed with GDM vs. those without GDM and effects on use of delivery interventions and interventions related to formula use, separation of infant and mother, or breastfeeding challenges/failure. The prior review only compared harms of screening vs. no screening. For comparative effectiveness (Key

Question 3), the comparator was an alternative screening approach, based on tests and criteria used, timing during pregnancy, or eligibility for the intervention (selective/risk-based vs. universal screening). For Key Question 4 on accuracy, the comparator was currently recommended diagnostic tests. For Key Question 5 on outcome associations, the exposure was a diagnosis of GDM based on more inclusive criteria (i.e., IADPSG or one abnormal value [OAV] of CC or NDDG) but not treated for GDM or meeting criteria used for routine care (i.e.. CC or NDDG with two abnormal values) and the comparator was no GDM (normal glucose tolerance [NGT]). For Key Questions 6 and 7, standard treatments, provided after diagnosis until delivery, were included. The comparator was no treatment/routine prenatal care.

Intermediate outcomes were excessive maternal weight gain in pregnancy and long-term maternal or childhood development of metabolic impairment. Health outcomes were defined mainly by their timing and subject: i) during pregnancy, including preeclampsia/gestational hypertension, cesarean delivery, induction of labor, preterm delivery (live birth before 37 weeks' gestation), and maternal birth trauma (latter two added, based on clinical input, after the final research plan but before analysis); ii) to the fetus/neonate, including mortality, birth injury, shoulder dystocia, fetal overgrowth (large for gestational age [LGA; least 90^{th} percentile in weight], macrosomia at 4000 and 4500g birthweight), and acute morbidity (hypoglycemia, hyperbilirubinemia, NICU admission, respiratory distress syndrome); and iii) over the long term for the mother (i.e., development of T2DM, cardiovascular outcomes, mortality or major morbidity from T2DM or cardiovascular disease [CVD], and quality of life) and their offspring during childhood (e.g., development of T2DM, cardiovascular outcomes, and neurocognitive outcomes). Harms from screening or a GDM diagnosis included adverse effects from screening tests (e.g., vomiting, anxiety from false positive) and consequences from the label of GDM to the woman, fetus or neonate, such as unnecessary delivery interventions (e.g., only indication being the GDM diagnosis), additional interventions with formula, separation of infant and mother, or breastfeeding challenges/failure. Harms from treatment were severe maternal or neonatal hypoglycemia, delivery of neonate who is small for gestational age (SGA; 10^{th} percentile of weight or lower) or low birth weight (2500 g or less), and poor long-term growth and development of the child. We did not exclude studies without a predefined definition of outcomes, but performed sensitivity analyses where applicable. We included studies published on or after 1995. We included settings applicable to primary care, and studies from any country.

Randomized **(**RCTs) and nonrandomized controlled trials (CCTs, e.g., prospective trials without randomization, controlled before-after studies; where allocation to the study groups is prospective and based on investigator decision) were included for Key Questions 1, 2, 3, 6 and 7; controlled observational studies were included for Key Questions 1 and 2, and for outcomes or comparisons without trial data for Key Questions 6 and 7. Prospective cohort studies were included for Key Question 4; the protocol was also modified to only include studies where all (or at least a sample) of women screening negative were given the reference standard OGTT, and (for risk-factor based screening models) when examining a validation rather than development cohort. For Key Question 5, retrospective or prospective cohort studies comparing women with GDM vs. those without GDM were included for Key Question 5. Studies of risk-factor based screening in KQ4 had to use a validation rather than development cohort to assess accuracy. For harms related to the labelling effects of a GDM diagnosis on the mother or neonate, we required

studies to compare outcomes in women with vs. without GDM and make adjustments for multiple potential confounders.

Data Abstraction and Quality Rating of Studies

For studies meeting inclusion criteria, we updated the previous review's data abstraction tables to summarize characteristics of study populations, interventions, comparators, outcomes (including their definitions), study designs, settings, and methods. One reviewer conducted data abstraction, which was reviewed for completeness and accuracy by another team member. Reviewers resolved discrepancies by discussion and consensus.

Design-specific appraisal tools were used to assess the quality (internal validity) of individual studies.[59-62] For studies on outcome associations for untreated GDM diagnosed using different criteria, we added a question to assess whether groups received the same standard of care (i.e., whether patients and providers were blind to OGTT results).[63] We tested each quality assessment tool on a sample of studies and developed guidelines for assessing the remaining studies. Based on the assessments and guidance by the USPSTF methods, we then rated studies as "good," "fair," or "poor", depending on the seriousness of the methodological shortcomings.[56] For each study, quality assessment was performed independently by two team members. Disagreements were resolved by consensus. We assessed the applicability of the evidence using USPSTF guidance, in terms of populations, setting, and intervention/diagnostic characteristics.

Data Synthesis

The outcome of preeclampsia/gestational hypertension was divided into preeclampsia, gestational hypertension, and hypertensive disorders in pregnancy (composite of former two); we considered sensitivity analysis when there was uncertainty about how these outcomes were defined or measured. For cesarean delivery, we prioritized primary (first) cesarean deliveries but also analyzed total (due to any indication) and emergency cesarean rates if reported; sensitivity analyses were conducted on the definitions used for cesarean deliveries. Stillbirth, neonatal death, and perinatal mortality were analyzed separately and as a composite. We analyzed shoulder dystocia and birth injury separately. We analyzed macrosomia separately at 4000 g and 4500 g thresholds. We analyzed outcomes related to acute neonatal morbidity separately (NICU admissions, respiratory distress syndrome, hypoglycemia, hyperbilirubinemia, APGAR scores under 7 at 1 and 5 minutes). For neonatal hypoglycemia, many studies did not report their definition or used a biochemical definition of neonatal hypoglycemia (i.e., values under 30 or 40 mg/dL) without mention of signs of hypoglycemia or the use of medical interventions. We did sensitivity analysis based on whether authors reported using a biochemical definition for neonatal hypoglycemia; further, when able, we also performed analysis for hypoglycemia defined as requiring intravenous therapy. Hyperbilirubinemia was usually defined as requiring phototherapy.

Evidence was synthesized narratively, unless data were suitable for pooling. The decision to pool was based on the judgment that the included studies were clinically and methodologically

similar. We explored heterogeneity with sensitivity and subgroup analyses, using our predefined variables for the population (e.g., severity of dysglycemia), interventions (e.g., no treatment vs. minimal intervention in control groups), and setting (i.e., removing studies from countries not categorized as very high on the Human Development Index 2019 [VHDI] (**Appendix A2 Table 1**), as well as for study quality and uncertain outcome definitions. For nonrandomized studies on intervention effects, we used the inverse-variance method for meta-analysis, using the most adjusted results from each study when available. For the association between additional GDM cases diagnosed using more inclusive criteria and health outcomes, our primary analysis relied on crude event rates, to reflect the results when only glycemic status, but no other patient characteristics, such as BMI or age, would be considered by clinicians. We then compared these findings to those from studies that provided adjusted findings. Meta-analyses were conducted using random effects models in Review Manager, version 5.1 (The Cochrane Collaboration, Copenhagen, Denmark). When moderate or greater heterogeneity (I^2 40 percent or greater) was observed, we performed sensitivity analysis using the profile likelihood method in Stata version 14.2 (StataCorp, College Station, Texas). For meta-analyses with few events and fairly equal sizes between arms, we used the Peto method.[64] Results are reported in relative risks (RR) or odds ratios (OR), depending of what was used for the analysis, and include 95 percent confidence intervals (95% CI). Pooled absolute risk differences (ARD) were calculated for statistically significant results and when one or more studies had zero events. When interpreting the direction of association, if findings did not quite reach statistical significance (e.g., upper limit of 95% CI 1.00 or 1.01 for an association with reduce risk) but the magnitude of the association could be clinically important (e.g., more than 20 to 25 percent) we concluded that there may be an association but comment on this imprecision. Otherwise imprecision is noted in the case of small sample sizes.

For diagnostic accuracy, we constructed 2x2 tables and calculated sensitivity, specificity, accuracy (true positive plus true negative divided by the total sample) and yield (i.e., GDM prevalence) of the screening tests. Where applicable, analyses were stratified by the timing of the index test in pregnancy. If studies were clinically homogenous (e.g., similar screening tools, diagnostic thresholds, timing) and more than three studies were included for a particular comparison, we pooled sensitivities and specificities using bivariate analysis (accounting for their correlation) and constructed hierarchical summary receiver operator characteristic curves.[65] When considering the various thresholds used in the studies, we pooled data for slightly different thresholds, while using a conservative approach (e.g., FPG of 79 mg/dL with 79.5 mg/dL, and 90 mg/dL with 89.5 mg/dL). We used the metandi program in Stata version 14.2 to fit the models and produce the pooled estimates. Using pooled point estimates for sensitivity and specificity, or the median of a range of estimates when no meta-analysis was conducted, we calculated corresponding positive and negative predictive values (PPV and NPV) for hypothetical cohorts with GDM prevalences of 7, 15 and 25 percent.

For analysis of trials with at least 10 studies, we assessed publication bias (small study effects) graphically with the funnel plot and quantitatively using Egger's test.[66]

For all Key Questions, the overall quality of evidence was determined using the approach described in the USPSTF Procedure Manual.[56] Evidence was rated "good", "fair", or "poor" based on study quality, consistency of results between studies, precision of estimates, risk of

reporting bias, applicability, and other study limitations. A summary of evidence table was developed to assess the overall quality of evidence for each Key Question using the approach described in the USPSTF Procedure Manual.[56]

Expert Review and Public Comment

The draft Research Plan was posted for public comment on the USPSTF Web site from February 28 to March 27, 2019. Based on the comments it received, some intermediate outcomes were re-classified as health outcomes; added additional subgroups to Key Questions 1, 3, and 6; revised Contextual Questions 3 and 4 to focus on specific outcomes of interest; clarified that Key Question 2 requires no comparator and that interventions for Key Questions 6 and 7 would be offered during pregnancy. The population was revised to include studies of populations in which less than 20 percent had known preexisting diabetes mellitus, recognizing that screening studies for GDM will likely include some women with unrecognized diabetes mellitus.

The draft report was reviewed by content experts (**Appendix A6**), representatives of Federal partners, USPSTF members, and AHRQ Medical Officers. It will be finalized after being posted for public comment.

Chapter 3. Results

A total of 12,302 references from electronic database searches and manual searches of recently published studies and systematic reviews were reviewed and 896 full-text papers were evaluated for inclusion. A total of 105 studies (reported in 116 publications) addressed the Key Questions; 18 were trials and 87 were observational studies. Sixty-nine studies were newly identified as part of this update and 36 of 97 were carried forward from the previous review; reasons for exclusion of studies from the prior report related to modified inclusion criteria (e.g., ineligible screening tests and comparators). Study characteristics and quality ratings are detailed in **Appendix B Tables 1** to **15**.

Key Question 1a. Does Screening for GDM Reduce Poor Health Outcomes? b. Does Screening for GDM Reduce Poor Intermediate Outcomes? c. Does the Effectiveness of Screening for GDM Vary According to Maternal Subgroup Characteristics?

Summary

- Four retrospective observational studies compared screening vs. no screening. The two studies from the previous review focused on selected subpopulations of women and showed no effect of screening; however, sample sizes were small and estimates imprecise.
- Vs. no screening, one new study (n=1,012) found one-step screening of at-risk women associated with a reduction in late (at least 28 weeks' gestation) stillbirth and another new study (n=2,780) found universal two-step screening associated with fewer cesarean deliveries and some improved birth outcomes. Findings from both studies were susceptible to confounding and selection bias.

Evidence

No trials were identified for this Key Question. Four observational studies (one case-control, three retrospective cohorts) compared screening vs. no screening; two were identified for this update[67,68] and two were in the prior review.[69,70] All studies compared women who underwent screening for GDM with women who were not screened; the studies did not analyze outcomes based on an intention/offer to screen. Screening approaches were risk-based in two studies[68,69] and universal in the others.[67,70] The two new studies screened for women with risk factors in early pregnancy.[67,68] Sample sizes ranged from 93 to 2,780 (total N=4,336). Studies were conducted in the United Kingdom,[68] Canada,[67] Thailand,[69] and the United States.[70] Apart from the study in Thailand, 82-97% of the women enrolled in the studies were white. One study was rated as good quality,[69] and three were rated as fair quality; methodological limitations in the fair-quality studies included possible selection biases,[68,70] and not accounting for all potential

confounders[67] (**Appendix B Tables 1** and **2)**. None of the studies reported intermediate outcomes.

Table 3 includes the evidence for this Key Question. The two retrospective cohort studies from the previous review focused on selected subgroups of women. A study from Thailand assessed women with one or more risk factors (most commonly age at least 30 years and family history of T2DM); 411 of 451 women were screened and 7.1 percent of those screened had GDM (2.9% in total population).[69] Screening was not associated with reduction in risk of hypertensive disorders in pregnancy, gestational hypertension, cesarean delivery, or large for gestational age [LGA], or with increased risk of small for gestational age [SGA]. Authors of the second study surveyed a subset of nurses in a large U.S. cohort study.[70] In a group of women not diagnosed with GDM (n=93), there was no difference between women who underwent screening with a 50 g OGCT vs. those who had not undergone screening in risk of macrosomia (7% in both groups). Data on macrosomia in women diagnosed with GDM was not reported. Findings from these two studies were highly imprecise due to small sample sizes.

The two new studies evaluated screening approaches that included first-trimester screening in certain risk groups. A case-control study of late (at least 28 weeks) stillbirths included 1,012 women (291 cases) from multiple sites in the United Kingdom.[68] Women with pre-existing T1DM and T2DM (self-reported) were excluded. Screening practices were not reported, although providers likely followed the 2015 NICE guidance. Women with at least one risk factor (South Asian or Black Caribbean ethnicity, BMI at least 30 kg/m^2, or previous pregnancy effected by GDM or macrosomic [at least 4,500 g] birth) were supposed to be offered screening at 24 to 28 weeks. Women with previous GDM were offered screening at first visit in the first or second trimester. Thirty-six and 33 percent of cases and controls had at least one risk factor for GDM (less than 1% with previous GDM), and 38 of 371 (10.2%) screened were diagnosed. Twenty-five percent of women with at least one risk factor were not screened, and were analyzed with the women not at-risk for GDM in the control group. In the women at-risk, screening was associated with a lower risk for stillbirth (adjusted OR [aOR] 0.68, [95% CI, 0.47 to 0.97]). Although adjusted for known risk-factor status, the analysis was not able to adjust for unrecorded differences in risk profile, the participant's engagement with health services, or variations in usual clinical practice which were noted by the authors.

A retrospective cohort study recruited 2,780 women delivering at a regional hospital in Quebec, Canada.[67] Most screening used a universal two-step approach (OGCT with IADPSG for OGTT), and first-trimester screening was encouraged for women with multiple risk factors. Incidence of GDM was 10.7 and 5.4 percent in those screened in the first (n=1,019) and second (n=993) trimester, respectively, and 6.6 percent in those not screened (n=768; 7.8% undergoing OGTT). Women with GDM were referred to specialized centers for diabetes education and treatment. Although age and ethnicity were similar between all groups, other important potential confounders were not reported and the analysis was not adjusted. Screening was associated with decreased risk of cesarean delivery (RR, 0.78 [95% CI, 0.66 to 0.92]; ARD, 4.8% fewer [95% CI, 8.2 to 1.5), birth injuries (fracture or dislocation; RR, 0.47 [95% CI 0.23 to 0.97]; ARD, 0.9% fewer [95% CI, 1.9 fewer to 0.10 more]), and admissions to the NICU (RR, 0.67 [95% CI, 0.58 to 0.78]; ARD, 8.7% fewer [95% CI, 12.3 to 5.2]). There were no differences in rates of macrosomia (RR, 1.24 [95% CI, 0.93 to 1.65]), hypoglycemia (RR, 0.95 [95% CI, 0.67 to 1.35]

or hyperbilirubinemia (RR, 0.98 [95% CI, 0.87 to 1.09]. Prespecified analyses comparing screening in first vs. second trimester found a significantly greater effect for NICU admissions from screening early, but no difference for other outcomes. No data was provided in any of the studies for other subgroups.

Key Question 2. What Are the Harms of Screening for and Diagnosis of GDM to the Mother, Fetus, or Neonate?

Summary

- No studies on harms of screening vs. no screening were included in the prior review; the current review did not limit inclusion to studies with a comparator of no screening.
- **Psychosocial harms associated with screening**. Two cohort studies (N=1,015) did not find undergoing screening or receiving a false positive result (i.e., positive on screening but not diagnosed) to be associated with an increase in anxiety or depressive symptoms.
- **Psychosocial harms associated with receiving a diagnosis of GDM**. One cohort study (n=100) found that receiving a GDM diagnosis may result in a small, transient increase in anxiety symptoms.
- **Cesarean deliveries associated with a GDM diagnosis**. One good-quality cohort study (n=3,778) found an association between prevalence of macrosomia and rates of cesarean deliveries in women with normoglycemia or untreated borderline GDM (status blinded to women and providers), but not in those with treated GDM where the cesarean rate was relatively high despite fewer cases of macrosomia, suggesting that the GDM diagnosis may have lowered the threshold for cesarean delivery.
- **Hospital experiences potentially impacting breastfeeding outcomes**. Three large studies employing survey data found some differences in hospital experiences potentially related to labelling (i.e., only related to the GDM diagnosis) and impacting breastfeeding outcomes for women with vs. without GDM, although confounding factors (e.g., breastfeeding intentions, varying hospital policies, treatment effects) could have impacted findings.

Evidence

The prior review did not include any studies of screening vs. no screening with data on harms.[2] As described in the methods section, for this review inclusion criteria were expanded to studies comparing women with vs. without GDM or a false positive screening result. We included seven observational studies (**Appendix B Table 3**).[71-77]

Study Characteristics

Sample sizes ranged from 100[71] to 157,187[76] (median n=1,773; total N=166,082). Mean age across five studies that reported this data was 30.5 years.[71,73-75,77] Three studies were conducted in the United States[72,74,76] and two were conducted in each of Canada[73,75] and Australia.[71,77] In the five studies reporting race/ethnicity, the proportion of non-Hispanic white women ranged

from 48 to 86 percent. Two studies excluded women with previous GDM[71,73] and one included many women in the GDM groups (40%) with previous GDM.[77] Four studies were undertaken in primary care or obstetrician offices,[71,73,75,77] while three used survey data.[72,74,76]

Five studies used a prospective cohort design[71,73-75,77] and two a cross-sectional design.[72,76] Three studies provided data on potential psychosocial harms (i.e., anxiety and/or depressive symptoms) from screening or a false positive result (i.e., positive on screening test but not diagnosed),[73,77] or from receipt of a positive diagnostic test.[71] Three studies examined hospital experiences related to breastfeeding outcomes in women with GDM vs. those without GDM.[72,74,76] Lastly, one study examined the likelihood of cesarean deliveries due to a GDM diagnosis in relation to rates of macrosomia.[75] The studies did not report findings for subgroup effects in relation to race/ethnicity.

Quality was rated good for three studies[72,75,76] and fair for four[71,73,74,77] (**Appendix B Table 4**). Most studies did not evaluate defined cohorts of women who underwent screening or received a GDM diagnosis, because they excluded those without follow-up assessments, which could have resulted in selection bias. The studies rated as good quality all adjusted their analysis for multiple important confounders (e.g., delivery and neonatal variables for postpartum outcomes). Ascertainment of GDM exposure was based on self-report in four studies,[72-74,76] although we did not rate down for this because potential harms may be related to labeling and perceived consequences of a perceived GDM diagnosis, even if inaccurate.

Psychosocial Harms Associated With Screening for GDM

A cohort study (n=202) reported on anxiety and depressive symptoms before screening, after screening (but before receiving results), and late in pregnancy.[77] Levels of anxiety were fairly low across the three time points in women with vs. without false positives or GDM and no differences were found (**Appendix D Table 1**). Clinically relevant depressive symptoms were present in 17 to 21 percent of women, without significant changes over time in either group.

A larger study (n=813) measured changes in state ("reactive") anxiety and depressive symptoms between 12-24 weeks' (before screening) and 32 weeks' gestation (after receiving results) in women reporting a false positive result, a negative OGCT result, or not testing (considered negative).[73] Women with previous GDM experience were excluded. Mean changes in both groups for anxiety and depression were minimal and no significant differences were found for the false positive vs. screen negative groups.

Psychosocial Harms Associated With Receiving a GDM Diagnosis

One small study (n=100) found that state ("reactive") anxiety was higher for women with vs. without GDM right after receiving results of the OGTT (mean 6 points on 60-point scale; p= 0.007), but that levels declined to reach similar levels to the NGT group at gestational week 36 and were stable until 6 weeks' postpartum.[71] Trait ("intrinsic") anxiety was similar between groups at all three time points.

Cesarean Deliveries Associated With a GDM Diagnosis

In one cohort study of an ethnically diverse population, rates of macrosomia and cesarean delivery were compared among women with untreated borderline GDM (n=115), treated overt GDM (n=143), and normoglycemia (n=3,520).[75] Patients and providers were blinded to the glycemic status of those without overt GDM. For women with untreated borderline GDM, rates of macrosomia were higher than for women with normoglycemia, and cesarean deliveries were associated with macrosomia (45.5% with vs. 23.5% without; p=0.02). Among women with treated GDM, cesarean deliveries were equally common whether the neonate was macrosomic (33% [5/15]) or not (33.6% [43/128]). On multivariate logistic regression accounting for several maternal characteristics including preeclampsia as well as fetal distress and breech, the aOR for cesarean was significant for patients with overt GDM (1.6 [95% CI, 1.0 to 2.5]), but not for those with a false positive screen (1.2 [95% CI, 0.9 to 1.5] or borderline GDM (1.2 [95% CI, 0.7 to 2.0]). Findings suggest that the diagnosis of GDM may have contributed to decisions to perform cesarean deliveries. Key Question 7 also addresses rates of cesarean deliveries vs. macrosomia based on findings from GDM treatment trials.

Hospital Experiences Associated With a GDM Diagnosis Potentially Impacting Breastfeeding Outcomes

Three studies reported survey findings comparing hospital experiences related to breastfeeding outcomes between women with vs. without GDM; the studies adjusted for various maternal, delivery, and neonatal factors.

One large survey of an ethnically diverse population (n=157,187)[76] found that women with GDM were about 15 to 20 percent less likely to report breastfeeding in the first hour, feeding only breast milk in the hospital, and/or feeding on demand, and were more likely to receive a formula gift pack compared with those without GDM. Although multiple variables were accounted for in the analysis (e.g., NICU admission, mode of delivery), neonatal hypoglycemia was not accounted for and residual confounding from BMI as well as variability in implementation of the initiatives by hospitals may have impacted results. In the second study (n=1,733),[72] women with vs. without GDM had similar rates of breastfeeding within the first hour but had fewer neonates (without an NICU admission) staying in their mother's room (aOR, 0.55 [95% CI, 0.36 to 0.85]). The third study found GDM associated with higher likelihood of hospital supplementation (aOR, 1.86 [95% CI, 1.27 to 2.72]) vs. no GDM; GDM also associated with shorter duration of breastfeeding, but this appeared to be mediated more by exclusive breastfeeding intentions in the third trimester than by supplementation.[74]

Key Question 3a. What Is the Comparative Effectiveness of Different Screening Strategies for GDM on Health Outcomes? b. What Is the Comparative Effectiveness of Different Screening Strategies for GDM on Intermediate Outcomes? c. Does the Comparative Effectiveness of Different Screening Strategies Vary According to Maternal Subgroup Characteristics, Including Timing During Pregnancy, Previous GDM Diagnosis, Family History of Type 2 Diabetes Mellitus, BMI, Age, or Race/Ethnicity?

Summary

- **IADPSG vs. CC screening.** Based on three RCTs (N=1,059), screening with IADPSG criteria may be associated with fewer primary cesarean deliveries (2 RCTs, N=833; RR, 0.73 [95% CI, 0.55 to 0.97]; ARD, 6.3% fewer [11.5 to 1.2]), LGA infants (3 RCTs, N=1,059; RR, 0.46 [95% CI, 0.25 to 0.83]; ARD, 3.2% fewer [5.7 to 0.8]), NICU admissions (1 RCT, n=786; RR, 0.49 [95% CI, 0.29 to 0.84]; ARD, 3.7% fewer [95% CI, 7.9 to 0.6]), and episodes of neonatal hypoglycemia (2 RCTs, N=1,012; RR, 0.52 [95% CI, 0.28 to 0.95]; ARD, 2.7% fewer [5.0 to 0.5]) vs. screening with CC criteria, with no differences in other pregnancy and neonatal outcomes.
- **IADPSG vs. WHO 1999.** One RCT (n=502) comparing IADPSG vs. WHO 1999 criteria found that there may be no differences in primary cesarean or preterm delivery rates. Findings for other outcomes were imprecise.
- **Early vs. usual timing for CC screening.** An RCT (n=922) enrolling obese women found early vs. usual screening with CC criteria potentially associated with increased risk of preeclampsia, though the difference was not statistically significant (RR, 1.42 [95% CI, 0.99 to 2.05]; ARD, 4.0% more [0.0 to 8.0]). There were no differences in risk of several other maternal and fetal/neonatal outcomes, though some estimates were imprecise.

Evidence

The prior review did not include a Key Question on the comparative effectiveness of different screening strategies.[2] This review included five RCTs (**Table 4** and **Appendix B Tables 5** and **6**).[78-82] Three RCTs [83-85] were excluded because they did not present data by randomized screening arm.

Study Characteristics

Sample sizes ranged from 47 to 922 (median 502; total N=2,483) and mean age from 25.4 to 31.9 years (median 28.5). Four trials reported mean BMIs ranging from 25.7 to 37.1 kg/m^2 (median 26.3).[78,79,81,82] Three trials were conducted in the United States,[79-81] one in Turkey,[82] and

one in Malaysia.[78] Only one study reported on the proportion of women with prior GDM (2.8%),[80] and none reported on history of T2DM. The U.S. trials enrolled large proportions (43 to 63%) of black women.[79-81]

Three RCTs (N=1,059)[80-82] compared one-step IADPSG vs. two-step CC screening, one RCT (n=502)[78] compared IADPSG (omitting one-hour value) vs. WHO 1999 (FPG value 6.1 mmol/L or greater and/or 2-hour 7.8 mmol/L or greater) criteria, and another RCT (n=922)[79] compared early (14 to 20 weeks' gestation) vs. usual (24 weeks or later) timing of screening with a two-step CC approach. Except for the comparison of early vs. usual screening,[79] the trials evaluated screening at 24 to 28 weeks' gestation, with one[80] also offering early screening for women with one or more risk factors. Screening was applied universally, although one trial[78] only enrolled women with one or more risk factors (including BMI over 27 and age over 24) and another[79] only enrolled obese (BMI 30 kg/m^2 or greater) women. In the two-step CC screening approaches, the OGCT thresholds were 130,[81] 135,[79,80] and 140 mg/dL.[82] All trials excluded women with a known history of preexisting diabetes. They also reported similar treatment between arms for women diagnosed with GDM. Four of the trials analyzed women who undertook screening, whereas the trial of early vs. usual screening[79] included women regardless of their screening uptake (84.3 and 95.9% received OGTT in early and usual timing groups, respectively). None of the studies reported data for intermediate outcomes or evaluated effects in subgroups.

The smallest RCT (n=47)[81] was rated good quality and the other four trials were rated fair quality. Methodological limitation in the fair-quality trials were open-label design, unclear risk for selection biases,[78,82] high attrition,[80] and possible selective reporting[82] (**Appendix B Table 6**).

IADPSG vs. CC Screening

Pregnancy Outcomes

Screening with IADPSG was associated with fewer primary cesarean deliveries than screening with CC criteria (2 RCTs, N=833; RR, 0.73 [95% CI, 0.55 to 0.97]; I^2=0%; ARD, 6.3% fewer [95% CI, 11.5 to 1.2]),[81,82] although one of the trials[81] only contributed two events (**Table 5** and **Appendix C Figure 1**). No differences were found between strategies in risk for preeclampsia (3 RCTs, N=1,059; RR, 0.66 [95% CI, 0.15 to 2.98]; I^2=76%),[80-82] gestational hypertension (1 RCT, n=786; RR, 0.98 [95% CI, 0.70 to 1.38]),[82] total cesarean deliveries (2 RCTs, N=273; RR, 1.02 [95 CI, 0.70 to 1.49]; I^2=0%),[80,81] induction of labor (2 RCTs, N=273; RR, 1.00 [95% CI, 0.76 to 1.32]; I^2=0%),[80,81] preterm deliveries (2 RCTs, N=1,012; RR, 0.75 [95% CI, 0.30 to 1.93]; I^2=72%),[80,82] or maternal birth trauma (e.g., third or fourth degree vaginal lacerations) (1 RCT; n=236; RR, 0.63 [95% CI, 0.15 to 2.58])[80] (**Table 5** and **Appendix C Figures 2 to 5**). There was unexplained inconsistency between RCTs for preeclampsia and preterm deliveries, with statistically significant findings favoring IADPSG screening from the largest trial[82] (**Figures 2** and **3** and **Appendix D Table 2**). Findings for excessive weight gain were imprecise.

Fetal/Neonatal Outcomes

Screening using IADSPG vs. CC criteria was consistently associated with decreased risk of LGA

infants (3 RCTs, N=1,059; RR, 0.46 [95% CI, 0.25 to 0.83]; I^2=0%; ARD, 3.2% fewer [95% CI, 5.7 to 0.8]),[80-82] and neonatal hypoglycemia (2 RCTs, n=1,012; RR, 0.52 [95% CI, 0.28 to 0.95]; I^2=0%; ARD, 2.7% fewer [95% CI, 5.0 to 0.5])[80,82] (**Figures 4** and **5**). One RCT[82] found IADPSG screening associated with decreased risk of NICU admissions (1 RCT, n=786; RR, 0.49 [95% CI, 0.29 to 0.84]; ARD, 3.7% fewer [95% CI, 7.9 to 0.6]);[82] one other small trial reported no NICU admission.[81] The pooled estimate for macrosomia (>4,000g) was imprecise, with unexplained inconsistency (3 RCTs, N=1,059; RR, 0.65 [95% CI, 0.27 to 1.56]; I^2=49%).[80-82] Results for mortality, shoulder dystocia, and APGAR scores at 5 minutes were imprecise, and for hyperbilirubinemia were imprecise and inconsistent (**Table 6** and **Appendix C Figures 6 to 10**).

IADPSG vs. WHO 1999 Criteria

Pregnancy Outcomes

One RCT (n=502)[78] found IADSPG and the WHO 1999 criteria associated with similar likelihood of primary cesarean deliveries (RR, 1.05 [95% CI, 0.78 to 1.41]) or preterm delivery (RR, 0.90 [95% CI, 0.47 to 1.73], though estimates were imprecise. Findings for hypertensive disorders in pregnancy were imprecise (**Table 5**).

Fetal/Neonatal Outcomes

Findings for shoulder dystocia, LGA and hypoglycemia in one RCT[78] were imprecise (**Table 6**).

Early vs. Usual Timing of CC Screening

Pregnancy Outcomes

An RCT (n=922)[79] enrolling obese women found early vs. usual screening with CC criteria potentially associated with increased risk of preeclampsia, though the difference was not statistically significant (RR, 1.42 [95% CI, 0.99 to 2.05]; ARD, 4.0% more [0.0 to 8.0]) (**Table 5**). No associations were found for gestational hypertension (RR, 1.29 [95% CI, 0.94 to 1.77]), hypertensive disorders in pregnancy (RR, 0.91 [95% CI, 0.75 to 1.10]), primary cesarean deliveries (RR, 0.86 [95% CI, 0.65 to 1.12]), or induction of labor (RR, 0.93 [95% CI, 0.82 to 1.07]). All findings had some imprecision. Although preterm delivery rates were not compared, average delivery times were earlier in the early screening group (36.7 ± 4.5 vs. 38.7 ± 1.7 weeks' gestation, respectively).

Fetal/Neonatal Outcomes

No associations were found between early and usual timing of CC screening for shoulder dystocia (RR, 0.96 [95% CI, 0.49 to 1.86]), macrosomia (RR, 1.20 [95% CI, 0.68 to 2.11]), LGA (RR, 1.05 [95% CI, 0.62 to 1.77]), hypoglycemia (RR, 1.17 [95% CI, 0.64 to 2.13]), or hyperbilirubinemia (RR, 1.26 [95% CI, 0.95 to 1.67]); findings were limited by imprecision (**Table 6**).

Key Question 4a. What Is the Diagnostic Accuracy of Commonly Used Screening Tests for GDM? b. Does the Accuracy of Commonly Used Screening Tests for GDM Vary According to Maternal Subgroup Characteristics, Including Timing During Pregnancy, BMI, Age, Race/Ethnicity, or Prevalence of GDM?

Summary

- For the 50 g OGCT vs. CC criteria, the joint pooled estimates of sensitivity and specificity for the 140 mg/dL cutoff (8 studies, N=6,190) were 81.9 (95% CI, 68.3 to 90.4) and 81.8 percent (95% CI, 71.2 to 89.1). Sensitivity was higher but specificity lower at 135 mg/dL (4 studies, N=1,554; 93.3% [95% CI, 23.7 to 99.8] and 78.9 percent [95% CI, 53.3 to 92.5]). Findings for 130 mg/dL were inconsistent from three studies.
- For the 140 mg/dL OGCT cutoff with NDDG criteria (6 studies, N=5,375), the sensitivity was slightly higher (85% [95% CI, 72.0 to 92.6]) and specificity similar (81.2% [95% CI, 75.9 to 85.6]) compared with the CC criteria. Sensitivity for the OGCT compared with IADPSG criteria was relatively low across all cutoffs; specificity for the OGCT at the 140 mg/dL cutoff vs. IADPSG criteria was fairly high (81% and 93% in two studies).
- For FPG vs. CC criteria, sensitivities and specificities were fairly similar using cutoffs of 85 mg/dL (4 studies, N=2,233; 88% [95% CI, 84 to 91] and 73% [95% CI, 46 to 90]) and 90 mg/dL (4 studies, N=2,233; 81% [95% CI, 75 to 85) and 82% [95% CI, 61 to 93]). Across all cutoffs, sensitivity appeared fairly high (above 90%) using 80 mg/dL or lower and specificity appeared high (90% or above) using cutoffs over 90 mg/dL.
- For FPG vs. IADPSG criteria at 24 weeks' gestation or later, thresholds at or below 80 mg/dL appeared to have high sensitivity but low specificity. Specificity did not exceed 90 percent at thresholds below 90 mg/dL.
- HbA1c screening was not associated with high enough sensitivity and specificity at any threshold (18 studies). Screening with HbA1c at 24 weeks' gestation may allow for ruling out GDM (i.e., sensitivity above 90%) at cutoffs of 4.5 to 5.0 percent (CC and NDDG) or 4.6 to 4.7 percent (IADPSG), but findings were based on a small number of studies. A good-quality study (n=1,158) of early screening vs. NDDG criteria suggested that the rule-out cutoffs may also apply (i.e., sensitivity was over 95% at 4.5 to 4.8% HbA1c).
- Single studies found different risk-based tools (some in combination with FPG) may have high enough sensitivity to rule out GDM and allow some women to avoid the OGCT; however, specificity was low.

Evidence

The prior review[1,2] included 51 prospective cohort studies on the accuracy of screening tests for GDM. It found the 50g OGCT with a glucose threshold of either 130 mg/dL or 140 mg/dL to be accurate; the 130 mg/dL cutoff improved sensitivity and reduced specificity (99% vs. 85% and 77% vs. 86%, respectively). The sensitivity and specificity for FPG at a threshold of 85 mg/dL

were 87 (95% CI, 81 to 91) and 52 percent (95% CI, 50 to 55), respectively. Eight studies examined risk factor-based screening using different diagnostic criteria but sensitivity and specificity varied widely. Limited evidence found that HbA1c as a screening test was associated with low accuracy. Sparse evidence was found for early screening for GDM and for screening with IADPSG criteria. The prior review noted limitations in the evidence, including partial verification bias (patients with negative tests did not undergo the reference standard) and use of index tests and diagnostic criteria not commonly used in the United States.

This review included 45 prospective cohort studies[38,86-129] (with two associated papers[36,130]). Sixteen studies[86-88,90,95-97,101,103,108,109,113,115,117,124,126] (with 1 associated paper[36]) were carried over from the prior review, and 29 studies[38,89,91-94,98-100,102,104-107,110-112,114,116,118-123,125,127-129] (1 associated publication[130]) were added in this review. Because of revised eligibility criteria, 35 studies from the prior review were excluded due to the use of an ineligible diagnostic criterion (n=10),[131-140] ineligible index test (n=9),[141-149] not performing the reference standard on at least a sample of the women with a negative screening result (n=15),[150-164] or (for risk models) not evaluating accuracy in a validation cohort (n=1).[165] In all studies, the entire population that undertook the index test of interest was offered the OGTT reference standard; in some studies the OGCT was used to select patients for screening with the FPG and HbA1c. No study reported on differences in accuracy for the subgroups of interest.

50g OGCT Screening Test

CC Criteria

Eight studies evaluated screening with a 1-hour 50 g OGCT against CC diagnostic criteria with a 100 g OGTT (**Appendix B Table 7**).[90,97,105,109,112,117,119,126] Sample sizes ranged from 89 to 3,836 (median 402; total N=6,190). Mean age ranged from 25 to 31.8 years in three studies that reported this data,[109,119,126] and BMI was 23.2[126] and 23.8 kg/m^2 [109] in two studies. Two studies were conducted in India;[112,119] and one study was conducted in each of Brazil,[90] Canada,[117] Mexico,[97] Pakistan,[105] Switzerland,[109] and Thailand.[126] One study[105] enrolled a low-risk population; another study only included women with at least one risk factor for GDM;[126] other studies enrolled unselected populations. Two studies screened some women earlier than 24 weeks' gestation (as early as 21[126] and 22[112] weeks). Prevalence of GDM ranged between 4.0 and 16.7 percent. Five studies were rated good quality,[90,97,109,117,126] and three fair quality,[105,112,119] due to potential selection biases (e.g., excluding some patients without outcome data due to others purposes of study), inadequate description of the reference standard (e.g., failure to provide details on fasting protocol), and/or issues related to flow and timing (e.g., some variation in timing of OGTT) (**Appendix B Tables 8** and **9**).

Eight studies (N=6,190) provided data for a 140 mg/dL threshold.[90,97,105,109,112,117,119,126] The joint pooled estimates of sensitivity and specificity were 81.9 (95% CI, 68.3 to 90.4) and 81.8 percent (95% CI, 71.2 to 89.1) (**Figure 6** and **Table 7**). Four studies (N=1,554) used a cutoff value of 135 mg/dL.[97,109,112,119] The joint pooled estimates of sensitivity and specificity were 93.3 (95% CI, 23.7 to 99.8) and 78.9 percent (95% CI, 53.3 to 92.5); statistical heterogeneity was present for both parameters. Three studies (N=1,034) provided data for an OGCT cutoff value of 130

mg/dL.[97,112,119] Sensitivities and specificities ranged from 75 to 100 percent, and 25 to 86 percent, respectively (**Figure 6**).

NDDG Criteria

Six studies evaluated screening with a 1-hour 50 g OGCT against NDDG diagnostic criteria with a 100g OGTT.[95,97,103,108,117,124] Sample sizes ranged from 42 to 3,836 (median 360; total N=5,375). Mean age ranged from 26 to 27.8 years. One study enrolled a high proportion (43%) of women with family history of DM;[97] others enrolled unselected populations. Two studies were conducted in Turkey;[95,124] and one study was conducted in each of Canada,[117] Mexico,[97] Spain,[108] and the United States.[103] Five studies performed the OGCT at 24 to 28 weeks' gestation,[95,97,103,108,117,124] and one at 25 to 27 weeks' gestation.[117] Prevalence of GDM ranged from 3.7 to 33 percent. Four studies were rated good quality,[95,97,103,117] and two fair quality,[108,124] due to potential issues with patient selection (e.g., exclusion of overt diabetes unclear), and either some concern about the index test (i.e., pre-specification of threshold not reported)[124] or flow and timing (i.e., exact timing of OGTT not reported).[108]

Six studies (N=5,375) provided data for 50 g OGCT screening with a 140 mg/dL cutoff (**Figure 7**).[95,97,103,108,117,124] Joint pooled estimates of sensitivity and specificity were 85.0 percent (95% CI, 72.0 to 92.6) and 81.2 percent (95% CI, 75.9 to 85.6), respectively (**Table 7**). Two studies (N=487) provided data for a cutoff value of 135 mg/dL.[97,124] The sensitivities were 88.5[97] and 78.6 percent[124], and specificities were 84.2[97] and 46.4[124] (**Figure 7**). One study (n=445) used an OGCT cutoff value of 130 mg/dL.[97] Sensitivity and specificity were 90.7 and 79.4 percent, respectively (**Appendix D Table 3)**.

IADPSG Criteria

Two good-quality studies evaluated screening with the 50g OGCT against IADPSG criteria using a 2-hour 75g OGTT in unselected populations.[92,107,130] One study reported in two publications (n=1,811) took place in Belgium.[92,130] Mean age was 30.8 years and BMI was 24.1 kg/m^2. The OGCT was performed at 24 to 28 weeks' gestation. The second study (n=280) from Nigeria performed the index test at 24 to 31 weeks' gestation.[107] Women had a mean age of 30.4 years and BMI of 27.2 kg/m^2; 13.2 percent had a family history of DM. Prevalence of GDM was 12.6[92,130] and 16.4 percent.[107]

Both studies reported on all three cutoff values.[92,107,130] Sensitivities were low (below 70%) at all cutoffs; specificities were 81.0 and 93.2 percent (140 mg/dL), 76.1 and 88.0 percent (135 mg/dL), and 70.2 and 84.2 percent (130 mg/dL) (**Figure 8**).

Sacks Criteria

One good-quality study (n=445), conducted in Mexico, assessed accuracy of the OGCT vs. a diagnosis of GDM at 24 to 28 weeks' gestation using Sacks 1989 criteria (requiring two abnormal values using thresholds of FPG at 95 mg/dL, 1-hour 170 mg/dL, 2-hour 151 mg/dL, or 3-hour 130 mg/dL).[97] Forty-three percent had a family history of DM. Prevalence of GDM was 13.9 percent.

The study provided data for cutoffs of 140, 135, and 130 mg/dL (**Appendix D Table 3**).[97] Sensitivities were 82.3, 83.9, and 88.7 percent, respectively, and specificities were 88.0, 87.2, and 82.2 percent.

Fasting Plasma Glucose

CC Criteria

Seven studies evaluated screening with FPG against CC criteria with a 3-hour 100g OGTT;[86,87,96,101,109,112,119] one study used a 2-hour 75g OGTT.[86] Sample sizes ranged from 89 to 4,602 (median 520; total N=8,661). Mean age was 29.1 years in the five studies reporting this data,[86,87,96,109,119] and mean BMI in two studies was 23.8[109] and 28.1 kg/m^2.[96] Two studies were conducted in each of India[112,119] and the United Arab Emirates;[86,87] and one in each of France,[96] Switzerland,[109] and the United States.[101] FPG was measured at 24 to 28 weeks' gestation in all studies. One study only included low-risk women;[101] two studies only included women with a positive OGCT,[87,96] or who were determined to be at high risk based on clinical risk factors;[87] the remaining four studies enrolled unselected populations. Prevalence of GDM ranged from 7.2 to 31.8 percent. Two studies were rated good quality,[101,109] and five fair quality,[86,87,96,112,119] due to one or more concerns about patient selection (e.g., using selective populations), reference standard (e.g., no clear description of fasting protocol) and/or flow and timing (e.g., some variation in timing of OGTT).

The studies provided data to pool estimates for test characteristics of FPG at four cutoffs: 79,[87,109,119] 85,[87,112,119] 90,[87,112,119] and 95.5 mg/dL[87,96,112] (**Figure 9** and **Table 7**). Joint estimates of sensitivity and specificity, respectively, were:

- 79 mg/dL: 96 percent (95% CI, 92 to 98) and 35 percent (95% CI, 30 to 41)
- 85 mg/dL: 88 percent (95% CI, 84 to 91) and 73 percent (95% CI, 46 to 90)
- 90 mg/dL: 81 percent (95% CI, 75 to 85) and 82 percent (95% CI, 61 to 93)
- 95.5 mg/dL: 58 percent (95% CI, 32 to 81) and 98 percent (95% CI, 88 to 100)

There was insufficient data to pool at other specific cutoffs. However, results were consistent with the pooled findings. Across cutoffs, sensitivity was below 80% for thresholds 90 mg/dL or higher and above 90% for cutoffs 80 mg/dL or lower and specificity was above 90% for cutoffs above 90 mg/dL and below 35% for cutoffs below 80 mg/dL. At an FPG cutoff of 92 mg/dL (the threshold used in the IADPSG criteria) sensitivity from three studies[96,101,119] was inconsistent (range 26 to 76%) (**Figure 9** and **Appendix D Table 4**).

NDDG Criteria

One good-quality U.S. study (n=123) evaluated FPG screening against NDDG criteria at 24 to 28 weeks' gestation.[101] The study included low-risk women 19 to 40 years old with no prior history of GDM; 40 percent were Mexican-American. Prevalence of GDM was 13.0 percent. At a 93 mg/dL cutoff, sensitivity and specificity were 81.3 and 87.9 percent, respectively.

IADPSG Criteria

Nine studies diagnosed GDM using IADPSG criteria.[38,89,104,110,116,120,123,128,129] Sample sizes ranged from 246 to 24,854 (median 3,616; total N=59,278). Mean age was 27.7 years. Two studies were conducted in each of China[128,129] and India;[89,120] and one study in each of Brazil,[123] Iran,[110] Norway,[104] Sweden,[116] and South Africa.[38] Mean BMI was 24.6 kg/m^2 in six studies that reported this data.[38,104,110,116,120,123] Six studies measured FPG at 24 to 28 weeks' gestation;[38,89,104,116,123,128] one at 20 to 24 weeks' gestation;[110] one at below 20 weeks' gestation;[120] and one at median 13.4 weeks' gestation.[129] The OGTT was measured at 24 weeks' gestation or longer, except in one study where the FPG and OGTT were undertaken at 20 to 24 weeks.[110] Two studies only included low-risk women;[110,116] none selectively included at-risk women. Prevalence of GDM ranged from 7.0 to 18.3 percent. Three studies were rated good quality,[89,104,129] and six fair quality,[38,110,116,120,123,128] due to minor issues in patient selection (e.g., excluding those with self-reported pre-existing diabetes), index test (e.g., pre-specification of cutoffs not reported), reference standard (e.g., no clear description of fasting protocol) and timing (e.g., some variation in timing of the OGTT).

Four studies provided data to pool estimates at the 90 mg/dL cutoff measured at 24 weeks' gestation or longer (**Figure 10**).[89,116,123,128] Joint estimates of sensitivity and specificity were 79 (95% CI, 65 to 89) and 96 percent (95% CI, 95 to 97) (**Table 7**). The 90 mg/dL cutoff is similar to the level of FPG (92 mg/dL) that is diagnostic using this criteria, based on one abnormal value. All thresholds at or below 80 mg/dL appeared to have sensitivity over 90 percent, to rule-out GDM, whereas the specificity did not reach over 90 percent at cutoffs under 90 mg/dL (**Figure 10** and **Appendix D Table 4**).

Two studies provided data for test characteristics of FPG measured before 24 weeks at 79[110,129] and 85 mg/dL[120,129] cutoffs (**Figure 11**). Studies reporting on the 79 mg/dL cut-off used different timing for the OGTT (**Appendix D Table 4**). Findings from two studies of early screening with a FPG of 85 mg/dL vs. the OGTT at 24 to 28 weeks were inconsistent.

Sacks Criteria

One good-quality U.S. study (n=4,507) evaluated FPG screening vs. a diagnosis of GDM using Sacks criteria.[115] Median age was 28.3 years and 69.3 percent were Latina. One-third had a family history of DM. Women were screened early in pregnancy (mean 10.7 weeks' gestation). Prevalence of GDM was 6.7 percent.

The study provided data for FPG at six cutoffs: 70, 75, 80, 85, 90, and 95 mg/dL.[115] Sensitivity and specificity ranged from 34.0 (95 mg/dL cutoff) to 100 percent (70 mg/dL cutoff) and 2.0 (70 mg/dL cutoff) to 92.0 percent (95 mg/dL cutoff) (**Appendix D Table 4**).

HAPO 2.0 Criteria

One fair-quality study (n=3,616) conducted among low-risk women in Sweden, screened with FPG at 24 to 28 weeks and confirmed a diagnosis of GDM using modified HAPO 2.0 criteria (no

1-hour glucose value).[116] Mean age was 27.9 years and BMI was 23.8 kg/m^2; 89 percent were of Nordic origin. Prevalence of GDM was 7.2 percent.

The study provided data for FPG at five cutoffs: 79, 83, 86.5, 90, and 94 mg/dL[116] (**Appendix D Table 4**) Sensitivity and specificity ranged from 89.0 (94 mg/dL cutoff) to 96.0 percent (79 mg/dL and 83 mg/dL cutoffs) and 54.0 (79 mg/dL cutoff) to 98.0 percent (94 mg/dL cutoff), respectively. The optimal cutoff was 90 mg/dL, where sensitivity and specificity were 91.0 and 92.0 percent.

Hemoglobin A1c

Eighteen studies evaluated screening with HbA1c.[88,91,93,94,99,100,102,106,110,111,113,114,118,121,122,124,125,127] Sample sizes ranged from 42 to 1,989 (median 453; total N=10,488). Mean age was 29.1 years (range 26.1 to 32.7) and mean BMI was 24.2 kg/m^2 (ranged 22.4 to 25.7 kg/m^2). Three studies were conducted in India;[93,113,122] two studies were from each of China,[99,127] Turkey,[118] Iran,[110,114] and Australasia;[100,102] and single studies were conducted in Brazil,[94] Norway,[106] Spain,[91] Romania,[125] Singapore,[111] Thailand,[121] and the United Arab Emirates.[88]

Five studies evaluated HbA1c screening against CC criteria with both tests done at or after 24 weeks' gestation.[88,94,99,113,125] Four studies used a 3-hour 100g OGTT and one study[113] used a 2-hour 75g OGTT. Three studies only enrolled women with a positive OGCT,[88,99] or clinical risk factors.[88,125] Prevalence of GDM ranged from 7.1 to 29 percent. One study was rated good quality,[113] and four were rated fair quality. Frequent methodological limitations included poor reporting of fasting protocols and pre-specification of index test thresholds.[88,94,99,125]

Three studies evaluated screening with HbA1c vs. NDDG criteria.[91,121,124] Two small studies (N=156) measured HbA1c at or after 24 weeks' gestation,[121,124] and another (n=1,158) measured HbA1c in the first trimester. One study only enrolled women with abnormal OGCT results.[121] GDM prevalence ranged from 13 to 33 percent. One study was rated good quality,[91] and two were fair quality,[121,124] due to no pre-specification of the index test threshold, and (in one[124]) not reporting patient recruitment methods.

For HbA1c screening against IADPSG criteria, four studies performed screening at 24 to 28 weeks' gestation,[102,113,118,122] three performed screening prior to 20 weeks' gestation (with diagnosis of GDM at 24 to 28 weeks),[110,111,127] and four screened at broad time points or throughout pregnancy.[93,100,106,114] All studies enrolled unselected populations. Prevalence ranged from 7.2 to 29 percent (mean 14.8%). One study was rated good quality[113] and ten were rated fair quality,[102,118,122] due to one or more concerns related to poor reporting on patient selection, selection of the cutoffs, and fasting protocols.

Against each criteria and for each time point, one or two studies contributed data for most thresholds (**Appendix D Tables 5** to **7**). Three studies contributed data for screening at the 5.2 and 5.7 percent HbA1c thresholds vs. IADPSG at 24 to 28 weeks (**Figures 12** and **13**). Findings at the 5.2 percent cutoff were inconsistent; at the 5.7 percent cutoff the median specificity was 91 percent; and at cutoffs currently used for diagnosis (6.0 and 6.1 percent HbA1c) specificity was over 97 percent. Overall, the evidence does not suggest that there is a threshold for which

sensitivity and specificity would both be high enough to replace the OGCT as a screening test. Sensitivity was above 90 percent for the 4.5 and 5.0 percent cutoffs against CC and NDDG criteria, and for the 4.6 and 4.7 percent cutoffs against IADPSG when screening was within the second trimester (e.g., more than 18 weeks' gestation), suggesting a potential role as a rule-out threshold to determine who might be able to avoid an OGCT (**Appendix D Tables 5** and **7**). A good-quality study (n=1,158) of early screening with HbA1c vs. NDDG criteria suggested that the rule-out cutoffs may also apply (i.e., sensitivity was over 95% at 4.5 to 4.8% HbA1c) (**Appendix D Table 6**).

Risk Factor-Based Screening

CC Criteria

One fair-quality study (n=341)[90] from the prior review validated a risk-based tool developed in Brazil against CC criteria (source unavailable) (**Appendix B Tables 7, 10** and **11**). The screening test was positive with a FPG of 90 mg/dL or greater (assessed before 20 weeks' or during the OGTT at 24 to 28 weeks' gestation [mean timing not reported]) and/or one or more of several risk factors (**Table 8**). Women with previous GDM were excluded. Fifty-four percent of women screened positive. Sensitivity was 84.6 percent and specificity was 47.3 percent. GDM prevalence was 3.8 percent.

NDDG Criteria

One good-quality study from Canada,[36,117] evaluated risk-based screening in a large cohort study with confirmation of GDM with NDDG criteria.[36] Scores for age, BMI, and race/ethnicity were combined with OGCT thresholds that varied by risk score and two slightly different models were developed (**Table 8**). Women with scores from risk factor assessment of 0 or 1 (out of maximum 10) were not screened with the OGCT. Performance of the risk scoring strategies was evaluated using an internal validation cohort (n=1,571) that was not used to develop the risk score. In the validation cohort, the index and diagnostic tests were performed at 25 to 27 and 27 to 29 weeks' gestation, respectively, and GDM prevalence was 4.4 percent. For the two different strategies, sensitivities were 82.6 and 81.2 percent, and specificities were 80.3 and 80.9 percent. Both risk models performed with greater accuracy than the 50g OGCT on its own in this study; using the risk-based scoring allowed for 34.6 percent of women to avoid the OGCT.

IADPSG Criteria

A fair-quality study in Austria (n=258) validated a two-step screening algorithm against IADPSG criteria at 24 weeks' gestation or later for diagnosis.[98] The risk model was developed for use in women not meeting IADPSG criteria based on FPG of 5.1 mmol/L (92 mg/dL); scoring combined FPG under 5.1 mmol/L with several risk factors (history of GDM, glycosuria, age, relative with T2DM, preconception dyslipidemia, ethnicity) and a score of 0.2 was used as the cutoff (**Table 8**). GDM prevalence was 23 percent. Sensitivity and specificity were 98.3 and 16.6 percent.

Key Question 5. What Is the Association Between Diagnosis of GDM and Outcomes in Women Meeting More Inclusive But Not Less Inclusive Diagnostic Criteria for GDM?

Summary

- Women with untreated GDM using more inclusive criteria are probably at increased risk for preeclampsia (11 studies), hypertensive disorders in pregnancy (9 studies), total cesarean deliveries (20 studies), and preterm deliveries (17 studies) vs. women with NGT. Findings for primary (first) cesarean delivery, induction of labor, maternal birth trauma, and excessive weight gain were generally inconsistent and imprecise.
- There were robust associations between a diagnosis of GDM using more inclusive criteria (including IADPSG) and increased risks of macrosomia (22 studies), LGA (21 studies), neonatal hypoglycemia (13 studies) and hyperbilirubinemia (10 studies); associations persisted after adjustment for confounding.
- Estimates for the associations between a diagnosis of GDM using more inclusive criteria and risk of perinatal mortality, birth injury, and shoulder dystocia were generally imprecise or not statistically significant after controlling for confounders.
- There was no association between more inclusive GDM criteria vs. NGT for risk for NICU admissions (11 studies), including analyses that adjustment for potential confounding.
- Estimates for the associations between a diagnosis of GDM using more inclusive criteria and risk of respiratory distress syndrome and low APGAR scores at 1 or 5 minutes were imprecise and inconsistent.
- For long-term outcomes, GDM using one abnormal value (OAV) on CC criteria may not be associated with childhood (5 to 13 years) obesity vs. NGT, but OAV on NDDG may be associated with increased risk of maternal impaired glucose tolerance at 3 months' postpartum. Findings for maternal development of T2DM and metabolic syndrome were from single studies and imprecise.

Evidence

The prior review[2] included 38 observational studies found associations with increased risk for women with various criteria of GDM or dysglycemia (e.g., OGCT positive but no GDM) vs. normal glucose tolerance (NGT) of caesarean deliveries, shoulder dystocia, macrosomia (except for IADPSG criteria), and LGA. Higher levels of glycemia did not consistently demonstrate greater risk for these outcomes.

Twenty-five studies[9,150,166-188] from the prior report were excluded because they did not compare diagnostic criteria of interest. This review includes 31 cohort studies[189-219] (with one associated publication[220]) comparing outcomes (often retrospectively) between women with NGT and those meeting more inclusive GDM criteria than routinely used in the United States (**Appendix B Table 12**). Thirteen studies were carried forward from the prior report.[191-194,199,202,205-207,212-214,216]

Study Characteristics

Sample sizes ranged from 131 to 22,804 (median 1,927; total N=105,492), mean age from 22.7 to 34.7 years (median 31.1 and 30.1 years in GDM and NGT groups, respectively), and mean BMI from 21.1 to 35.6 kg/m^{-2} (median 23.7) in the GDM groups and from 20.5 to 32.7 kg/m^{-2} (median 23.7) in the NGT groups. Seven studies were conducted in the United States (one also including Canadian participants in HAPO cohort);[191,195,197,199,205,213,218] two in Canada;[212,214] one in Mexico,[209] seven in Europe,[190,193,194,204,206,207,216] ninet in Asia,[198,200,202,203,208,211,215,217,219] and four in the Middle East.[189,192,201,210] Of eight studies reporting on family history of T2DM,[194,198,200,208,209,212,216,218] the proportion in women with GDM ranged from 9.6 to 59 percent and in NGT women was 5.8 to 44.3 percent. Few studies reported on previous GDM, and only one study excluded women with previous GDM.[205] Except for eight studies,[190,193,206,210,212-214,219] all limited inclusion to women with singleton pregnancies. Of the five U.S. studies reporting race, four[197,199,205,218] had diverse study populations (50% or fewer white women) and one had 71 percent white women.[195] When reported, the large majority of women in the studies from Europe[190,194,216] and Canada[212] were white.

Eleven studies were prospective[191,196,200,202,203,205,206,212,214,216,218] and 20 were retrospective cohort studies. Four main GDM exposure (but untreated) groups were compared with an NGT group: women meeting OAV on NDDG criteria but not NDDG GDM (6 studies),[191,192,202,212,214,217] OAV on CC criteria but not CC GDM (14 studies),[189,193,194,196,198,199,201,205,206,210,211,213,216,217] IADPSG but not CC criteria (11 studies),[190,195,197,200,203,204,207-209,215,218] and IADPSG but not NDDG criteria (1 study).[219] One study reported on outcomes for women meeting both OAV on NDDG (but not NDDG GDM) and OAV on CC (but not CC GDM) criteria.[217] Within these broad categories, some deviations to the recommended screening or diagnostic tests (e.g., one- vs. two-step CC, two-step IADPSG) were noted; in addition, the NGT groups sometimes included those only positive or negative on the OGCT. These variations were considered in analyzing the results. In seven of the eleven studies of IADSPG criteria, the criteria were applied to an OGTT within a two-step approach and in four of these seven a 100 g 3-hour OGTT was used.[190,195,197,207] Timing of screening was 24-28 weeks in most studies.

The definitions of outcomes varied or were often not reported, with the most uncertainty for neonatal hypoglycemia. None of the studies reporting on hypertension indicated (or standardized) the timing of the outcome measurement.

Twenty-six studies were rated fair quality and five good quality (**Appendix B Table 13)**.[205,213,214,216,218] In fair-quality studies, blinding of patients and providers to glycemic status or for outcome assessment did not occur; risk for selection bias was also common.

Pregnancy Outcomes

Women with GDM meeting more inclusive criteria had between a 15 and 100 percent increased risk of hypertensive disorders in pregnancy vs. women with NGT (9 studies, N=27,852; absolute effects showing between 1 to 5% more cases) (**Table 9** and **Figure 14**).[194,195,197,201,204,205,209,216,217] These findings may relate to an increased risk of preeclampsia (11 studies, N=32,879; 60 to 93% relative increase with 1.5 to 3.3% more cases) (**Figure 15**)[190,192,198,200,202,

[203,207,209,214,215,218] rather than gestational hypertension; the associations between GDM diagnosis meeting more inclusive criteria vs. NGT and risk of hypertension from five studies on hypertension were inconsistent and imprecise (**Appendix C Figure 11**).[190,198,207,209,219] Findings were similar, but somewhat less precise, after adjustment for numerous variables, including family history of hypertension, gestational age at the OGTT, and maternal urinary tract infection (**Appendix D Table 8**).

Results consistently found diagnosis of GDM using more inclusive criteria associated with 20 to 30 percent increased risk for total cesarean deliveries (20 studies, N=64,520)[189,190,192-194,198,202,206-211,213-217] (**Figure 16**). The absolute difference was 7 to 13 percent more cesarean deliveries. However, this may overestimate the effects in the United States as four studies[198,209,215,217] from non-VHDI countries reported high event rates in the NGT group (32 to 74%). GDM using more inclusive criteria was associated with an approximate 40 percent higher risk (1 to 2% higher in absolute terms) for preterm deliveries vs. NGT (17 studies, N=49,116) (**Figures 17 and 18**);[190,192,195,198,200-204,208-211,215-218] there was consistency across diagnostic criteria and in adjusted analyses (**Appendix D Table 8**). Findings for primary cesarean deliveries (6 studies, N=24,354),[195,197,200,201,203,218] induction of labor (4 studies, N=8,024),[189,200,203,204] and maternal birth trauma (5 studies, N=25,270)[195,197,200,208,217] were limited by inconsistency and/or imprecision but suggested no associations between GDM diagnosis using more inclusive criteria and increased risk (**Table 9** and **Appendix C Figures 12** to **14**).

Fetal/Neonatal Outcomes

There were robust associations between more inclusive GDM criteria vs. NGT and increased risk of macrosomia (22 studies, N=89,661; about 50-100% increased risk and absolute effects ranging from 2.6 to 8.1% more cases)[189-195,197-199,201,203,206-210,214-217,219] (**Figure 19**) and LGA (21 studies, N=52,649; 60-70% increase with 4.7 to 6.0% more cases)[189-193,195,197,198,200-209,213,216,218] in crude (**Figure 20**) and adjusted analyses (**Appendix D Table 9**); unlike the 2013 USPSTF report, this finding was consistent with studies that used the most inclusive GDM criteria (IADPSG) likely due to the availability of more studies. More inclusive GDM criteria were also associated with increased risk of neonatal hypoglycemia (13 studies, N=45,369)[189,192-194,198,200-203,213,216,218,219] (**Figure 21**) and hyperbilirubinemia (10 studies, N=26,973)[192,193,198,200,201,203,208,214,216,218] (**Appendix C Figure 15)**, though the latter had some variability in the degree of increased risk.

More inclusive GDM criteria were not associated with increased risk of mortality vs. NGT (8 studies, N=42,303; 161 events),[193,197,198,200-202,216,219] although findings had some imprecision (**Appendix C Figure 16**). One good-quality study (n=3,637)[214] found no association between having OAV on NDDG criteria vs. NGT and risk of birth injury (**Table 10**). Findings across criteria did not show an association vs. NGT for increased risk of shoulder dystocia (10 studies, N=32,969),[189,190,195,197,198,201,205,208,216,217] though there was some inconsistency (**Table 10** and **Appendix C Figure 17**). There was no association between more inclusive GDM criteria vs. NGT for risk for NICU admissions (11 studies, N=39,452)[190,197,198,200,201,203,208,210,216-218], including analyses that adjustment for potential confounding (**Table 10** and **Appendix C Figure 18**).

Findings for the association between more inclusive GDM criteria and risk of respiratory distress syndrome (4 studies, N=2,432)[189,198,202,216] or low APGAR scores at 1 minute (5 studies, N=12,586)[197,198,202,208,216] or 5 minutes (7 studies, N=20,169)[190,197,198,201,202,208,216] were imprecise and inconsistent (**Appendix C Figures 19 to 21**).

Long-Term Maternal and Childhood Outcomes

Two U.S. studies (n=9,941)[196,199] found no associations between OAV on CC vs. NGT and risk for childhood (at 5 to 7 years[199] and 3 years[196]) obesity (BMI over 85th and 95th percentiles) (**Table 11**). A study from Canada (n=350)[212] found associations between OAV on NDDG and increased risk of impaired glucose tolerance (RR, 2.13 [95% CI, [1.14 to 3.99]) and T2DM (RR, 19.8 [95% CI, 1.03 to 379.34]) at 3 months' postpartum. Diagnosis of GDM using OAV on NDDG criteria was associated with higher risk (75%) metabolic syndrome vs. NGT, though estimates were imprecise.

Key Question 6a. Does Treatment of GDM During Pregnancy Reduce Poor Health Outcomes? b. Does Treatment of GDM During Pregnancy Reduce Poor Intermediate Outcomes? c. Does the Effectiveness of Treatment of GDM Vary According to Maternal Subgroup Characteristics, Including Timing and Criteria Used for Diagnosis During Pregnancy, Severity of Hyperglycemia, BMI, Age, or Race/Ethnicity?

Summary

- Treatment of GDM at or after 24 weeks' gestation was associated with decreased risk of primary (first) cesarean deliveries (3 trials; RR, 0.70 [95% CI, 0.54 to 0.91]; I^2=0%; ARD, 5.3% fewer [95% CI, 10.3 to 0.24]) and preterm deliveries (4 trials; RR, 0.75 [95% CI, 0.56 to 1.01]; I^2=0%; ARD, 2.6% fewer [95% CI, 4.9 fewer to 0.02 more]) vs. no treatment, although the latter finding had some imprecision.
- There might be an association between treatment for GDM vs. no treatment and decreased risk of preeclampsia (5 trials, N=1,384; RR, 0.60 [95% CI, 0.35 to 1.01]; I^2=3%; ARD, 1.0% fewer [95% CI, 4.5 fewer to 2.4 more]), after excluding an outlier trial. For hypertensive disorders in pregnancy, there was marked inconsistency between trials and no association with reduced risk (3 trials, N=2,626; RR, 0.85 [95% CI, 0.50 to 1.43]; I^2=80%]. Treatment was not associated with reduced risk of gestational hypertension (2 trials; with some imprecision).
- Treatment for GDM was not associated with reduced risk of total cesarean deliveries (8 trials), emergency cesarean deliveries (1 trial), induction of labor (5 trials), or maternal birth trauma (2 trials).
- In terms of fetal/neonatal outcomes, treatment for GDM at or after 24 weeks' gestation, vs. no treatment, was associated with reduced risk of shoulder dystocia (4 trials; RR, 0.42 [95% CI, 0.23 to 0.77]; I^2= 0%; ARD, 1.3% fewer [95% CI, 4.3 to 1.6]), macrosomia (8

trials; RR, 0.53 [95% CI, 0.41 to 0.68]; I^2=42%; ARD, 8.9% fewer [12.0 to 5.9]), LGA (7 trials; RR, 0.56 [95% CI, 0.47 to 0.66]; I^2=0%; ARD, 8.4% fewer [95% CI, 10.8 to 6.1]), and NICU admissions (5 trials; RR, 0.73 [95% CI, 0.53 to 0.99]; I^2=0%; ARD, 2.0% fewer [95% CI, 4.5 fewer to 0.5 more]). Treatment for GDM was associated with reduced risk of birth injury (e.g., fracture or nerve palsies) in three trials reporting events (OR, 0.33 [95% CI, 0.11 to 0.99]; I^2=0%) but not when combining data from seven trials reporting on the outcome (ARD, 0.2% fewer [95% CI, 0.6 fewer to 0.2 more]).

- There was no association between treatment for GDM and risk of mortality, respiratory distress syndrome, neonatal hypoglycemia, hyperbilirubinemia, or APGAR scores; though results for many of these outcomes were heterogeneous and/or imprecise.
- One trial found no association between treatment for GDM vs. no treatment and maternal impaired fasting glucose, obesity, metabolic syndrome or T2DM at 5 to 10 years. No study measured effects of treatment for GDM on long-term quality of life, cardiovascular outcomes, or mortality or major morbidity from T2DM.
- For long-term intermediate and health outcomes in the child, treatment of mothers for GDM, vs. no treatment, was not associated with reduced risk of overweight/obesity (over 4 to 7 years), obesity (7 to 9 years), impaired glucose tolerance (median 9 years) or impaired fasting glucose (median 7 to 9 years). Evidence on T2DM was too sparse to determine effect of treatment of mothers for GDM. No study measured cardiovascular or neurocognitive outcomes.
- There was insufficient evidence to determine effects of treatment vs. no treatment for GDM in early pregnancy (using HbA1c or IADPSG criteria before 14 to 15 week's gestation); findings from four small trials were highly imprecise and limited by risk of bias.
- Subgroup analyses from one trial found no differences in effects of GDM treatment for several maternal and fetal outcomes based on timing of treatment initiation, race/ethnicity, severity of dysglycemia, or BMI. Across trials, differences in GDM diagnostic criteria did not appear to impact findings for several outcomes or explain inconsistency. Findings are most applicable to two-step screening approaches.

Evidence

The prior review[2] found that treatment for GDM at or after 24 weeks' gestation was associated with reduced risk of preeclampsia (3 RCTs, N=2,014; RR, 0.62 [95% CI, 0.43 to 0.89]), macrosomia (5 RCTs, N=2,643; RR, 0.50 [95% CI, 0.35 to 0.71]), LGA (3 RCTs, N=2,261; RR, 0.56 [95% CI, 0.45 to 0.69], and shoulder dystocia (3 RCTs, N=2,044; RR, 0.42 [95% CI, 0.23 to 0.77]) vs. no treatment. No associations were found between GDM treatment and risk of neonatal hypoglycemia, cesarean deliveries, or induction of labor. Findings were based on 5 RCTs[41,42,221-223] and 6 cohort studies[75,167,172,176,224,225], and were largely driven by two large RCTs of women with GDM.[41,42] For outcomes for which results were inconsistent between studies, different study glucose threshold entry criteria did not explain the variation.

The current review excluded cohort studies because more RCT evidence is now available. We included the previous five RCTs, and added eight new trials [226-233] and six associated papers[234-239] reporting subgroup analyses or long-term followup (**Tables 12** and **13**, and **Appendix B Table 14**).

Study Characteristics

Sample sizes ranged from 21 to 1000 (median 103; total N=4,235), with three trials each having 700 to 1000 participants.[41,42,233] Mean ages ranged from 26.8 to 33.3 years (median 30.3) and BMI from 23.1 to 34.5 kg/m^2 (median 28.6). Three trials were conducted in each of the United States,[42,221,230] and Europe,[222,227,232] two in Australia[41,231] and Turkey,[226,229] and one in Canada,[223] New Zealand,[228] and China.[233] Two of the U.S. trials included a diverse population of women,[42,230] whereas one included 94 percent Hispanic women.[221] A large RCT from Australia included 75 percent white women.[41] Few trials reported on the proportion of women with a family history of T2DM or prior GDM. Two trials excluded women with previous GDM,[42,226] and all but one[41] excluded multiple gestations.

Eleven RCTs, and two CCTs (one prospective trial without random allocation and one subgroup analysis of an RCT of GDM prevention [examining those getting GDM])[226,232] were included. Seven trials examined standard treatment after testing for GDM at or after 24 weeks' gestation,[41,42,221,223,226,229,233] two enrolled women after diagnosis in early pregnancy or at or after 24 weeks,[222,227] and four studied treatment of early GDM (before 14 or 15 weeks' gestation).[228,230-232] The glycemic criteria in three trials was not mild GDM, but a positive OGCT with a negative OGTT on CC criteria.[221,222,226] One of the new trials used a 2-step screening approach with a 50g OGCT and OGTT with IADSPG criteria.[233] In the three largest trials,[41,42,233] there were some differences between baseline levels of glycemia; the older two trials had similar FPG but different 2-hour postload levels (i.e., FPG 86.5 mg/dL in both and 2-hour levels of 153 mg/dL[41] and 173 mg/dL[42]), and a third trial[233] had slightly higher FPG but lower 2-hour levels (i.e., FPG 91 mg/dL and 2-hour 151 mg/dL). In the four early pregnancy treatment studies, two used HbA1c for diagnosis of hyperglycemia,[228,230] and the other two used IADPSG/WHO 2013 criteria.[231,232] The interventions of all trials included dietary/medical nutrition therapy. Three trials did not report protocols for providing insulin or oral medication;[222,226,232] eight reported using insulin when needed to maintain set glucose targets,[41,42,221,223,227,229,230,233] and two (both of early treatment)[228,231] reported using insulin or metformin as needed. All trials except for two[226,232] included regular self-monitoring of blood glucose. The control interventions were routine pregnancy care, except in three trials[221,223,233] that included regular monitoring of blood glucose and/or some form of basic education. Outcome definitions varied to some extent. Apart from two trials that did not report data,[223,228] weeks' gestation at delivery was similar between groups in all trials.

Quality was rated good for three blinded RCTs of treatment at or after 24 weeks,[41,42,227] and fair for all other trials (**Appendix B Table 15**). The trials rated as fair quality[221-223,226,228-233] were open-label; other limitations included inadequate information regarding randomization and allocation concealment methods.

Treatment at or After 24 Weeks' Gestation

Pregnancy Outcomes

Preeclampsia

Six trials found no association between GDM treatment vs. no treatment and risk of preeclampsia, but there was statistical heterogeneity and some imprecision in the pooled estimate (N=2,084; RR, 0.99 [95% CI, 0.46 to 2.16]; I^2=59%)[42,221,226,227,229,233] (**Table 13** and **Figure 22**). Heterogeneity was not well explained by any single variable, but decreased substantially when one outlier study was removed (5 trials, N=1,384; RR, 0.60 [95% CI, 0.35 to 1.01]; I^2=3%; ARD, 1.0% fewer [95% CI, 4.5 fewer to 2.4 more]) (**Appendix D Table 10**). The outlier was an RCT from China,[233] which found treatment vs. minimal intervention in women with relatively low BMI (mean 23 kg/m^2) associated with an increased risk of preeclampsia.

Gestational Hypertension

Two RCTs from the United States[42] and China[233] found that treatment for GDM was not associated with reduced risk for gestational hypertension, though there was some imprecision (N=1,631; RR, 0.82 [95% CI, 0.54 to 1.25]; I^2=0%) (**Appendix C Figure 22**).

Hypertensive Disorders in Pregnancy

There was no difference between treatment for GDM vs. no treatment and risk of hypertensive disorders in pregnancy (3 trials, N=2,626; RR, 0.85 [95% CI, 0.50 to 1.43]; I^2=80%] (**Figure 23**); heterogeneity was high, with two trials [41,239] showing an association with decreased risk (N=1,931; RR 0.64 [0.51 to 0.81]; I^2=0%) and one trial[233] showing an association with increased risk (n=700; RR, 1.80 [95% CI, 0.99 to 3.28]). The reason for this discrepancy was not clear. In all trials, hypertensive disorders were defined as gestational hypertension with or without preeclampsia.

Total Cesarean Deliveries

Treatment for GDM was not associated with reduced risk of any cesarean delivery (8 RCTs, N=3,583; RR, 0.95 [95% CI, 0.83 to 1.08]; I^2=43%)[41,42,221-223,227,229,233] (**Figure 24**). Findings were similar in sensitivity analyses (**Appendix D Table 10**). Results may have been impacted by differing practice patterns; in one RCT,[42] treatment was associated with a reduced risk of cesarean deliveries without an increase in labor inductions, whereas in another RCT[41] there was no association between treatment and fewer cesareans, but an association with increased likelihood of induced labors.

Primary Cesarean Delivery

Three trials found treatment for GDM associated with decreased risk of primary cesarean deliveries vs. no treatment (N=1,114; RR, 0.70 [95% CI, 0.54 to 0.91]; I^2=0%; ARD, 5.3% fewer [95% CI, 10.3 to 0.24])[42,221,226] (**Appendix C Figure 23**).

Emergency Cesarean Delivery

Only one trial reported on emergency cesarean deliveries; the point estimate favored treatment but was not statistically significant (n=1,000; RR, 0.81 [95% CI, 0.62 to 1.05]).[41]

Induction of Labor

Treatment for GDM was not associated with decreased risk of induction of labor (5 RCTs, N=2,783; RR, 1.18 [95% CI, 0.92 to 1.52]; I^2=45%)[41,42,221,227,233] (**Appendix C Figure 24**). Sensitivity analyses had no impact on findings. Indications for induction of labor may have varied across trials.

Preterm Delivery

Treatment was associated with decreased risk of preterm delivery vs. no treatment, although the difference was just below the threshold for statistical significance (4 trials, N=1,933; RR, 0.75 [95% CI, 0.56 to 1.01]; I^2=0%; ARD, 2.3 fewer [95% CI, 4.9 fewer to 0.02 more])[42,226,229,233] (**Figure 25**).

Maternal Birth Trauma

Treatment for GDM was not associated with reduced risk of maternal birth trauma vs. no treatment (2 trials; N=1,100; RR, 1.04 [95% CI, 0.92 to 1.18]; I^2=0%)[41,226] (**Appendix C Figure 25**). One trial (n=1,000)[41] contributed almost all events and defined the outcome as any perineal trauma.

Fetal/Neonatal Outcomes

Mortality

Two trials (n=1,730)[41,233] found no association between treatment for GDM vs. no treatment and risk of fetal/neonatal mortality (Peto OR, 0.49 [95% CI, 0.16 to 1.45]; I^2=68%), but there were few mortality events (**Table 15** and **Appendix C Figure 26)**. One RCT (n=1,030 neonates) reported 5 events in the no treatment group (3 stillbirth, 2 neonatal),[42] and another (n=700) reported 4 events in both groups (all perinatal).[233]

Birth Injury and Shoulder Dystocia

Treatment vs. no treatment for GDM was associated with a decreased risk of birth injury (i.e., bone fractures or nerve palsies) when analyzing trials with events (3 trials with events; N=2,028; Peto OR, 0.33 [95% CI, 0.11 to 0.99]; I^2=0%)[41,42,227] but not when using absolute rates and adding the four trials without events (7 trials, N=3,328; ARD, 0.2% fewer [95% CI, 0.6 fewer to 0.2 more]) (**Figure 26**).[41,42,223,226,227,229,233] In one trial (n=700)[233] the lack of birth injury events was attributed to the high prevalence (over 60%) of cesarean deliveries in both groups. Similarly, treatment vs. no treatment for GDM was associated with a decreased risk of shoulder dystocia in trials with events (3 trials; N=2,028; RR, 0.42 [95% CI, 0.23 to 0.77]; I^2= 0%),[41,42,221] but not

when adding the trial (n=700)[233] without events and high prevalence of cesarean deliveries (ARD, 1.3% [95% CI, 4.3 fewer to 1.6 more]) (**Figure 27**).

Macrosomia

Treatment for GDM was associated with decreased risk of macrosomia (greater than 4,000 grams) vs. no treatment (8 trials, N=3,644; RR, 0.53 [95% CI, 0.41 to 0.68]; I^2=42%; ARD, 8.9% fewer [95% CI, 12.0 to 5.9])[41,42,221-223,226,229,233] (**Figure 28**). The magnitude of effect remained similar in all sensitivity analyses (**Appendix D Table 11**). For macrosomia defined as greater than 4,500 grams, the estimate suggested decreased risk with treatment but was imprecise (3 RCTs, N=1,066; RR, 0.72 [95% CI, 0.39 to 1.35]; I^2=0%)[223,227,233] (**Appendix C Figure 27**).
Large for gestational age. Seven trials consistently found treatment for GDM associated with decreased risk of LGA vs. no treatment (N=3,329; RR, 0.56 [95% CI, 0.47 to 0.66]; I^2=0%; ARD, 8.4% fewer [95% CI, 10.8 to 6.1])[41,42,222,226,227,229,233] (**Figure 29**).

Admission to NICU

Treatment for GDM was associated with reduced risk for NICU admissions vs. no treatment (5 trials, N=1,600; RR, 0.73 [95% CI, 0.53 to 0.99]; I^2=0%; ARD, 2.0% fewer [95% CI, 4.5 fewer to 0.5 more])[42,222,226,227,229] (**Figure 30**). One large (n=1,000) trial found treatment associated with increased risk of neonatal nursery admissions (70.5 vs. 61.3%; RR, 1.15 [95% CI, 1.05 to 1.26]).[41]

Respiratory Distress Syndrome

Only two RCTs reported on this outcome; one estimate favored treatment[42] and the other favored no treatment[41] (**Appendix C Figure 28**). Pooled results found no association but were limited by heterogeneity and imprecision (RR, 1.05 [95% CI, 0.48 to 2.28]; I^2=58%).

Neonatal Hypoglycemia or Hyperbilirubinemia

Five trials found no association between treatment for GDM vs. no treatment and hypoglycemia (any severity), although there was some imprecision (N=2,238; RR, 1.10 [95% CI, 0.83 to 1.45]; I^2=0%).[42,222,223,229,233] Findings from sensitivity analyses were similar to the main analysis. Two good-quality RCTs[41,42] found no association between treatment at or after 24 weeks' gestation vs. no treatment and increased risk of hypoglycemia requiring intravenous treatment, although the estimate was imprecise (N=981; RR, 1.02 [0.60 to 1.76]; I^2=58%) (**Table 19**). Findings were very similar for hyperbilirubinemia (5 RCTs, N=2,564; RR, 0.84 [95% CI, 0.65 to 1.08]; I^2=0%).[41,42,222,223,227] (**Appendix C Figures 29 and 30**).

APGAR Scores

One trial reported on APGAR scores below 7 at 1 minute; findings were imprecise with zero events in the treatment group and seven in the group receiving a minimal intervention (n=700; RR, 0.07 [95% CI, 0.00 to 1.24]).[233] Findings were similar and consistent for scores above 7 at 5

minutes reported in two RCTs (N=1,231; RR, 0.62 [95% CI, 0.27 to 1.41]; I^2=0%)[41,229] (**Appendix C Figure 31**).

Long-Term Maternal Outcomes

Long-Term Intermediate Outcomes: Metabolic Impairment and Obesity

A followup study to one of the included RCTs[42] (n=457; 48% of the original study population) found no association between treatment vs. no treatment and reduced risk of impaired fasting glucose (RR, 1.08 [95% CI, 0.79 to 1.47]), obesity (RR, 1.09 [95% CI, 0.87 to 1.38]), or metabolic syndrome (RR, 0.93 [95% CI, 0.71 to 1.22]) at a median 7 years' followup.[238] Findings for metabolic syndrome were very similar after adjusting for race/ethnicity and time since diagnosis.

Long-Term Health Outcomes

The long-term followup from an RCT described above also found no association between treatment vs. no treatment and risk of T2DM, though the estimate was imprecise (RR, 1.09 [95% CI, 0.59 to 2.01]).[238] No study measured long-term quality of life, cardiovascular outcomes, or mortality or major morbidity from T2DM.

Long-Term Childhood Outcomes

Long-Term Intermediate Outcomes: Obesity and Metabolic Impairment

Three trials reported long-term followup of children born to mothers with GDM.[239-241] There was no association between maternal treatment vs. no treatment and risk of childhood overweight over 4 to 10 years (2 studies, N=699; RR, 0.96 [95% CI, 0.69 to 1.33]; I^2=49%),[239,240] or obesity over 5 to 11 years (2 studies, N=585; RR, 1.02 [95% CI, 0.66 to 1.59]; I^2=24%)[239,241] (**Appendix C Figure 32).** Two studies reported imprecise estimates for impaired fasting glucose[239,241] and impaired glucose tolerance[241] over 5 to 11 years.

Long-Term Health Outcomes

Two studies reported only one case of childhood T2DM after 5 to 11 years[239,241] (**Table 16**). No study measured cardiovascular outcomes or neurocognitive outcomes.

Treatment in Early Pregnancy

Four trials[228,230-232] on early treatment (before 14 or 15 weeks' gestation) vs. usual care (i.e., screening at 24-28 weeks with treatment if diagnosed with GDM) reported on excessive weight gain in pregnancy and several short-term health outcomes including preeclampsia, hypertensive disorders in pregnancy, cesarean deliveries, induction of labor, preterm delivery, shoulder dystocia, macrosomia, LGA, NICU admissions, hypoglycemia, and hyperbilirubinemia.

However, findings for all outcomes were highly imprecise (largest analysis N=229 with few events) (**Table 17** and **Appendix C Figures 34 to 49**).

Subgroup Effects Based on Maternal Characteristics

Timing of Diagnosis

A secondary analysis of one RCT (n=932; 97% of RCT population)[237] found no interaction between timing of treatment initiation and cesarean deliveries, NICU admissions, or LGA. Although there was an interaction between timing of treatment initiation and hypertensive disorders, there was not a clear time trend (e.g., progressively earlier treatment initiation was not associated with progressively decreased risk) (**Appendix D Table 10** and **11**).

Criteria for Diagnosis/Glycemic Severity

Subgroup analyses of one RCT (n=931)[236] showed no impact of different criteria (i.e., NDDG vs. CC excluding NDDG, all with FPG under 95 mg/dL) for diagnosis/glycemic severity on various maternal, pregnancy, and neonatal outcomes (**Appendix D Tables 10** and **11**). Three of the included trials (N=483)[221,222,226] had eligibility criteria of lower levels of glycemia (i.e., OGCT positive); sensitivity analysis in which these trials were removed did not change conclusions (**Appendix D Tables 10** and **11**). Of three large trials,[41,42,233] with inconsistency in findings for preeclampsia and hypertensive disorders in pregnancy (**Figures 22** and **23**), one[233] used more inclusive criteria than the others for eligibility (i.e., IADPSG which uses OAV for diagnosis), though levels of FPG were slightly higher (i.e., 91 vs. 86.5 mg/dL) and 2-hour postload levels similar (i.e, 151 vs. 153[41] and 173 mg/dL[42]) at baseline between trials so this variable did not seem to explain the inconsistency. Baseline glycemia was similar between groups in all three trials.

BMI

One trial[235] found no interaction between BMI and effects of treatment on LGA (**Appendix D Table 11)**. Sample sizes in some of the BMI categories were very small.

Race/Ethnicity

One RCT[234] compared effects of treatment for GDM in for Hispanic (n=371) and non-Hispanic white women (n=397). It found no significant subgroup effects for hypertensive disorders in pregnancy, preterm delivery, macrosomia, LGA, NICU admissions, any hypoglycemia, and hyperbilirubinemia (**Appendix D Tables 11** and **11**).

Early treatment studies. Estimates from one RCT were too imprecise to determine interactions between BMI and early treatment vs. usual care[230] (**Appendix D Tables 12 and 13**).

Key Question 7. What Are the Harms of Treatment of GDM, Including Severe Maternal and Neonatal Hypoglycemia, Delivery of Neonates Who Are Small for Gestational Age, and Poor Long-Term Growth and Development Outcomes in the Child?

Summary

- Treatment at 24 week's gestation or later is probably not associated with increased risk of SGA; findings for maternal hypoglycemia were imprecise.
- Findings from small RCTs of early treatment vs. usual care were imprecise or not reported (maternal hypoglycemia).
- Treatment at 24 or greater weeks' gestation was associated with a large reduction in macrosomia (RR, 0.53 [95% CI, 0.41 to 0.68]) but no association with total cesarean deliveries (RR, 0.95 [95% CI, 0.83 to 1.08]). Because these outcomes would be expected to have an effect in the same direction, some cesareans that could have been avoidable due to the effects of improved glycemia in reducing macrosomia may still have been undertaken.

Evidence

Data for the trials included for Key Question 6 also addressed harms from treatment for GDM (**Tables 12** and **13**, and **Appendix B Table 14**).

Maternal Hypoglycemia

One RCT (n=69)[227] that allocated women with GDM (fasting under 7.0 mmol/L or 2-hour value 10.0 to less than 12.2 mmol/L) to treatment including insulin as needed (61% in treatment group) or to routine care reported that no women in either group had severe hypoglycemia (requiring the assistance of another person).

Small for Gestational Age and Low Birth Weight

Treatment at or after 24 weeks' gestation was not associated with increased risk of SGA vs. no treatment (6 trials, N=2,646; RR, 1.10 [0.83 to 1.47]; I^2=0%)[41,42,221,222,226,229] (**Appendix C Figure 50**). Findings were similar, with slightly fewer events in the treated group, in one large trial[41] that reported fairly high use of insulin in the treatment group (i.e., 20% vs. 3% in controls). Subgroup analyses of one RCT[42] also found no difference in risk of SGA based on ethnicity (Hispanic vs. non-Hispanic white women)[234] or glycemic status[236] (**Appendix D Table 15**). One RCT found no association between treatment and risk of low birth weight (n=700; RR, 1.06 [95% CI, 0.52 to 2.20])[233] (**Table 19**). Two of the early treatment RCTs (n=64) reported on small for gestational age, but findings were highly imprecise.[228,231]

Cesarean Deliveries

Interpreting effects of treatment on cesarean deliveries requires consideration of effects on macrosomia. A cohort study[75] on the association between a GDM diagnosis and cesarean deliveries in discussed in Key Question 2.

Eight RCTs (N=3,583) of treatment at 24 weeks' gestation or later reported on rates of total cesarean deliveries and nine reported on macrosomia (>4,000g in 8 RCTs and >4,500g in 1 RCT).[41,42,221-223,226,227,229,233] Comparing pooled results, there was a large association with reduced risk of macrosomia (>4,000 g, N=3,614; RR, 0.53 [95% CI, 0.41 to 0.68]; I^2=42%) but no association with risk of total cesarean deliveries (N=3,582; RR, 0.95 [95% CI, 0.83 to 1.08]; I^2=43%). Results within individual studies agree with this finding (**Appendix D Table 15**). When examining data on primary cesarean deliveries, where macrosomia may contribute more as an indicator, findings (primarily from one trial[42]) indicated a reduction in risk of both cesarean deliveries and macrosomia, but less so for primary cesarean deliveries. Findings from RCTs of early treatment vs. usual care were too inconsistent and imprecise to determine effects on likelihood of cesarean deliveries.[228,230-232]

Poor Long-Term Growth and Development Outcomes in the Child

None of the trials reported on these outcomes.

Contextual Questions

Contextual Question 1. What is the Association Between Measures of Serum Glucose (e.g., Fasting and Postload Glucose Concentrations, Percent Hemoglobin A1c) and Outcomes, and Does It Differ Based on Timing of Measurement?

We examined one 2016 systematic review (including 28 studies with up to 64,851 participants and most studies from high-income Western countries)[24,242] and five studies having adjusted analyses (N=31,945 participants)[243-247] that addressed the associations between glucose levels and health outcomes in women not treated for hyperglycemia. The systematic review and four studies evaluated hyperglycemia based on serum blood glucose and one study based on serum HbA1c. All findings are likely only applicable to the standard timing of GDM screening at 24 weeks' gestation or later.

Serum Glucose and Pregnancy Outcomes

Tables 20 and **22** provide a summary of unadjusted and adjusted results for pregnancy outcomes from the systematic review.[24,242] Postload glucose concentrations had positive linear associations (ORs 1.19 to 1.37 per mmol/L increase in serum glucose) with preeclampsia; findings for hypertensive disorders in pregnancy and cesarean delivery were inconsistent but suggest there may associations. Associations with increasing FPG were stronger for these three outcomes

(ORs 1.6 to 2.15). For preterm delivery, no associations with postload glucose values (after adjustment for confounders) were found in the review; an adjusted analysis for FPG also found no association. Few studies in the review reported on labor induction, but significant associations were found for FPG (OR 1.31) and postload serum glucose (ORs 1.1 to 1.3). Adjusted analyses from the review for all outcomes and associations with serum glucose indicated that associations remained but attenuated particularly between FPG values and preeclampsia (aOR 1.58). The review found that there was no clear evidence of a threshold effect. Studies published since the review also found linear associations between hypertensive disorders in pregnancy and postload serum glucose (n=1,360 untreated women in a large blinded GDM treatment RCT)[246] or FPG (n=5,230 women from Spain),[245] but no associations between cesarean delivery and serum values 1 hour after the OGCT (n=158 black U.S. women)[243] or based on FPG (n=5,230 women from Spain).[245] Findings from the study in Spain[245] agreed with those from the review on prematurity.

Serum Glucose and Fetal/Neonatal Outcomes

Tables 21 and **22** provide a summary of adjusted and unadjusted results for fetal outcomes from the systematic review.[24,242] Macrosomia and LGA were associated with postload serum glucose values (ORs 1.14 to 1.32) and, to a greater extent, with FPG (ORs 2.06 and 2.11). Review findings for shoulder dystocia and neonatal hypoglycemia also showed linear associations with postload and fasting glucose values, although FPG may not have as strong of n association with hypoglycemia (OR 1.37). Associations with macrosomia, LGA, and shoulder dystocia were larger for FPG than after a glucose load. The observed associations persisted in adjusted analyses from the review for all outcomes and associations with serum glucose. Similar to pregnancy outcomes, the review did not find a clear threshold effect. Subsequently published studies also found a significant linear association for LGA across values during the 3-hour OGTT[246] and for FPG.[245] No association (n=5,203) was found between FPG and macrosomia in one study;[245] another study (n=1,360)[246] only found associations between shoulder dystocia and postload glucose concentrations, but not FPG.

Serum Glucose and Long-Term Childhood Outcomes

A followup of 4,160 children enrolled in the multinational HAPO cohort found few (n=10) events of T2DM at 10 to 14 years of age.[244]

Serum Hemoglobin A1c and Pregnancy Outcomes

Analysis of data from the multinational HAPO cohort (n=21,062)[247] found associations between a 1 SD increase in HbA1c (0.4%) and preeclampsia (OR, 1.27 [95 CI, 1.19 to 1.37]), primary cesarean deliveries (OR, 1.09 [95% CI, 1.04 to 1.13]), and preterm delivery (OR, 1.17]95 CI, 1.10 to 1.24]).[247] The magnitudes of association were similar to those for a 1 SD increase in serum glucose from the 2-hour OGTT results.

Serum Hemoglobin A1c and Fetal/Neonatal Outcomes

In the HAPO cohort,[247] associations were found between HbA1c and the outcomes of LGA and clinical neonatal hypoglycemia (ORs per 1 SD increase 1.15 [95% CI, 1.09 to 1.21] and 1.13

[95% CI, 1.02 to 1.25], respectively). The association for LGA was smaller than those found for serum glucose values from the 2-hr OGTT (ORs for FPG, 1-hour, and 2-hour values were 1.39, 1.45, and 1.38, respectively).

Contextual Question 2. What Is the Association Between GDM Diagnosed Before 24 Weeks of Gestation and Outcomes, and Does It Differ Based on Screening Strategy, Timing of Diagnosis, and Severity of Risk Factors?

One retrospective cohort study (n=2,780)[67] examined in Key Question 1 comparing screening vs. no screening found the association for reduced risk of NICU admission more pronounced for women screened in the first vs. second trimester (RR, 0.57 [95% CI, 0.48 to 0.69] vs. RR, 0.78 [95% CI, 0.66 to 0.92], respectively; subgroup effect p=0.05). The effects for other outcomes were not significant, and findings were not adjusted for important confounders.

One small U.S. RCT (n=202 with 22% early dropout) compared early (under 15 weeks' gestation) vs. later (at 28 weeks) treatment for women with hyperglycemia in early pregnancy.[248] A similar number of women in each group required oral medication or insulin use (34.2 vs. 33%; p=0.84). No significant differences between arms were found for macrosomia (1.5% vs. 5.0%; p=0.84) or cesarean delivery (31.0% vs. 27.0%; p=0.64).

Four small trials from Key Question 6 allocated women with hyperglycemia early in pregnancy to treatment or usual care.[228,230-232] All findings were highly imprecise (largest analysis N=229 with rare events), precluding any reliable conclusions.

A 2017 systematic review included 13 cohort studies (N=15,260) evaluating outcomes in women treated for GDM before 24 weeks' gestation vs. women treated later.[249] **Table 23** provides a summary of results from the systematic review. In meta-analyses, women treated early were at higher risk for perinatal mortality (RR 3.58) and neonatal hypoglycemia (RR 1.61) than women treated later. Likelihood of insulin use was significantly greater among early-onset women (RR 1.71) indicating more severe hyperglycemia. Event rates were higher with early treatment for some other outcomes (hypertensive disorders in pregnancy, shoulder dystocia, SGA) but these associations were not statistically significant. No associations were seen for cesarean delivery, LGA, macrosomia, NICU admissions, preterm delivery, hyperbilirubinemia, or respiratory distress syndrome. Findings are difficult to interpret because analyses did not account for confounders and because of heterogeneity between studies. The largest included study from that review (n=4873)[250] found no independent association for risk of LGA and macrosomia when adjusting for confounders.

Four additional retrospective cohort studies (total N=3,461) from the United States[251-253] and Ireland[254] with adjusted analyses were examined. All studies included selectively screening high-risk women in early pregnancy. Results suggest there may be large increased risks for some pregnancy and neonatal outcomes, though there was some inconsistency. In one U.S. cohort of 1,369 women with GDM (167 [12.3%] diagnosed prior to 24 weeks gestation [early]), a significant increased risk of macrosomia was found among women with early-onset GDM (aOR, 2.0 [95% CI, 1.00 to 4.15]) but no differences were found for other outcomes (including preterm delivery, LGA, hypertensive disorders of pregnancy, NICU admission, and neonatal morbidity

composite).[251] One of the other U.S. studies found no significant associations for risk of cesarean delivery, preeclampsia, macrosomia, LGA, SGA, or birth injury between women screened and diagnosed (n=85) early in pregnancy (before 20 weeks' gestation, via risk factors) and women screened and diagnosed (n=457) later.[252] However, risk for preterm delivery was higher in women with early- vs. late-GDM (aOR, 1.78 [95% CI, 1.01 to 3.15]). A U.S. study of obese (BMI greater than or equal to 30 kg/m^2) women compared outcomes between a GDM diagnosis at or before 20 weeks' gestation compared with after 20 weeks.[253] Earlier GDM diagnosis was associated with an increased risk for NICU admission after accounting for BMI, age, gestational age, and chronic hypertension (aOR, 6.50 [95% CI, 1.37 to 30.83]), but there were no associations for several other outcomes including preterm delivery and macrosomia. In the study from Ireland (n=1,471), an early vs. routine timing for GDM diagnostic tests was associated with an increased risk for gestational hypertension (aOR 2.3 [95% CI, 1.46 to 3.62), LGA (aOR 2.7 [95% CI, 1.82 to 4.05]), NICU admissions (aOR 1.83 [95% CI, 1.2 to 2.8), and preterm delivery (aOR 2.25 [95% CI, 1.14 to 4.43), but not with risk for preeclampsia or stillbirth.[254]

Over a median 5.5 years' followup, one large U.S. multiethnic cohort study (n=322,323; 7.8% GDM-exposed) demonstrated an association between the development of autism spectrum disorder (ASD) among children (n=3,388 with ASD) when GDM was diagnosed at 26 weeks' gestation or earlier vs. no GDM diagnosis (aHR, 1.40 [95% CI, 1.14 to 1.72]), but not when GDM was diagnosed after 26 weeks' gestation vs. no GDM diagnosis (aHR, 0.86 [95% CI, 0.73 to 1.02]).[255] Another study using the same cohort (n=333,182; 8.8% GDM-exposed) found no association between timing of GDM and subsequent attention-deficit and hyperactivity disorder (ADHD) in children (4 to 8.9 years old; n=17,415 with ADHD) after adjusting for potential confounders like gestational age at birth (p=0.16).[256]

Contextual Question 3. What Are the Long-Term Health Consequences, for the Mother From a Diagnosis of GDM, and for the Child From Their Mother's GDM Diagnosis, From Neonatal Hypoglycemia, Shoulder Dystocia, or Fetal Overgrowth?

Long-Term Maternal and Childhood Health Consequences From GDM

For this section we examined studies on health outcomes occurring 6 months or longer after delivery in women diagnosed with GDM or their children. We prioritized studies that accounted in their analysis for key confounders (i.e., BMI for development of T2DM or CVD, gestational age at delivery for childhood neurocognitive outcomes). Most systematic reviews did not provide result based on adjusted study findings. Most studies examined were large and conducted in U.S.-relevant countries. All findings are in comparison with women without GDM.

Long-Term Health Consequences of GDM for the Mother

Six observational studies (over 62,000 women with previous GDM) consistently found that GDM was associated with increased risk of subsequent T2DM (aORs 5.44 to 22.6).[257-262] The variation in magnitude of estimates may have been due to different followup periods (1 to 11.4 years with larger risk based on shorter periods), comparison groups (higher risk when compared

with women who were not overweight), surveillance bias (i.e., more women with GDM screened/tested for T2DM), and different degrees of attrition. One of the studies (with median followup of 5.3 years) found that risk of T2DM was substantively elevated in women who were both overweight and had prior GDM, suggesting an interaction between these factors (incidence 36% vs 1.1%; aHR, 40.1 [95% CI, 34.4 to 46.6]).[258] Three studies found statistically significant interaction effects indicating black women had a higher likelihood than non-Hispanic white women of incident T2DM after a GDM diagnosis.[257,261,262]

Seven retrospective cohort studies (237,993 women with previous GDM) suggested that GDM vs. no GDM is associated with increased risk (aHRs 1.45 to 2.8) of ischemia heart disease and myocardial infarction over the long term; findings over the short term[263] and for risks of stroke and heart failure were inconsistent.[257,258,260,263-266] A systematic review that analyzed adjusted data for a composite CVD outcome, or from data on the most prevalent CVD outcome in each study, found that GDM associated with increased risk of CVD vs. no GDM (9 studies, N= 5,390,591; aHR 1.59 [95% CI, 1.35 to 1.85], I^2 = 86.3%).[267] Risk for CVD outcomes may be mediated by development of T2DM; for example, one study found an increased risk of myocardial infarction in women with GDM who had developed T2DM was over double that for those who did not develop T2DM (aHR, 3.71 [95% CI, 1.70 to 7.67] vs. aHR, 1.32 [95% CI, 0.92 to 1.89]; both vs. no GDM).[264]

Two small studies (n=2,046) found no association between GDM and risk of kidney disease.[268,269] One large prospective cohort study from Israel (n=104,751; 9,888 with GDM) reported higher incidence of several ophthalmic outcomes (e.g., glaucoma, diabetic retinopathy, retinal detachment) in those with previous GDM vs. no GDM after mean 12 years of follow-up (for ophthalmic morbidity: aHR, 2.1 [95% CI, 1.5 to 2.8]) (the risk was greater for those who had also experienced preeclampsia).[270]

Long-Term Health Consequences of Mother's GDM for the Child

A followup of children born to mothers in the HAPO cohort (n=4,160) over 10 to 14 years found very few events (n=10) of T2DM,[259] whereas two large Canadian studies (n=358,480[271] and n=321,008[272]) reported increased risk for T2DM over 17.7 and 15.1 years (0.80 vs. 0.26 cases per 1000 person years and HR, 3.03 [95% CI, 2.44 to 3.76], respectively).[271] These Canadian studies[271,272] found that although First Nations status did not modify the risk for T2DM after exposure to GDM, the incidence of GDM has higher in First Nations women and the independent effects of both GDM and First Nation status for development of T2DM makes First Nations children particularly disproportionally affected. A population-based cohort study (n=216,197) found an association between a mother's diet-controlled GDM (n=9,460) and increased risk of hospitalization for cardiovascular-related disease over 18 years (aHR, 1.6 [95% CI, 1.2 to 2.2]).[273]

Nine cohort studies examined childhood neurocognitive outcomes.[255,256,274-280] Three cohort studies found no association when examining GDM overall and risk for ASD; although results suggested differential risk depending upon timing of GDM diagnosis and maternal prepregnancy BMI.[255,274,275] Four studies did not find a clear association between exposure to GDM overall and development of ADHD in offspring, or consistent modification of risk based on maternal weight

or timing of GDM diagnosis.[256,274,275,277] Single studies found that severity of hyperglycemia[256] and SES[277] may impact the association between GDM and neurocognitive outcomes. Two cohort studies found no association between maternal GDM and early childhood intellectual disability (ID) (at 6[274] and 3[278] years) in multiethnic, low income populations. As with ASD, risk was mediated by maternal obesity. Four studies found no clear association between GDM and developmental delay (DD) though studies varied in respect of timing, outcomes and findings.[274,275,279,280] As with other outcomes, risk may be mediated by maternal obesity.[274]

Long-Term Childhood Health Consequences From Neonatal Hypoglycemia, Shoulder Dystocia, or Fetal Overgrowth

In this section, we examine studies on associations between exposure to neonatal hypoglycemia, shoulder dystocia, or fetal overgrowth and risk for long-term health outcomes. We did not identify any studies that examined these exposures in children of mothers with GDM or that accounted for the mother's GDM status. Large U.S-relevant studies that adjusted for important confounders were sought.

Long-Term Health Consequences for the Child From Neonatal Hypoglycemia

Table 24 presents results from a systematic review examining the association between neonatal hypoglycemia and long-term neurodevelopmental outcomes.[281] Adjustment for confounders was not a study inclusion criterion although these results were used when available. No association was found between neonatal hypoglycemia and risk of neurodevelopment impairment (validated scales of developmental or intelligence) over 2 to 5 years, though associations (ORs 2 to 3.5) were found for visual-motor impairment and executive dysfunction (at 2 to 5 years), as well as low language and low numeracy (at 6 to 11 years). Studies reporting adjusted estimates were also available. A longitudinal prospective cohort study found no differences in a number of different neurodevelopmental outcomes at ages 2[282] or 4.5[283] years in over 400 children with or without neonatal hypoglycemia. This same study found that children who had neonatal hypoglycemia were at increased risk of visual impairment compared with those without neonatal hypoglycemia (aRR, 3.67 [95% CI, 1.15 to 11.69]); all other auditory, visual processing, emotional/behavioral difficulty and communication scores were not significantly different between groups. Secondary analyses of an RCT (n=745) that followed premature (37 or less weeks' gestation) and low birthweight (2500g or greater) children found no differences in intellectual or academic achievement at 3, 8 and 18 years of age between those with and without neonatal hypoglycemia.[284] Conversely, two studies found associations between exposure to neonatal hypoglycemia and lower proficiency in literacy and mathematics among children at 3.5 to 4 years (n=832; all premature) [285] and 10 years of age (n=1,395).[286]

Long-Term Health Consequences for the Child From Shoulder Dystocia

One study from Israel of children with (n=343) and without (n=206,388) shoulder dystocia found no differences in rates of hospitalizations for a variety of psychiatric and neurological disorders up to age 18.[287]

Long-Term Health Consequences for the Child From LGA or Macrosomia

One Australian study (n=449,857) found no association between increased risk of poorer developmental and educational outcomes at 4 to 7 and 7 to 9 years of age and being born LGA (n=49,439) vs. appropriate for gestational age; in fact, LGA may have been associated with decreased risk.[288] Another study from Canada (n=1,685) found no association between being born LGA (n=311) and poor verbal ability or externalizing behavior problems (hyperactivity/inattention, conduct disorder/physical aggression, and indirect aggression) at 4 to 5 years of age.[289] Two cohort studies from the United States[274] and Canada[290] found no association between exposure to LGA or macrosomia and a variety of developmental disabilities (e.g., autism, intellectual disability, ADHD). One study of several European countries (n=10,468) examined associations between LGA/macrosomia at birth (n=1,340) and cardiovascular outcomes at 2 to 8 years of age, and found no differences in total cholesterol, HDLs, LDLs, triglycerides, or systolic and diastolic blood pressure.[291]

Contextual Question 4. Are Postpartum Interventions Effective for Reducing Incidence of Long-Term Health Outcomes in Women Previously Diagnosed With GDM and/or Their Children?

Lifestyle Interventions

The most recent systematic review we identified included eight postpartum RCTs measuring incidence of T2DM from lifestyle interventions compared with usual care.[292] Meta-analysis found a nonsignificant reduction in diabetes incidence over about 1 to 2 years among women with prior GDM who received various postpartum lifestyle interventions (most including diet and exercise) vs. usual care (8 studies, N=1,742 [180 events]; RR, 0.75 [95% CI, 0.55 to 1.03]). Interventions that were initiated within 6 months of delivery were associated with reduced risk (5 studies, N=1,015; RR, 0.61 [95% CI, 0.40 to 0.94]). Two other RCTs not included in the review, from the United States (telephone intervention derived from Diabetes Prevention Program (DPP); n=2,280)[293] and Canada,[294] did not find an association between postpartum interventions and reductions in 12 month incidence of prediabetes or diabetes (n=2,280; HR, 0.90 [95% CI, 0.78 to 1.04]) or diabetes (n=97; OR, 0.12 [95% CI, 0.01 to 1.97]). The interventions were fairly intensive lifestyle programs; attrition was high in both trials.

A planned subgroup analysis of the U.S. DPP RCT comparing an intensive lifestyle program, metformin, and placebo with a standard lifestyle program examined development of T2DM over 3 years based on history of GDM (n=350 with and n=1,416 without).[295] Compared with placebo, the intensive lifestyle program was associated with similar impact on risk reduction for T2DM in the GDM (n=117) and no GDM groups (n=465) (ARD, 53.4 vs. 49.2%, interaction p = 0.74). In another age-adjusted analysis after 10 years of followup, the DPP Outcomes Study (DPPOS) included 288 women with prior GDM (82% of original) and found that women who had been randomized to the lifestyle intervention were 35.2% ($p<0.05$) less likely to develop diabetes compared with those assigned to placebo, for a number needed to treat of 11.3 to prevent one case of diabetes in 10 years.[296]

Pharmacological Interventions

As described above, subgroup analysis of the DPP RCT found that women with prior GDM randomized to 850 mg of metformin twice daily were 50 percent less likely to develop diabetes over 3 years compared to similar women taking placebo (p=0.002).[295] Metformin was associated with greater impact on risk reduction (compared with placebo) in the GDM compared with the no GDM group (n=465) (50.4 vs. 14.4%, interaction p = 0.06), despite similar glucose levels at baseline. After 10 years of followup, women randomized to metformin were 40.4 percent (p<0.05) less likely to develop diabetes compared with placebo (NNT=7.2 to prevent one case of diabetes in 10 years).[296]

Chapter 4. Discussion

Summary of Review Findings

Table 25 summarizes the evidence reviewed for this update. This report differs from the 2012 USPSTF review[2] by including additional evidence on potential harms of screening and GDM diagnosis; evaluating comparative effectiveness of different screening strategies; and focusing on screening tests and criteria currently used in the United States. To further inform USPSTF considerations, this review also addressed Contextual Questions on outcomes associated with a GDM diagnosis early in pregnancy, long-term health consequences of GDM, and effects of postpartum interventions. Although findings regarding effectiveness of screening and treatment and accuracy of screening criteria were generally consistent with the prior review, new evidence suggests that use of more inclusive GDM screening criteria (e.g., IADSPG) may be associated with improved health outcomes compared with previous criteria (e.g., CC or NDGG), and provides more robust evidence regarding the effectiveness of treatments and accuracy of screening tests. New evidence also suggests that early (14 to 20 weeks' gestation) vs. usual timing of screening may not be associated with improved outcomes.

As in the prior review, evidence on the benefits of screening vs. no screening was sparse and limited to observational studies. Two small studies included in the previous review focused on selected subpopulations of women and found no associations with outcomes.[69,70] Of two new studies, one[68] found that risk-based screening (2-hour 75g OGTT NICE criteria) associated with a reduced risk of late stillbirth and the other study[67] found universal two-step screening associated with fewer cesarean deliveries, birth injuries and NICU admission. In relation to subgroups of interest, a prespecified analysis in the latter study comparing screening in first vs. second trimester found a significantly greater effect for NICU admissions from screening early, but no difference for other outcomes. However, findings from both studies were susceptible to confounding and selection bias.

New to this report, we included seven studies on harms associated with undertaking screening for or diagnosis of GDM. Studies found no effects on depression/anxiety from screening and only a small, transient increase after diagnosis.[71,73,77] A GDM diagnosis may lower the threshold for surgical/cesarean delivery.[75] Three studies[72,74,76] found some differences in hospital experiences for women with vs. without GDM that may be due to labelling and impact breastfeeding outcomes, although confounding factors (e.g., breastfeeding intentions, varying hospital policies) could have impacted findings. Evidence was based on observational studies with methodological limitations, precluding strong conclusions.

Also new to this update, we examined five trials on the comparative effectiveness of different screening strategies. Screening using one-step IADPSG vs. two-step CC criteria identified on average twice as many cases of GDM (12.5% IADPSG vs. 5.6% CC) and was associated with fewer primary cesarean deliveries (number needed-to-screen [NNS] 16), LGA infants (NNS 31), episodes of neonatal hypoglycemia (NNS 37), and NICU admissions (NNS 27).[80-82] Most evidence came from one fair-quality trial[82] based on data provided by the authors for use in a systematic review[297] that was not reported in the original article; we were unable to verify the

data used in the systematic review with the authors. No associations were found for several other pregnancy and neonatal outcomes, though there was inconsistency in many analyses. One trial[78] comparing screening with IADPSG vs. WHO 1999 criteria (both resulting in high prevalence about 36%) found no difference in outcomes but findings were imprecise. One trial[79] in obese women found early (14 to 20 weeks' gestation) screening with CC criteria potentially associated with increased risk of preeclampsia vs. usual (after 24 weeks') screening (NNT 25), with no differences in other outcomes. Only the trial of early vs. usual timing of screening evaluated results based on invitation to screen; the other trials analyzed outcomes based on those who actually underwent screening. No study reported analyzing outcomes for different subgroups of interest.

In this update we included 45 prospective cohort studies evaluating the diagnostic accuracy of commonly used screening tests. As in the prior report, this update found that the OGCT has reasonably good accuracy against diagnosis with CC and NDDG criteria at 24 or more weeks' gestation, with trade-offs between higher sensitivity (using lower cutoffs of 130 or 135 md/dL) and specificity (using 140 mg/dL cutoff). For FPG as a screening test at 24 or more weeks' gestation, an 85 or 90 mg/dL cutoff may have reasonable accuracy for a CC diagnosis and values at or under 80 mg/dL appear useful to rule out GDM; potential advantages of FPG are that it is reproducible, preferable to those who cannot tolerate a glucose load, and correlates better with outcomes of interest. As noted in Contextual Question 1, associations with outcomes were stronger with FPG than with post-glucose load values. For HbA1c, there was no threshold associated with sufficient sensitivity and specificity to serve as a screening test. There was some evidence on the accuracy of early screening with FPG and HbA1c against early or later diagnosis, but most thresholds only had data from single studies. Few studies validated the accuracy of risk-based screening and no study reported analyzing outcomes for different subgroups of interest. Overall, the use of different reference criteria across studies complicated interpretation. Further, screening tests were evaluated for their ability to predict results of the OGTT rather than pregnancy or neonatal outcomes.

Evidence reviewed for this report indicated that women who would be considered to have GDM if diagnostic criteria were made more inclusive than those most commonly used in the United States at present (e.g., one abnormal value of CC or NDDG criteria, IADPSG but excluding those with CC or NDDG GDM) have an increased likelihood of several pregnancy and fetal/neonatal outcomes compared with women without GDM using any criteria, if untreated. Compared with the prior report, we excluded studies on outcomes for women with GDM meeting current criteria (e.g. unrecognized CC or NDDG GDM based on two abnormal values) or who were positive on screening tests but negative on all OGTT thresholds (i.e., false positives). Further, we had more evidence on outcome associations for women meeting IADPSG but not CC criteria. This report found more robust evidence for several outcomes (e.g., increased risk of hypoglycemia and preterm birth but not NICU admissions), and findings are more specific to the current dilemma of choosing which GDM criteria to apply. Similar to the prior report, evidence on long-term health outcomes was scarce. Some studies used variations to the recommended practices for each criteria (e.g., IADPSG using a 100g rather than 75g glucose load); however, such variations were thought to be applicable to clinical practice in the United States. Separate from this question, when looking at serum glucose values on a continuum

(Contextual Question 1) there was a dose-dependent association with increased risk for several outcomes, without evidence of a clear glucose threshold.

The prior report found treatment for mild GDM at or after 24 weeks' gestation associated with approximately 40 to 50% fewer cases of preeclampsia, shoulder dystocia, macrosomia, and LGA vs. no treatment. Some evidence suggested no difference for NICU admission, neonatal hypoglycemia, cesarean deliveries, or induction of labor. The current report included eight additional trials,[226-233] four of which evaluated early treatment. Treatment vs. no treatment was associated with reduced risk of primary cesarean deliveries (number needed to treat [NNT] 19), preterm deliveries (NNT 38), shoulder dystocia (NNT 77), macrosomia (NNT 11), LGA (NNT 12), birth injuries (e.g., fracture or nerve palsies) (NNT 500), and NICU admissions (NNT 50). Findings were robust except for preterm delivery (imprecise) and birth injury (imprecise and inconsistent). Treatment vs. no treatment was associated with reduced risk for preeclampsia (5 trials), after excluding an outlier trial. The outlier trial, conducted in China,[233] found treatment vs. a minimal intervention in women with relatively low BMI (23 kg/m2) associated with increased risk of preeclampsia. The analyses of NICU admissions and preeclampsia excluded data from one previously included large trial after clarifying with trial authors that the outcomes were different, specifically, neonatal nursery admission and hypertension with or without preeclampsia, respectively.[41] No association was found for reduced risk of gestational hypertension. Similar to the previous review, this update found no association between treatment vs. no treatment and risk of total cesarean deliveries (8 trials), induction of labor (5 trials), or neonatal hypoglycemia. However, there was some imprecision and inconsistency; for the outcomes of total cesarean deliveries and induction of labor different results across trials may have been due in part to lack of blinding and/or practice variation. Evidence from four studies[238-241] indicated no effects on long-term outcomes in mothers and children but findings were limited by imprecision and attrition and the length of followup (5-10 years) may have been insufficient. There was no clear association between treatment for GDM during pregnancy and reduced risk of T2DM. Although Contextual Question 3 found an association between GDM and increased risk of long-term T2DM, pre-existing diabetes may not have been excluded and the effects of glucose control were not accounted for, which could have confounded results. Four small trials[228,230-232] provided insufficient evidence to determine effects of treatment for GDM diagnosed early in pregnancy vs. no treatment.

As with the prior review, evidence on harms of treatment was somewhat limited but did not indicate serious adverse effects; treatment was not associated with increased risk of SGA and findings for severe maternal hypoglycemia were imprecise. Similar to the findings for the question on harms of a GDM diagnosis, GDM may be associated with increased risk for cesarean deliveries. None of the trials of treatment at 24 or more weeks' gestation used oral medications as part of their treatment protocols, so the potential harms from these medications would not have been captured. The ADA prefers insulin over metformin and glyburide because it does not cross the placenta to a measurable extent.[44] Use of glyburide in pregnancy has been found to be associated with up to a two-fold increased risk of neonatal hypoglycemia[298,299] and metformin may be associated with increased childhood adiposity measures.[300,301] Some data indicate that glyburide may be used as first-line treatment by some practitioners,[49] although review findings indicating that glyburide is the least effective treatment for GDM may change practice.[299,302]

Analyses[234-237] of one trial[42] found no differences in effects of GDM treatment for several maternal and fetal outcomes based on timing of treatment initiation, race/ethnicity, severity of dysglycemia, or BMI. Differences in GDM diagnostic criteria did not appear to impact findings for several outcomes or explain inconsistency across trials. However, evidence from trials using "borderline" GDM (i.e., positive on screening but not diagnostic tests) was limited; the findings overall were heavily weighted by three large trials[41,42,233] that used two-step approaches.

Because direct evidence on the effects of GDM screening on health outcomes remains limited, the indirect chain of evidence including diagnostic accuracy and the effects from treatment is also important for informing decisions regarding optimal screening approaches (e.g., two-step, one-step, or standalone screening test; more inclusive vs. less inclusive criteria). Because the treatment evidence is most applicable to women with GDM diagnosed using two-step approaches, the applicability of evidence on treatment effectiveness to one-step screening approaches (i.e., IADPSG) or a standalone screening test (i.e., without a diagnostic OGTT) for diagnosis of GDM is uncertain. Using more inclusive criteria for GDM will result in more women (about two-fold but possibly more when using IASPSG[23]) being diagnosed and treated, and a clearer picture of the net benefit and potential for overdiagnosis and overtreatment is warranted. The additional resources required to have all women undertake an OGTT (in one-step screening) and to provide more women counselling and treatment for GDM (if using more inclusion criteria) should also be considered. Regarding diagnostic accuracy, among hypothetical cohorts of women at average or higher risk for GDM (e.g., 7 and 15% prevalence), use of standalone screening tests (e.g., OGCT or FPG) at optimal thresholds would result in high negative predictive values (96 to 99%) but lower positive predictive values (e.g., 25% at 7% and 45% at 15% prevalence) (**Appendix D Tables 16 and 17**). Therefore, although the accuracy data helps determine which screening tests are most useful in a two-step approach—helping to accurately rule out GDM and allow many women to avoid the OGTT (reducing resources and associated side effects)—reliance on these tests alone for diagnosis and treatment would result in a high number false-positive results, especially in general-prevalence populations, and potentially result in overtreatment.

Limitations

We excluded non-English language studies, which could introduce language bias. We did not formally assess for publication bias with graphical or statistical tests due to small numbers of studies and heterogeneity between studies.[66] Studies had some methodological limitations (e.g., lack of blinding of patients and healthcare providers, potential selection biases in diagnostic accuracy studies); however, results were similar in sensitivity analyses or when quality was otherwise considered. Women with GDM, as well as women with obesity, will often have metabolic disturbances other than impaired glucose metabolism and vascular disturbances that can affect nearly all of the pregnancy outcomes of interest. Due to these potential confounding effects, RCTs are very important for evaluating the effectiveness of screening and treatment. From an anticipated lack of trials, we included observational studies for the effects of screening vs. no screening and recognize the limitations from these studies including confounding. We only included trials when these were available for our questions on different screening strategies and treatment. We also sought to focus on higher quality evidence on accuracy of screening by

excluding studies that only provided the reference standard to people positive on screening. For evaluating outcome associations, where observational designs are able to provide high-quality evidence, we included studies that did not adjust their analysis for confounders but reported analyses that adjusted for confounders when available. We included studies comparing women with and without a GDM diagnosis for harms of screening (e.g., cesarean deliveries, breastfeeding patterns); however, it is difficult to separate out effects of a GDM diagnosis from other factors such as GDM itself, treatment, and hospital practices.

Some studies were conducted in lower income countries in which screening and treatment for GDM as well as management of pregnancy may differ from the United States. We focused on screening and diagnostic criteria used in the United States and results appeared consistent across geographic settings. There was also variability across studies in application of GDM criteria, population characteristics, and other factors. Studies that applied older definitions for GDM, or before recommendations to screen for pre-existing diabetes early in pregnancy, would have included some women with diabetes who are expected to have worse outcomes.[13] The potential impact on the results from inclusion of women with a higher level of risk is hard to predict and the applicability of the results may be limited to some degree for populations for which there is close adherence to screening for pre-existing diabetes. Because of anticipated heterogeneity, we performed random effects analyses using the Dersimonian-Laird model. We performed sensitivity and stratified analyses to evaluate statistical heterogeneity and used an alternative random effects model (profile likelihood) when statistical heterogeneity was present.[303] Findings were robust in sensitivity analyses based on the statistical method used and other factors.

Another limitation was that definitions of some outcomes varied or were not reported. We addressed this by contacting authors for additional information and adding specificity to our outcome definitions (e.g., separating any degree of hypoglycemia from that requiring IV treatment). In addition, we conducted sensitivity analysis based on outcome definitions used when uncertainty remained.

Emerging Issues/Next Steps

Variability in clinical practice remains with regard to which criteria tom use for screening and diagnosing GDM.[46,49,304] More evidence regarding effects of different criteria and timing of screening could reduce uncertainty about optimal screening approaches and potentially reduce inconsistency in clinical practice. Although evidence indicates that women with untreated GDM diagnosed based on more inclusive criteria have worse pregnancy and birth outcomes than women with normal glucose tolerance, more screening and treatment trials specific to these criteria are needed to determine if outcomes are improved among the extra women that would be identified as having GDM with these more inclusive criteria.

This update identified three trials comparing IADPSG vs. CC criteria reflecting growing interest in evaluating one-step vs. two-step screening strategies. While we have low confidence in the existing evidence, two recently completed (but not yet published) U.S. trials on screening using IADPSG vs. CC criteria (NCT02309138[305] and NCT02266758) may be very informative; results of another trial on IADPSG vs. NDDG from Spain should also be available soon

(NCT03421262). To supplement this evidence, ongoing trials of treatment for women with positive OGCT screening results but not GDM (ACTRN12607000174482[306]) and IADPSG GDM but excluding those with two abnormal glucose values (NCT02708758) could further inform the magnitude of treatment effects for women with lesser degrees of dysglycemia. Recommendations for changes in screening approaches should consider trade-offs between benefits and harms (including possible overdiagnosis and overtreatment). Furthermore, one-step screening has previously been found to be more costly than a two-step approach in terms of glucose testing .[37]

To reduce resources required and inconvenience associated with screening, there may be increased interest in screening tests that allow some women to avoid the OGCT, including risk-based screening tools. Evidence is also needed on accuracy of early screening and to build upon the single existing trial of treatment for GDM diagnosed early in pregnancy vs. later; findings from an ongoing trial on this topic are anticipated in about two years (ACTRN12616000924459).[307]

Relevance for Priority Populations, Particularly Racial/Ethnic Minorities and Older Adults

Ethnic minority groups have elevated risk for GDM[14,32,33] and its long-term consequences including development of subsequent T2DM.[257,261,262] Evidence comparing accuracy or effects of treatment based on race/ethnicity was limited. Few studies reported subgroup analyses based on these factors; however, one large treatment trial[234] found no subgroup effects, some studies enrolled diverse populations, and there was geographic diversity across studies (including studies conducted in Asia). There was no indication based on the evidence in this report that findings would differ in racial/ethnic groups. None of the studies focused on or reported effects specific to Indigenous women.

The evidence is most applicable to women with singleton pregnancies and in adulthood rather than adolescence. Mean age was usually around 30 years; no study directly evaluated how effects varied according to age. Most of the treatment interventions relied on frequent self-monitoring of blood glucose and clinic visits to monitor glucose targets, which could reduce applicability of findings to women with limited or no insurance coverage, access to healthcare, or ability to perform self-monitoring.

Future Research

Several important gaps in the current literature exist:

- Additional research is needed on potential harms associated with a label of GDM, particularly as more inclusive diagnostic criteria is considered.
- More trials are needed to clarify issues regarding earlier screening and treatment, particularly as they relate to the diagnosis, treatment, and long-term outcomes of overt diabetes.

- More trials are needed to compare effects of two- vs. one-step diagnosis and to determine optimal thresholds.
- Research is needed to determine the effects of treatment of GDM diagnosed specifically using more inclusive criteria in relation to the number of abnormal values and the number of steps required for diagnosis. We are aware of currently two large completed but unpublished trials that will help inform about the effects of treatment of GDM diagnosed with more inclusive criteria.
- Further study of the long-term metabolic impact on offspring whose mothers have been treated for GDM is warranted, with a focus on the type of treatment exposure *in utero*.
- Based on fairly robust evidence of increased risk for T2DM and cardiovascular outcomes associated with GDM, more trials of postpartum interventions (lifestyle with or without pharmacotherapy) including longer followup would be informative. Trials that consider specific cultural practices of women with previous GDM are needed.
- A greater understanding about the potential for short-and long-term harms from treatments in pregnancy, particularly with use of oral medications, is needed.
- More evidence is needed related to treatment effects based on BMI, in order to inform whether any modifications to treatment may optimize outcomes across the range of different BMIs. Further, more information is needed on effects in subgroups defined by race/ethnicity, age, and other factors (e.g., prior GDM status).

Conclusions

Direct evidence on effects of screening vs. no screening remains very limited. Diagnosis of GDM using more inclusive criteria likely identifies additional women at increased risk of adverse maternal and neonatal/fetal outcomes. Although evidence suggests that one-step screening using more inclusive criteria may be associated with better outcomes vs. standard (two-step) criteria, large ongoing trials will provide more evidence. Screening tests are reasonably accurate for identifying women who do not need to proceed to a diagnostic test as part of a two-step strategy, but at this time are likely not sufficient to diagnose GDM. Treatment for GDM at or after 24 weeks' gestation, in women primarily diagnosed using two-step diagnostic approaches, is associated with improvement in some maternal and several fetal/neonatal outcomes, without risk for severe harms. Research is needed to determine effects of GDM management on the long-term outcomes in the mother and child, and to clarify effects of screening and treatment of GDM in early pregnancy.

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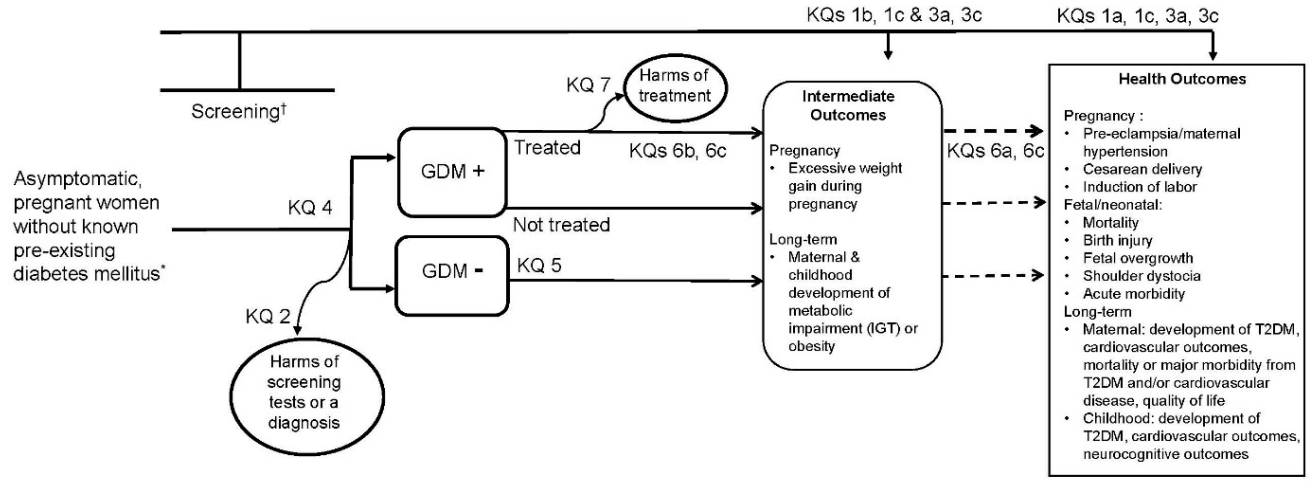
Figure 1. Analytic Framework and Key Questions



Abbreviations: GDM = gestational diabetes mellitus; IGT = impaired glucose tolerance; KQ = key question; T2DM = type 2 diabetes mellitus

* No assumptions will be made about whether hyperglycemia first discovered early in pregnancy (e.g., in the first trimester) is GDM or some other form of diabetes; the term GDM will be used to include all women with hyperglycemia but not meeting criteria for overt diabetes at any time point during pregnancy.
† Screening using two-step (screening first and, when indicated, diagnostic tests second) or one-step (diagnostic tests only) strategies, each based on various criteria and thresholds, and offering treatment to patients diagnosed with GDM.

Key Questions:

1 a. Does screening for GDM reduce poor health outcomes? b. Does screening for GDM reduce poor intermediate outcomes? c. Does the effectiveness of screening for GDM vary according to maternal subgroup characteristics, including timing during pregnancy, previous GDM diagnosis, family history of type 2 diabetes mellitus, body mass index, age, or race/ethnicity?

2. What are the harms of screening for and diagnosis of GDM to the mother, fetus, or neonate?

3 a. What is the comparative effectiveness of different screening strategies for GDM on health outcomes? b. What is the comparative effectiveness of different screening strategies for GDM on intermediate outcomes? c. Does the comparative effectiveness of different screening strategies vary according to maternal subgroup characteristics, including timing during pregnancy, previous GDM diagnosis, family history of type 2 diabetes mellitus, body mass index, age, or race/ethnicity?

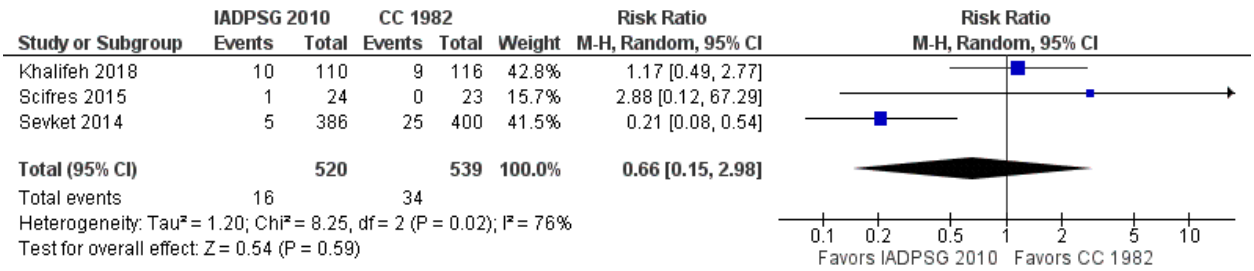
4 a. What is the diagnostic accuracy of commonly used screening tests for GDM?
b. Does the accuracy of commonly used screening tests for GDM vary according to maternal subgroup characteristics, including timing during pregnancy, body mass index, age, race/ethnicity, or prevalence of GDM?

5. What is the association between diagnosis of GDM and outcomes in women meeting more inclusive but not less inclusive diagnostic criteria for GDM?

6 a. Does treatment of GDM during pregnancy reduce poor health outcomes? b. Does treatment of GDM during pregnancy reduce poor intermediate outcomes? c. Does the effectiveness of treatment of GDM vary according to maternal subgroup characteristics, including timing and criteria used for diagnosis during pregnancy, severity of hyperglycemia, body mass index, age, or race/ethnicity?

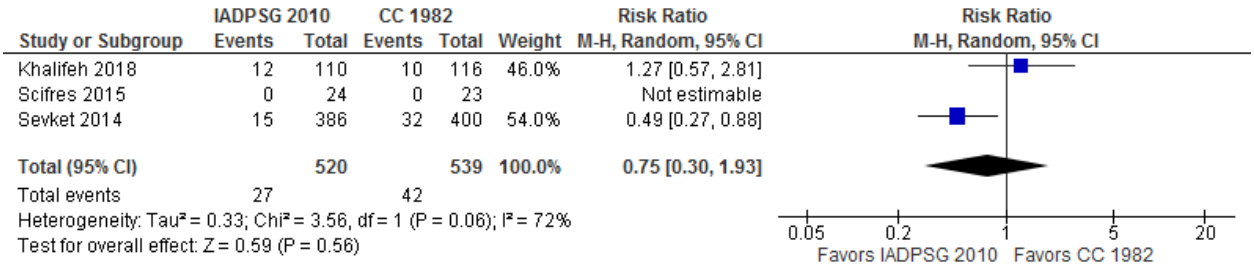
7. What are the harms of treatment of GDM, including severe maternal and fetal/neonatal hypoglycemia, delivery of neonates who are small for gestational age, and poor long-term growth and development outcomes in the child?

Figure 2. Meta-Analysis of Trials: Preeclampsia, IADPSG vs. CC Screening Strategies (KQ3)



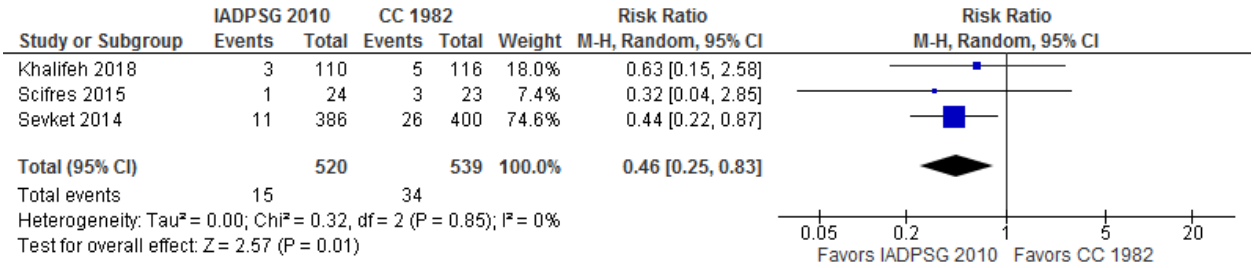
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Figure 3. Meta-Analysis of Trials: Preterm Delivery, IADPSG vs. CC Screening Strategies (KQ3)



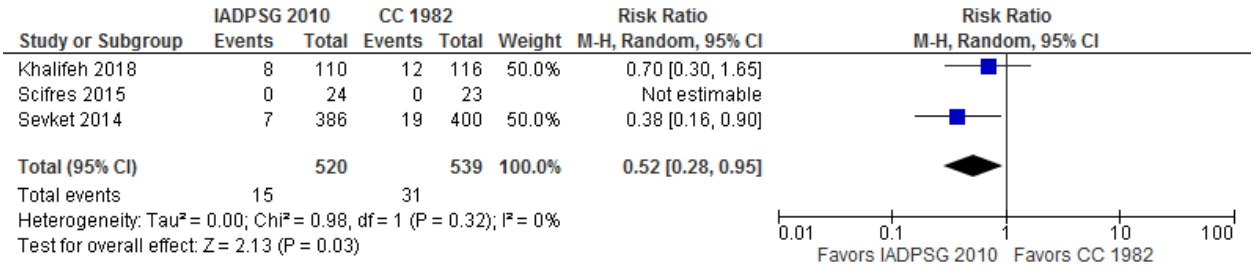
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Figure 4. Meta-Analysis of Trials: Large for Gestational Age, IADPSG vs. CC Screening Strategies (KQ3)



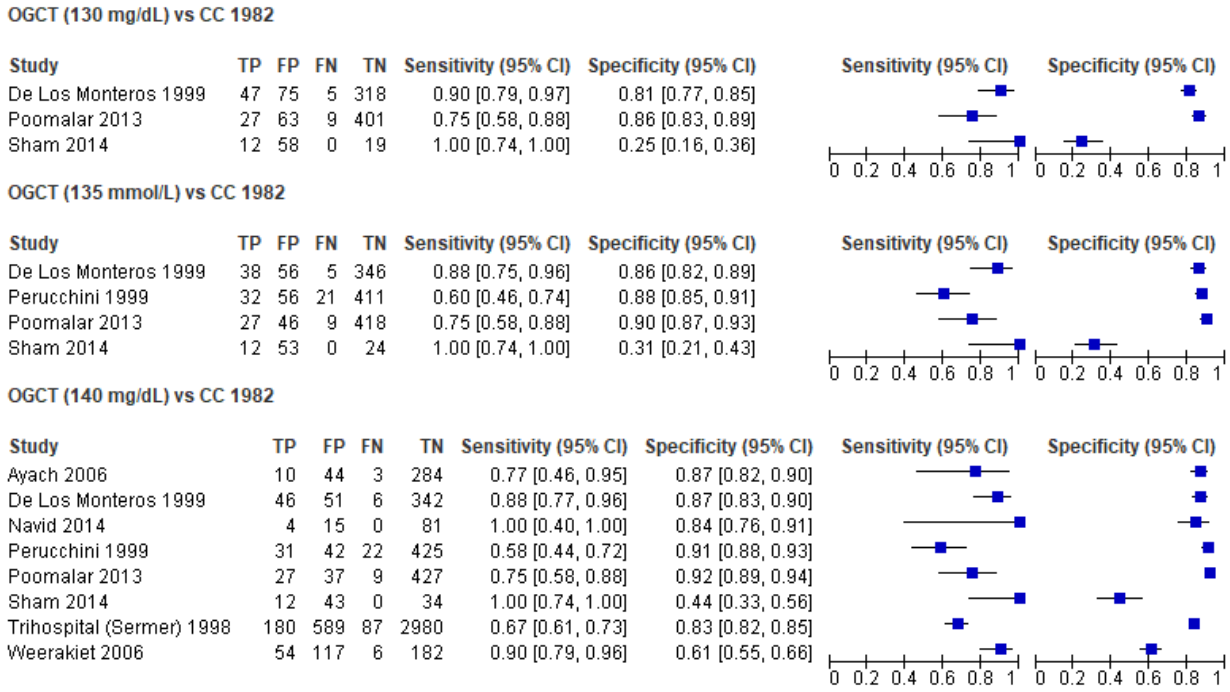
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Figure 5. Meta-Analysis of Trials: Neonatal Hypoglycemia, IADPSG vs. CC Screening Strategies (KQ3)



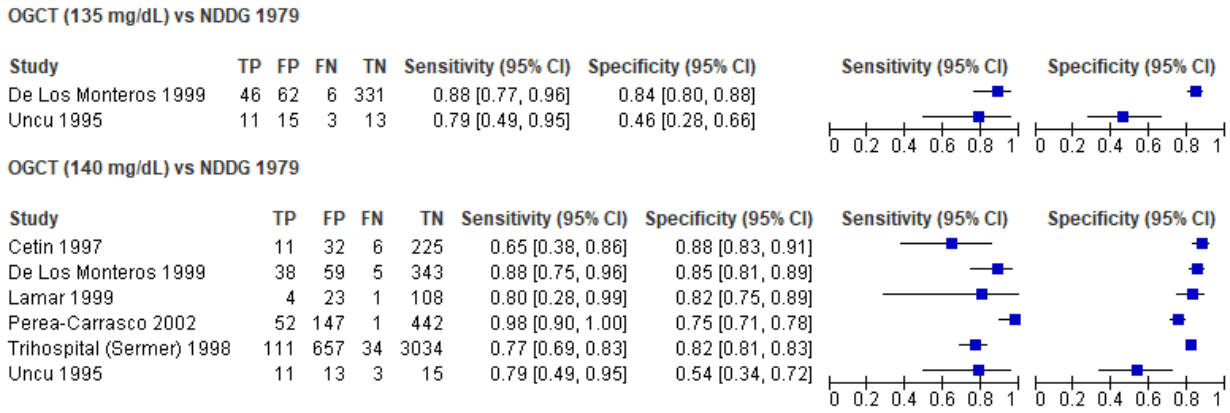
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Figure 6. Forest Plots of Sensitivity and Specificity of 50 g Oral Glucose Challenge Test by Carpenter and Coustan Diagnostic Criteria (KQ4)



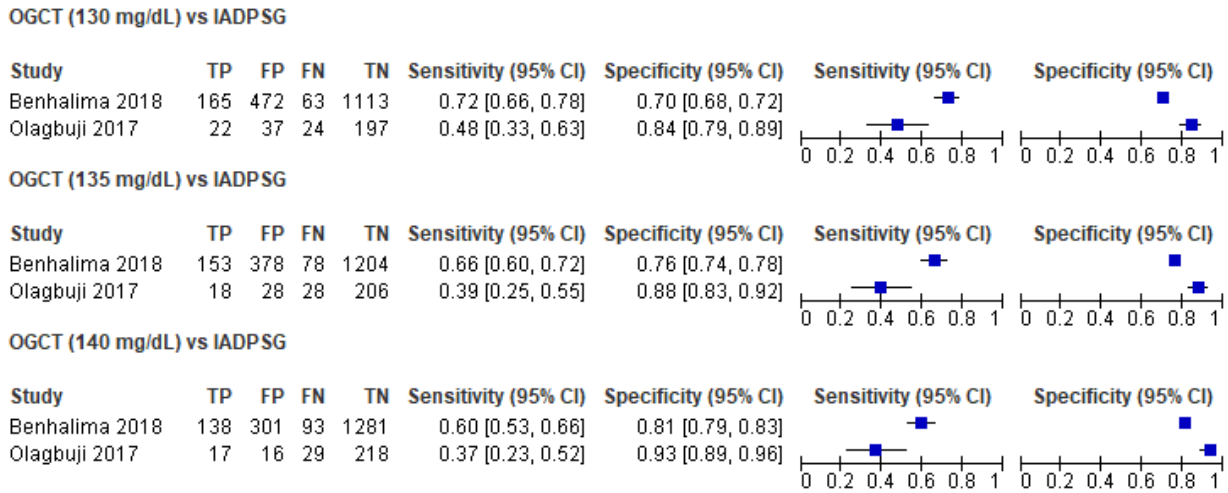
Abbreviations: CI = confidence interval; CC = Carpenter and Coustan; FN = false negative; FP = false positive; g = grams; OGCT = oral glucose challenge test; TN = true negative; TP = true positive

Figure 7. Forest Plots of Sensitivity and Specificity of 50 g Oral Glucose Challenge Test by NDDG Diagnostic Criteria (KQ4)



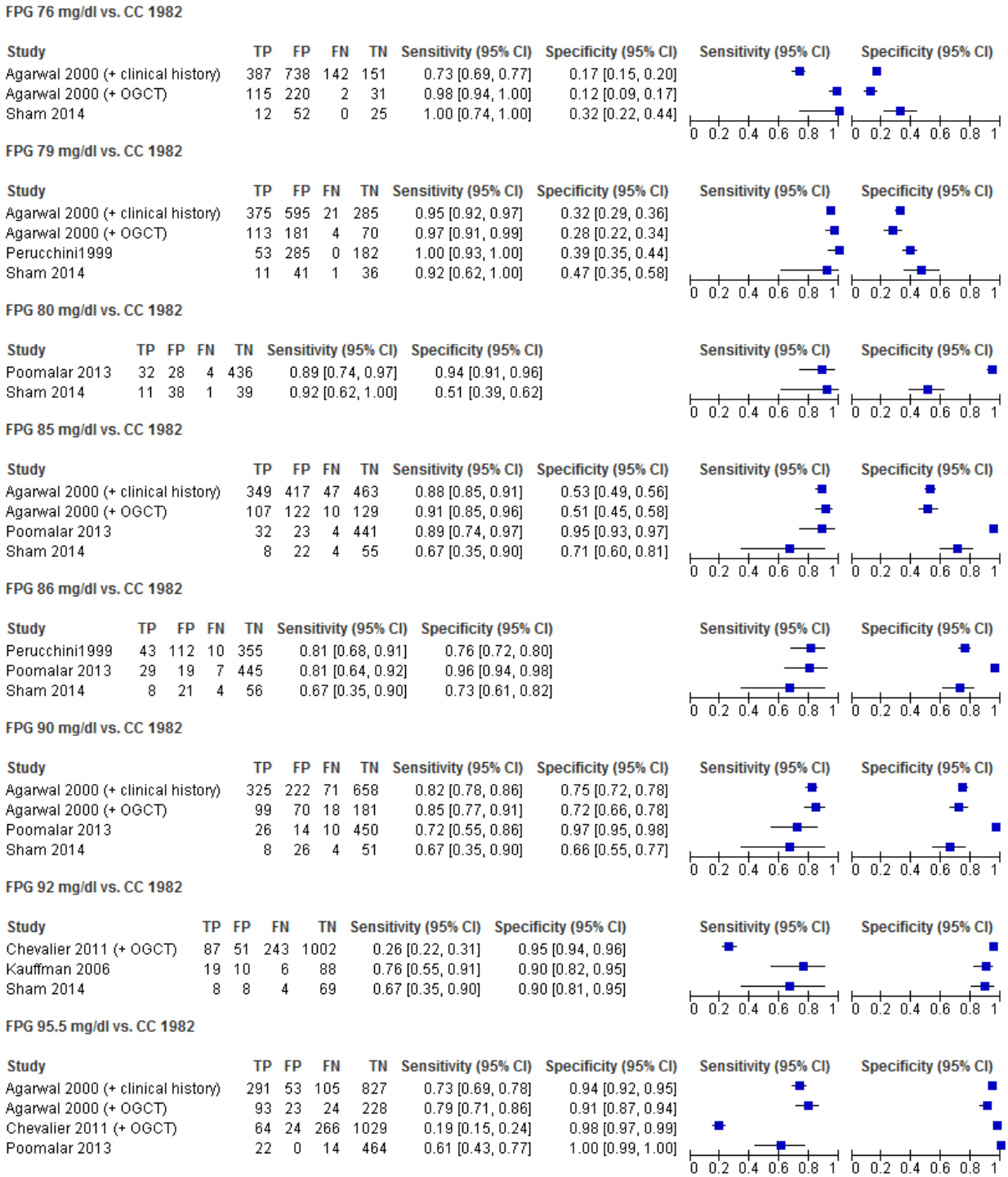
Abbreviations: CI = confidence interval; FN = false negative; FP = false positive; g = grams; KQ = key question; NDDG = National Diabetes Data Group; OGCT = oral glucose challenge test; TN = true negative; TP = true positive

Figure 8. Forest Plots of Sensitivity and Specificity of 50 g Oral Glucose Challenge Test by IADPSG Diagnostic Criteria (KQ4)



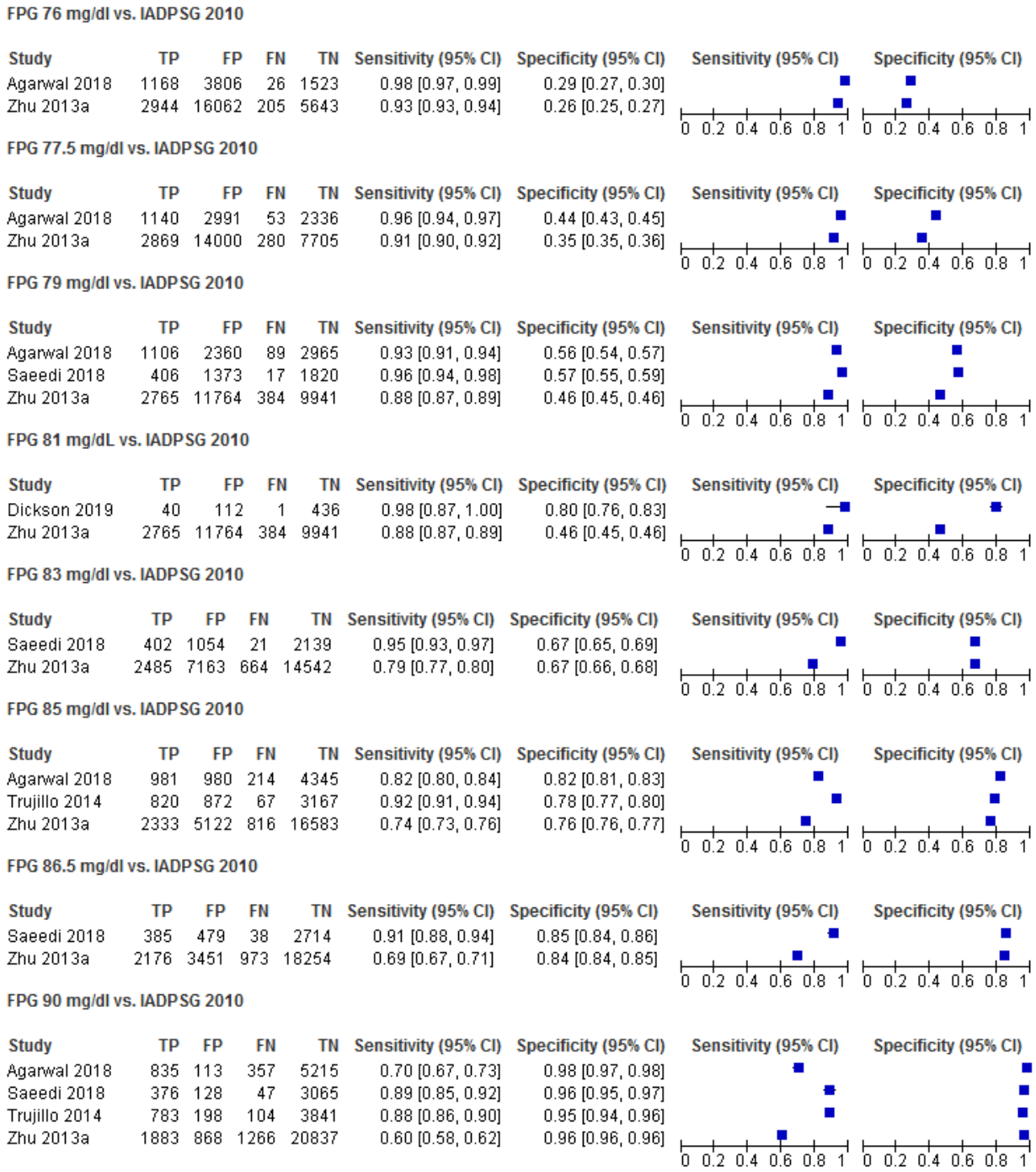
Abbreviations: CI = confidence interval; FN = false negative; FP = false positive; g = grams; IADPSG = International Association of the Diabetes and Pregnancy Study Groups; KQ = key question; OGCT = oral glucose challenge test; TN = true negative; TP = true positive

Figure 9. Forest Plots of Sensitivity and Specificity of Fasting Plasma Glucose by Carpenter and Coustan Diagnostic Criteria (KQ4)



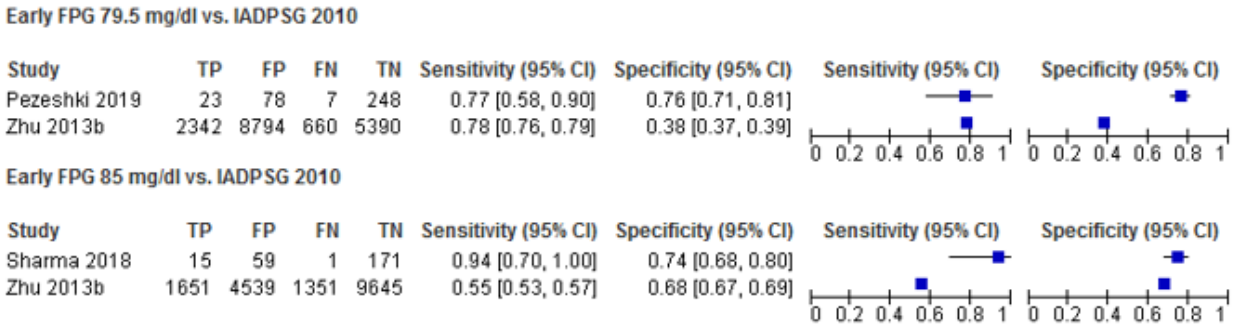
Abbreviations: CI = confidence interval; CC = Carpenter and Coustan; FN = false negative; FP = false positive; FPG = fasting plasma glucose; KQ = key question; OGCT = oral glucose challenge test; TN = true negative; TP = true positive

Figure 10. Forest Plots of Sensitivity and Specificity of Fasting Plasma Glucose by IADPSG Diagnostic Criteria (KQ4)



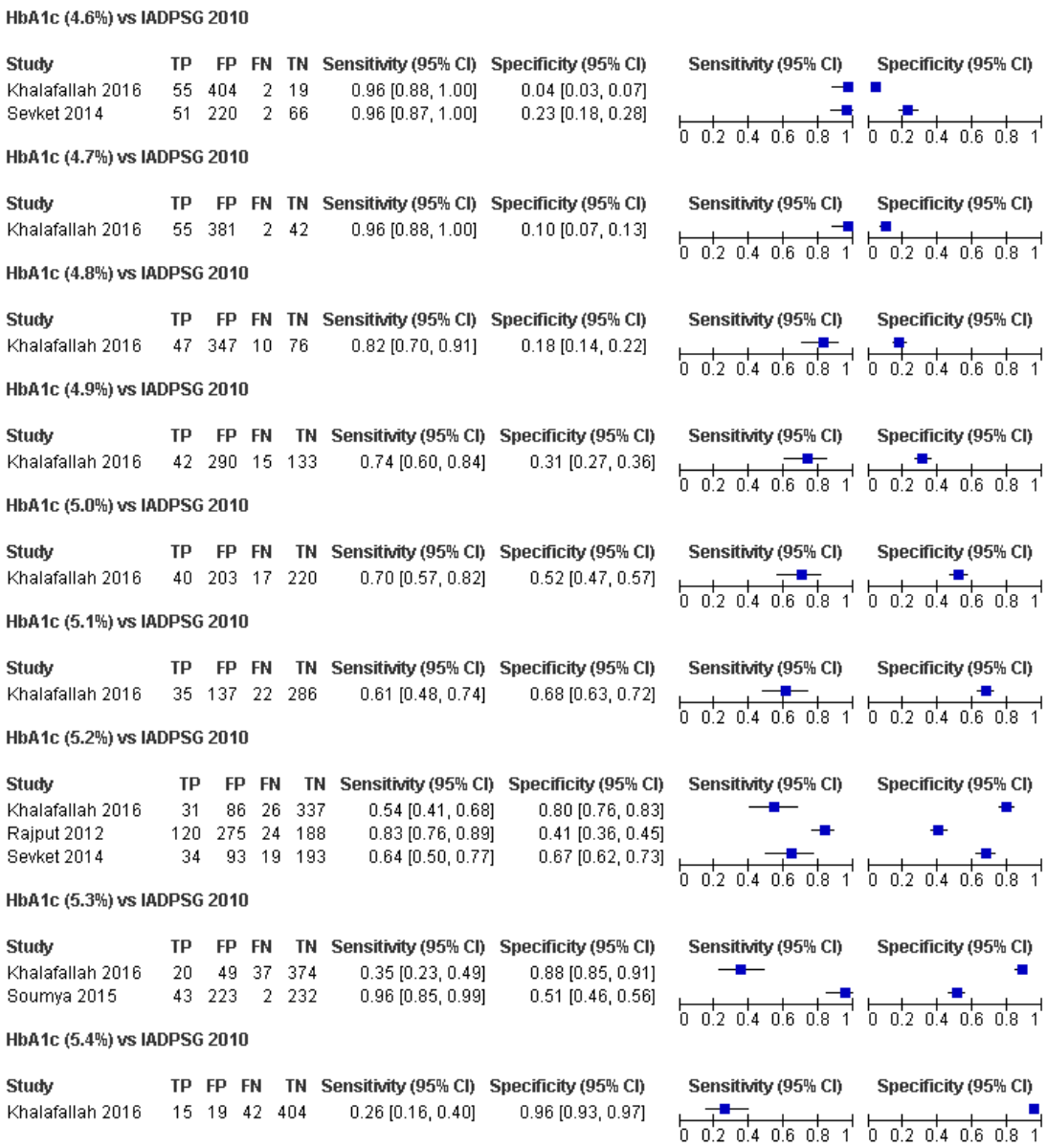
Abbreviations: CI = confidence interval; FN = false negative; FP = false positive; FPG = fasting plasma glucose; IADPSG = International Association of the Diabetes and Pregnancy Study Groups; KQ = key question; OGCT = oral glucose challenge test; TN = true negative; TP = true positive

Figure 11. Forest Plots of Sensitivity and Specificity of Early Fasting Plasma Glucose by IADPSG Diagnostic Criteria (KQ4)



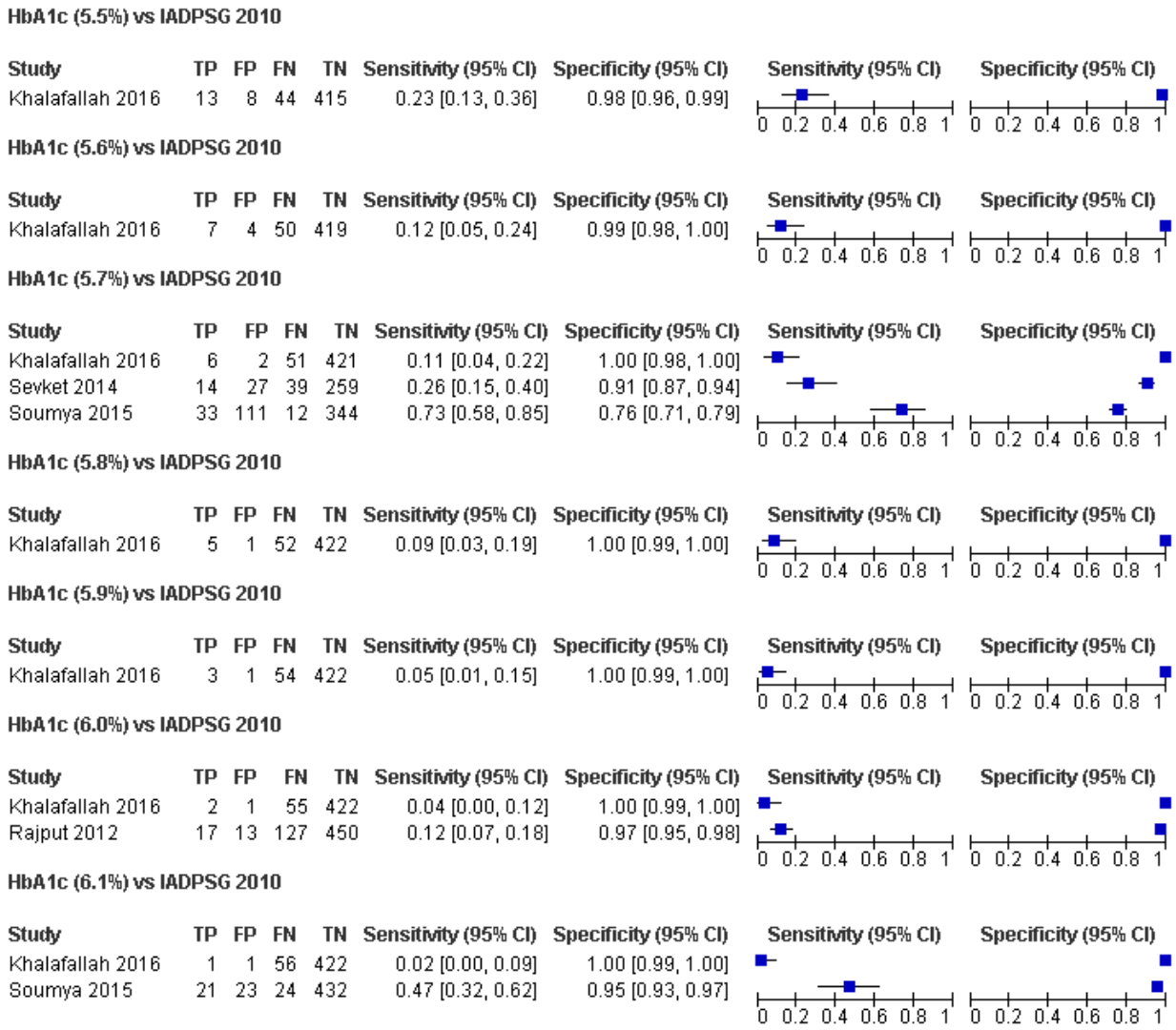
Abbreviations: CI = confidence interval; FN = false negative; FP = false positive; FPG = fasting plasma glucose; IADPSG = International Association of the Diabetes and Pregnancy Study Groups; KQ = key question; OGCT = oral glucose challenge test; TN = true negative; TP = true positive

Figure 12. Forest Plots of Sensitivity and Specificity: HbA1c vs. IADPSG 2010 at 24 to 28 Weeks' Gestation, Lower Thresholds (KQ4)



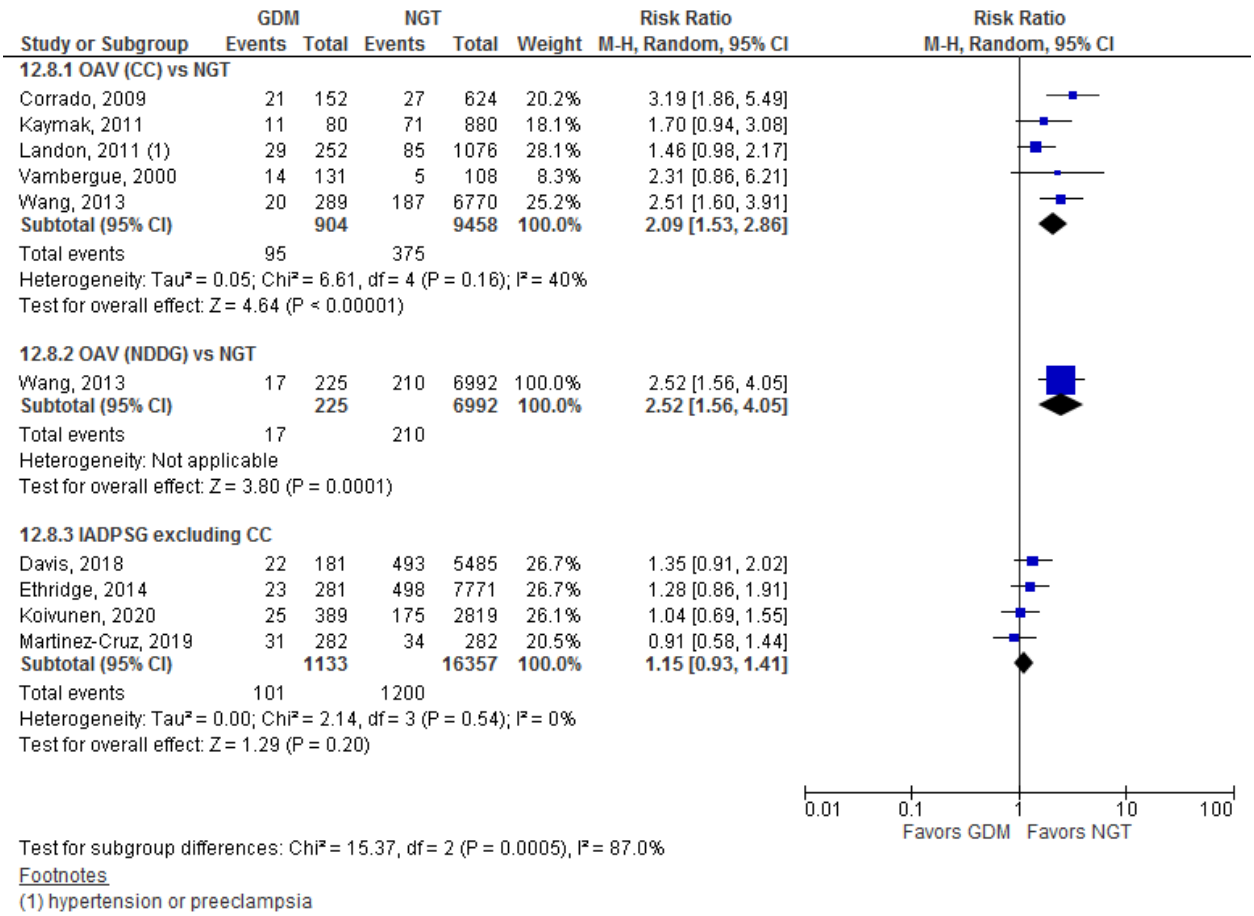
Abbreviations: CI = confidence interval; FN = false negative; FP = false positive; IADPSG = International Association of the Diabetes and Pregnancy Study Groups; KQ = key question; OGCT = oral glucose challenge test; TN = true negative; TP = true positive

Figure 13. Forest Plots of Sensitivity and Specificity: HbA1c vs. IADPSG 2010 at 24 to 28 Weeks' Gestation, Higher Thresholds (KQ4)



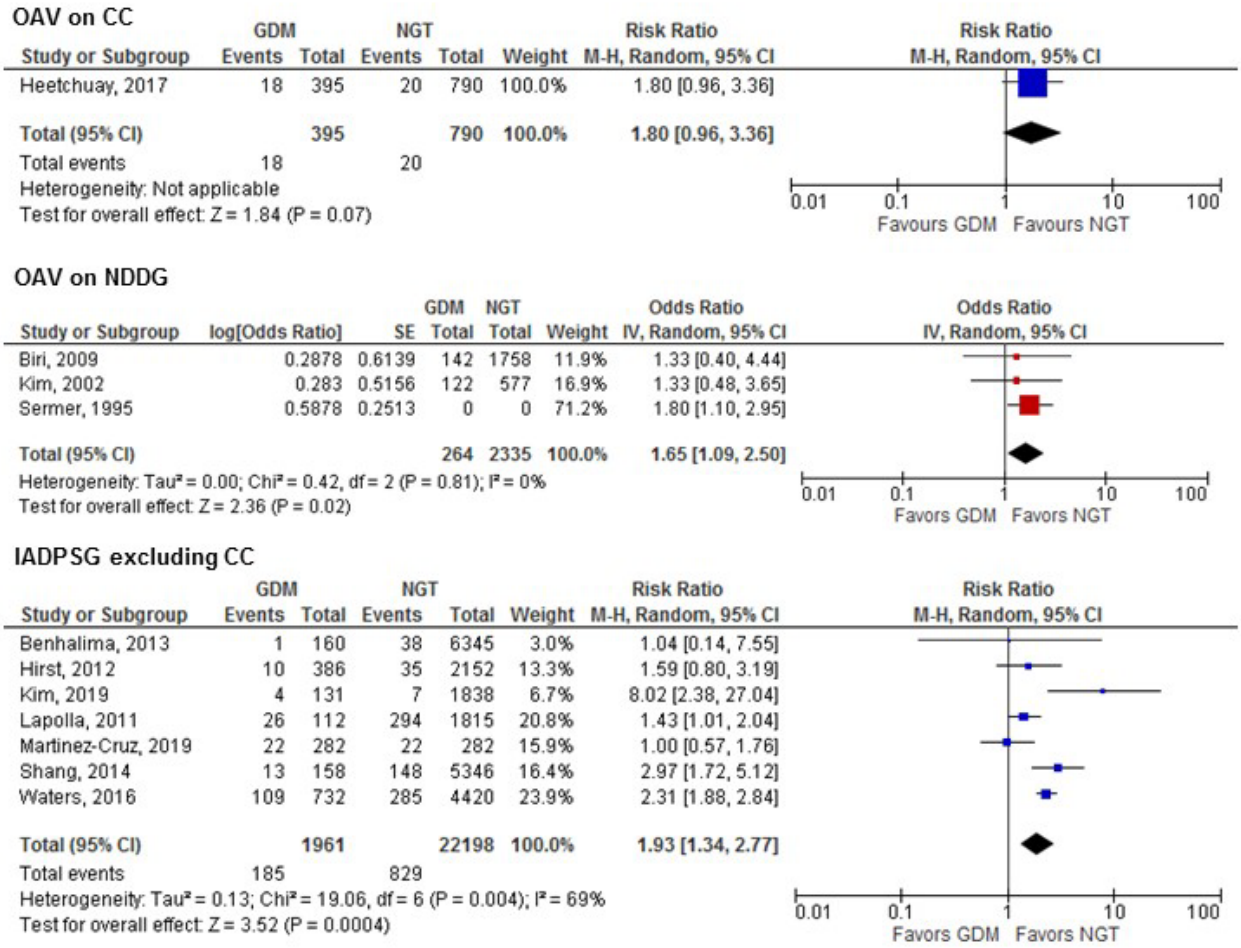
Abbreviations: CI = confidence interval; FN = false negative; FP = false positive; HbA1c = hemoglobin A1c; IADPSG = International Association of the Diabetes and Pregnancy Study Groups; KQ = key question; TN = true negative; TP = true positive

Figure 14. Forest Plots for Associations Between Inclusive GDM Criteria and Hypertensive Disorders in Pregnancy (KQ5)



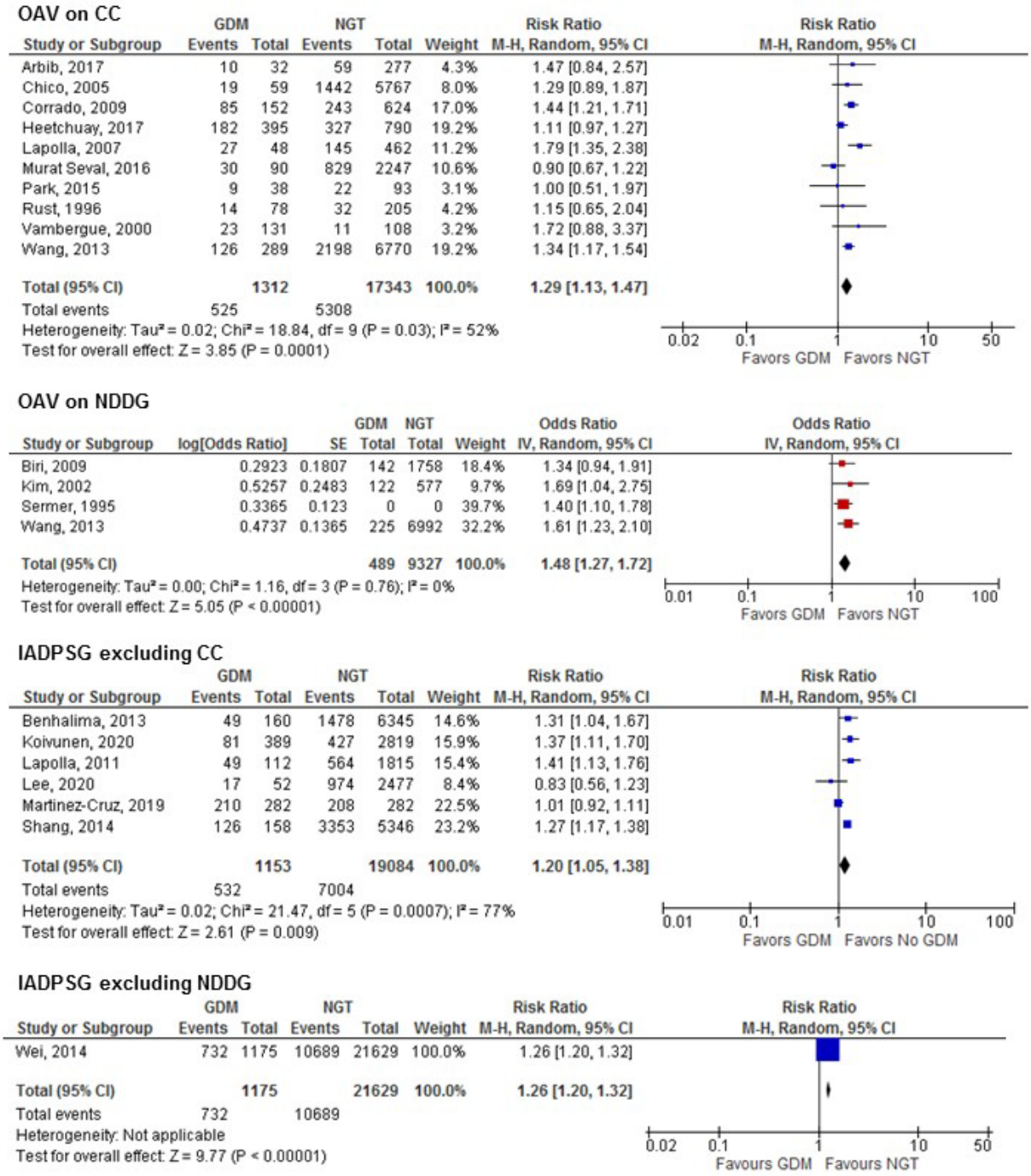
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance

Figure 15. Forest Plots for Associations Between Inclusive GDM Criteria and Preeclampsia (KQ5)*



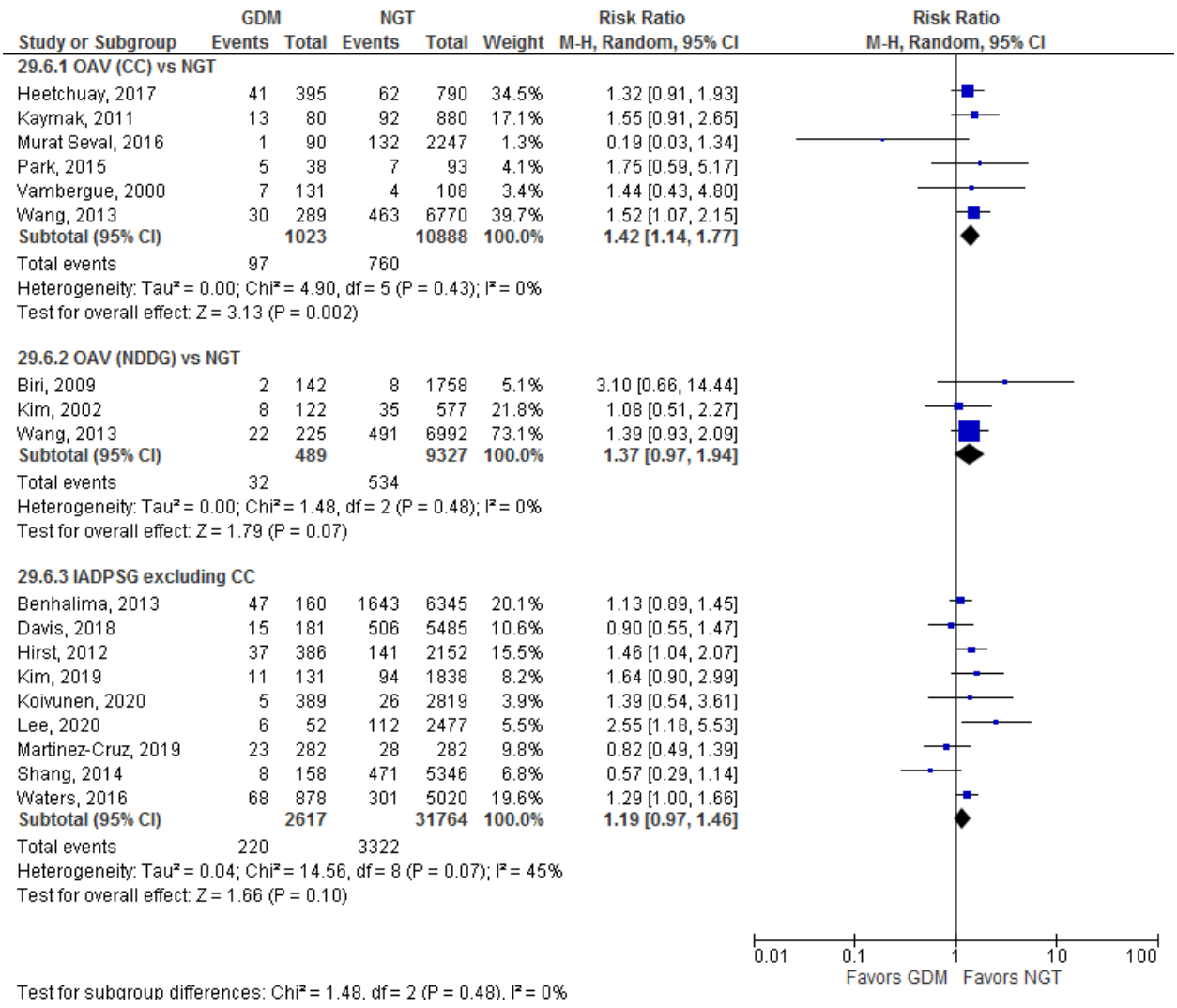
Abbreviations: Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; IV = inverse variance; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value
*OAV on NDDG was analyzed using inverse variance method because Sermer 1995 (n=3,637) only provided and odds ratio and 95% CI but not events rates or sample sizes per group; these are crude analyses.

Figure 16. Forest Plots for Associations Between Inclusive GDM Criteria and Total Cesarean Deliveries (KQ5)*



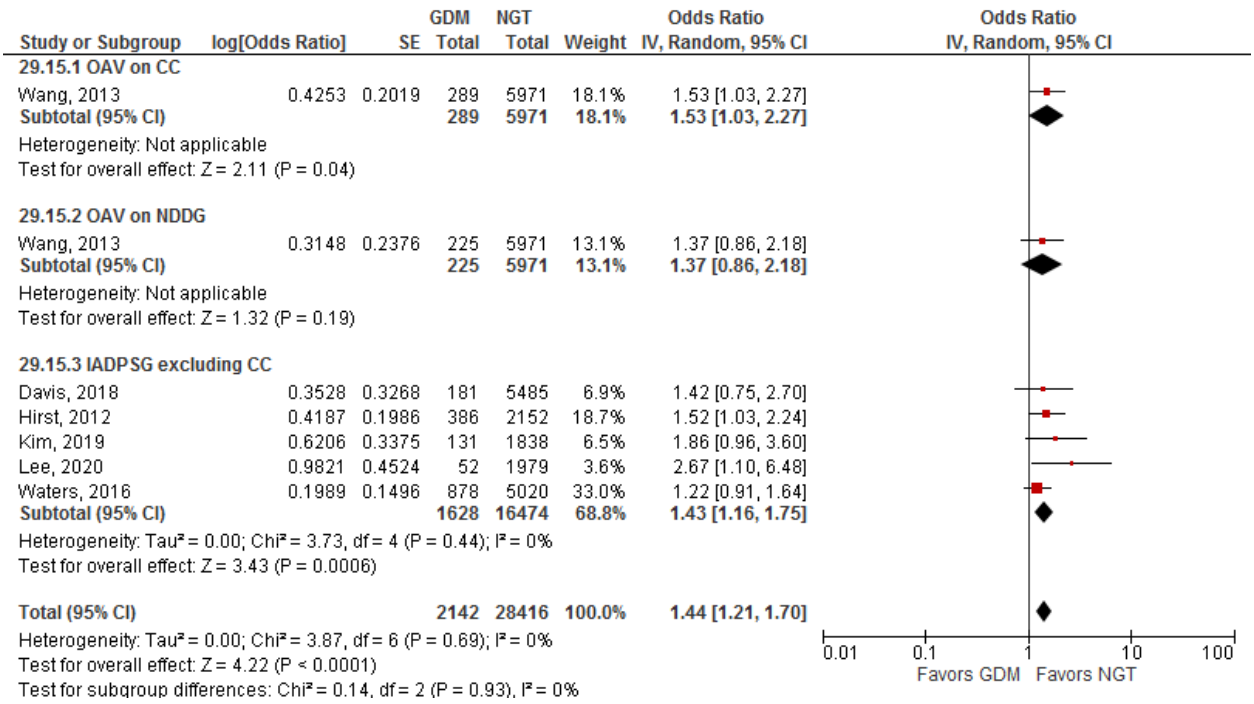
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; IV = inverse variance; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value
*OAV on NDDG was analyzed using inverse variance method because Sermer 1995 (n=3,637) only provided and odds ratio and 95% CI but not events rates or sample sizes per group; these are crude analyses.

Figure 17. Forest Plots for Crude Associations Between Inclusive GDM Criteria and Preterm Deliveries (KQ5)



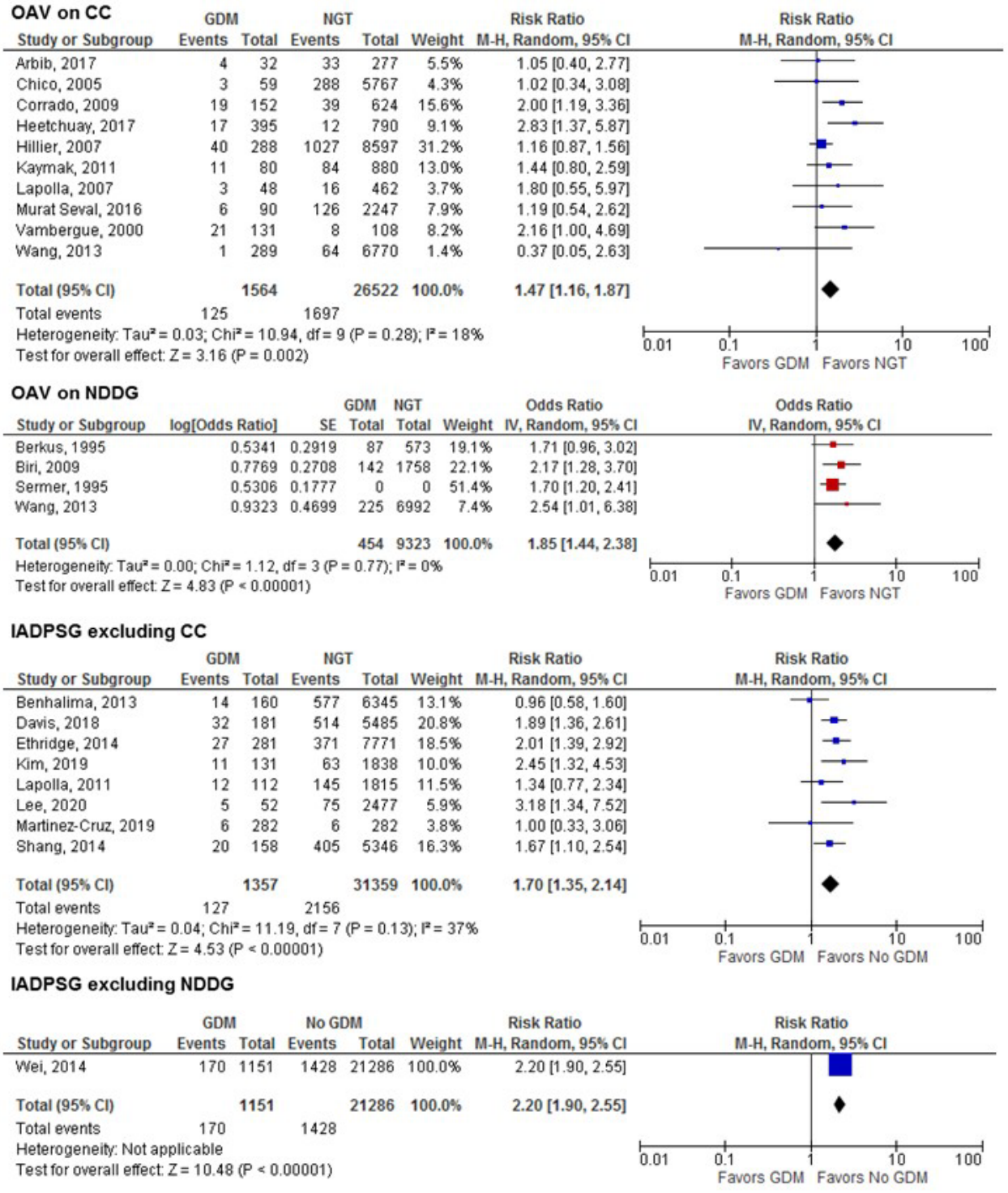
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Figure 18. Forest Plots for Adjusted Associations Between Inclusive GDM Criteria and Preterm Deliveries (KQ5)



Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; IV = inverse variance; KQ = key question; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value; SE = standard error

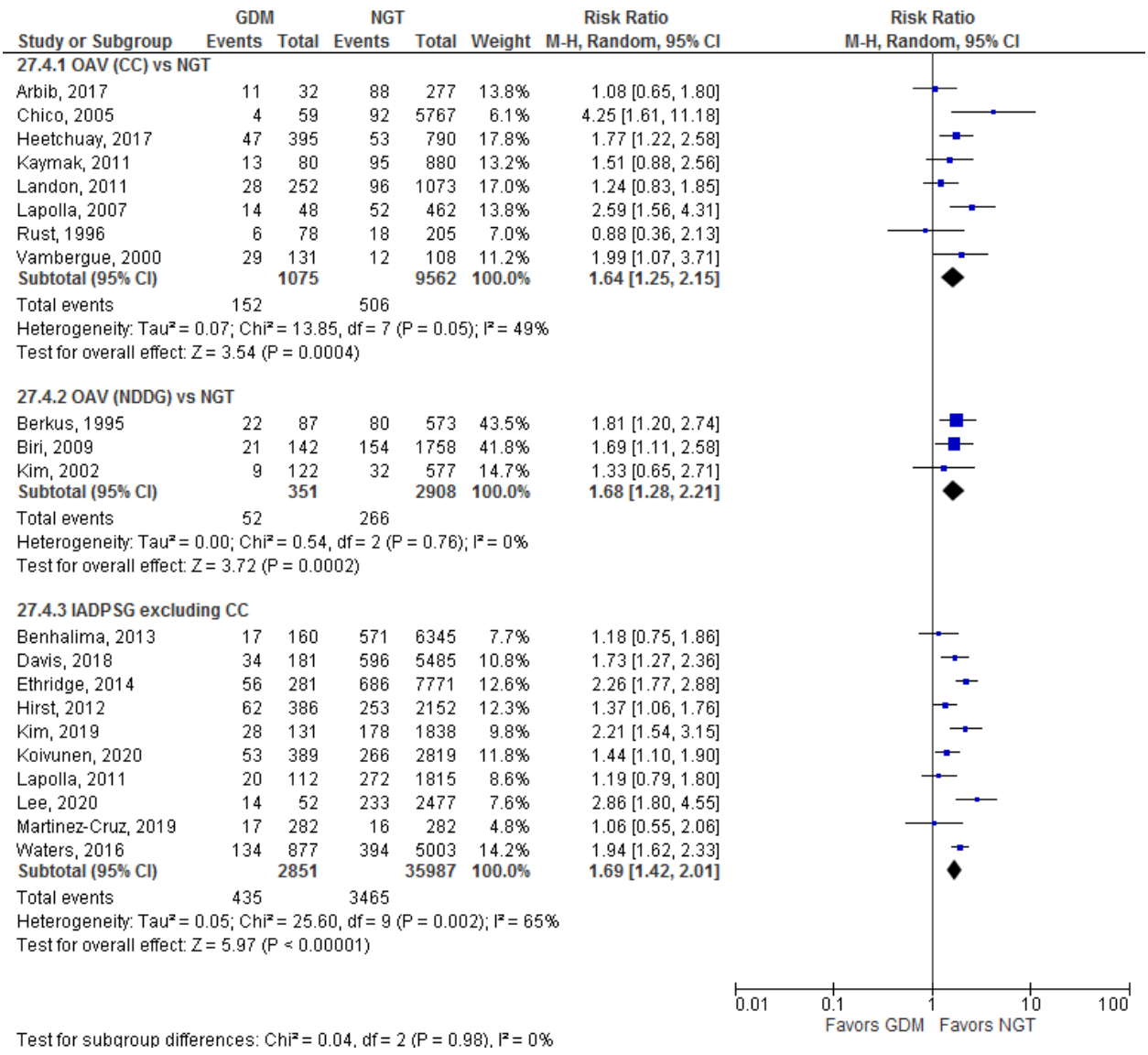
Figure 19. Forest Plots for Associations Between Inclusive GDM Criteria and Macrosomia (KQ5)*



Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; IV = inverse variance; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value; SE = standard error

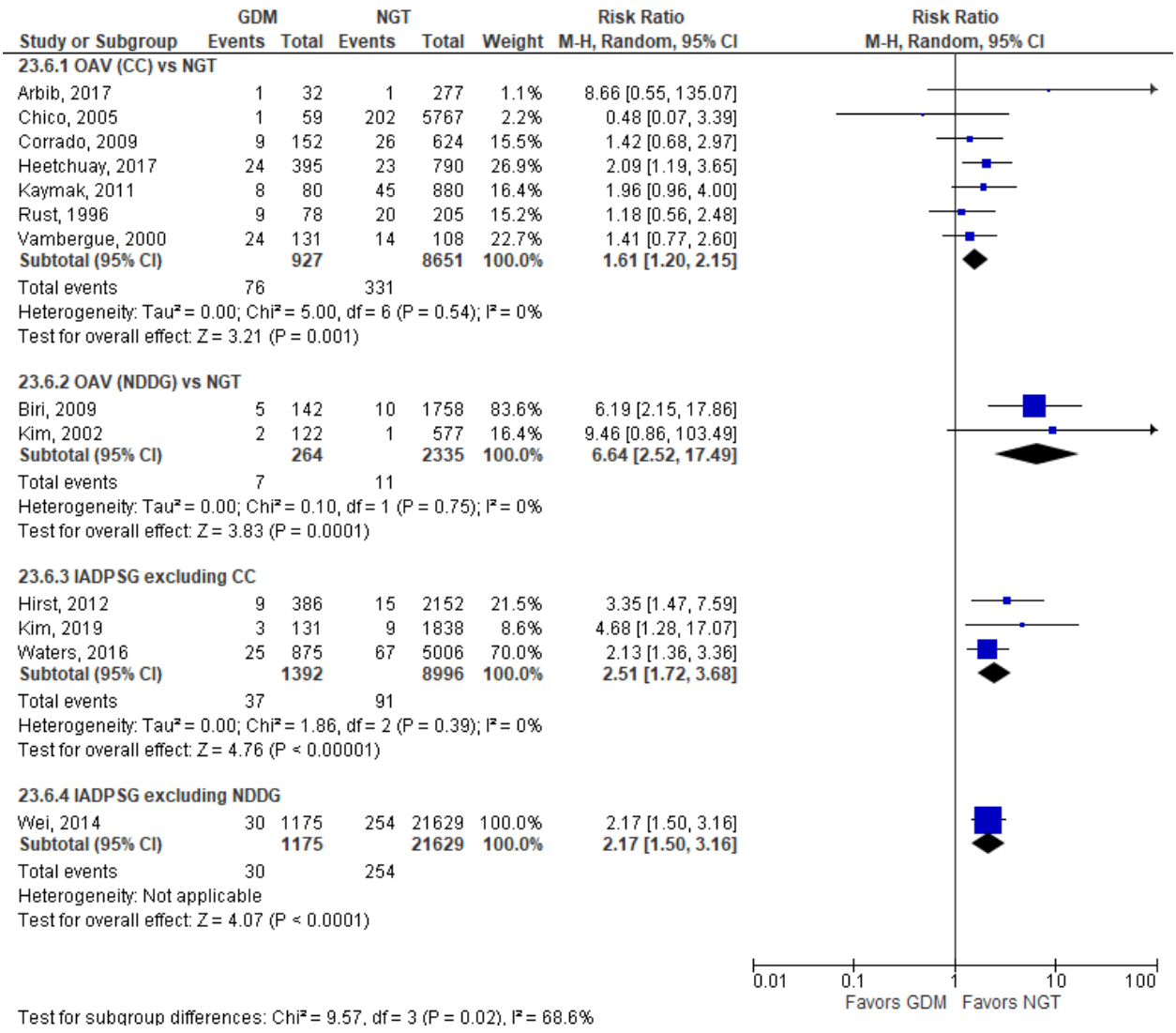
*OAV on NDDG was analyzed using inverse variance method because Sermer 1995 (n=3,3637) only provided and odds ratio and 95% CI but not events rates or sample sizes per group; these are crude analyses.

Figure 20. Forest Plots for Associations Between Inclusive GDM Criteria and Large for Gestational Age (KQ5)



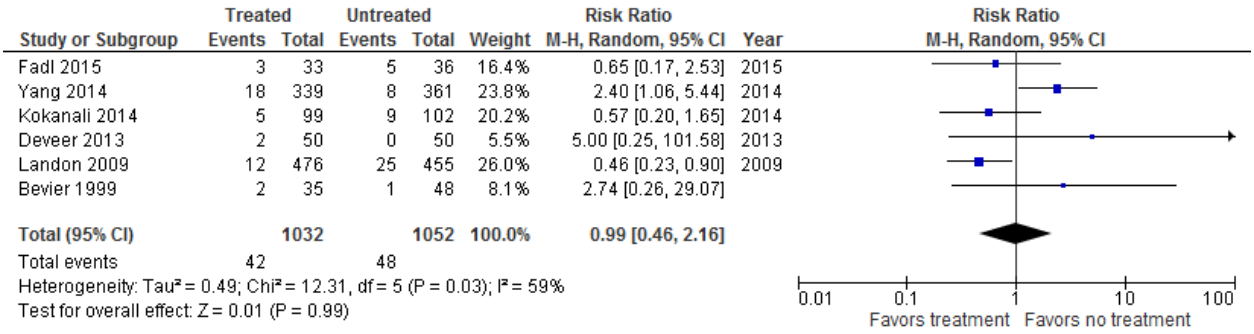
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; IV = inverse variance; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Figure 21. Forest Plots for Associations Between Inclusive GDM Criteria and Neonatal Hypoglycemia (KQ5)



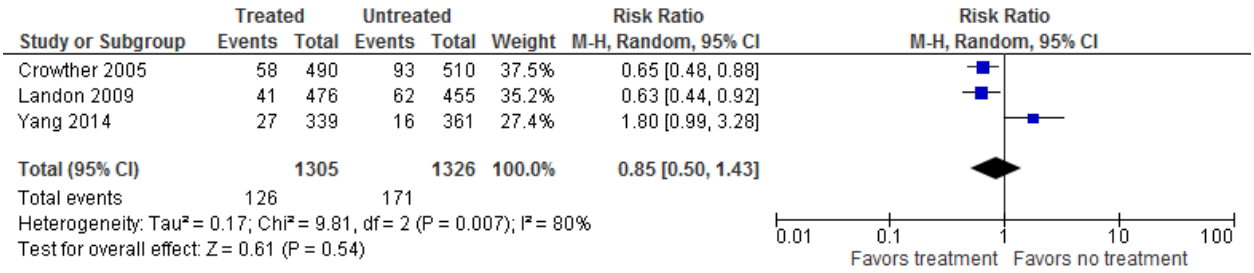
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Figure 22. Meta-Analysis of Trials: Preeclampsia, Treated vs. Untreated GDM (KQ6)



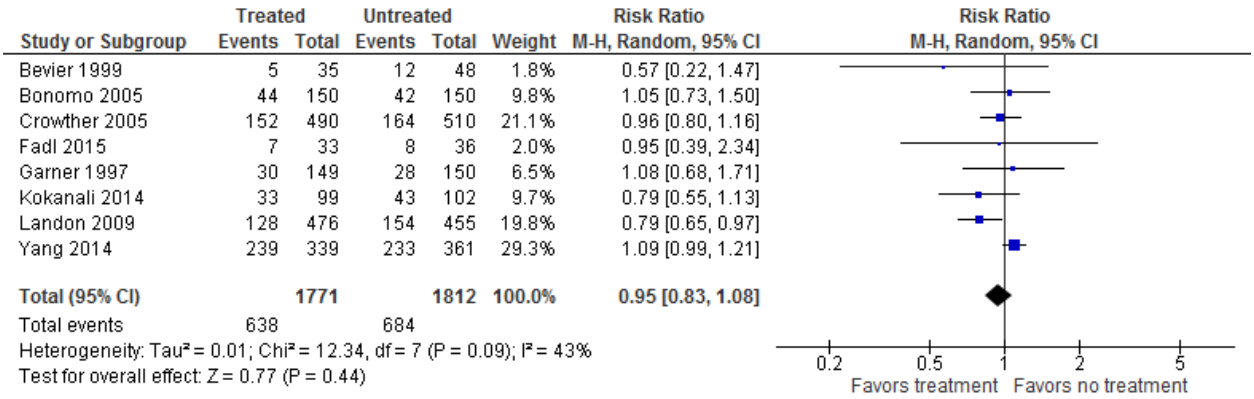
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Figure 23. Meta-Analysis of Trials: Hypertensive Disorders of Pregnancy, Treated vs. Untreated GDM (KQ6)



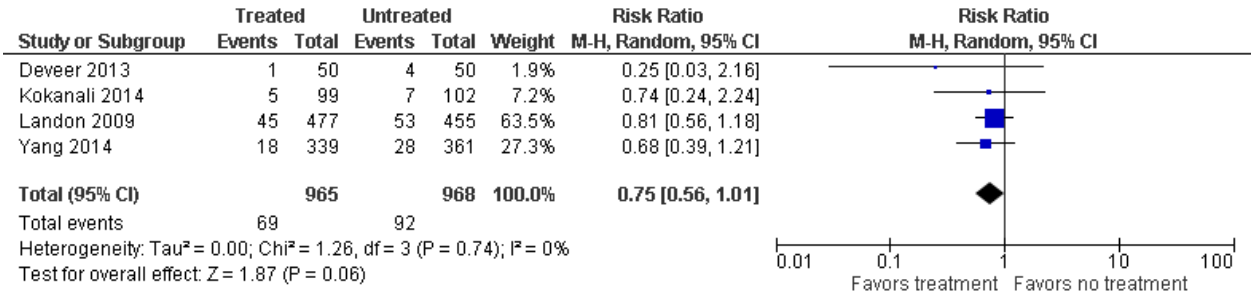
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Figure 24. Meta-Analysis of Trials: Total Cesarean Deliveries, Treated vs. Untreated GDM (KQ6)



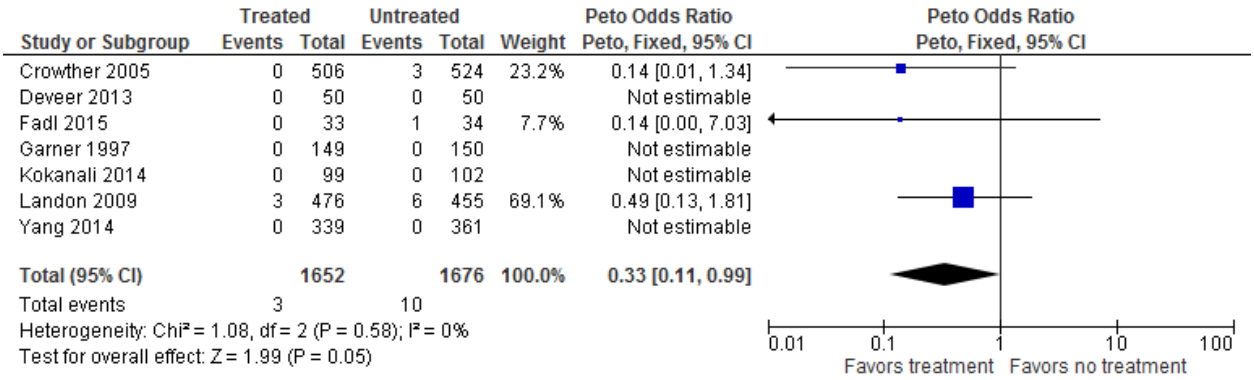
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Figure 25. Meta-Analysis of Trials: Preterm Delivery, Treated vs. Untreated GDM (KQ6)



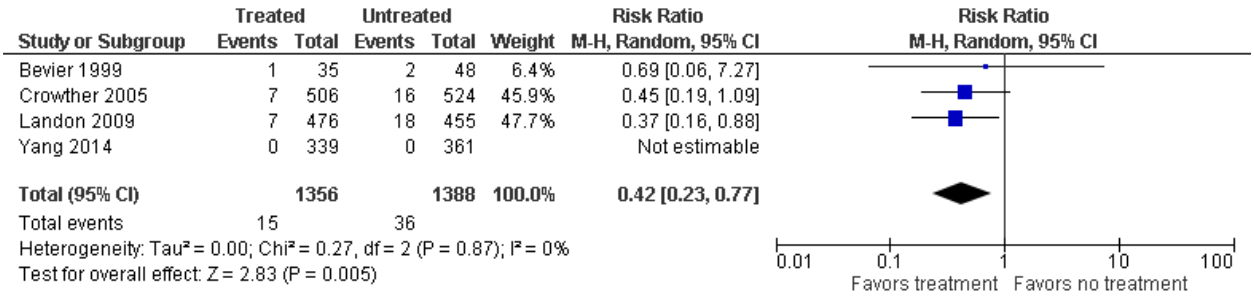
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Figure 26. Meta-Analysis of Trials: Birth Injury, Treated vs. Untreated GDM (KQ6)



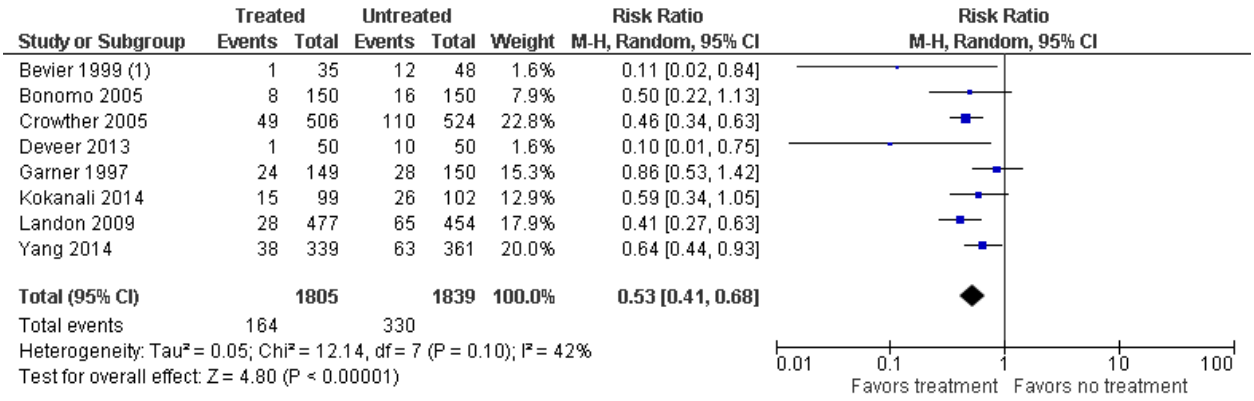
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question

Figure 27. Meta-Analysis of Trials: Shoulder Dystocia, Treated vs. Untreated GDM (KQ6)



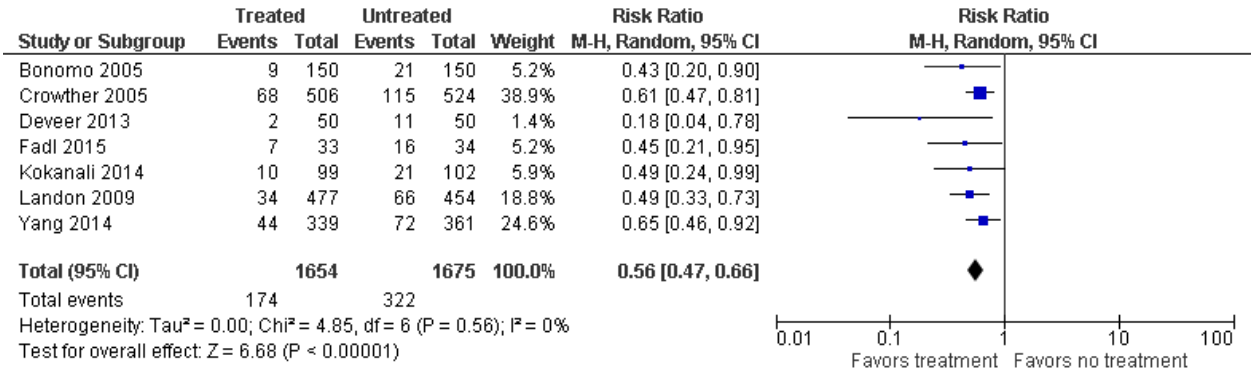
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Figure 28. Meta-Analysis of Trials: Macrosomia (>4000 g), Treated vs. Untreated GDM (KQ6)



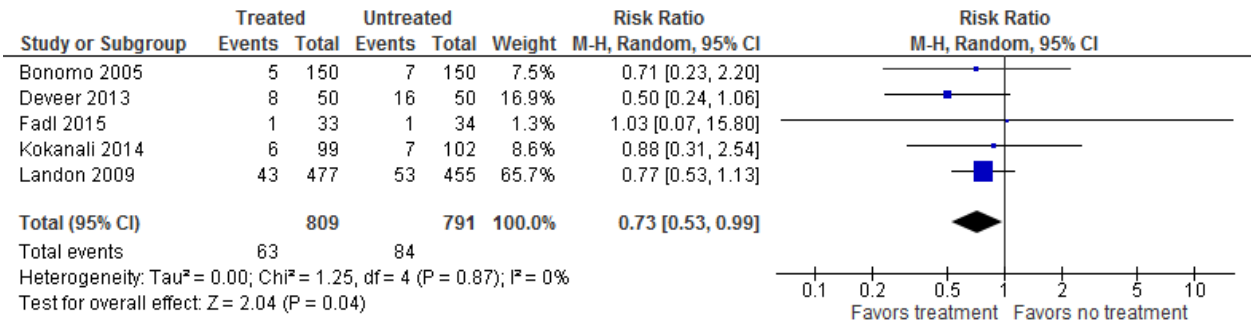
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Figure 29. Meta-Analysis of Trials: Large for Gestational Age, Treated vs. Untreated GDM (KQ6)



Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Figure 30. Meta-Analysis of Trials: NICU Admission, Treated vs. Untreated GDM (KQ6)



Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel; NICU = neonatal intensive care unit

Table 1. Current Screening Strategies* and Thresholds for GDM

	Development of Criteria	Current Use in Guidance	Glucose Load	Minimum Number of Abnormal Values	Fasting Threshold	1hr Threshold	2hr Threshold	3hr Threshold
In two-step screening after positive (i.e., 130-140 mg/dL/7.2-7.8 mmol/L) OGCT	Carpenter Coustan 1982[18]	ACOG 2013-2018[7] NIH 2013[308] ADA 2000-2020[8]	100 g	2	95 mg/dL 5.3 mmol/L	180 mg/dL 10.0 mmol/L	155 mg/dL 8.6 mmol/L	140 mg/dL 7.8 mmol/L
	NDDG 1997[19]	ACOG 2013-2018[7] NIH 2013[308]	100 g	2	105 mg/dL 5.8 mmol/L	190 mg/dL 10.5 mmol/L	165 mg/dL 9.1 mmol/L	145 mg/dL 8.0 mmol/L
	DC (a.k.a. CDA) 2013[309]-2018[30] (HAPO 2.0)	DC 2013[309]-2018[30] SOGC 2016[310]	75 g	1	95 mg/dL 5.3 mmol/L	191 mg/dL 10.6 mmol/L	160 mg/dL 9.0 mmol/L	-
In two-step screening after risk-factor assessment	NICE 2018[31]	NICE 2018[31]	75 g	1	101 mg/dL 5.6 mmol/L	-	140 mg/dL 7.8 mmol/L	-
	SIGN 2017[311]	SIGN 2017[311]	See IADPSG					
One-step screening only using diagnostic test	IADPSG[21] (HAPO 1.75)	WHO 2013[47]-2018[312] ADA 2011[313]-2020[8] Endocrine Society 2013-2018[46] DC 2013[309]-2018[30] (alternative) & SOGC 2016[310] (alternative) ADIPS 2014[314] FIGO[315]	75 g	1	92 mg/dL 5.1 mmol/L	180 mg/dL 10.0 mmol/L	153 mg/dL 8.5 mmol/L	
	EASD 1996[316]	-	75 g	1	108 mg/dL 6.0 mmol/L	-	162 mg/dL 9.0 mmol/L	-

Abbreviations: ACOG = American College of Obstetricians and Gynecologists; ADA = American Diabetes Association; ADIPS = Australasian Diabetes in Pregnancy Society; DC = Diabetes Canada; EASD = European Association for the Study of Diabetes; FIGO = International Federation of Gynecology and Obstetrics; HAPO = Hyperglycemia and Adverse Pregnancy Outcome; IADPSG = International Association of Diabetes in Pregnancy Study Groups; NDDG = National Diabetes Data Group; NICE = National Institute for Health and Care Excellence; NIH = U.S. National Institutes for Health; OGCT = oral glucose challenge test; SIGN = Scottish Intercollegiate Guidelines Network; SOGC = Society of Obstetricians and Gynaecologists of Canada; WHO = World Health Organization

*This table includes the currently recommended screening strategies that were included in this review. One study included for Key Question 3 compared IADPSG criteria to WHO 1999 criteria, which uses thresholds of FPG ≥6.1 mmol/L and/or 2 hr ≥7.8 mmol/L.

Table 2. Major Recommendations on Screening for GDM in the United States

Group	Recommendation
USPSTF[5]	The USPSTF recommends screening for GDM in asymptomatic pregnant women after 24 weeks of gestation. (B recommendation) The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for GDM in asymptomatic pregnant women before 24 weeks of gestation. (I statement) No recommendation for screening approach.
ADA[8]	Test for gestational diabetes mellitus at 24–28 weeks of gestation in pregnant women not previously known to have diabetes. (A Recommendation) The ADA recommends using the IADPSG criteria, or a 2-step approach with a 50g non-fasting screening test follows by a 100g OGTT with at least 2 glucose values meeting or exceeding the diagnostic thresholds described by CC.
ACOG[317]	All pregnant women should be screened for GDM with a laboratory-based screening test(s) using blood glucose levels. Screening for GDM generally is performed at 24–28 weeks of gestation. Two-step screening is recommended. For the *screening test*, practitioners are advised to select a single, consistent threshold (between 130-140 mg/dL), based on factors such as community prevalence rates of GDM. For *diagnosis*, a 3-hr OGTT using CC or NDDG criteria are recommended, based on considerations of baseline prevalence of diabetes in specific communities and the availability of resources to appropriately manage women in whom GDM will be diagnosed by any given protocol. Individual practices and institutions may choose to use the IADPSG's recommendation, if appropriate, for the population they serve.
NIH Consensus Development Program[308]	The panel recommends that the two-step approach be continued.
Endocrine Society[46]	Recommends that pregnant women not previously identified (either during testing performed early in pregnancy or at some other time before 24 weeks' gestation) with overt diabetes or gestational diabetes be tested for gestational diabetes by having a 2-hour, 75-g OGTT performed at 24 to 28 weeks' gestation. (Level 1; moderate quality) Recommends that gestational diabetes be diagnosed on this test using the IADPSG criteria (majority opinion of this committee). (Level 1; moderate quality)
AAFP[318]	The AAFP supports the 2014 recommendations of the USPSTF.

Abbreviations: AAFP = American Academy of Family Physicians; ACOG = American College of Obstetricians and Gynecologists; ADA = American Diabetes Association; CC = Carpenter Coustan; IADPSG = International Association of Diabetes in Pregnancy Study Groups; NDDG = National Diabetes Data Group; NIH = U.S. National Institutes for Health; OGTT = oral glucose tolerance

Table 3. Evidence From Observational Studies on Screening vs. No Screening for GDM (KQ1)

Author, Year, Country Screening Strategy Quality Applicability	Outcome	Events/Score in Screened	Events/Score in Not screened	Relative Risk (Odds Ratio, if specified) [95% Confidence Interval]
Stacey, 2019[68] United Kingdom 2-step: screen for 1+ risk factor then 75g 2hr OGTT (NICE) Fair Moderate (ethnic composition and risk status based on South Asian and Black Caribbean screening)	Still birth	93 cases of stillbirth & 269 controls of 362 screened	183 cases of stillbirth & 440 controls in 623 not screened	aOR, 0.68 [0.47 to 0.97] accounting for being "at risk" Effects appear to be mainly within at-risk group: in women not receiving screening, being at-risk had higher odds of stillbirth aOR, 1.44 [1.01 to 2.06]
Hivert, 2012[67] Canada 2-step: 50g OGCT and 75g 2hr OGTT IADPSG; early screening in those with multiple risk factors Fair Moderate (screening at specialized clinic offering some care and expedited referral; >93% White)	Cesarean delivery	348/2012 (17.3%) GCT 1st trimester: 160/1019 GCT 2nd trimester: 188/993	170/768 (22.1%)	Screened vs not screened: 0.78 [0.66 to 0.92] 1st trimester screen vs not screened: 0.71 [0.58 to 0.86] 2nd trimester screen vs not screened: 0.86 [0.71 to 1.03] Subgroup effects p=0.26
	Macrosomia (>4000 g)	182/2012 (9%) GCT 1st trimester: 95/1019 GCT 2nd trimester: 87/993	56/768 (7.3%)	Screened vs not screened: 1.24 [0.93 to 1.65] 1st trimester vs not screened: 1.28 [0.93 to 1.75] 2nd trimester vs not screened: 1.20 [0.87 to 1.66] Subgroup effects: p=0.79
	Birth injury (fracture and dislocation)	16/2012 (0.8%) GCT 1st trimester: 9/1019 GCT 2nd trimester: 7/993	13/768 (1.7%)	Screened vs not screened: 0.47 [0.23 to 0.97] 1st trimester vs not screened: 0.52 [0.22 to 1.21] 2nd trimester vs not screened: 0.42 [0.17 to 1.04]
	Respiratory distress (not defined)	201/2012 (10.0%) GCT 1st trimester: 98/1019 GCT 2nd trimester: 103/993	101/768 (13.2%)	Screened vs not screened: 0.76 [0.61 to 0.95] 1st trimester vs not screened: 0.73 [0.56 to 0.95] 2nd trimester vs not screened: 0.79 [0.61 to 1.02] Subgroup effects: p= 0.74
	Hypoglycemia	105/2012 GCT 1st trimester: 51/1019 GCT 2nd trimester: 54/993	42/768	Screened vs not screened: 0.95 [0.67 to 1.35] 1st trimester vs not screened: 0.92 [0.61 to 1.36] 2nd trimester vs not screened: 0.99 [0.67 to 1.47]
	Hyperbilirubinemia	690/2012 GCT 1st trimester: 340/1019 GCT 2nd trimester: 350/993	270/768	Screened vs not screened: 0.98 [0.87 to 1.09] 1st trimester vs not screened: 0.95 [0.83 to 1.08] 2nd trimester vs not screened: 1.00 [0.88 to 1.14]
	Admission to NICU	364/2012 (18.1%) GCT 1st trimester: 157/1019 GCT 2nd trimester: 207/993	206/768 (26.8%)	Screened vs not screened: 0.67 [0.58 to 0.78] 1st trimester vs not screened: 0.57 [0.48 to 0.69] 2nd trimester vs not screened: 0.78 [0.66 to 0.92] Subgroup effects: p=0.05

Table 3. Evidence From Observational Studies on Screening vs. No Screening for GDM (KQ1)

Author, Year, Country Screening Strategy Quality Applicability	Outcome	Events/Score in Screened	Events/Score in Not screened	Relative Risk (Odds Ratio, if specified) [95% Confidence Interval]
Chanprapaph, 2004[69] Thailand Selective 2-step: 50g OGCT (≥140 mg/dL) followed by 100g OGTT (NDDG) Good Poor (results compared only in women with risk factors, different healthcare system)	Preeclampsia	21/411	0/40	4.46 [0.27 to 75.00]
	Gestational hypertension	4/411	0/40	0.89 [0.05 to 16.91]
	Cesarean	81/411	5/40	1.72 [0.65 to 4.52]
	Preterm delivery	42/411	2/40	2.16 [0.50 to 9.29]
	LGA (>90%ile)	50/411	3/40	1.71 [0.51 to 5.75]
	SGA (<10 %ile)	42/411	3/40	1.40 [0.41 to 4.75]
Solomon, 1996[70] U.S. 2-step: 50g OGCT with many using NDDG Fair Poor (only data for women without GDM)	Macrosomia (>4300 g)	6/77	1/16	1.04 [0.13 to 8.30]

Abbreviations: aOR = adjusted odds ratio; IADPSG = International Association of Diabetes in Pregnancy Study Groups; LGA = large for gestational age; NDDG = National Diabetes Data Group; NICE = National Institute for Health and Care Excellence; NICU = neonatal intensive care unit; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance tests; SGA = small for gestational age

Table 4. Summary of Trials Comparing Different GDM Screening Strategies (KQ3)

Author, Year, Country Study Design Quality	Inclusion Criteria	Exclusion Criteria	Screening Strategy 1	Screening Strategy 2	Treatment Differences Gestational Weeks (wGA) at Delivery	# Enrolled; #Analyzed
Khalifeh 2018,[80] U.S. RCT Fair (open label; 79% women analyzed)	Women without preexisting DM	Women with history of pre-existing diabetes or a history of bariatric surgery; failure to attend screening (after randomization; n=35)	**IADPSG 2010 (universal, 75g 1-step)** at 24-28 wGA, or at initial prenatal visit if ≥ 1 risk factor[a] (and repeated at 24-28 wGA if –ve) (n=123, GDM=10 [8.1%]; NR by timing)	**CC 1982 (universal, 100g 2-step; ≥135mg/dL)** at 24-28 wGA, or at initial prenatal visit if ≥ 1 risk factors[a] (and repeated at 24-28 wGA if –ve) (n=126, GDM=7 [5.6%]; NR by timing) 4.2% did not complete OGTT	Treatment for GDM was the same regardless of group allocation; delivery at 39 0/7 to 39 6/7 week was recommended to all women with GDM; medication or insulin G1 4.1% vs G2 3.2% wGA at delivery NR	284; 226
Scifres 2015,[81] U.S. RCT Good	18-45 years old, singleton pregnancy between 18-24 weeks gestational age (wGA) receiving prenatal care at an outpatient obstetrical clinic at a large academic teaching hospital	OGCT >200mg/dL (n=0), pre-existing diabetes mellitus (DM) or +ve screen for DM within 1st trimester (<24 wGA), multiple gestations, corticosteroid use 30 days prior to enrollment, gastric bypass surgery, use of fertility treatments to conceive, plan to deliver at different hospital, inability to complete testing before 30 completed wGA, or anticipated preterm delivery for maternal or fetal indications	**IADPSG 2010 (universal, 75g 1-step)** at 24-28 wGA. (n=24, GDM=1 [4%]) *all patients first given OGCT and if >200mg/dl excluded and not randomized	**CC 1982 (universal, 100g 2-step; OGCT ≥130 mg/dL)** at 24- 28 wGA. (n=23, GDM=0 [0%]) *initial OGCT, if >200mg/dl excluded and not randomized	Treatment for GDM performed according to clinical care standards of each participant's provider; SMBG; first line medication glyburide or insulin (n=0) wGA at delivery G1 39.3 ± 1.1 vs. G2 39.6 ± 1.3	47; 47
Sevket 2014,[82] Turkey RCT Fair (unclear allocation concealment; open label)	Women 24-28 wGA, referred for GDM screening and coming for screening visit	Multiple pregnancies, pre-existing diabetes, fetal anomalies diagnosed prenatally, delivery <28 wGA, those who made errors in protocol	**IADPSG 2010 (universal, 75g 1-step)** at 24-28 wGA. (n=386, GDM=56 [14.5%])	**CC 1982 (universal, 100g 2-step; OGCT ≥140mg/dL)** at 24- 28 wGA. (n=400, GDM=24 [6%])	Treatment for GDM was the same regardless of group allocation; endocrinologists with SMBG, diet, and, if needed, medication; protocol for delivery NR wGA at delivery NR	856; 786 Publication only presents results for non-GDM patients.

Table 4. Summary of Trials Comparing Different GDM Screening Strategies (KQ3)

Author, Year, Country Study Design Quality	Inclusion Criteria	Exclusion Criteria	Screening Strategy 1	Screening Strategy 2	Treatment Differences Gestational Weeks (wGA) at Delivery	# Enrolled; #Analyzed
Sevket 2014, continued.						Saccone et al.[297] obtained missing data by contacting study authors.
Basri 2018,[78] Malaysia Fair (failure to report randomization and allocation methods)	≥1 risk factors[b] for GDM at 14-17 wGA and attending tertiary hospital and referral center	Multiple pregnancies, previously diagnosed type 1 DM or type 2 DM, inability to complete OGTT	**IADPSG 2010 (universal, 75g 1-step, no 1hr value)** <28 wGA. If results were –ve or new risk factor emerged, repeated testing between 28-32 wGA. (n=259, GDM=100 [38.6%])	**WHO 1999 (universal, 75g 1-step; FPG ≥6.1 mmol/L and/or 2 h ≥7.8 mmol/L)** <28 wGA. If results were –ve or new risk factor emerged, repeated testing between 28-32 wGA. (n=261, GDM=99 [37.9%])	Treatment for GDM is the same regardless of group allocation (dietary and SMBG with medication or insulin if blood sugar profile unsatisfactory); insulin use G1 8% vs G2 6.1.1%, oral hypoglycemic medications G1 4% vs G2 4% wGA at delivery NR	520; 502
Harper 2020,[79] U.S. RCT Good (open label but blinded assessment of gestational hypertension and preeclampsia)	Obese (≥30 kg/m^2), non-anomalous, singleton gestations, receiving prenatal care <20 wGA at the university hospital	Pre-existing DM, major medical illness (cardiac disease, HIV, hemoglobinopathy, oxygen requirement), bariatric surgery, prior cesarean section, known fetal anomalies, chronic prednisone use	**Early screening by CC 1982 (universal, 100g 2-step; OGCT ≥135 mg/dL) at 14-20 wGA.** If negative underwent repeat screening at 24-28 wGA. (n=454, GDM=69 [17.8%]) *All had HbA1c at 14-20 wGA and 24-28 wGA with >6.5%=GDM; if 6.2-6.5% underwent 2-step screening for GDM 84.3% received early screening	**Routine screening by CC 1982 (universal, 100g 2-step; OGCT ≥135 mg/dL) at 24-28 wGA.** (n=458, GDM=56 [12.6%]; 1 GDM before 24 wks) *All had HbA1c at 14-20 wGA and 24-28 wGA with >6.5%=GDM; if 6.2-6.5% underwent 2-step screening for GDM 95.9% received screening	Treatment for GDM was the same regardless of group allocation (diabetes educator and SMBG; insulin, glyburide or metformin chosen at discretion of provider if glucose targets not met); insulin G1 2.4% vs G2 0.7%, p=0.03; any diabetic medication G1 6.8% vs G2 4.3%, p=0.34 wGA at delivery G1 36.7 ± 4.5 vs. G2 38.7 ± 1.7	962; 922

Table 4. Summary of Trials Comparing Different GDM Screening Strategies (KQ3)

Abbreviations: CC = Carpenter and Coustan; DM = diabetes mellitus; g = gram(s); GDM = gestational diabetes mellitus; HIV = human immunodeficiency virus; IADPSG = International Association of Diabetes in Pregnancy Study Groups; NDDG = National Diabetes Data Group; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; RCT = randomized controlled trial; SMBG = self-monitoring of blood glucose; wGA = weeks' gestation; WHO = World Health Organization

[a] Risk factors included: ≥30kg/m^2, previous GDM, history of macrosomic baby (>4kg), or polycystic ovarian syndrome.

[b] Risk factors included: history of GDM, first degree relative with DM, BMI >27, age 25 years and above, current obstetric problem, (essential hypertension, pregnancy-induced hypertension, polyhydramnios, current steroid use), previous macrosomic infant (>4kg), previous unexplained stillbirth, fetus with congenital anomaly, persistent glycosuria, recurrent urinary tract infection or vaginal discharge.

Table 5. Effects From Trials Comparing Different GDM Screening Strategies on Pregnancy Outcomes (KQ3)

Outcome	Comparison	Number of Studies	Proportion of Events in Group 1* (or incidence % [95% CI])	Proportion of Events in Group 2 (or incidence % [95% CI])	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference of Significant Findings [95% CI]
Preeclampsia	IADPSG vs CC	3[80-82]	16/520	34/539	0.66 [0.15 to 2.98]; 76%	NA
	Early vs usual timing with CC	1[79]	62/459	44/463	1.42 [0.99 to 2.05]; NA	0.040 [0.00 to 0.081]
Gestational hypertension	IADPSG vs CC	1[82]	57/386	60/400	0.98 [0.70 to 1.38]; NA	NA
	Early vs usual timing with CC	1[79]	74/459	58/463	1.29 [0.94 to 1.77]; NA	NA
Hypertensive disorders of pregnancy	IADPSG vs. WHO 1999	1[78]	14/249	15/253	0.95 [0.47 to 1.92]; NA	NA
	Early vs usual timing with CC	1[79]	136/459	151/463	0.91 [0.75 to 1.10]; NA	NA
Total cesarean deliveries	IADPSG vs CC	2[80,81]	37/134	38/139	1.02 [0.70 to 1.49]; 0%	NA
Primary cesarean deliveries	IADPSG vs CC	2[81,82]	65/410	91/423	0.73 [0.55 to 0.97]; 0%	-0.063 [-0.115 to -0.112]
	IADPSG vs. WHO 1999	1[78]	66/249	64/253	1.05 [0.78 to 1.41]; NA	NA
	Early vs usual timing with CC	1[79]	79/459	93/463	0.86 [0.65 to 1.12]; NA	NA
Induction of Labor	IADPSG vs CC	2[80,81]	55/134	58/139	1.00 [0.76 to 1.32]; 0%	NA
	Early vs usual timing with CC	1[79]	212/454	229/458	0.93 [0.82 to 1.07]	NA
Preterm delivery	IADPSG vs CC	2[80,82]	27/496	42/516	0.75 [0.30 to 1.93]; 72%	NA
	IADPSG vs. WHO 1999	1[78]	16/249	18/253	0.90 [0.47 to 1.73]; NA	NA
Maternal birth trauma	IADPSG vs CC	1[80]	3/110	5/116	0.63 [0.15 to 2.58]; NA	NA
Excessive gestational weight gain	IADPSG vs CC	1[81]	10/24	10/23	0.96 [0.49 to 1.86]; NA	NA

Abbreviations: CC = Carpenter Coustan; IADPSG = International Association of Diabetes in Pregnancy Study Groups; NA = not applicable; NDDG = National Diabetes Data Group; NICU = neonatal intensive care unit; WHO = World Health Organization

Table 6. Effect From Trials Comparing Different GDM Screening Strategies on Fetal/Neonatal Outcomes (KQ3)

Outcome	Comparison	Number of Studies	Proportion of Events in Group 1* (or incidence % [95% CI])	Proportion of Events in Group 2 (or incidence % [95% CI])	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference of Significant Findings [95% CI]
Perinatal mortality	IADPSG vs CC	2[80,82]	2/496	5/516	Peto odds ratio: 0.44 [0.10 to 1.94]; 0%	NA
	IADPSG vs NDDG	1[54]	0.33 [0.22 to 0.51]	0.32 [0.20 to 0.52]	0.63 [0.21 to 1.91] (not adjusted due to few events)	NA
Birth injury	IADPSG vs NDDG	1[54]	3.5 [3.1 to 4.0]	3.2 [2.8 to 3.8]	1.09 [0.79 to 1.49]	NA
Shoulder dystocia	IADPSG vs CC	2[80,81]	1/134	1/139	Peto odds ratio: 1.01 [0.06 to 16.08]; 48%	NA
	IADPSG vs. WHO 1999 (includes birth injury)	1[78]	1/249	0/253	3.05 [0.12 to 74.46]; NA	NA
	Early vs usual timing with CC	1[79]	30/459	32/463	0.96 [0.49 to 1.86];]; NA	NA
Macrosomia > 4000 grams	IADPSG vs CC	3[80-82]	21/520	36/539	0.65 [0.27 to 1.56]; 49%	NA
	Early vs usual timing with CC	1[79]	25/459	21/463	1.20 [0.68 to 2.11]	NA
Large for gestational age	IADPSG vs CC	3	15/520	34/539	0.46 [0.25 to 0.83]; 0%	-0.032 [-0.057 to -0.008]
	IADPSG vs. WHO 1999	1[78]	7/249	3/253	2.37 [0.62 to 9.06]; NA	NA
	Early vs usual timing with CC	1[79]	27/459	26/463	1.05 [0.62 to 1.77]; NA	NA
Neonatal hypoglycemia	IADPSG vs CC	2[80,82]	15/496	31/516	0.52 [0.28 to 0.95]; 0%	-0.027 [-0.05 to -0.005]
	IADPSG vs. WHO 1999	1[78]	3/249	4/253	0.76 [0.17 to 3.37]; NA	NA
	Early vs usual timing with CC	1[79]	22/459	19/463	1.17 [0.64 to 2.13]; NA	NA
Neonatal hyperbilirubinemia	IADPSG vs CC	2[80,82]	32/496	33/516	1.57 [0.31 to 7.82]; 76%	NA
	Early vs usual timing with CC	1[79]	90/459	72/463	1.26 [0.95 to 1.67]; NA	NA
Admission to NICU	IADPSG vs CC	1[82]	18/386	38/400	0.49 [0.29 to 0.84]; NA	-0.037 [-0.079 to -0.006]
APGAR score <7 at 5 minutes	IADPSG vs CC	1[80]	1/110	2/116	0.53 [0.05 to 5.73]; NA	NA

Abbreviations: CC = Carpenter Coustan; IADPSG = International Association of Diabetes in Pregnancy Study Groups; NA = not applicable; NDDG = National Diabetes Data Group; NICU = neonatal intensive care unit; WHO = World Health Organization

*Peto odds ratio was used when pooling studies with very rare or no events.

Table 7. Joint Estimates of Sensitivity and Specificity of GDM Screening Tests From Pooled Analyses (KQ4)

Criteria	Index Test and Cutoff	Timing of Index Test (Weeks' GA)	Sensitivity (95% CI)	Specificity (95% CI)
CC	50 g OGCT 135 mg/dL	24-28	93 (24 to 100)	79 (53 to 93)
	50 g OGCT 140 mg/dL	21-28 (most 24-28)	82 (68 to 90)	82 (71 to 89)
	FPG 79 mg/dL	24-28	96 (92 to 98)	35 (30 to 41)
	FPG 85 mg/dL	22-28	88 (84 to 91)	73 (46 to 90)
	FPG 90 mg/dL	22-28	81 (75 to 85)	82 (61 to 93)
	FPG 95.5 mg/dL	24-28	58 (32 to 81)	98 (88 to 100)
NDDG	50 g OGCT 140 mg/dL	24-28	85 (72 to 93)	81 (76 to 86)
IADPSG	FPG 90 mg/dL	24-28	79 (65 to 89)	96 (95 to 97)

Abbreviations: CC=Carpenter and Coustan; CI=confidence interval; FPG=fasting plasma glucose; GA=gestational age; IADPSG= International Association of Diabetes and Pregnancy Study Groups; NDDG=National Diabetes Data Group; OGCT=oral glucose challenge test

Table 8. Evidence on Accuracy of Risk Factor Screening for GDM (KQ4)

Diagnostic Criteria	Author, Year Country	Risk-Factor Based Index Test	Timing of Index & Timing of OGTT (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
CC	Ayach, 2006[90] Brazil	FPG ≥ 90 mg/dL and/or ≥ 1 risk factor (age ≥ 30 years, pre-gestational BMI ≥ 27 kg/m^2, previous gestational diabetes, family history of DM, macrosomia, fetal death with no apparent cause, recurrent miscarriages and malformation) **Validating:** Rudge & De Luca (1981-1994)	Risk factors and/or FPG: <20 or 24-28 OGTT: 24-28	341	3.8	84.6	47.3	48.7
NDDG 1979	Naylor, 1997[36] Canada	OGCT + clinical risk factors: age (≤30: 0 points, 31-34: 1 point, ≥35: 2 points), BMI (≤ 22: 0 points, 22.1-25.0: 2 points, ≥ 25.1: 3 points), race (white: 0 points, Black: 0 points, Asian: 5 points, Other: 2 points) + OGCT (≥128, 130, or 140 mg/dL by clinical risk score) Scores 0 and 1 are not screened with OGCT. Strategy A used a risk score of 2-3 and a 50g OGCT cutoff of ≥140 mg/dl or a score above 3 and a 50g OGCT cutoff at ≥128 mg/dl to predict GDM Strategy B used the same 50g OGCT threshold for a risk score of 2-3 but for those with a score above 3 the 50g OGCT cutoff was ≥130 mg/dl. **Validating:** model developed within the study	OGCT + risk factors: 25-27 OGTT: 27-29	1571	4.4	Strategy A: 82.6 Strategy B: 81.2	Strategy A: 80.3 Strategy B: 80.9	Strategy A: 84.0 Strategy B: 84.9
IADPSG	Gobl, 2012[98] Austria	Risk model (0.2 cut-off with FPG <5.1 mmol/L), incorporating: history of GDM, glycosuria, age, relative with type 2 DM, preconception dyslipidemia, ethnicity, FPG **Validating**: development cohort model within study	Risk factors: 1st visit OGTT: ≥ 24 (indicates allows for Dx <24 wGA but #s NR)	258	22.9 (29/59 by FPG; 30/59 by FPG <5.1 and risk model at 0.2 cut-off)	98.3	16.6	35.3

Abbreviations: CC = Carpenter Coustan; CDA = Canadian Diabetes Association; DM = diabetes mellitus; FPG = fasting plasma glucose; GDM = gestational diabetes; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NA = not applicable; NR = not reported; NDDG = National Diabetes Data Group; OAV = one abnormal value; OGTT = oral glucose tolerance test

Table 9. Evidence From Observational Studies on the Association Between a Diagnosis of GDM and Pregnancy Outcomes in Women Meeting More But Not Less Inclusive Diagnostic Criteria (KQ5)

Outcome	Comparison	Number of Studies	Inclusive GDM Group (events/N)	NGT Group (events/N)	Relative Risk [95% CI]; I^2	Absolute Risk Difference of Significant Findings [95% CI]
Preeclampsia	OAV (CC) vs NGT	1[198]	18/395	20/790	1.80 [0.96 to 3.36]; NA	NA
	OAV (NDDG) vs NGT	3[192,202,214]	8/264	46/2335 (Data and numbers per group were not provided by one study (n=3,637)[214]	OR 1.65 [1.09 to 2.50]; 0% (RR 1.62 [1.09 to 2.41])	0.015 [0.002 to 0.039]
	IADPSG (excluding CC) vs NGT	7[190,200,203,207,209,215,218]	185/1961	829/22198	1.93 [1.34 to 2.77]; 69%	0.0328 [-0.0044 to 0.0700]
Gestational hypertension	OAV (CC) vs NGT	1[198]	13/395	32/790	0.88 [0.47 to 1.62]; NA	NA
	IADPSG (excluding CC) vs NGT	3[190,207,209]	21/554	304/8442	1.01 [0.45 to 2.24]; 61%	NA
	IADPSG (excluding NDDG) vs NGT	1[219]	52/1175	749/21629	1.28 [0.97 to 1.68]; NA	NA
Hypertensive disorders of pregnancy	OAV (CC) vs NGT	5[194,201,205,216,217]	95/904	391/9458	2.09 [1.53 to 2.86]; 40%	0.050 [0.030 to 0.070]
	OAV (NDDG) vs NGT	1[217]	17/225	210/6992	2.52 [1.56 to 4.05]; NA	0.046 [0.019 to 0.080]
	IADPSG (excluding CC) vs NGT	4[195,197,204,209]	101/1133	1200/16357	1.15 [0.93 to 1.41]; 0%	NA
Total cesarean deliveries	OAV (CC) vs NGT	10[189,193,194,198,206,210,211,213,216,217]	525/1312	5308/17343	1.29 [1.13 to 1.47]; 52%	0.078 [0.034 to 0.123]
	OAV (NDDG) vs NGT	4[192,202,214,217]	217/489	3399/9327 (Data and numbers per group were not provided by one study (n=3,637)[214]	OR 1.48 [1.27 to 1.72]; 0% (RR 1.28 [1.17 to 1.39)	0.092 [0.056 to 0.129]
	IADPSG (excluding CC) vs NGT	6[190,204,207-209,215]	532/1153	7004/19084	1.20 [1.05 to 1.38]; 77%	0.0695 [0.0131 to 0.1258]
	IADPSG (excluding NDDG) vs NGT	1[219]	732/1175	10689/21629	1.26 [1.20 to 1.32]; NA	0.129 [0.100 to 0.157]
	OAV (CC) vs NGT	1[201]	30/80	218/880	1.51 [1.12, 2.05]; NA	0.127 [0.017 to 0.237]

Table 9. Evidence From Observational Studies on the Association Between a Diagnosis of GDM and Pregnancy Outcomes in Women Meeting More But Not Less Inclusive Diagnostic Criteria (KQ5)

Outcome	Comparison	Number of Studies	Inclusive GDM Group (events/N)	NGT Group (events/N)	Relative Risk [95% CI]; I^2	Absolute Risk Difference of Significant Findings [95% CI]
Primary cesarean deliveries	IADPSG (excluding CC) vs NGT	5[195,197,200,203,218]	433/1707	4591/21687	1.10 [0.91, 1.34]; 77%	NA
	IADPSG (excluding CC) vs NGT *(adjusted)*	4[195,200,203,218]	1426	13916	aOR 0.94 [0.69 to 1.28]; 73%	NA
Induction of Labor	OAV (CC) vs NGT	1[189]	0/32	1/277	2.81 [0.12 to 67.54]; NA	NA
	IADPSG (excluding CC) vs NGT	3[200,203,204]	93/906	648/6809	1.13 [0.93 to 1.39]; 0%	NA
Preterm delivery	OAV (CC) vs NGT	6[198,201,210,211,216,217]	97/1023	760/10888	1.42 [1.14 to 1.77]; 0%	0.018 [-0.032 to 0.068]
	OAV (NDDG) vs NGT	3[192,202,217]	32/489	534/9327	1.37 [0.97 to 1.94]; 0%	0.012 [-0.0043 to 0.029]
	IADPSG (excluding CC) vs NGT	9[190,195,200,203,204,208,209,215,218]	220/2617	3322/31764	1.19 [0.97 to 1.46]; 45%	0.0076 [-0.0084 to 0.0236]
	IADPSG (excluding CC) vs NGT *(adjusted)*	5[195,200,203,208,218]	1628	16474	aOR 1.43 [1.16 to 1.75]; 0%	NA
Maternal birth trauma	OAV (CC) vs NGT	1[217]	289	5971	aOR 1.01 [0.49 to 2.08]; NA	NA
	OAV (NDDG) vs NGT	1[217]	225	5971	aOR 1.61 [0.80 to 3.24]; NA	NA
	IADPSG (excluding CC) vs NGT	4[195,197,200,208]	27/900	522/17885	1.19 [0.81 to 1.76]; 0%	NA
Excessive gestational weight gain	IADPSG (excluding CC) vs NGT	1[195]	63/181	1748/5485	1.09 [0.89 to 1.34]; NA	NA

Abbreviations: aOR = adjusted odds ratio; CC = Carpenter Coustan; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NA = not applicable; NGT = normal glucose tolerance; NDDG = National Diabetes Data Group; OAV = one abnormal value; OGCT = oral glucose challenge test

Table 10. Evidence From Observational Studies on the Association Between a Diagnosis of GDM and Fetal/Neonatal Outcomes in Women Meeting More But Not Less Inclusive Diagnostic Criteria (KQ5)

Outcome	Comparison	Number of Studies	Inclusive GDM Group (events/N)	NGT Group (events/N)	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference of Significant Findings [95% CI]
Mortality	All studies	8[193,197,198,200-202,216,219]	13/2629	148/39674	1.66 [0.93 to 2.95]; 0%	NA
Birth injury	OAV (NDDG) vs NGT	1[214]	3,637		OR 1.10 [0.60 to 2.02]; NA (RR not estimable)	NA
Shoulder dystocia	OAV (CC) vs NGT	5[189,198,201,205,216]	10/890	26/3131	1.55 [0.60 to 3.98]; 28%	NA
	OAV (NDDG) vs NGT	1[217]	225	5971	aOR 2.21 [0.51 to 9.58]; NA	NA
	IADPSG (excluding CC) vs NGT	4[190,195,197,208]	14/674	269/22078	1.79 [1.02 to 3.15]; 9%	0.0054 [-0.0083 to 0.0191]
	IADPSG (excluding CC) vs NGT*(adjusted)*	1[195]	181	5485	aOR [1.29 [0.40 to 4.19]; NA	NA
Macrosomia (>4000g)	OAV (CC) vs NGT	10[189,193,194,198,199,201,206,210,216,217]	125/1564	1697/26522	1.47 [1.16 to 1.87]; 18%	0.026 [-0.008 to 0.059]
	OAV (NDDG) vs NGT	4[191,192,214,217]	454	9323 (Events and numbers per group were not provided by one study (n=3,637)[214]	OR 1.85 [1.44 to 2.38]; 3.2% (RR 1.76 [1.40 to 2.19])	0.048 [0.025 to 0.074]
	IADPSG (excluding CC) vs NGT	8[190,195,197,203,207-209,215]	127/1357	2156/31359	1.70 [1.35 to 2.14]; 37%	0.0357 [0.0099 to 0.0614]
	IADPSG (excluding CC) vs NGT *(adjusted)*	3[195,203,208]	364	8758	aOR 2.21 [1.49 to 3.29]; 0%	NA
	IADPSG (not NDDG) vs NGT	1[219]	170/1151	1428/21286	2.20 [1.90 to 2.55]; NA	0.081 [0.060 to 0.101]; NA
Large for gestational age	OAV (CC) vs NGT	8[189,193,198,201,205,206,213,216]	152/1075	506/9562	1.64 [1.25 to 2.15]; 49%	0.047 [0.018 to 0.076]
	OAV (NDDG) vs NGT	3[191,192,202]	52/351	266/2908	1.68 [1.28 to 2.21]; 0%	0.053 [-0.0013 to 0.106]
	IADPSG (excluding CC) vs NGT	10[190,195,197,200,203,204,207-209,218]	435/2851	3465/35987	1.69 [1.42 to 2.01]; 64%	0.0595 [0.0337 to 0.0853]
	IADPSG (excluding CC) vs NGT *(adjusted)*	6[195,200,203,204,208,218]	2016	18605	aOR 1.73 [1.41 to 2.11]; 42%	NA

Table 10. Evidence From Observational Studies on the Association Between a Diagnosis of GDM and Fetal/Neonatal Outcomes in Women Meeting More But Not Less Inclusive Diagnostic Criteria (KQ5)

Outcome	Comparison	Number of Studies	Inclusive GDM Group (events/N)	NGT Group (events/N)	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference of Significant Findings [95% CI]
NICU admissions	OAV (CC) vs NGT	5[198,201,210,216,217]	47/958	634/10795	1.15 [0.84 to 1.57]; 0%	NA
	OAV (NDDG) vs NGT	1[217]	19/225	477/6992	1.24 [0.80 to 1.92]; NA	NA
	IADPSG (excluding CC) vs NGT	6[190,197,200,203,208,218]	145/1885	2083/25589	1.17 [0.99 to 1.38]; 0%	0.0091 [-0.0031 to 0.0214]
	IADPSG (excluding CC) vs NGT *(adjusted)*	4[200,203,208,218]	1444	10975	aOR 1.02 [0.81 to 1.28]; 0%	NA
Respiratory distress syndrome	OAV (CC) vs NGT	3[189,198,216]	4/558	10/1175	0.65 [0.18 to 2.35]; 0%	NA
	OAV (NDDG) vs NGT	1[202]	11/122	25/577	2.00 [1.02 to 3.94]	0.045 [-0.0085 to 0.099]
Hypoglycemia	OAV (CC) vs NGT	7[189,193,194,198,201,213,216]	76/927	331/8651	1.61 [1.20 to 2.15]; 0%	0.019 [0.0022 to 0.040]
	OAV (NDDG) vs NGT	2[192,202]	7/264	11/2335	6.64 [2.52 to 17.49]; 0% One study (n=3637): no association found for IV for hypoglycemia (data NR)[214]	0.020 [0.002 to 0.038]
	IADPSG (excluding CC) vs NGT	3[200,203,218]	37/1392	91/8996	2.51 [1.72 to 3.68]; 0%	0.016 [0.0072 to 0.025]
	IADPSG (excluding NDDG) vs NGT	1[219]	30/1175	254/21629	2.17 [1.50 to 3.15]; NA	0.014 [0.005 to 0.023]
Hyperbilirubinemia	OAV (CC) vs NGT	4[193,198,201,216]	137/665	388/7545	1.21 [1.02 to 1.45]; 0%	NA
	OAV (NDDG) vs NGT	2[192,214]	142	1758 (Events were not provided by one study (n=3,637)[214]	OR 2.04 [1.47 to 2.84]; 0% (RR 1.97 [1.45 to 2.68])	0.031 [0.014 to 0.054]
	IADPSG (excluding CC) vs NGT	4[200,203,208,218]	140/1444	1513/11473	1.32 [1.13 to 1.54]; 0%	0.0213 [-0.0040 to 0.0467]
APGAR score <7 at 1 minute	OAV (CC) vs NGT	1[198] 1[216]	12/395 6/131	22/790 0/108	1.09 [0.55 to 2.18]; NA 10.73 [0.61 to 88.43]; NA	NA
	OAV (NDDG) vs NGT	1[202]	6/122	12/577	2.36 [0.91 to 6.18]; NA	NA
	IADPSG (excluding CC) vs NGT	2[197,208]	26/333	676/10248	1.11 [0.76 to 1.62]; 0%	NA
APGAR score <7 at 5 minutes	OAV (CC) vs NGT	3[198,201,216]	8/606	31/1778	1.63 [0.70 to 3.83]; 0%	NA
	OAV (NDDG) vs NGT	1[202]	4/122	5/577	3.78 [1.03 to 13.89]; NA	0.024 [-0.0084 to 0.057]
	IADPSG (excluding CC) vs NGT	3[190,197,208]	5/493	223/16593	0.97 [0.30 to 3.11]; 29%	NA

Abbreviations: aOR = adjusted odds ratio; CC = Carpenter Coustan; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NA = not applicable; NGT = normal glucose tolerance; NDDG = National Diabetes Data Group; OAV = one abnormal value; OGCT = oral glucose challenge test

Table 11. Evidence From Observational Studies on the Association Between a Diagnosis of GDM and Long-term Outcomes in Women Meeting More But Not Less Inclusive Diagnostic Criteria (KQ5)

Outcome	Comparison	Number of Studies	Number of Patients (n/N)		Relative Risk [95% CI]	Absolute Risk Difference for Significant Findings [95% CI]
			Experimental	Control		
Childhood overweight (>85th percentile) - 5-7 years	OAV (CC) vs NGT	1[199]	77/288	2021/8608	1.14 [0.94 to 1.38]	NA
	OAV (CC) vs NGT	1[199]	288	6071	aOR 1.37 [1.01 to 1.86]	NA
Childhood overweight (85th - <95th percentile) - 13 years	OAV (CC) vs NGT	1[196]	2/36	137/1009	0.51 [0.13 to 2.00]	NA
Childhood obesity (>95th percentile) - 5-7 years	OAV (CC) vs NGT	1[199]	44/288	1056/8608	1.25 [0.94 to 1.64]	NA
	OAV (CC) vs NGT	1[199]	288	6071	aOR 1.30 [0.89 to 1.90]	NA
Childhood obsity (>85th percentile) - 13 years	OAV (CC) vs NGT	1 [196]	4/36	109/1009	1.03 [0.40 to 2.64]	NA
Maternal development of type 2 diabetes	OAV (NDDG) vs NGT	1[212]	3/91	0/259	19.78 [1.03 to 379.34]	0.033 [-0.0065 to 0.0724]
Maternal development of Impaired glucose tolerance or diabetes	OAV (NDDG) vs NGT	1[212]	15/91	20/259	2.13 [1.14 to 3.99]	0.0876 [0.0047 to 0.1705]
	OAV (NDDG) vs NGT (*adjusted)*	1[212]	91	93	aOR 5.70 [1.60 to 20.31]	NA
Maternal development of metabolic syndrome (IDF)**	OAV (NDDG) vs NGT	1[220]	16/91	26/259	1.75 [0.99 to 3.11]	NA
	OAV (NDDG) vs NGT *(adjusted)*	1[220]	91	259	aOR 2.16 [1.05 to 4.44]	NA
Maternal development of metabolic syndrome (AHA/NHLBI)**	OAV (NDDG) vs NGT	1[220]	14/91	23/259	1.73 [0.93 to 3.22]	NA

Abbreviations: aOR = adjusted odds ratio; CC = Carpenter Coustan; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NA = not applicable; NGT = normal glucose tolerance; NDDG = National Diabetes Data Group; OAV = one abnormal value; OGCT = oral glucose challenge test

*Bulleted lines are for sensitivity analysis: i) removing countries not classified as Very High Development Index countries (Wang 2013, Heethcuay 2017, Shang 2014, Hirst 2012, and Wei 2014),[198,200,215,217,219] ii) only using blinded studies (Landon 2011, Sermer 1995, Waters 2016, Chico 2005, Rust 1996, Vambergue 2000);[193,205,213,214,216,218] removing studies that did not define hypoglycemia (Arbib 2017, Heetchuay 2017, Kaymak 2011, Landon 2011, Rust 1996, Wei 2014),[189,198,201,205,213,219] and removing Arbib 2017[189] which applied screening in the third trimester after women screened negative at 24-28 weeks.

**AHA/NHLBI metabolic syndrome is defined as the presence of three or more of the following five disorders: 1) waist circumference of at least 88 cm; 2) serum triglycerides of at least 1.7 mmol/liter or drug treatment for hypertriglyceridemia; 3) HDL cholesterol below 1.29 mmol/liter or drug treatment for low HDL; 4) elevated blood pressure, defined as blood pressure of at least 130/85 mm Hg or use of antihypertensive drug treatment in a patient with a history of hypertension; and 5) dysglycemia, defined as fasting glucose of at least 5.6 mmol/liter or previously diagnosed diabetes or use of drug treatment for hyperglycemia. The IDF definition of metabolic syndrome in women differs from the AHA/NHLBI version in that it requires the presence of waist circumference of at least 80 cm (≥90 cm in Japanese women), accompanied by at least two of the other four disorders (elevated triglycerides, low HDL, hypertension, dysglycemia; all defined in the same way as per AHA/NHLBI criteria.

Table 12. Summary of Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later (KQs 6 and 7)

Author, Year, Country Quality	# Randomized # Analyzed	Age (years; mean ± SD) BMI (kg/m^2; mean ± SD)	Glycemic Status at Enrollment (mean ± SD), mg/dl or %	Ethnicity Majority	Inclusion Criteria (level of glycemia and others as relevant)	Timing of Randomization Intervention Components Insulin Requirements Gestational Age at Birth
Bevier, 1999[221] U.S. Fair (no blinding and 19.5% IOD)	103 83 (35 vs 48)	G1: 26.3 ± 6.0 G2: 27.4 ± 5.4 Weight (kg) G1: 68.2 ± 11.4 G2: 72.4 ± 12.0	G1: HbA1c at 28 wGA (%): 4.7 ± 0.6 G2: HbA1c at 32 wGA (%): 4.7 ± 0.7	94% Hispanic	OGCT+ve and OGTT-ve on OGTT by O'Sullivan and Mahan criteria *No hypertension, history of preterm delivery or SGA	24-28 wGA G1: Diet, SMBG, and insulin if needed; RBG weekly and HbA1 testing at 28 and 32 wks G2: Regular RBG with insulin if needed; HbA1c testing at 28 and 32 wks; repeat OGTT at 30-32 wks G1: Insulin 1/35 vs. G2: 4/48 G1: 39.6 ± 1.3 vs G2: 39.4 ± 1.5 wks
Bonomo, 2005[222] Italy Fair (no blinding)	300 300 (150 vs 150; replaced 21)	G1: 31.1 ± 4.7 G2: 30.7 ± 5.1 G1: 23.1 ± 4.4 G2: 23.0 ± 4.5	OGCT: 8.44 ± 0.89 mmol/L Fasting: 84.7 ± 9.0 HbA1C: 4.9 ± 0.5%	100% Caucasian	OGCT+ve and OGTT-ve on CC (OAV excluded)	At booking for those with risk factors; 24-28 wGA for those without risk factors; repeated at 30-34 wGA for those –ve on OGTT which excluded 15 after randomization G1: Diet, SMBG, biweekly blood work including FPG and HbA1C G2: reassured and no extra management Medication NR G1: 39.4 ± 1.2 vs G2: 39.6 ± 1.7 wks
Deveer, 2013[226] Turkey Fair but considering CCT (no blinding or allocation concealment; inadequate sequence generation)	100 100 (50 vs. 50)	G1: 29.5 ± 5.8 G2: 31.2 ± 5.6 G1: 28.0 ± 3.6 G2: 29.1 ± 4.8	OGCT: 153.2 ± 28.8	NR	OGCT+ve and OGTT-ve *No history of T2DM or GDM, or stillbirth	24- 28 wGA G1: Diet G2: No additional management Medication NR G1: 38.7 ± 1.2 vs. G2: 38.9 ± 1.1 wks
Crowther, 2005[41] Australia Good (Fair for 4-5 yr followup in Gillman 2010 due to n=199)	1000 1000 (490 vs. 510; 506 vs 524 infants)	G1: 30.9 ± 5.4 G2: 30.1 ± 5.5 G1: 26.8 (23.3–31.2) G2: 26.0 (22.9–30.9)	Fasting: 86.5 ± 12.6 2hr: 153.2 ± 14.4	75.2% Caucasian	≥1 risk factors for GDM on selective screen or OGCT+ve, and OGTT at 24-34 wGA with fasting <140mg/dl and 2h 140-198 mg/dl *Excluded those with a history of GDM; did not excluded twins	24-34 wGA G1: Diet, SMBG QID, insulin as needed G2: Routine care with OGTT if indications (at provider discretion) G1: 20% insulin vs. G2 3% G2: 39.0 (IQR 38.1-40) vs G2: 39.3 (IQR 38.3-40.4) wks; p=0.01

Table 12. Summary of Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later (KQs 6 and 7)

Author, Year, Country Quality	# Randomized # Analyzed	Age (years; mean ± SD) BMI (kg/m^2; mean ± SD)	Glycemic Status at Enrollment (mean ± SD), mg/dl or %	Ethnicity Majority	Inclusion Criteria (level of glycemia and others as relevant)	Timing of Randomization Intervention Components Insulin Requirements Gestational Age at Birth
Fadl, 2015[227] Sweden Good (Fair for outcomes with potential SOR [shoulder dystocia, neonatal hypoglycemia, preterm deliveries])	72 69 (33 vs. 36 [34 with exclusion of early miscarriage])	G1: 32.6 ± 5.9 G2: 30.6 ± 5.5 (62% obese) G1: 31.3 ± 6.4 G2: 32.6 ± 5.9	OGTT results (mg/dl): G1: fasting 102.7 ± 10.8; 2h 191.0 ± 9.7 G2: fasting 102.7 ± 12.6; 2h 192.8 ± 9.0 (capillary blood)	71% Nordic	OGTT before 34 wGA (criteria 1+ risk factor or RBG >9.0mmol/L); 75g capillary OGTT: fasting <126 mg/dlL or 2hr value ≥180 to <220 mg/dl	If early RBG >9 mmol/L, then given early OGTT (n=NR), if normal RBG then OGTT done at 28-32 wGA G1: Diet, SMBG QID, insulin as needed G2: Routine care G1: 67% insulin vs.G2 NR G1: 275 (range 258-288) vs G2: 273 (221-209) days
Kokanali, 2014[229] Turkey Fair (blinding NR, allocation concealment NR)	201 201 (99 vs 102)	At delivery G1: 27.9 ± 5.8 G2: 27.9 ± 5.8 Pre-gestational: G1: 26.4 ± 2.7 G2: 26.7 ± 3.45	NR	NR	OGCT+ve and one abnormal value (OAV) on CC	24-28 wGA G1: Diet therapy with dietician, SBMG (details NR), insulin as needed G2: Routine care G1 NR insulin vs G2 NR G1: 269.1 ± 12.5 vs G2: 286.8 ± 13.4 days
Landon, 2009[42] U.S. Good* (Good for subgroup analysis for timing of treatment initiation[237] and level of glycemia[236], but fair for subgroups on BMI[235] and race/ethnicity[234] and long-term followup[238,239])	958 (485 vs. 473) 931 for most except hypoglycemia [n=738; 77%])	G1: 29.2 ± 5.7 G2: 28.9 ± 5.6 G1: 30.1 ± 5.0 vs. G2: 30.2 ± 5.1	G1: FPG 86.6 ± 5.7; 1h 191.8 ± 21.9; 2h 173.7 ± 21.8; 3h 137.3 ± 29.0 G2: FPG 86.3 ± 5.7; 1h 193.4 ± 19.3; 2h 173.3 ± 19.6; 3h 134.1 ± 31.5	57% Hispanic	Between 24-31 wGA; >135 on OGCT; FPG <95 mg/dL and 2 or 3 abnormal on CC OGTT *Excluded women with chronic hypertension, previous GDM, stillbirth	24-31 (mean 28.8 ± 1.6 wGA) G1: Diet, SMBG, insulin as needed (50% or greater of fasting or postprandial levels elevated) G2: Routine care, RPG at provider discretion G1: 7.6% insulin vs. G1 0.4% G1: 39.0 ± 1.8 vs. G2: 38.9 ± 1.8 wks
Garner, 1997[223] Canada Fair (insufficient blinding of patients)	300 299 (149 vs. 150)	G1: 30.7 ± 4.8 G2: 30.7 ± 4.6 Pre-pregnancy weight (kg) G1: 68.9 ± 16.9 G2: 71.2 ± 19.8	75g OGCT (mg/dl): 182.0 ± 28.8	91% Caucasian	+ve 75g OGCT and GDM criteria (FPG 4.8 mmol/ l, 1-h 10.9 mmol/ l and 2-h 9.6 mmol/l [number abnormal NR])	24-32 wGA G1: Tertiary care center follow up with obstetrician and endocrinologist; Diet, daily SMBG, biweekly fetal monitoring, insulin as needed [13 (7.8%) met T2DM criteria]

Table 12. Summary of Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later (KQs 6 and 7)

Author, Year, Country Quality	# Randomized # Analyzed	Age (years; mean ± SD) BMI (kg/m^2; mean ± SD)	Glycemic Status at Enrollment (mean ± SD), mg/dl or %	Ethnicity Majority	Inclusion Criteria (level of glycemia and others as relevant)	Timing of Randomization Intervention Components Insulin Requirements Gestational Age at Birth
Garner 1997, continued. Fair for 7-11 Year followup[241]					diagnosed between 24–32 wGA; otherwise low-risk pregnancy *Excluded women with chronic hypertension	G2: Primary care provider; twice weekly SMBG (results sent to independent observer); no fetal monitoring unless indicated [16 (10.6%) women meeting T2DM criteria were given treatment] G1: 24% insulin vs. G2 NR but 10.6% T2DM Gestational age NR
Yang, 2014[233] China Fair (unclear sequence generation; no blinding or patients or providers)	948 (130 vs 112 excluded from break in protocol from renovations) 700 (361 vs. 339)	G1: 29.9 ± 3.5 G2: 29.7 ± 3.2 Pre-pregnancy BMI: G1: 22.9 ± 3.6 G2: 23.4 ± 3.9	OGTT results (mg/dl): G1: fasting 91.9 ± 10.8; 1h 182.0 ± 25.2; 2h 151.4 ± 21.6 G2: fasting 90.1 ± 9.0; 1h 180.2 ± 23.4; 2h 151.4 ± 25.2	97% Han Chinese	GDM diagnosed with 2-step IADPSG 2010 criteria (with 50g OGCT)(not meeting T2DM criteria using FPG and HbA1c) *Excluded those with chronic hypertension	24-29 wks; mean 26.3 ± 1.4 wGA G1: Shared care system (primary care hospital then obstetric hospitals) with team of nurses and doctors; diet, physical activity, SMBG G2: One hospital-based education session by diabetes educator (diet and physical activity but no SMBG); insulin if HbA1c >6.5% at 34 wks G1: 1.2% insulin vs G2: 0.3% G1: 39.2 ± 2.1 vs. G2: 39.4 ± 2.9; p=0.24

Abbreviations: BMI = body mass index; CC = Carpenter Coustan; CCT = controlled clinical trial; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; IQR = interquartile range; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; QID = quater in die (four times daily); RBG = random blood glucose; SD = standard deviation; SMBG = self-monitoring blood glucose; SOR = selective outcome reporting; T2DM = type 2 diabetes mellitus; wGA = weeks' gestation; wk(s) = week(s); yr(s) = year(s)

Table 13. Summary of Trials of Treatment vs. No Treatment for GDM in Early Pregnancy (KQs 6 and 7)

Author, Year, Country Quality (concerns)	# Randomized # Analyzed	Age (years; mean ± SD) BMI (kg/m^2; mean ± SD) (unless stated otherwise)	Glycemic Status at Enrollment (mean ± SD), mg/dl or %	Ethnicity majority	Inclusion criteria (Level of glycemia and others as relevant)	Timing of Randomization Intervention Components Insulin Requirements Gestational Age at Birth
Hughes, 2018[228] New Zealand Fair (unclear for baseline imbalances; no blinding)	47 44 (23 vs. 21)	Age at expected delivery date: G1: 30.5 (28.0-34.5) G2: 32.0 (29.5-36.0) BMI at baseline: G1: 29.6 (24.1-35.6) G2: 30.3 (27.1-38.4)	HbA1c at booking: G1: 42 (41-45) G2: 42 (41-45) (6.0% ± 2.4%)	51% Asian	HbA1c 5.9%-6.4% (41-46 mmol/mol) at booking	<14 wGA G1: Diabetes clinic and lead maternity carer (midwife or obstetrician): ongoing lifestyle education, daily SMBG (before and after each meal), and medication as required (metformin and/or insulin) G2: Standard care with lead maternity caregiver and 75g OGTT screening at 24 wGA (IADPSG or New Zealand criteria: FBG ≥5.5 mmol/L [99 mg/dL]) or 2hr BG ≥9.0 mmol/L [162 mg/dL]), with referral if GDM G1: 17/23 (metformin in 14 and insulin in 15 women)[all before 24 wks] vs G2: 11/22 (metformin in 3 and insulin in 11 women) Gestational age NR
Osmundson, 2016[230] U.S. Fair (no blinding, significant loss to followup, and some possible selective outcome reporting)	95 (50 vs 45) 83 (42 vs 41) 74 with delivery data (37 vs 37)	G1: 32.4 ± 5.1 G2: 34.3 ± 5.2 Pre-pregnancy BMI: G1: 27.2 (24.8-33.2) G2: 27.4 (22.6-32.7)	HbA1c (%) G1: 5.8 (5.7-5.9) G2: 5.8 (5.7-5.9)	45% Hispanic; 37% Asian	HbA1c 5.7-6.4% before 14 wGA *Excluded women with a prior infant with birth injury or shoulder dystocia possibly attributable to diabetes, or prior macrosomic infant	<14 wGA (mean 11.1 wks) G1: Diet with Certified Diabetes Educator, SMBG QID, insulin as needed; OGTT at 26-28 wks with negatives continuing dietary but reduced SMBG G2: Routine prenatal care with screening OGTT at 26-28 wks G1: 35.9% insulin vs. G2: 26.3% G1: 38.3 ± 2.3 vs. G2: 38.2 ± 2.0 wks
Simmons, 2018[231] New Zealand Good	21 20 (11 vs 9)	G1: 29 ± 5 G2: 30 ± 7 G1: 32.3 ± 7.8 G2: 33 ± 7.0	Early (<20wGA) OGTT results (mmol/L): G1: fasting 91.9 ± 7.2; 1h 144.1 ± 30.6; 2h 126.1 ± 34.2 G2: fasting 93.7 ± 5.4; 1h 151.4 ± 28.8; 2h 122.5 ± 30.6	55% Caucasian	With risk factors and GDM on 75g OGTT by IADPSG criteria, <20wGA	4-20 wGA G1: Education, diet, SMBG, metformin or insulin as needed G2: Routine prenatal care, with screening at 24-28 wGA G1: 36% insulin or metformin vs. G2: 40% G1: 38.7 ± 1.4 vs G2: 39.2 ± 0.6 wks

Table 13. Summary of Trials of Treatment vs. No Treatment for GDM in Early Pregnancy (KQs 6 and 7)

Author, Year, Country Quality (concerns)	# Randomized # Analyzed	Age (years; mean ± SD) BMI (kg/m^2; mean ± SD) (unless stated otherwise)	Glycemic Status at Enrollment (mean ± SD), mg/dl or %	Ethnicity majority	Inclusion criteria (Level of glycemia and others as relevant)	Timing of Randomization Intervention Components Insulin Requirements Gestational Age at Birth
Vinter, 2018[232] Denmark CCT (subgroup analysis of GDM prevention RCT) Fair (not randomized)	90 90 (36 vs 54)	29.0 ± 4.4 34.5 ± 4.3 (pre-pregnancy or 1st trimester)	Venous fasting: 93.7 ± 3.6 Capillary 2hr: 117.1 ± 19.8 (1st trimester)	100% Caucasian	BMI 30-40 kg/m^2 (pre-pregnancy or 1st measured weight in pregnancy); diagnosed retrospectively with GDM by modified WHO 2013 criteria in early pregnancy (12-15 wGA; (venous FPG ≥5.1 mmol/L and/or 2h capillary ≥8.5 mmol/L), but not meeting Danish criteria for GDM (2h capillary ≥9.0 mmol/L) at any time (12-15, 28-30 or 34-36 wGA)	12-15 wGA G1: Lifestyle intervention: 4 diet counseling sessions with a trained dietician, encouraged to perform 30-60 min daily exercise with a free full membership to a fitness center for 6 months until delivery (included closed exercise classes with a physiotherapist 1h weekly); no SMBG or insulin assessment per protocol G2: Routine care Both groups were monitored with fasting blood samples, OGTTs, sonographic fetal biometry, and measurements of maternal weight and blood pressure G1: NR vs G2: NR (unlikely) G1: 40 (39-41.3) vs G1: 40.7 (39-41.3)

Abbreviations: BMI = body mass index; CCT = controlled clinical trial; CC = Carpenter Coustan; G = group; FPG = fasting plasma glucose; GDM = gestational diabetes mellitus; IQR = interquartile range; OAV = one abnormal value; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; NR = not reported; QID = quarter in die (i.e. four times daily); RBG = random blood glucose; SGA = small for gestational age; SMBG = self-monitoring blood glucose; T2DM = type 2 diabetes mellitus; wk(s) = week(s); wGA = weeks' gestation; yr(s) = year(s)

Table 14. Effects From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later on Pregnancy Outcomes (KQ6)

Outcome	Analysis	Number of Trials with Events	Number of Events/ Treated	Number of Events/ Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference of Significant Findings [95% CI]
Preeclampsia	All studies	6[42,221,226,227,229,233]	42/1032	48/1052	0.99 [0.46 to 2.16]; 59%	NA
	• Removing nonVHDI studies	5[42,221,226,227,229]	24/693	40/691	0.60 [0.35 to 1.01]; 3%	-0.010 [-0.045 to 0.024]
Gestational hypertension	All studies	2[42,233]	38/815	45/816	0.82 [0.54 to 1.25]; 0%	NA
Hypertensive disorders of pregnancy	All studies	3[41,42,233]	126/1305	171/1326	0.85 [0.50 to 1.43]; 80%	NA
	• Only blinded and VHDI studies	2[41,42]	99/966	155/965	0.64 [0.51 to 0.81]; 0%	-0.057 [-0.086 to -0.027]
Cesarean delivery	All studies	8[41,42,221-223,227,229,233]	638/1771	684/1812	0.95 [0.83 to 1.08]; 43%	NA
Primary cesarean delivery	All studies	3[42,221,226]	81/561	113/553	0.70 [0.54 to 0.91]; 0%	-0.0525 [-0.103 to -0.0024]
Emergency cesarean delivery	All studies	1[41]	80/490	103/510	0.81 [0.62 to 1.05]; NA	NA
Induction of Labor	All studies	5[41,42,221,227,233]	338/1373	285/1410	1.18 [0.92 to 1.52]; 45%	NA
Preterm delivery	All studies	4[42,226,229,233]	69/965	92/968	0.75 [0.56 to 1.01]; 0%	-0.023 [-0.049 to 0.002]
Maternal birth trauma	All studies	2[41,226]	255/540	255/560	1.04 [0.92 to 1.18]; 0%	NA

Abbreviations: CI = confidence interval; NA = not applicable; VHDI = Very High Development Index country

Table 15. Effects From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later on Fetal/Neonatal Outcomes (KQ6)

Outcome	Number of Trials with Events	Number of Events/ Treated	Number of Events/Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Mortality	2[41,233]	4/845	9/885	Peto OR 0.49 [0.16 to 1.45]; 68%	NA
Birth injury	3[41,42,227]	3/1015	10/1013	Peto OR 0.33 [0.11, 0.99]	-0.002 [-0.006 to -0.002]
Shoulder dystocia	3[41,42,221]	15/1017	36/1027	0.42 [0.23 to 0.77]; 0%	-0.013 [-0.043 to 0.016]
Macrosomia (>4000g)	8[41,42,221-223,226,229,233]	164/1805	330/1839	0.53 [0.41 to 0.68]; 42%	-0.089 [-0.120 to -0.059]
Macrosomia (>4500g)	3[223,227,233]	16/521	23/545	0.72 [0.39 to 1.35]; 0%	NA
Large for gestational age	7[41,42,222,226,227,229,233]	174/1654	322/1675	0.56 [0.47 to 0.66]; 0%	-0.084 [-0.108 to -0.061]
NICU admission	5[42,222,226,227,229]	63/809	84/791	0.73 [0.53 to 0.99]; 0%	-0.020 [-0.045, 0.0051]
Respiratory distress syndrome	2[41,42]	36/983	32/979	1.05 [0.48 to 2.28]; 58%	NA
Any hypoglycemia	5[42,222,223,229,233]	91/1118	80/1120	1.10 [0.83 to 1.45]; 0%	NA
Hypoglycemia requiring IV treatment	2[41,42]	60/981	58/979	1.02 [0.60 to 1.76]; 58%	NA
Hyperbilirubinemia	5[41,42,222,223,227]	101/1288	119/1276	0.84 [0.65 to 1.08]; 0%	NA
Apgar score <7 at 1 min	1[233]	0/339	7/361	0.07 [0.00 to 1.24]; NA	NA
Apgar score <7 at 5 min	2[41,229]	9/605	15/626	0.62 [0.27 to 1.41]; 0%	NA

Abbreviations: CI = confidence interval; NA = not applicable; NICU = neonatal intensive care unit

Table 16. Effects From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later on Long-Term Outcomes (KQ6)

Outcome	Number of Trials	Number of Events/ Treated	Number of Events/Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference for Significant Findings [95% CI]
Childhood overweight or obese (BMI ≥85th percentile)(4-10 years)	2[239,240]	117/358	120/341	0.96 [0.69 to 1.33]; 49%	NA
Childhood obesity (BMI ≥95th percentile) (5-11 years)	2[239,241]	63/297	62/288	1.02 [0.66 to 1.59]; 24%	NA
Childhood metabolic impairment	1 (IGT)[241] 2 (IFG)[239,241]	4/47 12/257	0/25 13/205	4.88 [0.27 to 87.06] 0.79 [0.37 to 1.69]	NA
Childhood development of T2DM	2[239,241]	1/265	0/214	NA	NA
Long-term maternal development of metabolic impairment (Impaired Fasting Glucose)	1[238]	66/243	54/214	1.08 [0.79 to 1.47]; NA	NA
Long-term maternal development of T2DM (5-10 years)	1[238]	21/243	17/214	1.09 [0.59 to 2.01]; NA	NA
Long-term maternal development of metabolic syndrome (5-10 years)	1[238]	73/243	69/214	0.93 [0.71 to 1.22]; NA After adjustment for race-ethnicity and time since diagnosis: 0.95 [0.73 to 1.25]	NA
Long-term maternal obesity (≥30kg/m^2)	1[238]	98/243	79/214	1.09 [0.87 to 1.38]; NA	NA

Abbreviations: BMI = body mass index; CI = confidence interval; GDM = gestational diabetes mellitus; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; NA = not applicable; T2DM = type 2 diabetes mellitus

Table 17. Effects From Trials of Treatment vs. No Treatment for GDM in Early Pregnancy on Pregnancy Outcomes (KQ6)

Outcome	Number of Trials	Number of Events/Treated	Number of Events/Untreated	Relative Effects [95% CI]; I^2	Absolute Risk Difference for Significant Findings [95% CI]
Preeclampsia	3[228,230,232]	4/109	8/120	0.69 [0.21, 2.23]; 0%	NA
Gestational hypertension	2[230,232]	7/74	12/90	0.75 [0.31, 1.84]; 0%	NA
Hypertensive disorders of pregnancy	3[230-232]	14/85	17/99	0.92 [0.46, 1.81]; 0%	NA
Cesarean delivery	4[228,230-232]	34/107	41/121	0.91 [0.56, 1.48]; 35%	NA
Primary cesarean delivery	1[230]	5/37	10/37	0.50 [0.19, 1.32]; NA	NA
Emergency cesarean delivery	3[228,231,232]	12/70	16/84	0.81 [0.37, 1.78]; 11%	NA
Induction of labor	3[228,230,231]	33/71	27/67	1.12 [0.76, 1.67]; 3%	NA
Preterm delivery	2[228,232]	3/59	3/75	1.27 [0.27, 6.07]; 0%	NA
Excessive gestational weight gain	2[230,232]	15/70	31/89	0.65 [0.37, 1.15]; 6%	NA

Abbreviations: CI = confidence interval; NA = not applicable

Table 18. Effects From Trials of Treatment vs. No Treatment for GDM in Early Pregnancy on Fetal/Neonatal Outcomes (KQ6)

Outcome	Number of Trials	Number of Event/Treated	Number of Events/Untreated	Relative Effects [95% CI]; I^2 (RR unless otherwise)	Absolute Risk Difference of Significant Findings [95% CI]
Mortality	3[228,230,231]	0/71	2/67	Peto OR 0.12 [0.01 to 1.95]	NA
Birth injury	1[228]	0/23	0/21	Not estimable	NA
Shoulder dystocia	3[228,231,232]	0/70	2/84	Peto OR 0.11 [0.00 to 5.57	NA
Macrosomia (>4000g)	2[230,232]	15/73	21/91	0.89 [0.33, 2.42]; 42%	NA
Macrosomia (>4500g)	1[232]	0/36	3/54	0.21 [0.01, 3.99]; NA	NA
Large for gestational age	3[228,231,232]	8/70	13/84	0.68 [0.18, 2.54]; 35%	NA
NICU admission	3[228,231,232]	10/70	12/84	0.98 [0.28, 3.43]; 29%	NA
Any hypoglycemia	3[228,230,231]	10/63	6/60	1.77 [0.62, 5.03]; 0%	NA
Hyperbilirubinemia	2[228,230]	10/59	6/57	1.57 [0.65 to 3.82]; 0%	NA

Abbreviations: CCT = controlled clinical trial; CI = confidence interval; NA = not applicable; NICU = neonatal intensive care; OR = odds ratio; RR = relative risk

Table 18. Effects From Trials of Treatment vs. No Treatment for GDM in Early Pregnancy on Fetal/Neonatal Outcomes (KQ6)

Outcome	Number of Trials with Events	Number of Events/Treated (n/N)	Number of Events/Untreated	Relative Effects (RR) [95% CI]; I^2	Absolute Risk Difference [95% CI]
Small for gestational age	6[41,42,221,222,226,229]	92/1317	84/1329	1.10 [0.83 to 1.47]; 0%	NA
Low birthweight	1[233]	14/339	14/361	1.06 [0.52 to 2.20]; NA	NA

Abbreviations: CI = confidence interval; NA = not applicable; RR = relative risk

Table 20. Contextual Question 1 Evidence: Pooled Odds Ratio for Associations Between a 1-mmol/L Increase in Glucose Concentration and Pregnancy Outcomes, by Test*

	Preeclampsia		Hypertensive disorders of pregnancy		Cesarean delivery		Preterm delivery		Induction of labor	
Test	Study count; N	OR [95% CI]	Study count; N	OR [95% CI]	Study count; N	OR [95% CI]	Study count; N	OR [95% CI]	Study count; N	OR [95% CI]
1-h post-50g OGCT	6; 58,270	1.25 [1.13 to 1.39]	1; 1,157	1.02 [0.75 to 1.38]	7; 36,616	1.35 [1.23 to 1.49]	2; 27,126	1.06 [0.96 to 1.17]	1; 13,902	1.30 [1.20 to 1.41]
Fasting (before 75g or 100g load)	4; 39,345	2.15 [1.45 to 3.19]	3; 5,551	1.91 [1.49 to 2.43]	6; 47,746	1.59 [1.49 to 1.70]	3; 17,257	0.77 [0.62 to 0.96]	2; 12,484	1.31 [1.14 to 1.50]
1-h post-load (75g or 100g)**	2; 22,732	1.19 [1.15 to 1.24]	--	--	2; 24,684	1.18 [1.15 to 1.20]	--	--	--	--
2-h post-75g OGTT	3; 35,720	1.22 [1.14 to 1.30]	2; 4,174	1.21 [1.08 to 1.35]	7; 41,130	1.10 [0.98 to 1.24]	5; 18,816	1.07 [1.00 to 1.15]	2; 12,485	1.11 [1.03 to 1.19]
2-h post-100g OGTT	1; 3,628	1.37 [1.14 to 1.65]	1; 1,358	1.14 [0.96 to 1.35]	2; 3,915	1.14 [1.04 to 1.25]	1; 249	0.87 [0.41 to 1.87]	--	--
2-h post-load (75g or 100g)**	4; 39,348	1.23 [1.18 to 1.29]	3; 5,532	1.19 [1.08 to 1.30]	9; 45,045	1.10 [0.96 to 1.25]	6; 19,065	1.07 [0.99 to 1.15]	2; 12,485	1.10 [1.04 to 1.16]

Abbreviations: CI = confidence interval; g = gram; h = hour; N = number; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; OR=odds ratio

* Adapted from Farrar et al.[24,242]

Table 21. Contextual Question 1 Evidence: Pooled Odds Ratio for Associations Between a 1-mmol/L Increase in Glucose Concentration and Fetal Outcomes, by Test*

	Macrosomia		LGA		Shoulder dystocia		Neonatal hypoglycemia	
Test	Study count; N	OR [95% CI]	Study count; N	OR [95% CI]	Study count; N	OR [95% CI]	Study count; N	OR [95% CI]
1-h post-50g OGCT	7; 64,851	1.14 [1.10 to 1.18]	4; 30,626	1.32 [1.19 to 1.46]	2; 27,688	1.26 [1.10 to 1.43]	3; 15,619	1.38 [1.00 to 1.92]
Fasting (before 75g or 100g load)	6; 28,303	2.06 [1.86 to 2.28]	7; 46,680	2.11 [1.73 to 2.58]	4; 18,615	1.97 [1.36 to 2.85]	2; 19,998	1.37 [1.20 to 1.57]
1-h post-load (75g or 100g)†	--	--	2; 24,684	1.24 [1.20 to 1.27]	--	--	--	--
2-h post-75g OGTT	5; 19,524	1.19 [1.14 to 1.25]	9; 48,321	1.20 [1.13 to 1.28]	3; 17,260	1.41 [1.03 to 1.92]	2; 19,998	1.13 [1.09 to 1.18]
2-h post-100g OGTT	2; 3,877	1.29 [1.15 to 1.44]	2; 1,645	1.35 [1.17 to 1.55]	2; 1,645	1.56 [1.21 to 1.99]	1; 287	1.09 [0.66 to 1.80]
2-h post-load (75g or 100g)*	7; 23,401	1.21 [1.16 to 1.26]	11; 49,966	1.22 [1.19 to 1.25]	5; 18,905	1.38 [1.22 to 1.56]	3; 20,285	1.13 [1.09 to 1.18]

Abbreviations: LGA = large for gestational age; OGTT = oral glucose tolerance test; OR=odds ratio

* Adapted from Farrar et al.[24,242]

† Too few studies precluded pooled analysis of 1-hour postload glucose levels for the 75g OGTT and 100g OGTT. Combining glucose levels from the 75g and 100g OGTT led to similar findings to those from the 75g OGTT alone, aligning with assumptions that the associations between glucose and outcomes will be the same for both tests

Table 22. Pooled Adjusted* Odds Ratios for Associations Between a 1-mmol/L Increase in Glucose Concentration From Three Cohorts†

Test	Preeclampsia	Cesarean delivery	Preterm delivery	Macrosomia	LGA	Shoulder dystocia
Fasting	1.58 [1.38 to 1.81]	1.26 [1.17 to 1.35]	0.93 [0.71 to 1.23]	1.90 (1.64 to 2.20)	1.84 (1.60 to 2.12)	1.68 (1.32 to 2.13)
2-h post-75g OGTT	1.16 [1.06 to 1.27]	1.06 [1.03 to 1.08]	1.11 [1.02 to 1.20]	1.12 (1.05 to 1.20)	1.09 (1.04 to 1.15)	1.19 (1.10 to 1.27)

Abbreviations: CI = confidence interval; g = gram; h = hour; LGA = large for gestational age; OGTT = oral glucose tolerance test

* The review authors analyzed individual patient data from two cohorts, and adjusted for BMI, age, ethnicity; for the HAPO cohort all models adjusted for field center, age, BMI, height, smoking status, alcohol use, family history of diabetes, gestational age at OGTT, infant's sex, hospitalization before delivery, mean arterial pressure, parity (not included in primary cesarean delivery model), cord-blood plasma glucose level. These findings were combined with adjusted analysis from the HAPO cohort

† Adapted from Farrar et al.[24,242]

Table 23. Contextual Question 2 Evidence: Pooled Estimates for the Association Between Timing of GDM Diagnosis and Outcomes*

Outcome	Study Count; Total N	Relative Risk [95% Confidence Interval]	Absolute Risk Difference for Early vs. Late Treatment of GDM	Quality of Evidence (GRADE)†
Hypertensive disorders in pregnancy	10, N=10,091	1.34 [0.98 to 1.82]	32 more per 1000 (2 less to 76 more)	Very low (I^2=73%; selective screening of high-risk women in few studies)
Caesarean delivery	9, N=9,685	1.09 [0.94 to 1.26]	28 more per 1000 (19 fewer to 81 more)	Very low I^2=76%
LGA	7, N=9,622	1.07 [0.86 to 1.35]	13 more per 1000 (26 fewer to 66 more)	Low
Macrosomia	10, N=9,966	1.05 [0.77 to 1.41]	5 more per 1000 (25 fewer to 44 more)	Low
Shoulder dystocia	2, N=2,936	1.76 [0.96 to 3.24]	12 more per 1000 (1 fewer to 26 more)	Very low Few events
SGA	5, N=5,900	1.27 [0.92 to 1.75]	20 more per 1000 (6 fewer to 55 more)	Low
NICU admission	5, N=7,992	1.16 [0.90 to 1.49] Developed countries (4 studies): 1.12 [1.04 to 1.22]	33 more per 1000 (21 fewer to 102 more)	Low
Preterm delivery	7, N=7,039	1.16 [0.84 to 1.61]	13 more per 1000 (13 fewer to 49 more)	Low
Neonatal hypoglycemia	7, N=6,818	1.61 [1.02 to 2.55] Developed countries: 1.47 [0.82 to 2.64]; 5	82 more per 1000 (3 more to 207 more	Low
Hyperbilirubinemia	7, N=9,231	1.16 [0.91 to 1.48]	21 more per 1000 (12 fewer to 62 more)	Low
Respiratory distress syndrome	5, N=6,351	1.00 [0.76 to 1.32]	0 fewer per 1000 (9 fewer to 12 more)	Very low Few events
Perinatal mortality	7, N=9,130	3.58 [1.91 to 6.71] Developed countries (6 studies): 3.61 [1.90 to 6.84]	6 more per 1000 (2 more to 14 more)	Low

Abbreviations: ADHD = Attention-deficit and Hyperactivity Disorder; ASD = Autism Spectrum Disorder; GRADE = Grading of Recommendations, Assessment, Development, and Evaluation; GA = gestational age; HDP = hypertensive disorders of pregnancy; LGA = large for gestational age; OR = odds ratio; RDS = respiratory distress syndrome; RD = risk difference; RR = risk ratio; SGA = small for gestational age

* Adapted from Immanuel and Simmons.[249]

† As determined by authors; observational studies started at low quality.

Table 24. Contextual Question 3 Evidence: Estimates for the Association Between Neonatal Hypoglycemia and Long-Term Neurodevelopmental Outcomes*

Outcome	Study Count, Total N	Odds Ratio [95% CI]	Quality of Evidence (GRADE)†
Early childhood (2-5 years) **Neurodevelopmental impairment**	6, N=1,657	1.16 [0.86 to 1.57]	Very low 4 studies high ROB in several domains; only 2 adjusted
Early childhood (2-5 years) **Visual-motor impairment**	2, N=508	3.46 [1.13 to 10.57]	Low
Early childhood (2-5 years) **Executive dysfunction**	1; N=463	2.50 [1.20 to 5.22]	Low
Early childhood (2-5 years) **Any cognitive impairment**	3, N=746	1.11 [0.73 to 1.69]	Very low 2 studies high ROB, 1 adjusted
Early childhood (2-5 years) **Epilepsy**	4, N=772	1.93 [0.76 to 4.85]	Very low 2 studies high ROB, results imprecise, 1 adjusted
Early childhood (2-5 years) **Low language/literacy**	1, N=37	5.23 [0.26 to 105.50]	Very low
Mid-childhood (6-11 years) **Neurodevelopmental impairment**	2, N=54	3.62 [1.05 to 12.42]	Very low Both studies high ROB imprecise results
Mid-childhood (6-11 years) **Visual-motor impairment**	-	-	No data
Mid-childhood (6-11 years) **Executive dysfunction**	-	-	No data
Mid-childhood (6-11 years) **Any cognitive impairment**	-	-	No data
Mid-childhood (6-11 years) **Epilepsy**	-	-	No data
Mid-childhood (6-11 years) **Low language/literacy**	1, N=1,395	2.04 [1.20 to 3.47]	Low
Mid-childhood (6-11 years) **Low numeracy**	1, N=1,395	2.04 [1.21 to 3.44]	Low

Abbreviations: CI = confidence interval; ROB=risk of bias; GRADE=Grading of Recommendations Assessment, Development and Evaluation.

* Adapted from Shah et al.[281]
† As determined by Shah et al; all observational studies started at low certainty.

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
1. Does **screening** for gestational diabetes mellitus (GDM) reduce (a) poor health outcomes or (b) poor intermediate outcomes, and (c) do the effects vary by maternal subgroup characteristics?	Screening versus no screening	Prior report: 2 retrospective cohorts (N=544) Update: 1 case-control and 1 retrospective cohort (N=3,792) .	Risk-based screening (75g 2hr OGTT NICE criteria) was associated with a reduced risk of late (≥28 weeks' gestation) stillbirth (OR, 0.68 [95% CI, 0.47 to 0.97]). Universal 2-step screening (50g OGCT and 75g 2hr OGTT using IADPSG), with those having risk factors screened in first trimester (51% of screened), associated with reduced risk of cesarean sections (ARD 5%), birth injuries (<1%), and admissions to the NICU (>8% admissions); and no differences for macrosomia, hypoglycemia or hyperbilirubinemia. For NICU admissions, effects for women screened in first trimester were larger than for those screened later. Two small studies from the prior review focused on selected subpopulations and showed no associations with screening.	Consistency unknown with 1 study for each outcome Reasonably precise for stillbirth, cesarean sections, birth injuries, and NICU admissions; some imprecision for macrosomia	Observational studies without intention/offer to screen designs. Some concerns about selection biases and confounding. Selective outcome or analysis reporting not detected.	Insufficient	Findings mainly applicable to screening approaches with targeted screening for those with risk factors
2. What are the **harms** of screening for and diagnosis of GDM to the mother, fetus, or neonate?	Screening versus no screening and GDM vs. no GDM	Prior report: 0 Update: 5 cohorts and 2 cross-sectional (N= 166,082)	Evidence from observational studies on harms of screening (2 studies) or a GDM diagnosis (5 studies) was limited, but suggested that undergoing screening or receiving a false positive result may not be associated with anxiety; receiving a GDM diagnosis may result in a small, transient increase in anxiety symptoms; and that the diagnosis may have some adverse labeling effects impacting delivery management and hospital experiences associated with breastfeeding.	Harms of screening: reasonably consistent; some imprecision Harms of GDM diagnosis: reasonably consistent (labeling); unknown consistency (anxiety)	Observational studies; not intention/offer-to-screen designs. Findings on hospital experiences may be confounded by hospital policies, GDM treatment, and intentions before delivery.	Low for no association between undergoing screening and anxiety symptoms Low for possible unnecessary cesarean delivery due to GDM	Studies from Canada and Australia with predominately white women; screening used the OGCT

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
3. What is the **comparative effectiveness of different screening strategies** for GDM on (a) health outcomes or (b) intermediate outcomes, and (c) do the effects vary by subgroup character-istics?	IADPSG versus CC screening	Prior report: 0 Update: 3 RCTs (N=1,059)	Pregnancy outcomes: Primary cesarean deliveries (RR, 0.73 [95% CI, 0.55 to 0.97]; ARD, 6.3%); no association for preeclampsia, gestational hypertension, total cesarean deliveries, induction of labor, preterm birth, or maternal birth trauma Fetal/neonatal outcomes: LGA infants (RR, 0.46 [95% CI, 0.25 to 0.83]; ARD, 3.2%), neonatal hypoglycemia (RR, 0.52 [95% CI, 0.28 to 0.95]; ARD, 2.7%; one study had zero events), and NICU admissions (RR, 0.49 [95% CI, 0.29 to 0.84]; ARD, 3.7%); no association for macrosomia or shoulder dystocia Long-term outcomes: No data	Pregnancy outcomes: Consistency unknown or inconsistency and some imprecision for all outcomes; imprecise for preeclampsia Fetal/neonatal outcomes: Consistent but some imprecision for LGA ; consistency unknown or inconsistency and some imprecision for hypoglycemia, NICU admissions and macrosomia; imprecise for shoulder dystocia	2 trials with most events were open-label; possible selective outcome or analysis reporting in largest trial where inconsistency between 2 publications could not be explained despite seeking author contact; not intention-to-screen analysis; published results are pending for two large RCTs	Pregnancy outcomes: Low for association with fewer primary cesarean deliveries and for no association with other outcomes; insufficient for preeclampsia Fetal/neonatal outcomes: Low for association with fewer LGA, hypoglycemia, and NICU admissions; low for no association with macrosomia; insufficient for shoulder dystocia.	2 trials conducted in US, with one having large (65%) minority population; largest trial conducted in Turkey; comparison highly applicable

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
3. What is the **comparative effectiveness of different screening strategies** for GDM on (a) health outcomes or (b) intermediate outcomes, and (c) do the effects vary by subgroup character-istics? **(Continued)**	IADPSG versus WHO 1999 screening	Prior report: 0 Update: 1 RCT (n=502)	Pregnancy outcomes: No association for primary cesarean, preterm delivery, or hypertensive disorders in pregnancy Fetal/neonatal outcomes: No association for shoulder dystocia, LGA, or hypoglycemia Long-term outcomes: No data	Pregnancy outcomes: Consistency unknown; some imprecision for primary cesarean deliveries; imprecise for preterm deliveries and hypertensive disorders Fetal/neonatal outcomes: Consistency unknown; imprecise Long-term outcomes: No data	Open-label and possible selection biases; not intention-to-screen analysis	Pregnancy outcomes: Low for no association with primary cesarean delivery; insufficient for preterm delivery and hypertensive disorders Fetal/neonatal outcomes: Insufficient Long-term outcomes: No data	Trial from Malaysia; comparator of WHO 1999 criteria appear to be used infrequently in U.S.
	Early versus usual timing for CC screening	Prior report: 0 Update: 1 RCT (n=922)	Pregnancy outcomes: Preeclampsia (RR, 1.42 [95% CI, 0.99 to 2.05]; ARD, 4.0%); no association for gestational hypertension, hypertensive disorders in pregnancy, primary cesarean delivery, induction of labor Fetal/neonatal outcomes: No association for shoulder dystocia, macrosomia, LGA, hypoglycemia, hyperbilirubinemia Long-term outcomes: No data	Pregnancy outcomes: Consistency unknown; some imprecision Fetal/neonatal outcomes: Consistency unknown; some imprecision Long-term outcomes: No data	No concerns; intention-to-screen analysis	Pregnancy outcomes: Low for association with more preeclampsia and for no association for other outcomes Fetal/neonatal outcomes: Low for no association for all outcomes Long-term outcomes: No data	U.S. trial with mostly black and Hispanic population; 100% obese; excluded women with prior cesarean section; comparison highly applicable

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
4. a) What is the **diagnostic accuracy of commonly used screening tests** for GDM? b) Does the accuracy of commonly used screening tests for GDM vary according to maternal subgroup characte-ristics, including timing during pregnancy, body mass index, age, race/ethnicity, or prevalence of GDM?	50 OGCT versus CC	Prior report: 5 studies (N=5,501) Update: 8 studies (n=6,190)	Pooled estimates: 140 mg/dL: sensitivity 81.9% (95% CI, 68.3 to 90.4), specificity 81.8% (95% CI, 71.2 to 89.1) 135 mg/dL: sensitivity 93.3% (95% CI, 23.7 to 99.8), specificity 78.9% (95% CI, 53.3 to 92.5) Not pooled: 130 mg/dL: sensitivities (75 to 100%) and specificities (25 to 86%)	140 mg/dL: Reasonably consistent and precise 135 mg/dL: Some inconsistency and imprecision 130 mg/dL: Inconsistent and some imprecision	Half of the studies for each analysis were fair quality, but this did not appear to influence findings	Moderate (140 mg/dL) and low (135 mg/dL) for reasonably good accuracy; insufficient for 130 mg/dL	Studies varied widely in country of origin; screening and diagnostic test highly applicable
	50 g OGCT versus NDDG	Prior report: 6 studies (n=5,375) Update: 0	Pooled estimates: 140 mg/dL: sensitivity 85.0% (95% CI, 72.0 to 92.6), specificity 81.2% (95% CI, 75.9 to 85.6) Not pooled: 135 mg/dL: sensitivity 88.5 and 78.6%; specificities 84.3 and 46.4% 130 mg/dL: sensitivity and specificity were 90.7 and 79.4%	140 mg/dL: Reasonably consistent and precise 135 mg/dL: some inconsistency in specificity 130 mg/dL: unknown consistency and some imprecision	4 of 6 studies were good quality, and quality did not appear to influence findings	Moderate (140 mg/dL) and low (135 mg/dL) for reasonably good accuracy; insufficient for 130 mg/dL	See 50g OGCT versus CC
	50 g OGCT versus IADPSG	Prior report: 0 Update: 2 studies (n=2,091)	Not pooled: Sensitivity: low (<70%) across all cutoffs Specificity: 140 mg/dL 81.0 and 93.2%; 135 mg/dL 76.1 and 88.0%; 130mg/dL 70.2 and 84.2%	Reasonably consistent and precise	No concerns	Moderate for poor accuracy	See 50g OGCT versus CC
	Fasting plasma glucose versus CC	Prior report: 4 studies (N=6,889) Update: 3 studies (N=1,972)	Pooled estimates: FPG 79 mg/dL: sensitivity 96% (95% CI, 92 to 98), specificity 35% (95% CI, 30 to 41) FPG 85 mg/dL: sensitivity 88% (95% CI, 84 to 91), specificity 73% (95% CI, 46 to 90) FPG 90 mg/dL: sensitivity 81% (95% CI, 75 to 85), specificity 82% (95% CI, 61 to 93) FPG 95.5 mg/dL: sensitivity 58% (95% CI, 32 to 81), specificity 98% (95% CI, 88 to 100) Not pooled: Across all cutoffs, sensitivity appeared fairly high (>90%) using ≤80 mg/dL and specificity appeared high (≥90%) using cutoffs >90 mg/dL.	79, 85 and 90 mg/dL: sensitivity reasonably consistent and precise; some inconsistency for specificity ≤80 mg/dL: reasonably consistent (but most thresholds only reported by 2 studies) and precise for high sensitivity	2 studies included in pooled estimates used selective populations (positive on OGCT or with clinical risk factors) which may have impacted findings	Low (85 & 90 mg/dL) for reasonably good accuracy; low for reasonably high sensitivity (to rule out) with ≤80 mg/dL and specificity (to rule in) with >90mg/dL	See 50g OGCT versus CC

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
4. a) What is the **diagnostic accuracy of commonly used screening tests** for GDM? b) Does the accuracy of commonly used screening tests for GDM vary according to maternal subgroup character-istics, including timing during pregnancy, body mass index, age, race/ethnicity, or prevalence of GDM? **(Continued)**	Fasting plasma glucose versus IADPSG	Prior report: 0 Update: 9 studies (N=59,278)	At 24 weeks' or greater: Pooled estimate: FPG 90 mg/dL: sensitivity 79% (95% CI, 65 to 89), specificity 96% (95% CI, 95 to 97) Not pooled: FPG ≤80 mg/dL: high sensitivity (> 90%), low specificity (<60%) Early screening: 85 mg/dL: sensitivity 55 and 94% and specificity 68 and 74%	At 24 weeks or greater: FPG 90 mg/dL: some inconsistency but precise for sensitivity FPG ≤80 mg/dL: reasonably consistent (but most thresholds only reported by 2 studies) and precise for high sensitivity Early screening: inconsistent sensitivity	6 of 9 studies were fair quality, but quality did not appear to influence findings	Moderate (90 mg/dL at 24 weeks) for good accuracy; low (≤80 mg/dL) to rule out GDM; low for low accuracy when screening before 24 weeks	Studies varied in country and findings appear to be applicable to a diverse population; 90 mg/dL is very similar to the diagnostic value for FPG in this criteria which only requires one abnormal value
	HbA1c	Prior report: 3 studies (N=1,075) Update: 15 studies (n=9,413)	Against each criteria and for each time point, one or two studies contributed data for most thresholds. At no threshold were sensitivity and specificity both high enough for use as a primary screening test Sensitivity >90% at cutoffs of 4.5 to 5.0% (CC and NDDG) or 4.6 to 4.7% (IADPSG) in second trimester, at which may allow ruling out	Some inconsistency and imprecision	Most studies limited due to poor reporting on patient selection, selection of cutoffs, and fasting protocols	Low for poor accuracy across thresholds; low for <5.0% (CC and NDDG) and 4.7% and under (IADPSG) to rule out GDM reasonably well	See 50g OGCT versus CC
	Risk-based screening	Prior report: 2 studies (N=1,912) Update: 1 study (n=258)	Three studies compared different models with CC, NDDG and IADPSG criteria; for CC and IADPSG they incorporated FPG which seemed to increase sensitivity. All screening still used either FPG or and OGCT. Sensitivity may be high enough (82-98%) to rule out GDM; specificity (16-80%) too low to replace OGCT	Single studies for each tool and criteria; some imprecision	No concerns; all studies used validation cohorts	Low for poor accuracy for primary screening test; but may allow rule-out	Studies from Brazil, Canada, and Austria; unknown how many clinicians use risk-based screening

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
5. What is the association between diagnosis and **outcomes in women meeting more inclusive but not less inclusive diagnostic criteria** for GDM?	GDM versus no GDM	Prior report: 13 observational studies (N=27,071) Update: 18 cohort studies (n=78,421)	Pregnancy outcomes: Versus NGT, women meeting more inclusive criteria but not treated for GDM are probably at increased risk of: • Preeclampsia (60 to 93% increase; 1.5 to 3.3% more cases) • Hypertensive disorders in pregnancy (variable increased risk; 1 to 5% more cases) • Total cesarean deliveries (20 to 30% increase; 7 to 13% more cases [but NGT rates high]) • Preterm deliveries (40% increase; 0.8 to 1.8% more cases) No associations for primary cesarean delivery, induction of labor, maternal birth trauma, excessive weight gain Fetal/neonatal outcomes: Versus NGT, women meeting more inclusive criteria but not treated for GDM are probably at increased risk of: • Macrosomia (50 to 100% increase; 2.6 to 8.1% more cases) • LGA (60 to 70% increase; 4.7 to 6.0% more cases) • Neonatal hypoglycemia (60 to 150% increase; 1.4 to 2% more cases) • Hyperbilirubinemia (variable increased risk) No associations for perinatal mortality, birth injury, shoulder dystocia, NICU admissions, respiratory distress syndrome, low APGAR scores at 1 or 5 minutes Long-term outcomes (single studies): OAV on NDDG: maternal impaired glucose tolerance at 3 months' postpartum (RR, 2.13 [95% CI, 1.14 to 3.99]) and T2DM (RR, 19.8 [95% CI, 1.03 to 379.34]) OAV on CC: childhood obesity at 5 to 7 years (RR, 1.29 [95% CI, 0.94 to 1.64]) and at 13 years (RR, 1.03 [95% CI, 0.40 to 2.64])	Reasonably consistent and precise for preeclampsia, total cesarean deliveries, preterm delivery, macrosomia, LGA, hypoglycemia, hyperbilirubinemia, NICU admissions Some inconsistency for hypertensive disorders, and inconsistency and imprecision for gestational hypertension, primary cesarean delivery, induction of labor, maternal birth trauma, perinatal mortality, birth injury, shoulder dystocia, respiratory distress syndrome, low APGAR scores Long-term outcomes: unknown consistency and some imprecision (childhood obesity and maternal metabolic outcomes) or high imprecision (development of T2DM)	Blinding of patients and providers to glycemic status or for outcome assessment did not occur, although no women met criteria for GDM; adjusted analyses available Duration of followup was short for development of metabolic impairment and T2DM	Moderate for association with increased risk of preeclampsia, hypertensive disorders, total cesarean deliveries, preterm delivery, macrosomia, LGA, hypoglycemia, hyperbilirubinemia, and for no association with NICU admissions Low for no associations for other short-term outcomes and long-term obesity in childhood Insufficient for metabolic impairment and development of T2DM in (high-risk) mothers	All comparisons, including some variations to what is recommended for each criteria, are considered applicable to U.S. IADPSG excluding CC most applicable due to three large U.S. studies with diverse populations Absolute rates for total cesarean are likely over estimated because of high rates in non-VHDI countries >40% of participants in study of long-term maternal outcomes had a family history of T2DM

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
6. Does **treatment of GDM** during pregnancy a) reduce poor health outcomes, b) reduce poor intermediate outcomes, c) vary by maternal subgroup character-istics, including timing and criteria used for diagnosis during pregnancy, severity of hyperglyc-emia, body mass index, age, or race/ ethnicity?	Treatment for GDM at 24 week's gestation or later versus no treatment	Prior report: 5 trials Update: 4 trials (N=3,982)	Pregnancy outcomes: • Preeclampsia: RR, 0.60 (95% CI, 0.35 to 1.01); ARD, 1%, excluding one outlier • Primary cesarean delivery: RR, 0.70 (95% CI, 0.54 to 0.91); ARD, 5.3% • Preterm delivery: RR, 0.75 (95% CI, 0.56 to 1.01); ARD, 2.3% No association with hypertensive disorders of pregnancy, gestational hypertension, total or emergency cesarean delivery, induction of labor, maternal birth trauma Fetal/neonatal outcomes: • Birth injury: Peto OR, 0.33 (95% CI, 0.11 to 0.99); ARD, 0.2% • Shoulder dystocia: RR, 0.42 (95% CI, 0.23 to 0.77); ARD, 1.3% • Macrosomia >4000g: RR, 0.53 (95% CI, 0.41 to 0.68); ARD, 8.9% • LGA: RR, 0.56 (95% CI, 0.47 to 0.66); ARD, 8.4% • NICU admissions: RR, 0.73 (95% CI, 0.53 to 0.99); ARD, 2.0% No associations with mortality, macrosomia >4500g, respiratory distress syndrome, any hypoglycemia, hyperbilirubinemia, APGAR scores Long-term outcomes: No differences in childhood overweight (BMI ≥85th percentile) (4-10 years), obesity (BMI ≥95th percentile) (5-11 years), metabolic impairment, or T2DM; or in maternal obesity (≥30kg/m^2) or metabolic impairment (impaired fasting glucose), metabolic syndrome (5-10 years), or T2DM (5-10 years).	Consistent and precise for macrosomia >4000g and LGA Inconsistent and imprecise for preeclampsia, birth injury, and mortality Imprecise for gestational hypertension, primary cesarean delivery, emergency cesarean, preterm delivery Some inconsistency for induction of labor and shoulder dystocia Large inconsistency for hypertensive disorders Unknown consistency and large imprecision for childhood and maternal metabolic impairment and development of T2DM	Some concern for total cesarean delivery, induction of labor and NICU admissions from open-label designs Studies of long-term outcomes had high rates of attrition.	High for reduced risk of macrosomia >4000g and LGA Moderate for reduced risk of primary cesarean delivery, shoulder dystocia, and NICU admissions, and for no association with gestational hypertension, total cesarean deliveries, maternal birth trauma, respiratory distress syndrome, hypoglycemia, hyperbilirubine mia Low for reduced risk of preeclampsia, preterm labor, birth injury and for no association	Trials from various countries; 2 from the U.S. enrolled 97% and 57% Hispanic women with similar findings to the conclusions. Most data from 3 large trials with 2-step screening for GDM diagnosis. Eligibility criteria included singleton pregnancies for 12 trials, women without chronic hypertension in 4 trials, and women without previous GDM in the largest 2 trials

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
6. Does **treatment of GDM** during pregnancy a) reduce poor health outcomes, b) reduce poor intermediate outcomes, c) vary by maternal subgroup character-istics, including timing and criteria used for diagnosis during pregnancy, severity of hyperglyc-emia, body mass index, age, or race/ ethnicity? **(Continued)**	Treatment for GDM at 24 week's gestation or later versus no treatment (**Continued**)		Subgroups: No significant interactions based on timing of treatment initiation, criteria for diagnosis/glycemic severity, BMI (only assessed for LGA), or race/ethnicity. Sensitivity analyses removing 3 trials with eligibility based on screening positive but no GDM did not impact conclusions; one new trial enrolled women with GDM based on IADPSG criteria but FPG was higher and 2-hr postload glucose levels similar to other trials in the prior review, so this did not explain any inconsistency in effect			with hypertensive disorders, emergency cesarean delivery, induction of labor, mortality, macrosomia >4500g, and childhood obesity Insufficient for childhood and maternal metabolic impairment and development of T2DM	
	Early GDM treatment vs usual care	Prior report: 0 Update: 4 trials (N=253)	Pregnancy outcomes: No associations for preeclampsia, gestational hypertension, hypertensive disorders of pregnancy, cesarean delivery, primary cesarean delivery, emergency cesarean delivery, induction of labor, preterm delivery, excessive gestational weight gain Fetal/neonatal outcomes: No associations for mortality, birth injury, shoulder dystocia, macrosomia >4000g, macrosomia >4500g, LGA, NICU admissions, any hypoglycemia, hyperbilirubinemia Long-term outcomes: No data Subgroups: Interactions between BMI and early treatment versus usual care imprecise	Highly imprecise for all outcomes		Insufficient for all outcomes of early treatment	Trials from Australia, New Zealand, Denmark and the U.S., largely non-minority populations

Table 25. Summary of Evidence

Key Question	Comparison	Studies Observations (N) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
7. What are the **harms of treatment of GDM**, including severe maternal and neonatal hypoglyc-emia, delivery of neonates who are small for gestational age, and poor long-term growth and development outcomes in the child?	Treatment for GDM at 24 weeks' gestation or later versus no treatment	Prior report: 5 trials Update: 4 trials (N=3,982)	Pregnancy outcomes: No association with severe maternal hypoglycemia Large association with reduced risk of macrosomia (>4,000 g; RR, 0.53 [95% CI, 0.41 to 0.68]) but no association with risk of total cesarean deliveries (RR, 0.95 [95% CI, 0.83 to 1.08]); cesarean sections may be associated with GDM Fetal/neonatal outcomes: No association with SGA, low birthweight, neonatal hypoglycemia requiring IV glucose therapy Long-term outcomes: No data Subgroups: No effect of SGA based on ethnicity or glycemic status	Highly imprecise for maternal hypoglycemia Some imprecision and inconsistency for severe neonatal hypoglycemia (requiring IV treatment) Some imprecision for SGA	No concerns; results were consistent with those from 2 large good quality trials	Moderate for no association with SGA Low for no association with severe neonatal hypoglycemia Insufficient for severe maternal hypoglycemia	See Key Question 6
	Early GDM treatment vs usual care	Prior report: 0 Update: 3 trials (n=123)	No association with SGA	Highly imprecise for all outcomes	Open-label in 3 trials; 1 was not randomized and 1 had high attrition	Insufficient	See Key Question 6

Abbreviations: ARD = absolute risk difference; BMI = body mass index; CC = Carpenter-Coustan; FPG =fasting plasma glucose; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study groups; LGA = large for gestational age; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; NICU = neonatal intensive care unit; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; OR = odds ratio; RCT = randomized controlled trial; RR = relative risk; SGA = small for gestational age; T2DM = type 2 diabetes mellitus

Appendix A1. Search Strategies

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to May 10, 2019 (Updated to May 22 2020)

1	Diabetes, Gestational/
2	(GDM or booking diabetes).tw.
3	(gestation$ adj2 (diabet$ or DM or glucose intoleran$ or insulin resistan$)).mp.
4	(pregnan$ adj3 (diabet$ or DM or glucose intoleran$ or insulin resistan$ or dysglycem$)).mp.
5	(maternal adj2 (diabet$ or DM or glyc?emia or hyperglyc?emia or glucose or dysglycem$)).tw.
6	(hyperglyc?emia adj2 pregnan$).tw.
7	or/1-6
8	mass screening/
9	prenatal diagnosis/
10	screen$.ti,ab.
11	diagnos$.ti,ab.
12	Glucose Tolerance Test/
13	Blood Glucose/
14	(serum or blood glucose or maternal glucose).tw.
15	(OGTT or tolerance test$).tw.
16	(GCT or challenge test$).tw.
17	((fasting adj2 glucose) or FG or FBG).tw.
18	(Carpenter-Coustan or Carpenter Coustan or NDDG or IADPSG or HbA1c or A1c or glycated hemoglobin).tw.
19	Glycated Hemoglobin A/
20	or/8-19
21	intervention$.mp.
22	(treat$ or therap$).mp.
23	manage$.mp.
24	monitor$.mp.
25	exp sulfonylurea compounds/
26	Gliclazide/
27	Glyburide/
28	Tolbutamide/
29	sulfonylurea?.tw.
30	gliclazid$.tw.
31	glimepirid$.tw.
32	glipizid$.tw.
33	glyburid$.tw.
34	tolbutamid$.tw.
35	Metformin/
36	Metformin.tw.
37	(antidiabet$ or anti-diabet$).tw.
38	insulin$.mp.
39	glibenclamid$.mp.
40	acarbos$.mp.
41	exp Diet Therapy/

42 (diet adj2 (therap$ or restrict$ or advice)).tw.
43 medical nutrition$ therapy.tw.
44 MNT.tw.
45 exp Life Style/
46 (lifestyle$ or life-style$).mp.
47 Blood Glucose Self-Monitoring/
48 (blood glucose adj (self monitor$ or self-monitor$)).tw.
49 ((self monitor$ or self-monitor$) adj blood glucose).tw.
50 SMBG.tw.
51 Counseling/
52 counsel$.tw.
53 or/21-52
54 "Sensitivity and Specificity"/
55 "Predictive Value of Tests"/
56 ROC Curve/
57 specificit$.tw.
58 sensitivit$.tw.
59 predictive value.tw.
60 accurac$.tw.
61 diagnostic errors/
62 diagnostic error?.tw.
63 false negative reactions/
64 false positive reactions/
65 (false adj (negative or positive)).tw.
66 reference values/
67 reference standards/
68 or/54-67
69 (controlled clinical trial or randomized controlled trial or pragmatic clinical trial or equivalence trial).pt.
70 clinical trial.pt.
71 (randomi?ed or randomi?ation$ or randomly or RCT$).tw,kf.
72 Randomized Controlled Trials as Topic/
73 trial.ti.
74 Controlled Clinical Trial/ or Controlled Clinical Trials as Topic/
75 (control$ adj2 trial$).tw,kf.
76 Non-Randomized Controlled Trials as Topic/
77 (nonrandom$ or non-random$ or quasi-random$ or quasi-experiment$).tw,kf.
78 (nRCT or non-RCT).tw,kf.
79 Controlled Before-After Studies/
80 (control$ adj3 ((before and after) or before after)).tw,kf.
81 (pre- adj3 post-).tw,kf.
82 (pretest adj3 posttest).tw,kf.
83 Historically Controlled Study/
84 (control$ adj2 study).tw,kf.
85 Control Groups/
86 group$.tw,kf.

87 exp Cohort Studies/
88 cohort$.tw,kf.
89 Retrospective Studies/
90 (longitudinal or prospective or retrospective).tw,kf.
91 ((followup or follow-up or follow up) adj (study or studies)).tw,kf.
92 Observational study.pt.
93 (observation$ adj (study or studies)).tw,kf.
94 ((population or population-based) adj (study or studies or analys?s)).tw,kf.
95 Comparative Study.pt.
96 ((comparative or comparison) adj (study or studies)).tw,kf.
97 exp Case-Control Studies/
98 ((case-control$ or case-based or case-comparison) adj (study or studies)).tw,kf.
99 (case-series or case series).tw.
100 or/69-99
101 (animal$ or bovine$ or calf or calves or camel$ or canine$ or cat or cats or chimp$ or dog or dogs or equine$ or feline$ or goat$ or hamster$ or horse$ or llama$ or mice$ or monkey$ or mouse$ or pig or piglet$ or pigs or porcine$ or primate$ or rabbit$ or rat or rats or rodent$ or sheep$ or simian$ or swine$ or veterinar$).ti.
102 7 and (20 or 53)
103 68 or 100
104 102 and 103
105 104 not 101

Embase 1974 to 2019 May 10, 2019 (Updated in May 22 2020)

1 pregnancy diabetes mellitus/
2 (GDM or booking diabetes).tw.
3 (gestation$ adj2 (diabet$ or DM or glucose intoleran$ or insulin resistan$)).mp.
4 (pregnan$ adj3 (diabet$ or DM or glucose intoleran$ or insulin resistan$ or dysglycem$)).mp.
5 (maternal adj2 (diabet$ or DM or glyc?emia or hyperglyc?emia or glucose or dysglycem$)).tw.
6 (hyperglyc?emia adj2 pregnan$).tw.
7 or/1-6
8 mass screening/
9 prenatal diagnosis/
10 prenatal screening/
11 screen$.ti,ab.
12 diagnos$.ti,ab.
13 exp Glucose Tolerance Test/
14 Blood Glucose level/
15 (glucose adj (tolerance or intolerance or challenge)).tw.
16 (serum or blood glucose or maternal glucose).tw.
17 (OGTT or tolerance test$).tw.
18 (GCT or challenge test$).tw.
19 ((fasting adj2 glucose) or FG or FBG).tw.

20 (Carpenter-Coustan or Carpenter Coustan or NDDG or IADPSG or HbA1c or A1c or glycated h?emoglobin).tw.
21 glycosylated hemoglobin/
22 or/8-21
23 intervention$.mp.
24 (treat$ or therap$).mp.
25 manage$.mp.
26 monitor$.mp.
27 exp sulfonylurea derivative/
28 metformin/
29 sulfonylurea?.tw.
30 gliclazid$.tw.
31 glimepirid$.tw.
32 glipizid$.tw.
33 glyburid$.tw.
34 tolbutamid$.tw.
35 Metformin.tw.
36 (antidiabet$ or anti-diabet$).tw.
37 insulin$.mp.
38 glibenclamid$.mp.
39 acarbos$.mp.
40 exp Diet Therapy/
41 (diet adj2 (therap$ or restrict$ or advice)).tw.
42 medical nutrition$ therapy.tw.
43 MNT.tw.
44 exp lifestyle/
45 (lifestyle$ or life-style$).mp.
46 Blood Glucose Monitoring/
47 (blood glucose adj (self monitor$ or self-monitor$)).tw.
48 ((self monitor$ or self-monitor$) adj blood glucose).tw.
49 SMBG.tw.
50 Counseling/
51 counsel$.tw.
52 or/23-51
53 "Sensitivity and Specificity"/
54 predictive value/
55 receiver operating characteristic/
56 specificit$.tw.
57 sensitivit$.tw.
58 predictive value.tw.
59 accurac$.tw.
60 diagnostic error/
61 diagnostic accuracy/
62 diagnostic error$.tw.
63 false negative result/
64 false positive result/

65 (false adj (negative or positive)).tw.
66 reference value/
67 reference standard/
68 or/53-67
69 clinical trial/
70 controlled clinical trial/
71 randomized controlled trial/
72 pragmatic trial/
73 equivalence trial/
74 cohort analysis/
75 exp case control study/
76 Control Groups/
77 retrospective study/
78 trial.ti.
79 (control$ adj2 (trial$ or study or studies or group$)).tw.
80 (nonrandom$ or non-random$ or quasi-random$ or quasi-experiment$).tw.
81 (nRCT or non-RCT).tw.
82 (control$ adj3 ((before and after) or before after)).tw.
83 (pre- adj3 post-).tw.
84 (pretest adj3 posttest).tw.
85 group$.tw.
86 cohort$.tw.
87 (longitudinal or prospective or retrospective).tw.
88 ((followup or follow-up or follow up) adj (study or studies)).tw.
89 (observation$ adj (study or studies)).tw.
90 ((population or population-based) adj (study or studies or analys?s)).tw.
91 ((comparative or comparison) adj (study or studies)).tw.
92 ((case-control$ or case-based or case-comparison) adj (study or studies)).tw.
93 or/69-92
94 (animal$ or bovine$ or calf or calves or camel$ or canine$ or cat or cats or chimp$ or dog or dogs or equine$ or feline$ or goat$ or hamster$ or horse$ or llama$ or mice$ or monkey$ or mouse$ or pig or piglet$ or pigs or porcine$ or primate$ or rabbit$ or rat or rats or rodent$ or sheep$ or simian$ or swine$ or veterinar$).ti.
95 7 and (22 or 52)
96 68 or 93
97 95 and 96
98 97 not 94
99 limit 98 to (conference abstract or conference paper or editorial)
100 98 not 99

Appendix A1. Search Strategies

CINAHL Plus with Full Text, May 10, 2019 (Updated May 22, 2020)

#	Query
S69	S67 AND S68
S68	S22 or S65
S67	S4 and (S11 or S19)
S66	TI (animal* or bovine* or calf or calves or camel* or canine* or cat or cats or chimp* or dog or dogs or equine* or feline* or goat* or hamster* or horse* or llama* or mice* or monkey* or mouse* or pig or piglet* or pigs or porcine* or primate* or rabbit* or rat or rats or rodent* or sheep* or simian* or swine* or veterinar*)
S65	S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64
S64	(followup or follow-up or "follow up" or observation* or population or population-based or comparative or comparison or case-control* or case-based or case-comparison) n2 (study or studies or analys#s)
S63	pretest n3 posttest
S62	(pre- n3 post-)
S61	(nonrandom* or non-random* or quasi-random* or quasi-experiment* or nRCT or non-RCT or "time series" or cohort* or longitudinal or prospective or retrospective or case-series or case series)
S60	(control* n3 ("before and after" or "before after"))
S59	(control* n2 (trial* or study or studies or group*))
S58	(MH "Clinical Trials+") or (MH "Control Group") or (MH "prospective studies") or (MH "Case Control Studies+")
S57	TI trial* or group*
S56	randomi#ed or randomi#ation or randomly or RCT*
S55	PT "controlled clinical trial" or "randomized controlled trial" or "pragmatic clinical trial" or "equivalence trial" or "clinical trial" or "controlled before-after study" or "historically controlled study" or "retrospective study" or "observational study" or "comparative study" or "case-control study"
S54	S52 OR S53
S53	(specificit* or sensitivit* or (predictive w1 value*) or accurac* or (diagnostic w1 error*)) OR ((false w1 negative) or (false w1 positive))
S52	(MH "Sensitivity and Specificity") or (MH "Predictive Value of Tests") or (MH "ROC Curve") or (MH "Diagnostic Errors") or (MH "False Negative Reactions") or (MH "False Positive Reactions") or (MH "Reference Values") or (MH "Reference Standards")
S51	S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50
S50	(MH "Counseling") OR counsel*
S49	(MH "Blood Glucose Self-Monitoring") OR ("blood glucose" w1 "self monitor*" or "blood glucose" w1 "self-monitor*") OR SMBG
S48	(MH "Life Style Changes") OR (lifestyle* or life-style*)
S47	(MH "Diet Therapy") OR (diet w2 therap* or diet w2 restrict* or diet w2 advice) OR ("medical nutrition therapy" or MNT)
S46	(sulfonyurea? or gliclazid* or glimepirid* or glipizid* or glyburid* or tolbutamid*) OR (antidiabet* or anti-diabet*) OR (insulin* or glibenclamid* or acarbos* or metformin*)
S45	(MH "Sulfonylurea Compounds+")
S44	intervention* or treating or treatment* or therapy or therapies or manage* or monitor*
S43	S37 OR S38 OR S39 OR S40 OR S41 OR S42

S42 MH Hemoglobin A, Glycosylated
S41 (Carpenter-Coustan or "Carpenter Coustan" or NDDG or IADPSG or HbA1c or A1c or glycated h#emoglobin)
S40 (fasting n2 glucose) or FG or FBG
S39 (serum or "blood glucose" or "maternal glucose" or OGTT or "tolerance test" or GCT or "challenge test"
S38 (TI (screen* or diagnos*)) or (AB (screen* or diagnos*))
S37 (MH "mass screening") or (MH "prenatal diagnosis") or (MH "Glucose tolerance test") or (MH "Blood Glucose") or (MH "blood glucose monitoring")
S36 S33 OR S34 OR S35
S35 hyperglyc#emia n2 pregnan*
S34 ((gestation* w2 diabet* or gestation* w2 DM or gestation* w2 glucose intoleran* or gestation* w2 insulin resistan*)) OR ((pregnan* w3 diabet* or pregnan* w3 DM or pregnan* w3 glucose intoleran* or pregnan* w3 insulin resistan* or pregnanc* w3 dysglycem*)) OR ((maternal w2 diabet* or maternal w2 DM or maternal w2 glyc#emia or maternal w2 hyperglyc#emia or maternal w2 dysglycem*))
S33 MM Diabetes Mellitus, Gestational OR GDM OR "Booking diabetes"
S32 (followup or follow-up or "follow up" or observation* or population or population-based or comparative or comparison or case-control* or case-based or case-comparison) n2 (study or studies or analys#s)
S31 pretest n3 posttest
S30 (pre- n3 post-)
S29 (nonrandom* or non-random* or quasi-random* or quasi-experiment* or nRCT or non-RCT or "time series" or cohort* or longitudinal or prospective or retrospective or case-series or case series)
S28 (control* n3 ("before and after" or "before after"))
S27 (control* n2 (trial* or study or studies or group*))
S26 (MH "Clinical Trials+")
S25 TI trial* or group*
S24 randomi#ed or randomi#ation or randomly or RCT*
S23 PT "controlled clinical trial" or "randomized controlled trial" or "pragmatic clinical trial" or "equivalence trial" or "clinical trial" or "controlled before-after study" or "interrupted time series analysis" or "historically controlled study" or "retrospective study" or "observational study" or "comparative study" or "case-control study"
S22 S20 OR S21
S21 (specificit* or sensitivit* or (predictive w1 value*) or accurac* or (diagnostic w1 error*)) OR ((false w1 negative) or (false w1 positive))
S20 (MH "Sensitivity and Specificity") or (MH "Predictive Value of Tests") or (MH "ROC Curve") or (MH "Diagnostic Errors") or (MH "False Negative Reactions") or (MH "False Positive Reactions") or (MH "Reference Values") or (MH "Reference Standards")
S19 S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18
S18 (MH "Counseling") OR counsel*
S17 (MH "Blood Glucose Self-Monitoring") OR ("blood glucose" w1 "self monitor*" or "blood glucose" w1 "self-monitor*") OR SMBG
S16 (MH "Life Style Changes") OR (lifestyle* or life-style*)

Appendix A1. Search Strategies

S15	(MH "Diet Therapy") OR (diet w2 therap* or diet w2 restrict* or diet w2 advice) OR ("medical nutrition therapy" or MNT)
S14	(sulfonyurea? or gliclazid* or glimepirid* or glipizid* or glyburid* or tolbutamid*) OR (antidiabet* or anti-diabet*) OR (insulin* or glibenclamid* or acarbos* or metformin*)
S13	(MH "Sulfonylurea Compounds+")
S12	intervention* or treating or treatment* or therapy or therapies or manage* or monitor*
S11	S5 OR S6 OR S7 OR S8 OR S9 OR S10
S10	MH Hemoglobin A, Glycosylated
S9	(Carpenter-Coustan or "Carpenter Coustan" or NDDG or IADPSG or HbA1c or A1c or glycated h#emoglobin)
S8	(fasting n2 glucose) or FG or FBG
S7	(serum or "blood glucose" or "maternal glucose" or OGTT or "tolerance test" or GCT or "challenge test"
S6	(TI (screen* or diagnos*)) or (AB (screen* or diagnos*))
S5	(MH "mass screening") or (MH "prenatal diagnosis") or (MH "Glucose tolerance test") or (MH "Blood Glucose") or (MH "blood glucose monitoring")
S4	S1 OR S2 OR S3
S3	hyperglyc#emia n2 pregnan*
S2	((gestation* w2 diabet* or gestation* w2 DM or gestation* w2 glucose intoleran* or gestation* w2 insulin resistan*)) OR ((pregnan* w3 diabet* or pregnan* w3 DM or pregnan* w3 glucose intoleran* or pregnan* w3 insulin resistan* or pregnanc* w3 dysglycem*)) OR ((maternal w2 diabet* or maternal w2 DM or maternal w2 glyc#emia or maternal w2 hyperglyc#emia or maternal w2 dysglycem*))
S1	MM Diabetes Mellitus, Gestational OR GDM OR "Booking diabetes"

Appendix A2. Inclusion and Exclusion Criteria per Key Question

	Include	Exclude
Population	**KQs 1–5:** Pregnant women with no known history of pre-existing diabetes mellitus **KQs 6, 7:** Pregnant women with GDM or hyperglycemia **KQs 1c, 3c, 6c:** Pre-pregnancy body mass index (i.e., <25 vs. ≥25 kg/m^2, <30 vs. ≥30 kg/m^2); age (e.g., <25 vs. ≥25 years, <35 vs. ≥35 years); timing during pregnancy (e.g., <24 vs ≥24 weeks); race/ethnicity (i.e., non-Hispanic white, American Indian or Alaskan Native, African American, Asian, Hispanic, or Pacific Islander); family history of type 2 diabetes mellitus, history of GDM, identified as "high-risk" by study authors (KQs 1 and 3 only), and severity of hyperglycemia (KQ 6 only)	
Interventions/ Exposure	**KQs 1–3:** Screening using one- or two-step strategies,* followed by intention-to-treat patients with a diagnosis of GDM: • In two-step screening, the screening test must be FPG, 50-g OGCT, risk factor–based method (clinical or historical using ≥1 factors), or hemoglobin A1c; in both one- and two-step screening, the diagnostic tool must be FPG or OGTT (using any GDM criteria) • Screening strategies may vary the timing of screening based on patient characteristics (e.g., early screening for patients with risk factors vs. later screening for those without) **KQ 4:** Screening tests (i.e., FPG, 50-g OGCT, risk factor–based method, or hemoglobin A1c) **KQ 5:** Diagnosis of GDM using one of the below criteria, but no treatment of GDM or meeting two-step Carpenter-Coustan or NDDG criteria: • IADPSG (also known as HAPO 1.75 criteria, new World Health Organization GDM criteria, or the Diabetes Canada alternative strategy) • One-step Carpenter-Coustan, NDDG, or HAPO 2.0 criteria • Two-step Carpenter-Coustan or NDDG criteria (both using only one abnormal glucose value) or HAPO 2.0 criteria (also known as the Diabetes Canada preferred criteria) **KQs 6, 7:** Any treatment of GDM offered during pregnancy, including but not limited to dietary advice, physical activity, blood glucose monitoring, insulin therapy (all preparations), or glucose-lowering medications	**KQs 1–5:** Alternative methods to deliver glucose (e.g., candy bars)
Comparators	**KQs 1, 2:** No screening; for KQ2, may be no intervention comparison if study authors measure outcomes before and after screening in each participant **KQ 3:** Another screening strategy, such as one- vs. two-step screening, different diagnostic criteria or cut-offs, different timing in pregnancy (may be due to risk factors), or selective/risk-based vs. universal screening **KQ 4:** Any FPG or OGTT used for diagnosis **KQ 5:** No GDM by any criteria applied in the study (e.g., OCGT negative, OCGT positive but no GDM [false-positive result], both OGCT negative and false-positive results) **KQs 6, 7:** No treatment (i.e., no additional management or minimally active intervention, such as printed materials)	**KQs 1–5:** Alternative methods to deliver glucose (e.g., candy bars, glucose loads) with same diagnostic criteria **KQs 6, 7:** All active interventions

Appendix A2. Inclusion and Exclusion Criteria per Key Question

	Include	Exclude
Outcomes	**KQs 1, 3, 5, 6:** *Intermediate* • Pregnancy: Excessive gestational weight gain (as per guidance from the Institute of Medicine, or defined by study author) • Long-term: Maternal and childhood development of metabolic impairment (impaired glucose tolerance) or obesity *Health* • Pregnancy: Pre-eclampsia, gestational hypertension, cesarean delivery, and induction of labor • Fetal/neonatal: Mortality (miscarriage, stillbirth, neonatal death), birth injury (fracture, permanent nerve injury), acute morbidity (e.g., hypoglycemia, hyperbilirubinemia, NICU admission, respiratory distress syndrome), fetal overgrowth (large for gestational age or macrosomia), and shoulder dystocia • Long-term maternal: Development of type 2 diabetes mellitus; mortality or major morbidity from type 2 diabetes mellitus (e.g., retinopathy, neuropathy), cardiovascular disease, or both; and quality of life • Long-term childhood: Development of type 2 diabetes mellitus, cardiovascular outcomes, and neurocognitive outcomes **KQ 2:** Adverse effects from screening tests (e.g., vomiting, anxiety or depression for the mother), from a GDM diagnosis (i.e., consequences from the label of GDM to the woman, fetus or neonate, such as unnecessary delivery interventions, additional interventions with formula, separation of infant and mother, breastfeeding challenges/failure), or both **KQ 4:** Sensitivity, specificity, positive or negative predictive values, accuracy, and yield (i.e., prevalence) **KQ 7:** Severe maternal or neonatal hypoglycemia, delivery of neonate who is small for gestational age, and long-term growth and development of the child	**KQs 1, 3–6:** Other outcomes
Outcome assessment timing	Any duration of followup	
Setting	**KQs 1–3, 5–7:** Settings applicable to primary care; countries not categorized as "Very High" on the Human Development Index (as defined by the United Nations Development Programme) will be subject to sensitivity analysis **KQ 4:** Any setting	
Study designs	**KQs 1, 2:** RCTs, CCTs, and controlled observational studies **KQ 2:** Studies in which all patients are screened but harms are assessed before (i.e., earlier in pregnancy) and after screening **KQ 3:** RCTs and CCTs **KQ 4:** Prospective cohort studies, single arms of trials **KQ 5:** Observational studies and single-arm trials (i.e., trial arms not receiving treatment) **KQs 6, 7:** RCTs, CCTs; controlled observational studies, if no trials exist	Systematic reviews[†], abstracts, and conference proceedings

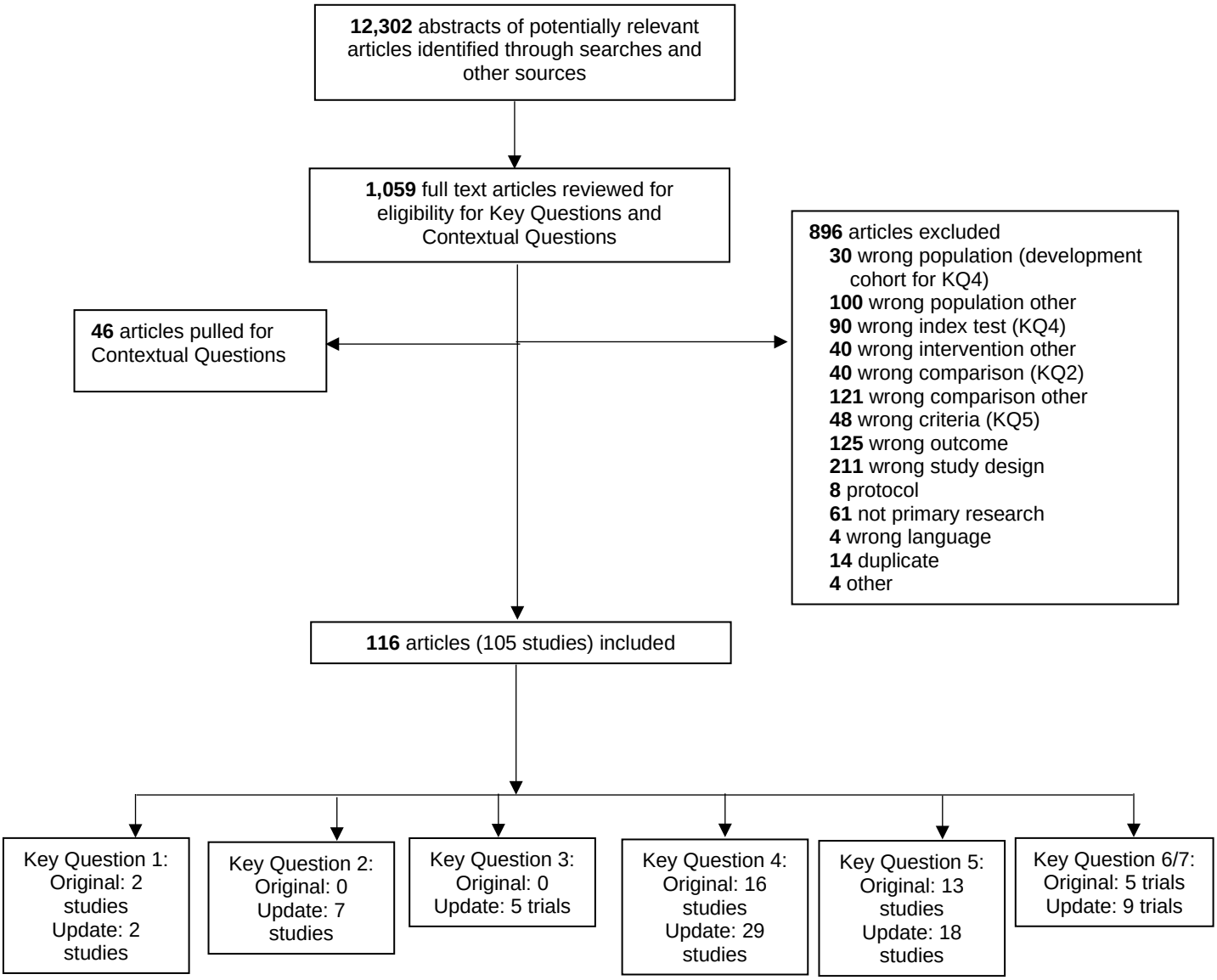
Appendix A2. Inclusion and Exclusion Criteria per Key Question

	Include	Exclude
Publication language	English	

Abbreviations: CCT=controlled clinical trial; FPG=fasting plasma glucose; GDM=gestational diabetes mellitus; HAPO=Hyperglycemia and Adverse Pregnancy Outcome Study; IADPSG=International Association of Diabetes and Pregnancy Study Group; KQ=key question; NDDG=National Diabetes Data Group; NICU=neonatal intensive care unit; OGCT=oral glucose challenge test; OGTT=oral glucose tolerance test; RCT=randomized, controlled trial.

*Two-step screening involves a screening test (e.g., 50-g OGCT, risk factor–based method) followed by a diagnostic test (i.e., OGTT), whereas one-step screening involves one test used for diagnosis in everyone.
†Systematic reviews, identified from a preliminary search for reviews on GDM and from searches for primary studies, will be scanned for potentially relevant studies but will not be included as the unit of analysis.

Appendix A2. Inclusion and Exclusion Criteria per Key Question



Appendix A4. Included Studies

1. Agarwal MM, Dhatt GS, Punnose J. Gestational diabetes: utility of fasting plasma glucose as a screening test depends on the diagnostic criteria. Diabet Med. 2006 Dec;23(12):1319-26. doi: 10.1111/j.1464-5491.2006.01987.x. PMID: 17116182.
2. Agarwal MM, Hughes PF, Punnose J, et al. Fasting plasma glucose as a screening test for gestational diabetes in a multi-ethnic, high-risk population. Diabet Med. 2000 Oct;17(10):720-6. doi: 10.1046/j.1464-5491.2000.00371.x. PMID: 11110505.
3. Agarwal MM, Hughes PF, Punnose J, et al. Gestational diabetes screening of a multiethnic, high-risk population using glycated proteins. Diabetes Res Clin Pract. 2001 Jan;51(1):67-73. doi: 10.1016/s0168-8227(00)00206-0. PMID: 11137184.
4. Agarwal MM, Punnose J, Sukhija K, et al. Gestational diabetes mellitus: using the fasting plasma glucose level to simplify the international association of diabetes and pregnancy study groups diagnostic algorithm in an adult South Asian population. Can J Diabetes. 2018 Oct;42(5):500-4. doi: 10.1016/j.jcjd.2017.12.009. PMID: 29545111.
5. Arbib N, Gabbay-Benziv R, Aviram A, et al. Third trimester abnormal oral glucose tolerance test and adverse perinatal outcome. J Matern Fetal Neonatal Med. 2017 Apr;30(8):917-21. doi: 10.1080/14767058.2016.1190825. PMID: 27186963.
6. Ayach W, Costa RA, Calderon Ide M, et al. Comparison between 100-g glucose tolerance test and two other screening tests for gestational diabetes: combined fasting glucose with risk factors and 50-g glucose tolerance test. Sao Paulo Med J. 2006 Jan 5;124(1):4-9. doi: 10.1590/s1516-31802006000100002. PMID: 16612455.
7. Basri NI, Mahdy ZA, Ahmad S, et al. The World Health Organization (WHO) versus the International Association of Diabetes and Pregnancy Study Group (IADPSG) diagnostic criteria of gestational diabetes mellitus (GDM) and their associated maternal and neonatal outcomes. Horm Mol Biol Clin Investig. 2018 Feb 17;34(1). doi: 10.1515/hmbci-2017-0077. PMID: 620980761.
8. Benaiges D, Flores-Le Roux JA, Marcelo I, et al. Is first-trimester HbA1c useful in the diagnosis of gestational diabetes? Diabetes Res Clin Pract. 2017 Nov;133:85-91. doi: 10.1016/j.diabres.2017.08.019. PMID: 28918341.
9. Benhalima K, Hanssens M, Devlieger R, et al. Analysis of pregnancy outcomes using the new IADPSG recommendation compared with the carpenter and coustan criteria in an area with a low prevalence of gestational diabetes. Int J Endocrinol. 2013;2013:248121. doi: 10.1155/2013/248121. PMID: 23365571.
10. Benhalima K, Van Crombrugge P, Moyson C, et al. A modified two-step screening strategy for gestational diabetes mellitus based on the 2013 WHO criteria by combining the glucose challenge test and clinical risk factors. J Clin Med. 2018 Oct;7(10):13. doi: 10.3390/jcm7100351. PMID: 30322138.
11. Berkus MD, Langer O, Piper JM, et al. Efficiency of lower threshold criteria for the diagnosis of gestational diabetes. Obstet Gynecol. 1995 Dec;86(6):892-6. doi: 10.1016/0029-7844(95)00319-m. PMID: 7501334.
12. Bevier WC, Fischer R, Jovanovic L. Treatment of women with an abnormal glucose challenge test (but a normal oral glucose tolerance test) decreases the prevalence of macrosomia. Am J Perinatol. 1999;16(6):269-75. doi: 10.1055/s-2007-993871. PMID: 10586979.
13. Bhavadharini B, Mahalakshmi MM, Deepa M, et al. Elevated glycated hemoglobin predicts macrosomia among Asian Indian pregnant women (WINGS-9). Indian J

Endocrinol Metab. 2017 Jan-Feb;21(1):184-9. doi: 10.4103/2230-8210.196003. PMID: 28217520.

14. Biri A, Korucuoglu U, Ozcan P, et al. Effect of different degrees of glucose intolerance on maternal and perinatal outcomes. J Matern Fetal Neonatal Med. 2009 Jun;22(6):473-8. doi: 10.1080/14767050802610344. PMID: 19479645.
15. Bonomo M, Corica D, Mion E, et al. Evaluating the therapeutic approach in pregnancies complicated by borderline glucose intolerance: a randomized clinical trial. Diabet Med. 2005 Nov;22(11):1536-41. doi: 10.1111/j.1464-5491.2005.01690.x. PMID: 16241919.
16. Braga FO, Negrato CA, Matta M, et al. Relationship between inflammatory markers, glycated hemoglobin and placental weight on fetal outcomes in women with gestational diabetes. Arch Endocrinol Metab. 2019 Feb;63(1):22-9. doi: 10.20945/2359-3997000000099. PMID: 30864628.
17. Cetin M, Cetin A. Time-dependent gestational diabetes screening values. Int J Gynaecol Obstet. 1997 Mar;56(3):257-61. doi: 10.1016/s0020-7292(96)02831-7. PMID: 9127158.
18. Chanprapaph P, Sutjarit C. Prevalence of gestational diabetes mellitus (GDM) in women screened by glucose challenge test (GCT) at Maharaj Nakorn Chiang Mai Hospital. J Med Assoc Thai. 2004 Oct;87(10):1141-6. PMID: 15560687.
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Appendix A5. Excluded Studies

1. Abbas A, Nasir H, Zehra A, et al. Assessment of depression as comorbidity in diabetes mellitus patients using Beck Depression Inventory II (BDI II) scale. J Young Pharm. 2015 Jul 01;7(3):206-16. PMID: 606004028. **Wrong population**.
2. Abbas AJ, Ali HA, M.M AL-R, et al. Association of serum preptin levels with insulin resistance in Iraqi women with gestational diabetes mellitus. Int Res J Pharm. 2019 Jan 01;10(1):49-55. PMID: 626383891. **Wrong study design**.
3. Abdollahi F, Zarghami M, Azhar MZ, et al. Predictors and incidence of post-partum depression: a longitudinal cohort study. J Obstet Gynaecol Re. 2014;40(12):2191-200. PMID: 25132641. **Wrong study design**.
4. Abdollahi F, Zarghami M, Azhar MZ, et al. Predictors and incidence of post-partum depression: a longitudinal cohort study. J Obstet Gynaecol Re. 2014;40(12):2191-200. PMID: 25132641. **Wrong comparison KQ2**
5. Abebe KZ, Scifres C, Simhan HN, et al. Comparison of two screening strategies for gestational diabetes (GDM2) trial: design and rationale. Contemp. Clin. Trials Commun. 2017;62:43-9. PMID: 28823926. **Protocol**.
6. Abell SK, Boyle JA, Earnest A, et al. Impact of different glycaemic treatment targets on pregnancy outcomes in gestational diabetes. Diabet Med. 2019;36(2):177-83. PMID: 30102812. **Wrong comparison**.
7. Abell SK, Shorakae S, Boyle JA, et al. Role of serum biomarkers to optimise a validated clinical risk prediction tool for gestational diabetes. Aust NZ J Obstet Gyn. 2019;59(2):251-7. PMID: 29900538. **Wrong index test KQ4**.
8. Abell SK, Shorakae S, Boyle JA, et al. Role of serum biomarkers to optimise a validated clinical risk prediction tool for gestational diabetes. Aust NZ J Obstet Gyn. 2019;59(2):251-7. PMID: 29900538. **Wrong population (KQ4 development cohort)**.
9. Abell SK, Teede HJ. The IADPSG diagnostic criteria identify women with increased risk of adverse pregnancy outcomes in Victoria. Aust NZ J Obstet Gyn. 2017;57(5):564-8. PMID: 28741654. **Wrong criteria KQ5**.
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13. Adam S, Rheeder P. Evaluating the utility of a point-of-care glucometer for the diagnosis of gestational diabetes. Int J Gynae Obstet. 2018;141(1):91-6. PMID: 29164614. **Wrong index test KQ4**.
14. Adam S, Rheeder P. Screening for gestational diabetes mellitus in a South African population: prevalence, comparison of diagnostic criteria and the role of risk factors.

SAMJ S Afr Med J. Suid-Afrikaanse Tydskrif Vir Geneeskunde. 2017;107(6):523-7. PMID: 28604326. **Wrong population (KQ4 development cohort)**.

15. Adam S, Rheeder P. Selective screening strategies for gestational diabetes: a prospective cohort observational study. J Diabetes Res. 2017;2017:2849346. PMID: 29201921. **Wrong outcome**.
16. Adams KM, Li H, Nelson RL, et al. Sequelae of unrecognized gestational diabetes. Am J Obstet Gynecol. 1998 Jun;178(6):1321-32. doi: 10.1016/s0002-9378(98)70339-4. PMID: 9662318. **Wrong study design**.
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Appendix A6. Expert Reviewers of the Draft Report

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- Dr. Elena Gorodetsky, Office of Research on Women's Health
- Cuilin Zhang, MD, PhD, MPH, National Institutes of Health, Division of Intramural Population Health Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development
- Erin Abramsohn, MPH, DrPH and Jennifer Fuld, PhD, Centers for Disease Control and Prevention
- Representatives from the Centers for Disease Control and Prevention; the National Institutes of Health, Division of Intramural Population Health Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development; the National Institutes of Health, Office of Research on Women's Health

Note: Reviewers provided comments on a prior version of the draft report and may or may not agree with the report findings

Appendix B Table 1. Studies on Effectiveness of Screening vs. No Screening (KQ1)

Author, year Study Design, Duration of Follow up Country	Women Enrolled, Total and Per Group (*n*) Maternal Age, *mean± SD (yr)* BMI, *mean ± SD (kg/m²)* *Race (%)* *Previous GDM & Family Hx of T2DM (%)*	Inclusion/ Exclusion Criteria	Gestational Age at Screening Screening Test(s) and Treatment of GDM Prevalence of GDM (%)	Outcomes & Analysis including subgroups
Stacey[68], 2019 Case-control, birth United Kingdom	1012 (283 with late stillbirths; 729 controls) NR 21% ≥30, 30.4% 25-29.9 (entire sample) White 82.4, South Asian 13.4, Black Caribbean 0.9 (entire sample) 0.7 & NR	**Inclusion:** Cases of **s**ingleton non-anomalous late stillbirths (≥28 wGA) and random sample (matched by gestation and unit of birth) of control women with ongoing pregnancies, which ended in live births that were recruited in 41 maternity units in the UK between April 2014 and March 2016 **Exclusion**: multiple pregnancies, pregnancies with congenital anomalies, <16 years of age; preexisting DM	Gestational age: NR (NICE guidance states 24-28 wGA unless previous GDM then right after booking appointment (whether 1st or 2nd trimester) Step 1: At-risk: any of South Asian or Black Caribbean ethnicity, BMI ≥ 30 kg/m², or previous pregnancy effected by GDM or macrosomic (≥ 4500 g) birth Step 2: OGTT: NICE FPG ≥ 101 mg/dL (5.6 mmol/l) or 2-hr ≥ 140 mg/dL (7.8 mmol/l) GDM prevalence: 10 in screened group	**Pregnancy:** Late stillbirth (≥ 28 wGA) Not intention to screen; used causal mediation analysis with logistic regression to explore the joint effects of a composite exposure of 'at risk' of GDM (n=330) and mediator of screening for GDM (n=362), using all data; models included the exposure ('at risk' of GDM) and mediator (screened for GDM) only, as all partial confounding variables were also partial mediators
Hivert[67], 2012 RCS, early neonatal period Canada	2780 (1019 1st trimester screened; 993 2nd trimester screened; 768 not screened) G1: 1st trimester screened: 28.2 ± 4.6 G2: 2nd trimester screened: 28.3 ± 5.1 G3: Not screened: 28.0 ± 5.0 NR G1: European descent 92.9	**Inclusion:** Pregnant women delivering at regional hospital 2008-2009 (all pregnant women eligible for clinic services) **Exclusion**: Multiple pregnancies	Gestational age: OGCT median 15.3 wGA (9.9 in G1, 27.0 in G2); OGTT median 27.9 wGA (7.8% of those in G3) Step1: 50 g OGCT threshold NR (36.5% in first trimester); in 1st trimester if at-risk Step 2: 75 g OGTT using IADPSG; some women received capillary glucose testing q.i.d. for 1 week instead (> 50% above target at one or more specific time periods during the day) Screening performed by physician request to a specialized prenatal blood sampling clinic (regional promotion of	**Pregnancy:** **c**esarean section **Fetal/neonatal:** macrosomia; birth injury (fracture and dislocation); hypoglycemia; hyperbilirubinemia; respiratory distress; admission to NICU Not intention to treat: unadjusted comparisons between G1 & G2 vs. G3 Subgroup: 1st vs. 2nd trimester screened vs. not screened

Appendix B Table 1. Studies on Effectiveness of Screening vs. No Screening (KQ1)

Author, year Study Design, Duration of Follow up Country	Women Enrolled, Total and Per Group (*n*) Maternal Age, *mean± SD (yr)* BMI, *mean ± SD (kg/m²)* *Race (%)* *Previous GDM & Family Hx of T2DM (%)*	Inclusion/ Exclusion Criteria	Gestational Age at Screening Screening Test(s) and Treatment of GDM Prevalence of GDM (%)	Outcomes & Analysis including subgroups
	G2: European descent 92.6 G3: European descent 95.8 G1: NR G2: NR G3: NR Not including patients from 2005-2006 or 2006-2007 years		universal screening in the second trimester and early screening for at-risk women); program includes rapid referral to Diabetes Centre with individualized treatment and insulin when indicated GDM prevalence: G1 & G2 7.7 vs. G3 6.6 (from OGTT)	
Chanprapaph[69], 2004	1,000 but used 451 eligible "at-risk" for analysis (411	**Inclusion:** Pregnant women attending and delivering at a single antenatal care center;	Gestational age: 24 - 28 wGA or 30 - 32 wGA	**Pregnancy:** PIH; GHT; cesarean section
Chanprapaph, 2004 Continued. RCS, birth Thailand	screened based on 1+ risk factor* vs. 40 with 1+ risk factor not screened) Screened: 31.5 ± 5.5 Not screened: 28.5 ± 4.7 Screened: 22.5 ± 3.8 Not screened: 22.0 ± 3.0 Thai population Screened: 0.2 & 22	attendance from Oct 2001 to Dec 2002. **Exclusion:** NR	Step 1: Risk factors* + 50 g OGCT; positive ≥ 140 mg/dL after 1 hour Step 2: 100 g OGTT using NDDG Treatment NR GDM prevalence: 7	**Fetal/neonatal:** LGA (>90th percentile); SGA (<10th percentile) Not intention-to screen analyses: i) screened due to 1+ risk factor vs. not screened (93% without risk factors) (not included), ii) screened due to 1+ risk factor vs. not screened with 1+ risk factor

Appendix B Table 1. Studies on Effectiveness of Screening vs. No Screening (KQ1)

Author, year Study Design, Duration of Follow up Country	Women Enrolled, Total and Per Group (*n*) Maternal Age, *mean± SD (yr)* BMI, *mean ± SD (kg/m²)* *Race (%)* *Previous GDM & Family Hx of T2DM (%)*	Inclusion/ Exclusion Criteria	Gestational Age at Screening Screening Test(s) and Treatment of GDM Prevalence of GDM (%)	Outcomes & Analysis including subgroups
	Not screened: 0.2 & 42.5			
Solomon[70], 1996 RCS, birth US	93 (77 screened & 16 not screened) Screened: 30.5 ± NR Not screened: 31.1 ± NR Screened: 23.0 ± NR Not screened: 23.6 ± NR	**Inclusion:** Female nurses; 25 to 42 yrs residing in 1 of 14 US states participating in Nurses Health Study II; random sampling of 100 with a pregnancy but no diagnosis of GDM between 1989 and 1991 **Exclusion:** NR but none had GDM	Gestational Age: NR but assume 24-28 using NDDG Step 1**:** 1 h 50 g OGCT, threshold NR All participants in analysis had NGT with negative screen No treatment would have been given (all GDM-ve)	**Fetal/neonatal:** Macrosomia ≥4300 g
Solomon, 1996 Continued.	Screened: 2.6 non-White ethnicity Not screened: 0 non-White ethnicity Screened: NR & 17 Not screened: NR & 12.5			

Abbreviations: BMI = body mass index; DM = diabetes mellitus; FPG = fasting plasma glucose; g = grams; G = group; GDM = gestational diabetes mellitus; GHT = gestational hypertension; hr = hour; Hx = history; IADPSG = International Association of Diabetes and Pregnancy Study Groups; kg/m^2 = kilogram per meter squared; LGA = large for gestational age; mg/dl = milligram per deciliter; mmol/l = millimole per liter; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; NICE = National Institute for Health and Care Excellence; NICU = neonatal intensive care unit; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; PIH = pregnancy-induced hypertension; q.i.d. = quater in die (4 times daily); RCS = retrospective cohort study; SD = standard deviation; SGA = small for gestational age; T2DM = type 2 diabetes mellitus; wGA = weeks' gestational age; yr(s) = year(s); +ve = positive; -ve = negative

*Screening GDM test was performed in pregnancies with risk factors including diabetic familial history, maternal age of 30 years old or greater, previous GDM or pregnancy induced hypertension, fetal anomaly, intrauterine fetal death, macrosomia, polyhydramnios, glycosuria, polydypsia, excessive weight gain, marked obesity or (body mass index; BMI > 30 kg/m2) and larger fundal height compared to gestational age; the common indications for GCT screening in the study were advanced maternal age (75.4%) followed by familial diabetic history (22.1%) and glycosuria (6.8%)

Appendix B Table 2. Quality Assessment of Studies on Effectiveness of Screening vs. No Screening (KQ1): Cohorts and Case-Controls

Author, Year	Representatives of exposed cohort	Selection of non-exposed cohort	Ascertainment of exposure	Outcome of interest not present at start of study/before screening	Controls for age, race, BMI	Controls for any additional factor	Assessment of outcome	Was follow up long enough for outcomes to occur?	Adequacy of cohort follow up	Quality rating
Solomon[70], 1996	Selected group of users e.g. nurses, volunteers; only analyzed non GDM women so all eligible not included	Same community as the exposed cohort (but not all eligible enrolled)	Written self-report	Yes	Yes	No	Self-report but birth weight easily recalled with accuracy & blinding unlikely to impact in this study	Yes	Complete follow up – all subjects accounted for (93% of eligible participated)	Fair, and some limited applicability
Chanprapaph[69], 2004	Selected population (all women had 1+ risk factor so does not represent screening only high risk with outcomes captured in all)	Same community as the exposed cohort	Secure record	Yes	Yes	No	Record linkage	Yes	Complete follow up – all subjects accounted for	Good, but some concerns for applicability
Hivert[67] 2012	Representative	Different population (no physician referral to clinic for screening; may have received less intense prenatal/usual care than those attending clinic)	Secure record used for ascertainment but some of the OGTTs in nonscreened group (7.8%) may have been for screening and some may have had OGCT elsewhere; would bias findings to null	Yes	Partly (age and ethnicity not statistically different between groups)	No	Record linkage	Yes	Complete follow up – all subjects accounted for	Fair

Appendix B Table 2. Quality Assessment of Studies on Effectiveness of Screening vs. No Screening (KQ1): Cohorts and Case-Controls

Author, Year, Study Design	Is the case definition adequate?	Represent-ativeness of the cases	Selection of Controls	Definition of Controls	Controls for age, race, BMI, previous GDM, family history of DM	Controls for any additional factor	Ascertainment of exposure	Same method of ascertainment	Non-response rate	Quality rating
Stacey[68], 2019, Case-control	Yes; Late still birth >28 wGA	Potential for selection bias due to consent procedures and response rate NR	Similar to cases, accounting for gestational age and maternity unit rates of stillbirth	Yes; still pregnant at same gestational age as cases & delivered	All partial confounding variables were concurrent partial mediators and not adjusted for (but no data on family history of GDM or engagement with healthcare)	Yes (accounted for previous macrosomia, smoking)	Structured interview with community midwife but unclear on timing of screening (part from NICE guidance) and no blinding to exposure status	Yes	Data available for 97% of 1012	Fair

Abbreviations: BMI = body mass index; DM = diabetes mellitus; GDM = gestational diabetes mellitus; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; wGA = weeks' gestational age

Appendix B Table 3. Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year Dates of study Country (Very high index? Yes/No) Study Design	Women Analyzed, *n* Maternal Age, *mean ± SD/median ± IQR (yr)* BMI, *mean ± SD (kg/m²)* Race (%) Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Screening Strategy (criteria, glucose load, timing)	Outcomes & Assessment
Daniells[71] 2003 2000-2001 Australia (Yes) Prospective double cohort (50 GDM vs 50 NGT)	100 (50 GDM [54% of eligible] & 50 NGT [response NR]) **GDM**: 31.4 ± 5.0 **No GDM:** 29.0 ± 4.8 (p=0.02) **GDM**: 27.4 ± 7.2 **No GDM**: 24.6 ± 3.8 (p=0.02) **GDM**: Australian born (66%) **No GDM**: Australian born (86%) **GDM**: 0 (excluded) & 30 **No GDM**: 0 (excluded) & 16	**GDM group:** visiting Diabetes Centre, singleton pregnancy, no previous GDM, tested after 26 wks, seen in the clinic both within 1 week of diagnosis and before 32 wks of gestation, ability to read and write English and follow protocol **GT control group:** recruited at prenatal clinic and private obstetrical providers (referral sites to Diabetes Clinic; otherwise same criteria as above	One-step using ADIPS 2hr 75g OGTT (FPG ≥99 mg/dL and/or 2-h 144 mg/dL), early 3rd trimester (mean 28 wks)	Anxiety (Speilberger State-Trait Anxiety Inventory [STAI]; each scale range 20-80); the State scale asks about how the participant feels "right now - at this moment," whereas the Trait scale asks the participant to respond to how they "generally feel." Assessed in 3rd trimester (~30 wks; after screening), antepartum (~36 wks) and 6 wks postpartum (latter 2 questionnaires sent home with first)
Doughty[72], 2018 2005-2007 U.S. (Yes) Cross-sectional	1,733 (postnatal respondents, of 4,902 enrolled in pregnancy) **GDM (n=107):** 18-24 yrs: 6 (5.6%); 25-29 yrs: 34 (31.8%); 30-34 yrs: 35 (32.7%); ≥35 yrs: 32 (29.9%) **No GDM (n=1,626):** 18-24 yrs: 310 (19.1%); 25-29 yrs: 567 (34.9%); 30-34 yrs: 488 (30.0%); ≥35 yrs: 261 (16.1%)	**Inclusion:** Women in their third trimester, enrolled in U.S. Infant Feeding Practices Study II (consumer opinion panel; secondary analysis from prenatal and neonatal questionnaires), ≥18 yrs old, mother and infant without medical conditions that affect feeding; infant >5lb and born after 35 wks gestation **Exclusion:** multiple gestations, NICU stay longer than 3 d, T1DM or T2DM,	NR, self-report of GDM status during 3rd trimester	Hospital experiences (neonatal factors and hospital experiences that could affect exclusive breastfeeding) Problems with breastfeeding in 1st 2 wks (17 questions regardless of breastfeeding) Delayed onset of lactation (>72 hrs)

Appendix B Table 3. Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year Dates of study Country (Very high index? Yes/No) Study Design	Women Analyzed, *n* Maternal Age, *mean ± SD/median ± IQR (yr)* BMI, *mean ± SD (kg/m²)* Race (%) Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Screening Strategy (criteria, glucose load, timing)	Outcomes & Assessment
Doughty, 2018 Continued.	**GDM:** <18.5: 0 (0.0%); 18.5 ≤25: 30 (28.0%); 25 ≤30: 29 (27.1%); ≥30: 48 (44.9%) **No GDM:** <18.5: 77 (4.7%); 18.5 ≤25: 780 (48.0%); 25 ≤30: 410 (25.2%); ≥30: 359 (22.1%) **GDM:** Non-Hispanic White: 92 (86.0%); Non-Hispanic Black: 0 (0.0%); Hispanic: 7 (6.5%); Other: 8 (7.5%) **No GDM:** Non-Hispanic White: 1,376 (84.6%); Non-Hispanic Black: 73 (4.5%); Hispanic: 104 (6.4%); Other: 73 (4.5%) **GDM**: NR & NR **No GDM**: NR & NR	missing data for relevant variables		
Kerbel[73] 1997 1992-1993 Canada (Yes) Prospective cohort	813 (of 2148 eligible [39%]) at 32 wks **FP** (n=88): 30.9 ± 3.6 **Perceived test negative** (n=494)/**not tested** (n=231): 30.4 ± 4.3 NR **FP:** born in North America 59% **Perceived test negative/not tested**:	**Inclusion:** attending a prenatal registration clinic at a large community hospital in suburban Toronto, Canada, between 12 and 24 wks gestation**;** singleton pregnancy **Exclusion:** previous GDM or DM, no data at 32 wks (n=1194 of 2091 enrolled)	**50g GCT (>140 mg/dL), 24-28 wks gestation, followed by 100g OGTT** (up to 1/3 did not screen or used selective approach), completed by 30 wks	Anxiety (STAI; range 20-80) in those with false positive test vs. not tested/perceived negative Depression (Center for Epidemiologic Studies-Depression Scale (CES-D)) Measured after enrollment (12-24 wks), 32wks and 36 wks (36 wks not in analysis for these outcomes)

Appendix B Table 3. Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year Dates of study Country (Very high index? Yes/No) Study Design	Women Analyzed, *n* Maternal Age, *mean ± SD/median ± IQR (yr)* BMI, *mean ± SD (kg/m^2)* Race (%) Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Screening Strategy (criteria, glucose load, timing)	Outcomes & Assessment
Kerbel, 1997 Continued.	born in North America 69% **FP**: 0 & NR **Perceived test negative/not tested**: 0 and NR			
Loewenberg Weisband[74], 2017 2005-2007 U.S. (Yes) Prospective cohort	2,262 (98% of sample but 4902 started IFP study; 127 of 160 with GDM had data on supplementation) **GDM** (n=160): 30.9 ± 5.1 **No GDM** (n=2139): 29.1 ± 5.3 **GDM**: normal (18.5–24.9 kg/m^2) 24.8; overweight (25.0–29.9 kg/m^2) 28.0; obese (≥30.0 kg/m^2) 47.1 **No GDM**: GDM: normal (18.5–24.9 kg/m2) 49.9; overweight (25.0–29.9 kg/m2) 26.6; obese (≥30.0 kg/m2) 23.5 **GDM**: White 84.5; Black 1.9; Hispanic 6.4; Other 7.1 **No GDM**: White 86.0; Black 4.2; Hispanic 5.8; Other 4.0 **GDM**: NR & NR **No GDM**: NR & NR	**Inclusion:** Women in their third trimester, enrolled in U.S. Infant Feeding Practices Study II (consumer opinion panel), ≥18 yrs old, mother and infant without medical conditions that affect feeding; infant >5lb and born after 35 wks gestation **Exclusion:** previous DM	GDM self-reported	Mediation analysis to assess whether hospital supplementation mediated the association between exclusive breastfeeding intention and (any) breastfeeding duration, by GDM. Prenatal questionnaire during 3rd trimester (after GDM dx) for intentions; supplementation in neonatal period; duration assessed during 1 yr in 10 questionnaires

Appendix B Table 3. Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year Dates of study Country (Very high index? Yes/No) Study Design	Women Analyzed, *n* Maternal Age, *mean ± SD/median ± IQR (yr)* BMI, *mean ± SD (kg/m²)* Race (%) Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Screening Strategy (criteria, glucose load, timing)	Outcomes & Assessment
Naylor[75], 1996 Sept 1989 to Mar 1992 (recruitment) Canada (Yes) Prospective cohort	3,778 (90% of screened; 31% participation rate in overall study) **GCT –ve, OGTT –ve (n=2940):** 30.9 ± 4.1 **GCT +ve (n=580):** 31.9 ± 4.3 **Untreated borderline GDM (n=115):** 32.1 ± 4.4 **Known treated GDM (n=143):** 32.7 ± 4.3 **GCT –ve:** 22.7 ± 3.8 **GCT +ve:** 23.1 ± 4.5 **Untreated borderline GDM:** 24.7 ± 5.8 **Known treated GDM:** 24.2 ± 4.8 **GCT –ve:** White: 2048 (69.7%); Black: 136 (4.6%); Asian: 165 (5.6%); Other/unknown: 591 (20.1%) **GCT +ve:** White: 377 (65.0%); Black: 21 (3.6%); Asian: 48 (8.3%), Other/unknown: 134 (23.1%) **Untreated borderline GDM:** White: 67 (58.3%); Black: 2 (1.7%); Asian: 17 (14.8%); Other/unknown: 29 (25.2%) **Known treated GDM:** White: 63 (44.1%); Black:	**Inclusion:** ≥24 yrs old, without known DM, from Toronto Tri-hospital Gestational Diabetes Project, singleton deliveries **Exclusion:** Delivery before 28 wks gestation	**50g GCT:** 26 wks ±7d, then all receive **100g 3hr OGTT by NDDG, 1979:** 28 wks ±7d *__Untreated borderline GDM:__ meeting CC 1982 criteria, but not NDDG for GDM dx (physicians blinded to results)	Risk of cesarean delivery, accounting for macrosomia (>4000 g & >4300 g)

Appendix B Table 3. Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year Dates of study Country (Very high index? Yes/No) Study Design	Women Analyzed, *n* Maternal Age, *mean ± SD/median ± IQR (yr)* BMI, *mean ± SD (kg/m²)* Race (%) Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Screening Strategy (criteria, glucose load, timing)	Outcomes & Assessment
Naylor, 1996 Continued.	8 (5.6%); Asian: 27 (18.9%); Other/unknown: 45 (31.5%) **GCT –ve:** 1.2 & NR **GCT +ve:** 3.3 & NR **Untreated borderline GDM:** 5.2 & NR **Known treated GDM:** 7.7 & NR			
Oza-Frank[76] 2017 2004-2011 US (Yes) Cross-sectional	157,187 (of 163,627 survey participants) **GDM** (n=14,409): ≤19 yrs: 4.9%; 20-24 yrs: 15.6%; 25-29 yrs: 26.2%; 30-34 yrs: 28.6%; ≥35 yrs: 24.6% **No GDM** (n=142,778): ≤19 yrs: 9.5%; 20-24 yrs: 23.1%; 25-29 yrs: 28.6%; 30-34 yrs: 24.4%; ≥35 yrs: 14.4% **GDM:** <18.5: 3.2%; 18.5-24.9: 37.0%; 25.0-29.0: 26.9%; ≥30.0: 32.8% **No GDM:** <18.5: 5.0%; 18.5-24.9: 54.2%; 25.0-29.0: 23.2%; ≥30.0: 17.5% **GDM**: Non-Hispanic White: 47.7% ; Non-Hispanic Black: 12.1% ; Asian: 7.9%; Hispanic: 29.9%; Other: 2.4%	**Inclusion:** completed CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) survey after recent live birth (12 states asking optional questions on hospital breastfeeding experiences (Phase 5 2004-2008 and Phase 6 2009-2011) **Exclusion:** Women reporting pre-gestational DM, missing data on prepregnancy diabetes or/and GDM	NR, self-reported GDM status	Hospital experiences associated with breastfeeding outcomes Survey based on Baby-Friendly hospital practices All women: • Hospital staff gave me information about breastfeeding • My baby stayed in the same room as me • I breastfed my baby in the hospital For women who answered that they ever breast fed (including pump): • I breastfed in the first hour after my baby was born • Hospital staff helped me learn how to breastfeed • My baby was fed only breast milk at the hospital • Hospital staff told me to breastfeed whenever my baby wanted • The hospital gave me a breast pump to use • The hospital gave me a gift pack with formula

Appendix B Table 3. Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year Dates of study Country (Very high index? Yes/No) Study Design	Women Analyzed, *n* Maternal Age, *mean ± SD/median ± IQR (yr)* BMI, *mean ± SD (kg/m²)* Race (%) Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Screening Strategy (criteria, glucose load, timing)	Outcomes & Assessment
Oza-Frank, 2017 Continued.	**No GDM**: Non-Hispanic White: 58.1%; Non-Hispanic Black: 12.4%; Asian: 4.3%; Hispanic: 23.1%; Other: 2.0% **GDM**: NR & NR **No GDM**: NR & NR			• The hospital gave me a telephone number to call for help with breastfeeding My baby used a pacifier in the hospital
Rumbold[77] 2002 NR Australia (Yes) Prospective cohort	209 (77% of OGCT neg responded in late pregnancy; # eligible NR) **GCT –ve (n=150):** 28 ± 5 **GCT +ve & OGTT –ve (n=37):** 30 ± 4 **GDM (n=25):** 30 ± 4 **GCT –ve:** 27 ± 5 **GCT +ve:** 29 ± 6 **GDM:** 30 ± 7 **GCT –ve:** Caucasian: 141 (94%); Asian: 3 (2%); Aboriginal: 0 (0%); Other: 6 (4%) **GCT +ve:** Caucasian: 29 (78%); Asian: 5 (14%); Aboriginal: 0 (0%); Other: 3 (8%) **GDM:** Caucasian: 20 (80%); Asian: 3 (12%); Aboriginal: 1 (4%); Other: 1 (4%) **GCT –ve:** 3 & 35 **GCT +ve:** 6 & 43 **GDM:** 40 & 28	**Inclusion:** English-speaking, ≥18 yrs old, attending the study hospital for antenatal care who had been screened or would later be screened for GDM **Exclusion:** Preexisting DM	RBS or 50g GCT: 24-28 wks, if +ve, underwent 75g 2h OGTT by WHO 1985: timing NR	Anxiety (Spielberger State-Trait Anxiety Inventory, STAI 6-item short-form; range 6-24); Depressive symptoms (EPDS ≥12) All outcomes assessed before screening, after screening with GCT (but not OGTT), and late in pregnancy (~36 wks) after GDM Dx (some only enrolled after screening +ve, no measure before screening for 52 participants and results combined with other participants)

Appendix B Table 3. Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Abbreviations: ADIPS = Australasian Diabetes in Pregnancy Society; BMI = body mass index; CC = Carpenter Coustan; CDC = Centers for Disease Control; CES-D = Center for Epidemiological Studies Depression Scale; d(s) = day(s); Dx = diagnosis; EPDS = Edinburgh Prenatal Depression Scale; FP = false-positive; FPG = fasting plasma glucose; g = grams; GDM = gestational diabetes mellitus; mg/dl = milligram per deciliter; hr = hour; mo(s) = month(s); IFP = Infant Feeding Practices; kg/m^2 = kilogram per meter squared; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; NICU = neonatal intensive care unit; NICHD = National Institute of Child Health and Human Development; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; OR = odds ratio; PIH = pregnancy-induced hypertension; PPD = postpartum depression; PRAMS = Pregnancy Risk Assessment Monitoring System; RBS = random blood sugar; STAI = State-Trait Anxiety Inventory; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus; Tx = treatment; wGA = weeks' gestational age; WHO = World Health Organization; yr(s) = year(s); +ve = positive; -ve = negative

Appendix B Table 4. Quality Assessment of Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year	Representativeness of exposed cohort	Selection of non-exposed cohort	Ascertainment of exposure (self-report desirable for psychosocial outcomes)	Outcome of interest not present at start of study/before screening	Controls for age, race, BMI	Controls for any additional factor (delivery variables; gestational age)	Assessment of outcome	Was follow up long enough for outcomes to occur?	Adequacy of cohort follow up	Quality rating
Daniells[71], 2003	Selected group; 54% of eligible participated; slightly older and less severe glycemia	Same community as the exposed cohort	Secure record; attending diabetes center for GDM	Yes; time trends used	Partly; statement that results based on age and race not different but methods NR and BMI also differed	Partly; subgroup for severity of GDM	Yes; self-report using validated questionnaire	Yes	Yes	Fair
Doughty[72] 2018	Selected group; <40% of main cohort study; many drop outs for results in postnatal period	Same community as the exposed cohort	Self-report	Yes; hospital experiences	Yes	Yes; type of delivery; removed those with NICU stay for some outcomes	Yes; self-report and many variables apart from GDM explored	Yes	Yes	Good
Kerbel[73] 1997	Somewhat representative; 39% of eligible at 32 weeks had complete data; subjects with complete and incomplete data were similar & low risk pregnancies	Same community as the exposed cohort	Self-report	Yes; pre- and post-Dx measurement	Partly; not BMI	Yes	Yes; self-report using validated questionnaire	Yes	Yes	Fair
Loewenberg Weisband[74] 2017	Selected population; <50% of main cohort study which was not nationally representative	Same community as the exposed cohort	Self-report	Yes; breast feeding intentions and	Yes	No	Self-report	Yes	20% loss in GDM for supplementation outcome	Fair

Appendix B Table 4. Quality Assessment of Studies on Harms Associated With the Screening Tests for, or With a Diagnosis of GDM (KQ2)

Author, Year	Representativeness of exposed cohort	Selection of non-exposed cohort	Ascertainment of exposure (self-report desirable for psychosocial outcomes)	Outcome of interest not present at start of study/before screening	Controls for age, race, BMI	Controls for any additional factor (delivery variables; gestational age)	Assessment of outcome	Was follow up long enough for outcomes to occur?	Adequacy of cohort follow up	Quality rating
				supplementation						
Naylor[75] 1996	Selected; 31% of eligible enrolled in cohort study; 90% of those screened had data	Same community as the exposed cohort	Secure records; all screened within study	Yes; macrosomia and cesarean delivery	Yes	Yes	Yes; medical records	Yes	Yes	Good
Oza Frank[76] 2017	Somewhat representative; response rates ~50%; rates were lower for Black mothers, mothers of low birthweight infants, unmarried mothers and mothers with less than 12 years of education	Same community as the exposed cohort	Self-report	Yes; hospital practices after birth	Yes	Yes	Unclear; self-report but 2-6 mos after giving birth	Yes	Yes	Good
Rumbold [77] 2002	Somewhat representative; NR how many eligible enrolled	Same community as the exposed cohort	Secure records; all screened within study	Yes; using time trends	No	No	Yes; self-report using validated scale	Yes; >20% OGCT -ve group dropped out	>20% OGCT -ve group dropped out	Fair

Abbreviations: BMI = body mass index; GDM = gestational diabetes mellitus; OGCT = oral glucose challenge test; mo(s) = month(s); NR = not reported; -ve = negative

Appendix B Table 5. Studies Comparing Different Screening Strategies (KQ3)

Author, year Study Design Dates of Study Country	Women Enrolled and Analyzed, *n* Maternal Age, *mean± SD (yr)* BMI, *mean ± SD; median IQR (kg/m^s)* Ethnicity/Race Previous GDM & Family History (Hx) of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Screening Strategies (dates implemented where applicable) Timing of Diagnostic Test Treatment (Tx) Differences
Basri[78], 2018 RCT Feb 2015 to Sep 2017 Malaysia	520 (502 analyzed) **G1 (IADPSG, n=259):** 31.1± 4.15 **G2 (WHO, n=261):** 31.9± 4.57 **Booking BMI (kg/m^2):** **G1:** 27 (15-46) **G2:** 26 (16-45) **G1:** Malay: 79.2%; Chinese: 13.9%; Indian: 6.2%; Others: 0.8% **G2:** Malay: 77.0%; Chinese: 16.9%; Indian: 3.8%; Others: 2.3% NR & NR	**Inclusion:** ≥1 risk factors for GDM, 14-37 wGA, attending tertiary hospital and referral center **Exclusion:** Multiple pregnancies, previously Dx T1DM or T2DM, inability to complete OGTT	Primary cesarean delivery (not for repeat or 2+ previous scars), hypertensive disorders of pregnancy (gestational hypertension or preeclampsia), LGA, neonatal hypoglycemia (<3.3 mmol/L) , shoulder dystocia or birth injury, preterm delivery (<37 wGA)	All patients screened for risk factors (including >25 yrs) and ≥1 required before randomization. If screening was done before 28 wGA and negative it was repeated at 28-32 wGA (some in G2 were Dx later because of this and higher 2hr threshold) **G1:** IADPSG 2010 (Universal, 1-step): 75g OGTT: FPG ≥5.1 mmol/L, 2h ≥8.5 mmol/L (no 1h value used) (n=259, GDM=100 [38.6%]) **G2:** WHO 1999 (Universal, 1-step): 75g OGTT: FPG ≥6.1 mmol/L, 2h ≥7.8 mmol/L (n=261, GDM=99 [37.9%]) *Tx for GDM is the same regardless of group allocation (dietary and SMBG with medication or insulin if unsatisfactory; insulin use G1: 5% vs. G2 5.1%)
Harper[79], 2020 RCT NR U.S.	962 (922) **G1 (early screen, 14-20 wks, n=459):** 27.2 ± 5.9 **G2 (routine screen, 24-28 wks, n=463):** 26.8 ± 5.9	**Inclusion:** Obese (BMI ≥30 kg/m^2), non-anomalous, singleton gestations, receiving prenatal care <20 wGA at the university hospital	Macrosomia (>4000 g), shoulder dystocia, primary cesarean delivery, gestational hypertension, preeclampsia (Systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90	**G1:** Early screening, CC 1982 (Universal, 2-step with 50g OGCT ≥135 mg/dL). If negative on early screening, offered repeat screening at 24-28 wGA) (n=454, GDM=69; 15.2%; 58% of GDM women in this group were diagnosed at repeat screening 24-28 wGA) 14-20 wGA

Appendix B Table 5. Studies Comparing Different Screening Strategies (KQ3)

Author, year Study Design Dates of Study Country	Women Enrolled and Analyzed, *n* Maternal Age, *mean± SD (yr)* BMI, *mean ± SD; median IQR (kg/m^s)* Ethnicity/Race Previous GDM & Family History (Hx) of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Screening Strategies (dates implemented where applicable) Timing of Diagnostic Test Treatment (Tx) Differences
Harper, 2020 Continued.	**G1:** 37.2 ± 6.6 **G2:** 37.0 ± 6.5 **G1:** White: 11.3%; Black: 61.0%; Native American: 0.4%; Asian: 0.2%; Hispanic: 26.6%; Other: 0.4% **G2:** White: 7.6%; 64.6%; 0.7%; 0.4%; 26.6%; 0.2% NR & NR	**Exclusion:** Pre-existing diabetes, major medical illness (cardiac disease, HIV, hemoglobinopathy, oxygen requirement), bariatric surgery, prior cesarean section, known fetal anomalies, chronic prednisone use	mmHg with either proteinuria or serum laboratory abnormalities= platelets <100,000, aspartate aminotransferase >80 IU/mL, creatinine >1.2 mg/dL, hyperbilirubinemia (>95th percentile for gestational age and hour of life or requiring phototherapy for Tx), hypoglycemia (<35 mg/dl), induction of labor, LGA	**G2:** Routine screening, CC 1982 (Universal, 2-step with 50g OGCT ≥135 mg/dL) (n=458, GDM=56; 12.2%) 24-28 wGA All had HbA1c measured at 14-20 and 24-28 wGA with >6.5% GDM. If 6.2-6.5%, 2-step GDM screening performed, and given Tx for GDM regardless of randomization arm. *Tx for GDM was the same regardless of group allocation (Diabetes educator and SMBG; insulin, glyburide or metformin chosen at discretion of provider if glucose targets not met) Insulin use G1 2.4% vs. G2 0.7%, p=0.03; any diabetic medication G1 6.8% vs G2 4.3%, p=0.03
Khalifeh[80], 2018 RCT Jun 2016 to Dec 2016 U.S.	284 (226 analyzed) **G1 (IADPSG, n=123):** 29.5 ±5.9 **G2 (CC, n=126):** 29.5 ±5.3 **BMI (≥30kg/m^2):** **G1:** 26.8% **G2:** 27.0% **G1:** White: 32.5%; Black: 52.0%; Hispanic: 4.9%;	**Inclusion:** Women without Hx of preexisting DM **Exclusion:** Preexisting DM or history of bariatric surgery	LGA, macrosomia (>4000 g), shoulder dystocia, hypoglycemia (<40 mg/dL), hyperbilirubinemia (requiring phototherapy), stillbirth (fetal demise >20 wks), neonatal death (within 28d of life), preeclampsia, induction of labor, cesarean delivery, maternal birth trauma (obstetrical anal sphincter injuries), 5 min Apgar score (<7), preterm delivery (<37wGA)	**G1+G2:** Early screening offered at 1st prenatal visit to women if they were obese (BMI ≥30kg/m^2, Hx of macrosomic baby (>4000g), or had polycystic ovary syndrome (PCOS). Repeated at 24-28 wGA if normal early OGTT. **G1:** IADPSG 2010 criteria (Universal, 1-step): 75g OGTT: FPG ≥5.1 mmol/L, 1h ≥10.0 mmol/L, 2h ≥8.5 mmol/L (n=123, GDM=10; 8.1%) 24-28 wGA **G2:** CC 1982 criteria (Universal, 2-step): 50g OGCT (≥135 mg/dL); 100g OGTT: FPG ≥5.3

Appendix B Table 5. Studies Comparing Different Screening Strategies (KQ3)

Author, year Study Design Dates of Study Country	Women Enrolled and Analyzed, *n* Maternal Age, *mean± SD (yr)* BMI, *mean ± SD; median IQR (kg/m^s)* Ethnicity/Race Previous GDM & Family History (Hx) of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Screening Strategies (dates implemented where applicable) Timing of Diagnostic Test Treatment (Tx) Differences
Khalifeh, 2018 Continued.	Asian: 9.0%; Other/declined to answer: 1.6% **G2:** White: 37.3%; Black: 48.4%; Hispanic: 2.4%; Asian: 7.9%; Other/declined to answer: 4.0% **G1:** 3.3% & 34.2% (Hx of GDM) **G2:** 2.4% & 31.0%			mmol/L, 1h ≥10.0 mmol/L, 2h ≥8.6 mmol/L, 3h ≥7.8 mmol/L (n=126, GDM=7; 5.6%) 24-28 wGA * Tx for GDM is the same regardless of group allocation; delivery at 39 0/7 to 39 6/7 wGA was recommended to all women with GDM; medication or insulin G1 4.1% vs G2 3.2%
Scifres[81], 2015 RCT May 2012 to Feb 2013 (recruitment) U.S.	47 (47 analyzed) **G1 (IADPSG, n=24):** 26.1 ±6.8 **G2 (CC, n=23):** 25.4 ±5.0 **G1:** 27.3 ±6.9 **G2:** 25.8 ±8.5 **G1:** Black: 37.5%; Caucasian: 45.8%; Other: 8.3%; Multiracial: 8.3% **G2:** Black: 47.8%; Caucasian: 43.5%; Other: 4.3%; Multiracial: 4.3%	**Inclusion:** Age 18-45 yrs, singleton pregnancy between 18 and 24 wGA receiving prenatal care at an outpatient obstetrical clinic at a large academic teaching hospital **Exclusion:** All women received 50g GCT at 24-28 wGA, and results >200 mg/dL Dx as GDM and excluded (n=0). Pre-existing DM or a positive screen for DM within the 1st trimester of pregnancy	Macrosomia (>4000 g), LGA, SGA, cesarean delivery (primary and repeat), gestational hypertension (systolic blood pressure of ≥140 mmHg or a diastolic blood pressure of ≥90 mmHg on two occasions at least 6 h apart occurring >20 wGA), preeclampsia (gestational hypertension plus detectable urinary protein ≥1+ by dipstick or ≥0.3g/24 h), shoulder dystocia, stillbirths, neonatal death, labor induction, excessive gestational weight gain, maternal birth trauma (3rd or	**G1:** IADPSG 2010 criteria (Universal, 1-step): 75g OGTT: FPG ≥5.1 mmol/L, 1h ≥10.0 mmol/L, 2h ≥8.5 mmol/L (n=24, GDM=1) 24-28 wGA **G2:** CC 1982 criteria (Universal, 2-step): 50g OGCT and results ≥130 mg/dL and <200 mg/dL; 100g OGTT: FPG ≥5.3 mmol/L, 1h ≥10.0 mmol/L, 2h ≥8.6 mmol/L, 3h ≥7.8 mmol/L (n=23, GDM=0) 24-28 wGA * NR (Tx for GDM performed according to clinical care standards of each participant's provider)

Appendix B Table 5. Studies Comparing Different Screening Strategies (KQ3)

Author, year Study Design Dates of Study Country	Women Enrolled and Analyzed, *n* Maternal Age, *mean± SD (yr)* BMI, *mean ± SD; median IQR (kg/m^s)* Ethnicity/Race Previous GDM & Family History (Hx) of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Screening Strategies (dates implemented where applicable) Timing of Diagnostic Test Treatment (Tx) Differences
Scifres, 2015 Continued.	NR & NR	(<24 wGA), multiple gestation, corticosteroid use in the 30 days prior to enrollment, gastric bypass surgery, use of fertility treatments to conceive, plan to deliver at a different hospital, inability to complete the glucose testing before 30 completed wGA, or anticipated preterm delivery for maternal or fetal indications	4th degree vaginal laceration), preterm birth, hypoglycemia, NICU admission	
Sevket[82], 2014 RCT May 2011 to Sept 2012 Turkey .	856 (786 analyzed) **G1 (IADPSG, n=386):** 28.0 ±4.9 **G2 (CC, n=400):** 28.5 ±5.0 **G1:** 25.4 ±4.0 **G2:** 25.9 ±4.7 NR **G1:** NR & 27.3% **G2:** NR & 21.5%	**Inclusion:** women between 24-28 wGA, referred for GDM screening **Exclusion:** Multiple pregnancies, pre-GDM, fetal anomalies diagnosed prenatally, delivery prior to 28 wGA, those who made errors in protocol	Preeclampsia (not defined), primary cesarean delivery, gestational hypertension, LGA, SGA, macrosomia (>4000g), hypoglycemia (clinical), hyperbilirubinemia (requiring radiotherapy), NICU admission, preterm delivery (<37 wGA), neonatal deaths	**G1:** IADPSG 2010 criteria (Universal, 1-step): 75g OGTT: FPG ≥5.1 mmol/L, 1h ≥10.0 mmol/L, 2h ≥8.5 mmol/L (n=386, GDM=56; 14.5%) 24-28 wGA **G2:** CC 1982 criteria (Universal, 2-step): 50g OGCT and positive if results ≥140mg/dL, Dx with GDM if ≥195mg/dL; 100g OGTT: FPG ≥5.3 mmol/L, 1h ≥10.0 mmol/L, 2h ≥8.6 mmol/L, 3h ≥7.8 mmol/L (n=400, GDM=24; 6%) 24-28 wGA *Tx for GDM is the same regardless of group allocation; protocol for delivery NR

Abbreviations: BMI = body mass index; CC = Carpenter Coustan; d = days; Dx = diagnosis; FBS = fasting blood sugar; FPG = fasting plasma glucose; G = group; g = grams; GDM = gestational diabetes mellitus; HbA1c = hemoglobin A1c; hr(s) = hour(s); Hx = history; IADPSG = International Association of Diabetes and Pregnancy Study Groups;

kg/m^2=kilograms per meter squared; LGA = large for gestational age; mg/dl = milligrams per deciliter; mmol/L = millimoles per liter; mmHg = millimeters of Mercury; MNT = medical nutrition therapy; NA = not applicable; NDDG = National Diabetes Data Group; NICU = neonatal intensive care unit; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; PCOS = polycystic ovary syndrome; RBS = random blood sugar; RCT = randomized controlled trial; SGA = small for gestational age; SMBG = self-monitoring of blood glucose; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus; Tx = treatment; wGA = weeks' gestational age; WHO = World Health Organization; wk(s) = week(s); yr(s) = year(s); +ve = positive; -ve = negative

Appendix B Table 6. Quality Assessment of Studies Comparing Different Screening Strategies (KQ3)

Author, Year	Sequence Generation	Allocation Concealment	Comparable at baseline	Blinding of participants and Providers	Blinding of outcome assessment	Incomplete Outcome Data	Selective Outcome Reporting	Other	Quality Rating
Basri[78] 2018	Unclear (methods NR)	Unclear (methods NR)	Unclear (few variables reported)	Unclear (methods NR)	Unclear (methods NR)	Low (no ITT but <10% attrition)	Low	Low	Fair
Harper[79]2020	Low	Low	Low	Unclear (open label but less concern for head-to-head trial)	Unclear (objective definitions & blinded for gestational hypertension, preeclampsia),	Low (not ITT but <5% attrition)	Low	Low	Fair
Khalifeh[80] 2018	Low	Low	Low	Unclear (open label but less concern for head-to-head trial)	Unclear (objective outcomes; blinding not reported)	High (79.5% analyzed [excluded women who did not undergo screening])	Low	Low	Fair
Scifres[81] 2015	Low	Low	Low	Low (providers and patients blinded to OGTT values; patients aware of group allocation)	Low (providers and study investigators blinded to OGTT values and study group)	Low (pregnancy outcomes 46/47; 15% lost for fetal/neonatal outcomes)	Low	Low	Good
Sevket[82] 2014	Low	Unclear (methods NR)	Low	Unclear (open label but less concern for head-to-head trial)	Unclear (methods NR)	Low (8% attrition)	Unclear (via author contact for women with GDM, not reported in primary publication)	Low	Fair

Abbreviations: GDM = gestational diabetes mellitus; ITT = intention to treat; NR = not reported; OGTT = oral glucose tolerance test

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Agarwal[87], 2000 June 1998 to Apr 2000 United Arab Emirates (Yes)	1692, 1644, 1644 Mean ± SD: 29.8 ± 5.87 (+hx) 30.2 ± 5.62 (+OGCT) NR NR & NR Indian subcontinent: 25.5% Arabs (all): 66.8% 'Other': 2.1% Unknown: 5.7%	**Inclusion:** attending antenatal clinic; referred for OGTT because of clinical history or +ve OGCT **Exclusion:** referred for OGTT with an elevated fasting, random, or post-prandial glucose and considered 'pre-screened	Selective, 2-step 513/1644 (31.2%) +ve hx, 396/1276 (31.0%) +ve OGCT, 117/368 (31.8%) FPG screening, mean ± SD: 28.1 ± 5.7 wGA (+ve hx) 28.7 ± 7.0 wGA (+ve OGCT at 24-28 wGA)	FPG (≥4.4 mmol/L, ≥5.3 mmol/L)	CC, 1991 (CC 1982) 100 g, 3 h 28.1 wGA (+ve hx) 28.7 wGA (+ve OGCT)
Agarwal[88], 2001 Dec 1997 to May 1998 United Arab Emirates (Yes)	430, 430, 426 Mean ± SD: 30.3 ± 5.5 NR NR & NR Indian subcontinent: 29.1% Arabs (all): 66.3% Other: 3.3% Unknown: 1.3%	**Inclusion:** attending antenatal clinic; referred for OGTT because +ve for risk factors or +ve OGCT **Exclusion:** NR	Selective, 2-step 114/426 (26.8%) Mean ± SD: 27.1 ± 6.1 wGA	HbA1c (≥5.0%)	CC, 1991 (CC, 1982) 100 g, 3 h NR
Agarwal[86], 2006 May 2004 to Sep 2005 United Arab Emirates (Yes)	NR, 4844, 4602 Mean ± SD: 28.4 ± 6.0 NR NR & NR Arabs: 75.5%	**Inclusion:** attending routine antenatal clinic, FPG <7.0 mmol/L (diagnosed with GDM by FPG alone) **Exclusion:** NR	Universal, 2-step 675/4602 (14.7%) Mean ± SD: 25.9 ± 6.3 wGA	FPG (≥4.7, ≥4.9, ≥5.0, ≥5.3 mmol/L)	ADA, 2004 (CC 1982) 75 g, 2 h Mean ± SD: 25.9 ± 6.3 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
	South Asian: 20.3% Other: 2.0% Unknown: 2.3%				
Agarwal[89], 2018 Jan 2013 to Dec 2015 India (No)	NR, 6520, 6520 Mean ± SD: 27.4 ± 3.9 NR NR & NR Predominantly South Asian	**Inclusion:** attending routine antenatal clinic **Exclusion:** Pre-existing DM	Universal, 1-step 1193/6520 (18.3%) 7.2% <24 wGA, 80.4% 24-28 wGA, 12.4% >28 wGA	FPG (≥4.3 mmol/L)	IADPSG, 2010 75 g, 2 h 7.2% <24 wGA, 80.4% 24-28 wGA, 12.4% >28 wGA
Ayach[90], 2006 Jul 1997 to Dec 1999 Brazil (No)	465, 364, 341 Age ≥30: 15.8% BMI ≥27: 14.4% NR & NR White: 61.0%	**Inclusion:** sought prenatal care in study hospital during 1st half of pregnancy **Exclusion:** History of DM, failure to perform or finish screening (86) or diagnostic test (18), withdrawal of consent or premature termination of pregnancy, miscarriage, pseudocyesis, premature birth, fetal death, intolerance to oral glucose test	Universal, 2-step 13/341 (3.8%) 24-28 wGA	50g OGCT (≥140 mg/dL) FPG ≥ 90 mg/dL and ≥ 1 risk factor (age ≥ 30 years, pre-gestational BMI ≥ 27 kg/m², previous gestational diabetes, family history of DM, macrosomia, fetal death with no apparent cause, recurrent miscarriages and malformation)	ADA, 2002 (CC 1982) 100 g, 3 h 24-28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Benaiges[91], 2017 Apr 2013 to Sep 2015 Spain (Yes)	NR, 1631, 1158, 1158 Mean ± SD: GDM: 33.3 ± 5.4 NGT: 32.6 ± 5.7 GDM: 27.5 ± 5.0 NGT: 25.1 ± 5 GDM: 23.7% & 50.7% NGT: 1.8% & 17.8% Caucasian: 51.4% South Central Asian: 17.9% Latin American: 12.9% Moroccan: 6.7% East Asian: 5.8% Other: 5.4%	**Inclusion:** >18 years old with singleton pregnancy **Exclusion:** Known DM, meeting ADA criteria for DM in 1st trimester, multiple pregnancies, spontaneous miscarriage or voluntary termination, not completing diagnostic work-up for GDM.	Universal, 2-step 152/1158 (13.1%) 1st trimester (≤12 wGA)	HbA1c (≥4.8% and ≥5.6%)	NDDG, 1979 100 g, 3 h 24-28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Benhalima[92], 2018 a) Benhalima[130], 2018 (associated publication, additional thresholds) Apr 2014 to Mar 2017 Belgium (Yes)	NR, 1987, 1811 GDM: 32.0 ± 4.7 NGT: 30.6 ± 3.9 GDM: 25.8 ± 5.5 NGT: 23.8 ± 4.4 GDM: 30.2% & 18.7% (1st degree relative) NGT: 5.3% & 11.8% (1st degree relative) GDM: Ethnic minority: 18.9% NGT: Ethnic minority: 8.2%	**Inclusion:** Age 18-45 years, presenting for prenatal care at 6-14 wGA **Exclusion:** Multiple pregnancy, pre-existing diabetes or pre-diabetes, history of bariatric surgery, normal follow-up and treatment not possible, participating in another study 90 days before start of study, planned home delivery or non-participating center	Universal, 2-step 231/1811 (12.6%) Mean ± SD: 24.5 ± 0.9 wGA	OGCT (≥130, ≥135, ≥140 mg/dL) OGCT (≥130 mg/dL) and ≥1 risk factors: ethnic minority background, BMI ≥30 kg/m², history of GDM	WHO, 2013 (IADPSG 2010) 75 g, 2 h Mean ± SD: 26.9 ± 1.1 wGA
Bhavadharini[93], 2017 Jan 2013 to Dec 2015 India (No)	NR, 1459, 1459 GDM: 27.3 ± 4.4 NGT: 25.9 ± 3.9 GDM: 25.7 ± 5.9 NGT: 23.7 ± 6.0 GDM: 5.6% & 39.5% NGT: 1.3% & 24.9% NR	**Inclusion:** Pregnant women at first booking **Exclusion:** NR	Universal, 1-step 195/1459 (13.4%) Mean ± SD: 19.5 ± 7.6 wGA	HbA1c (≥5.0%)	IADPSG, 2010 75 g, 2 h 1st trimester (based on FPG), or 2nd/ 3rd trimester (based on OGTT)

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Braga[94], 2019 Apr 2004 to Nov 2005 Brazil (No)	180, 180, 176 Median (IQR): GDM: 31.0 (29 to 37) NGT: 27.5 (24 to 32) Median (IQR): GDM: 27.8 (23.6 to 32.1) NGT: 22.8 (20.9 to 27.3) GDM: 16.7% & 83.3% NGT: 6.1% & 73.5% NR	**Inclusion:** Singleton pregnancy **Exclusion:** Patients HIV +ve	Universal, 1-step CC, 78/176 (44.3%) 24-28 wGA	HbA1c (≥5.1%)	CC, 1982 100 g, 3 h 24-28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Cetin[95], 1997 Cetin, 1997 Continued. Oct 1994 to Jan 1996 Turkey (Yes)	274, 274, 274 Median (range) G1: 27 (19-37) G2: 28 (18-37) G3: 29 (19-41) Median (IQR): G1: 24.8 (17.3-40.1) G2: 24.5 (17-40) G3: 25 (19.3-39.8) G1: 2.4% & 4.9% G2: 1.1% & 7.4% G3: 3.6% & 8.9% NR *Groups based on different timing of meal	**Inclusion:** Women >24 yrs, 24-28 wGA, examined by obstetrician before 20 wGA, singleton pregnancy **Exclusion:** History of pre-existing diabetes, preeclampsia, regular ingestion of any drug, delivery ≤28 wGA, premature rupture of membranes	Universal, 2-step 17/274 (6.2%) 24-28 wGA	OGCT (≥140 mg/dL)	NDDG, 1979 100 g, 3 h 1 wk after OGCT

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Chevalier[96], 2011 January 2002 to December 2006 France (Yes)	1451, 1451, 1383 Mean ± SD: 31.1 ± 5.4 Mean ± SD: 28.1 ± 5.1 6.9% & 38.4% (T2DM) Euro-Caucasian: 66.4% North African: 26.1% African: 5.7% Asian: 1.8%	**Inclusion:** all pregnant women who gave birth at the study hospital, whose post-glycaemia load on the 50 g glucose challenge test was 130-199 mg/dL **Exclusion:** GDM diagnosed on the first step of screening (glycemia >200 mg/dL following the O'Sullivan test)	Selective, 2-step 330/1383 (23.9%) Mean (range), 27 (9 to 37) wGA	FPG (>92, >95 mg/dL)	CC, 1982 100 g, 3 h Mean (range), 30 (11 to 40) wGA (22 (1 to 84) days after the OGCT)
De Los Monteros[97], 1999 Jul 1996 to Dec 1996 Mexico (No)	506, 453, 445 >25 yrs: 80.7% <25 yrs: 19.3% NR (55% >110% ideal body weight) NR & 42.5% (1 or both parents) NR	**Inclusion:** Pregnant women at 24-28 wGA, attending medical center for routine care **Exclusion:** History of DM, consent withdrawal during either glucose tolerance test, inability to recall last menstrual period, history of regular drug ingestion during pregnancy	Universal, 2-step NDDG, 43/445 (9.7%) CC, 52/445 (11.7%) Sacks, 62/445 (13.9%) 24-28 wGA	OGCT (≥130, ≥135, ≥140 mg/dL)	NDDG, 1979 CC, 1982 Sacks 100 g, 3 h 1 wk after OGCT

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Dickson[38], 2019 Apr 2016 to May 2017 South Africa (No)	969, 969, 589 27.8 ± 5.9 26.9 ± 5.8 0.5% & 16.9% 100.0% Black African	**Inclusion:** pregnant Black African women <28 wGA consecutively recruited from a single urban community health clinic **Exclusion:** <18 y old, known T1DM or T2DM	Universal, 1-step 41/589 (7.0%) 24-28 wGA	FPG (≥4.5mmol/L)	WHO, 2013 (IADPSG 2010) 75 g 2 h 24-28 wGA
Gobl[98], 2012 2007 to 2010 Austria (Yes)	NR, 258, 258 NR NR NR & NR NR	**Inclusion:** pregnant women attending for routine GDM screening **Exclusion:** patients with missing data, pre-existing DM	Universal, 1-step 59/258 (22.9%) ≥24 wGA	Risk model (0.2 cut-off with FPG <5.1 mmol/L), incorporating: history of GDM, glycosuria, age, relative with type 2 DM, preconception dyslipidemia, ethnicity, FPG)	IADPSG, 2010 75 g, 2 h ≥24 wGA
Ho[99], 2017 Mar 2006 to Sep 2013 China (No)	3253, 3253, 1989 Median (range): 31.0 (28.0-34.4) Median (range): 22.4 (20.0-24.8) NR & NR NR	**Inclusion:** +ve OGCT and subsequently underwent OGTT, delivered at the study hospital **Exclusion:** Multifetal pregnancy, pre-existing DM or hypertension, missing height data, refusal to participate	Selective, 2-step 576/1989 (29.0%) 22-39 wGA	HbA1c (≥5.7%)	CC, 1982 100 g, 3 h 21-36 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Hughes[100], 2014 Feb 2008 to Aug 2010 New Zealand (Yes)	4201, 974, 974 NR NR NR & NR NR	**Inclusion:** All women in the Christchurch are offered testing at time of their first prenatal bloods **Exclusion:** known DM, pregnancy loss, HbA1c ≥6.5%, receiving treatment for GDM at any stage in pregnancy or had multiple pregnancy, miscarriage, lost to follow-up, delivered elsewhere, HbA1c or OGTT >20 wGA	Universal, 1-step 170/974 (17.5%) <20 wGA	HbA1c (≥5.9%)	WHO, 2013 (IADPSG 2010) 75 g, 2 h Median (IQR): 99 (84-113) days gestation (<20 wGA)
Kauffman[101], 2006 NR United States (Yes)	NR, 132, 123 Range; 18-40 NR NR 0.0% (exclusion criteria) & NR White: 53% Mexican American: 40% Other: 7%	**Inclusion:** Randomly selected women attending obstetrical clinic, 24-28 wGA with consent to undergo 100 g, 3h OGTT in lieu of 50 g screen, 18-40 y old **Exclusion:** history of DM, GDM previously diagnosed in the current pregnancy, untreated endocrine disorders, medications with impact on	Universal, 1-step NDDG, 16/123 (13.0%) CC, 25/123 (20.3%) 24-28 wGA	FPG ≥92 mg/dL and ≥93 mg/dL	NDDG, 1979 CC, 1982 100 g, 3 h 24-28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
		circulating glucose or insulin levels			
Khalafallah[102], 2016 Sep 2012 to Jul 2014 Australia (Yes)	NR, 480, 480 Median (range): 29 (18-47) NR NR & NR Caucasian: 93% Asian: 4% Aboriginal: 3%	**Inclusion:** ≥18 y old, presenting for OGTT test at 24-28 wGA **Exclusion:** Twin pregnancies, early GDM diagnosis (<24 wGA)	Universal, 1-step 57/480 (11.9%) Mean ± SD: 25.7 ± 3.3 wGA	HbA1c (≥5.4%)	ADIPS, 2013 (IADPSG 2010) 75 g, 2 h Mean ± SD: 25.7 ± 3.3 wGA)
Lamar[103], 1999 NR U.S. (Yes)	NR, 160, 136 26 ± 5.3 NR NR & NR White: 72.0% Hispanic or African American: 27.0% *Only including participants and results for OGCT not jelly beans	**Inclusion:** Women in general obstetric population at institution ≥18 yrs and between 24-28 wGA **Exclusion:** History of overt insulin-dependent DM	Universal, 2-step 5/136 (3.7%) 24-28 wGA	50g OGCT (≥140 mg/dL)	ACOG, 1994 (NDDG, 1979) 100 g, 3 h Within 7-10 days of OGCT

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Lekva[104], 2018 2002 to 2008 Norway (Yes)	NR, 1031, 985 GDM (by IADPSG): 32.0 ± 4.3 NGT (by IADPSG): 31.0 ± 3.7 Median (range): GDM: 25.5 (23.1 to 28.5) NGT: 23.5 (21.5 to 25.7) GDM: NR & 10.4% NGT: NR & 9.8% All women were of Scandinavian heritage	**Inclusion:** low-risk women of Scandinavian heritage **Exclusion:** multiple pregnancies, known pre-gestational diabetes, severe chronic diseases	Universal, 1-step WHO 2013, 244/985 (24.8%) IADPSG, 241/985 (24.5%) 14 to 16 wGA	FPG (≥4.59 mmol/L)	WHO, 2013 IADPSG, 2010 75 g, 2 h 30 to 32 wGA
Navid[105], 2014 Jul 2006 to Jun 2007 Pakistan (No)	NR, 100, 100 >28 y: GDM: 57.9% NGT: 28.4% NR NR & 0.0% (exclusion criteria) NR	**Inclusion:** singleton pregnancy, primigravida or multigravida, aged 20 to 35 y, booked in 1st trimester **Exclusion:** History of T1DM, or T2DM, glucose intolerance, with bad obstetrical history, family history of DM, intrauterine devices, still births or early neonatal deaths,	Universal, 2-step 4/100 (4.0%) 24 to 28 wGA	OGCT (≥140 mg/dL)	CC, 1982 100 g, 3 h 24 to 28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
		congenital anomalies, macrosomic babies and patients with polyhydramnios			
Odsæter[106], 2016 Apr 2007 to Jan 2009 Norway (Yes)	875, 855, 627 to 677 Median (range): 30 (19 to 46) Median (range): 24.3 (18.4 to 39.9) 0.4% & 8.9% NR	**Inclusion:** ≥18 yrs old, single viable fetus **Exclusion:** high-risk pregnancies, diseases that could interfere with participation, living >30 min drive from study center	Universal, 1-step GDM "throughout pregnancy": 45/628 (7.2%) Early screening: 18 to 22 wGA Late screening: 32 to 36 wGA	HbA1c (≥4.7%, ≥4.8%, ≥5.0%)	IADPSG, 2010 (modified, no 1 h) 75 g, 2 h Early dx: 18 to 22 wGA Late dx: 32 to 36 wGA
Olagbuji[107], 2017 Sep 2015 to Feb 2016 Nigeria (No)	NR, 280, 280 Mean ±SD 30.4 ±4.9 27.1 ±5.0 NR & 13.2% (1st degree relative) NR	**Inclusion:** 18 to 45 yrs old, 24 to 31 36 wGA, singleton pregnancy **Exclusion:** known DM, serious medical disorder, hyperemesis gravidarum	Universal, 1-step 46/280 (16.4%, HIP) 24 to 31 wGA 2/46 patients with hyperglycemia in pregnancy (HIP) were DM	OGCT (≥130, ≥135, ≥140 mg/dL)	IADPSG, 2010 75 g, 2 h Within 1 wk of OGCT with a minimum interval of 3 days
Perea-Carrasco[108], 2002 NR Spain (Yes)	NR (recruited consecutively), 642, 642 NR NR	**Inclusion:** Attended routine antenatal clinic, OGCT and OGTT between 24-36 wGA **Exclusion:** Women expecting multiple births	Universal, 2-step 53/642 (8.3%) 24 to 36 wGA	OGCT (≥140mg/dL)	IWC, 3rd (same as NDDG 1979) 100 g, 3 h NR

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
	NR & NR NR				
Perucchini[109], 1999 1995 to 1997 Switzerland (Yes)	772, 558, 520 Mean ±SD, range: 28.4 ± 0.2, 17 to 45 23.8 ± 0.2 NR & NR White: 63.1% Asian: 19.0% African: 6.0% Others: 11.9%	**Inclusion:** Singleton pregnancy, attended hospital, delivery >28 wGA **Exclusion:** Pre-existing DM, not examined before 24 wGA	Universal, 2-step 53/320 (10.2%) 24 to 28 wGA	FPG (≥4.4 mmol/L, ≥4.8 mmol/L) OGCT (≥130, ≥135, ≥140 mg/dL)	IWC, 4th (same as CC 1982) 100 g, 3 h Within 1 wk of OGCT

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Pezeshki[110], 2019 Apr 2015 to Apr 2016 (recruitment) Iran (No)	432, 432, 356 Mean ±SD: 26.4 ± 4.3 25.3 ± 3.7 0.0% (exclusion criteria) & NR NR	**Inclusion:** 18 to 35 yrs old, <12 wGA at 1st visit, BMI 18.5 to 30 kg/m², BP <140/90mm/Hg at 1st visit **Exclusion:** History of T1DM, T2DM, or GDM, fetal macrosmia, using medications or having disease that affect carbohydrate metabolism, tobacco or alcohol use, anemia, hemoglobinopathies, hematologic conditions diseases that affect HbA1c, history of high triglycerides or cholesterol, multiparity	Universal, 1-step (20-24 weeks) 30/356 (8.4%) 1st trimester or 20 to 24 wGA; 24-28 wGA	FPG (≥79.5 mg/dL) HbA1c (≥5.75%)	ADA 2016 (IADPSG 2010) 75 g, 2 h 24 to 28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Poo[111], 2018 Jun 2016 to Jun 2017 Singapore (Yes)	NR, 191, 151 Mean: HbA1c <5.2%: 29 yrs HbA1c ≥5.2%: 32 yrs HbA1c <5.2%: 23.6 kg/m² HbA1c ≥5.2%: 25.7 kg/m² HbA1c <5.2%: 3.1% & 36.1% HbA1c ≥5.2%: 0.0% & 48.2% HbA1c <5.2%: Chinese: 50.5% Malay: 38.1% Indian: 4.1% Eurasian/Others: 7.2% HbA1c ≥5.2%: Chinese: 44.4% Malay: 18.5% Indian: 22.2% Eurasian/Others: 14.8%	**Inclusion:** <14 wGA **Exclusion:** known DM, multiple pregnancies, known haemoglobinopathies such as thalassaemia or other chronic medical conditions including chronic kidney or liver disease, which alter red cell survival	Universal, 1-step 17/151 (11.3%) <14 wGA	HbA1c (≥5.2%)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Poomalar[112], 2013 May 2006 to Apr 2007 India (No)	NR, 500, 500 NR NR NR & NR NR	**Inclusion:** women who presented to the antenatal outpatient department **Exclusion:** pre-existing DM, not consenting to participate	Universal, 2-step 36/500 (7.2%) 22 to 28 wGA (some up to 37 wGA)	FPG (≥4.7 mmol/L) OGCT (≥130, 135, 140 mg/dL)	CC, 1982 100 g, 3 h 1 wk after OGCT
Rajput[113], 2012 NR India (No)	NR, 607, 607 Age (yrs): 16–20: 18.1% 21–25: 58.2% 26–30: 19.9% >30: 3.8% BMI (kg/m²): <18.5: 38.2% 18.5–24.9: 53.6% ≥25: 8.2% NR & NR NR	**Inclusion:** all pregnant women 24 to 28 wGA **Exclusion:** pre-existing DM, anemia, chronic renal, pancreatic or other severe illness	Universal, 1-step ADA, 43/607 (7.1%) IADPSG, 14/607 (23.7%) 24 to 28 wGA	HbA1c (≥5.95%, ≥5.45%, ≥5.25%)	ADA, 2004 IADPSG, 2010 75 g, 2 h 24 to 28 wGA
Saadati[114], 2016 NR Iran (No)	NR, 158, 158 NR NR NR & NR NR	**Inclusion:** <20 wGA and referred for prenatal care, singleton pregnancies **Exclusion:** diagnosed DM, multiparous	Universal, 1-step IADPSG (<20 wGA), 46/158 (29.1%) <20 wGA	HbA1c (≥5.55%)	IADPSG, 2010 75 g, 2 h <20 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Sacks[115], 2003 Feb 1998 to Jul 1999 United States (Yes)	5557, 5557, 4507 Median (range): 28.3 (14.3–46.5) NR (overweight: 34.4%) 0 & 33.1% Latina: 69.2% Black: 11.5% White: 10.6% Asian: 6.3% Other/mixed: 2.4%	**Inclusion:** Prenatal visit at medical center, no known diabetic history, able to return for lab work and glucose testing **Exclusion:** Transferred care to other institution, began prenatal care or screened elsewhere, spontaneous abortion after enrollment	Universal, 2-step 302/4507 (6.7%) 10.7 ± 4.9 wGA	FPG (≥83, ≥85, ≥90, ≥95 mg/dL)	ADA, 2001 (Sacks criteria) 75 g, 2 h >23 wGA if not diagnosed in early pregnancy <23 wGA if early diagnosis
Saeedi[116], 2018 Jul 1994 to Jun 1996 Sweden (Yes)	4918, 3616, 3616 Mean ± SD 27.9 ± 4.8 23.8 ± 4.1 1.3% & 9.4% (1st degree relative) Non-Nordic origin: 11.2%	**Inclusion:** attending maternal healthcare and offered an OGTT **Exclusion:** NR	Universal, 1-step HAPO 1.75, 423/3616 (11.7%) HAPO 2.0, 260/3616 (7.2%) Risk factors: 1st visit FPG: 28 to 32 wGA	FPG (≥4.8 mmol/L, ≥5.0 mmol/L) Traditional risk factors (≥1): family history of DM, obesity (≥90kg, pre-pregnancy), previous LGA infant (≥4500g or ≥ mean +2SD), previous GDM	HAPO 1.75 (no 1 hr), HAPO 2.0 (no 1 hr) 75 g, 2 h 28 to 32 wGA

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Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Sermer[117], 1998 With associated paper Naylor[36], 1997 Sept 1989 to Mar 1992 Canada (Yes)	1)14007, 4274, 3836 2) 3131, 1571, 1571 NR NR NR & NR 1) White: 81.5% Asian: 9.0% Black: 5.3% Other: 4.3%	**Inclusion:** ≥24 yrs at time of delivery, no history of DM examined by physician before 24 wGA, delivery >28 wGA; 2) with sufficient data from OGCT and OGTT **Exclusion:** <24 yrs old 2) Non-singleton pregnancies	1) Universal, 2-step 2) Universal, 2-step 1) NDDG, 145/3836 (3.8%) CC, 265/3836 (6.9%) 2) NDDG, 69/1571 (4.4%) 3) 25 to 27 wGA	1) OGCT (≥140 mg/dL) 2) Selective screening: OGCT (≥140 mg/dL) (not used for analysis); OGCT clinical risk factors: age (≤30: 0 points, 31-34: 1 point, ≥35: 2 points), BMI (≤ 22: 0 points, 22.1-25.0: 2 points, ≥25.1 3 points), race (white: 0 points, Black: 0 points, Asian: 5 points, Other: 2 points) + OGCT (≥128, 130, or 140 mg/dL by clinical risk score)	1) NDDG, 1979 CC, 1982 2) NDDG, 1979 100 g, 3 h 27 to 29 wGA
Sevket[118], 2014 Jun 2011 to Jan 2012 Turkey (Yes)	NR, 339, 339 Mean ±SD 27.9 ± 5.2 25.5 ± 4.1 NR & NR NR	**Inclusion:** between 24 to 28 wGA, referred for GDM screening **Exclusion:** Known DM, women who made errors with protocol, anemia or other severe illness	Universal, 1-step 53/339 (15.6%) 24 to 28 wGA	HbA1c (≥4.7%, ≥5.2%, ≥5.7%)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA
Sham[119], 2014 Jan 2007 to May 2008 India (No)	NR, 103, 89 Mean: 25 yrs NR NR & NR	**Inclusion:** singleton pregnancy between 24 and 28 wGA **Exclusion:** pre-existing DM, patients with unknown dates	Universal, 2-step 12/89 (13.5%) OGCT: 24 to 28 wGA FPG: within 1 wk after OGCT	OGCT (≥130, ≥135, ≥140mg/dL) FPG (≥80.5 mg/dL, ≥90 mg/dL)	CC, 1982 100 g, 3 h Within 1 wk after OGCT

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
	NR				
Sharma[120], 2018 Jun 2014 to May 2016 India (No)	NR, 256, 246 Mean ±SD: **GDM:** 24.56 ± 2.87 **NGT:** 25.11 ± 4.11 **GDM:** 22.97 ± 2.68 **NGT:** 23.25 ± 2.59 **GDM:** 0.0% & 0.0% **NGT:** 0.0% & 4.8% NR	**Inclusion:** <20 wGA **Exclusion:** >20 wGA, history of pre-existing DM or FPG >126 mg/dL at first antenatal visit	Universal, 2-step 16/246 (6.5%) <20 wGA	FPG (≥84.5 mg/dL)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA
Siricharoenthai[121], 2019 Apr 2017 to Apr 2018 Thailand (No)	NR, 120, 114 Mean ±SD: 32.1 ± 5.2 24.4 ± 5.1 0.9% & 27.2% NR	**Inclusion:** singleton pregnancy, ≥24 wGA, abnormal OGCT **Exclusion:** medical conditions (i.e. DM, chronic kidney disease, anemia, hemoglobin variants), fetal abnormality	Selected, 2-step 35/114 (30.7%) 28.9 ± 5.2 wGA	HbA1c (≥4.5 %, ≥5.8%)	NDDG, 1979 100 g, 3 h 28.9 ± 5.2 wGA

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Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Soumya[122], 2015 NR India (No)	547, 500, 500 Mean ±SD: **GDM:** 28.6 ± 1.2 **NGT:** 25.8 ± 3.1 NR **GDM:** 0.0% (exclusion criteria) & 13.3% **NGT:** 0.0% (exclusion criteria) & 5.5% NR	**Inclusion:** <28 wGA **Exclusion:** History of DM or GDM, known hemoglobinopathy or hemoglobin variant, or level <10g/dL, GDM diagnosis before 24 wGA	Universal, 1-step 45/500 (9.0%) 24 to 28 wGA	HbA1c (≥5.3% & 5.7%)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA
Trujillo[123], 2014 May 1991 to Aug 1995 Brazil (No)	5564, 4926, 4926 Mean ±SD: 27.8 ± 5.4 26.0 ± 4.0 NR & 14.8% White: 44.8% Black: 13.7% Mixed: 41.1% Other: 0.4%	**Inclusion:** no Hx of DM, ≥20 yrs old **Exclusion:** reaching criteria for DM in pregnancy, receiving insulin treatment, multiple pregnancies, not performing OGTT or incomplete OGTT	Universal, 1-step 887/4926 (18.0%) 24 to 28 wGA	FPG (≥80 mg/dL)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA

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Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Uncu[124], 1995 NR Turkey (Yes)	NR, 42, 42 Mean ±SD: 27.05 ± 4.33 NR & NR NR	**Inclusion:** Attending outpatient clinic, GCT between 24 to 28 wGA **Exclusion:** Pregnancies beyond 28 weeks, previously diagnosed as DM	Universal, 2-step 14/42 (33%) 24 to 28 wGA	50g GCT (≥ 135, ≥140 mg/dL) HbA1c (≥ 7.2%)	NDDG, 1979 100 g, 3 h NR
Veres[125], 2015 NR (delivery Jan 2009 to Jun 2011) Romania (Yes)	NR, 165, 132 Mean ±SD: 28.29 ± 4.67 25.74 ± 3.92 NR & 6.1% NR	**Inclusion:** ≥18 yrs old, spontaneous pregnancies (without ovarian stimulation and/or assisted human reproductive technologies), absence of pathology associated to pregnancy, no chronic treatment with medication, presence of risk factors for GDM **Exclusion:** NR	Selective, 2-step 26/132 (19.7%) 24 to 28 wGA	HbA1c (≥5.1%, and ≥6.5%)	CC, 1982 100 g, 3 h 24 to 28 wGA
Weerakiet[126], 2006 Jul 2004 to Mar 2005 Thailand (No)	NR (recruited consecutively), 359 Mean ±SD: 31.8 ± 6.1 23.2 ± 4.3 NR & NR	**Inclusion:** Singleton pregnancy, presenting ≥1 risk factor for GDM: age >30, obesity, family history of DM, prior GDM, glucosuria, signs of hyperglycemia, history	Universal, 2-step 60/359 (16.7%) 21 to 27 wGA	50g OGCT (≥140 mg/dL)	ADA, 2000 (CC 1982) 100 g, 3 h 24 to 28 wGA

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Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
	NR	of poor obstetric outcome **Exclusion:** Hypertension, known DM, known chronic disease requiring Tx, positive result for syphilis, hepatitis B (HBSAg), HIV			
Wu[127], 2018 Nov 2014 to Feb 2015 China (No)	NR, 987, 690 Mean ±SD: **GDM:** 31.21 ± 3.30 **NGT:** 30.14 ± 3.23 **GDM:** 22.85 ± 2.66 **NGT:** 20.72 ± 2.61 NR & NR NR	**Inclusion:** women age 20-35 yrs old **Exclusion:** T2DM, FPG >5.6 mmol/L, alcohol consumption, cigarette smoking, haematological diseases, comorbidities or major organ dysfunction, thyroid disease history, in vitro fertilization-embryo transfer, multiple pregnancies, history of hypertension or hyperemesis	Universal, 1-step 107/690 (15.5%) 12 to 16 wGA	HbA1c (≥4.55%, ≥5.25%)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA

Appendix B Table 7. Studies on Accuracy of Screening Tests (KQ4)

Author, year Dates of study Country (Very high index? Yes/No)	Women Eligible, Recruited, Analyzed, *n* Maternal Age *(y)* BMI, *mean ± SD (kg/m²)* *Previous GDM & Family History of DM (%)* *Race and/or Ethnicity (%)*	Inclusion/Exclusion Criteria	Screening Practice^ *Prevalence of GDM, n (%)* Time of Screening (Index)	Index†, (Comment)	Reference†*, Date Load, Interval Time of GDM Confirmation
Zhu[128], 2013 (a) May 2011 to Feb 2012 China (No)	NR, 24854, 24854 NR NR NR & NR NR	**Inclusion:** pregnant women registered at the study hospitals **Exclusion:** known DM	Universal, 1-step 3149/24854 (12.7%) 24 to 28 wGA	FPG (≥4.4 mmol/L)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA
Zhu[129], 2013 (b) Jan 2010 to Feb 2012 China (No)	NR, 17186, 17186 NR NR NR & NR NR	**Inclusion:** NR **Exclusion:** Previously known diabetic patients	Universal, 1-step 3002/17186 (17.5%) 1st prenatal visit, median ± SD 13.4 ± 3.5 wGA	FPG (≥5.1 mmol/L)	IADPSG, 2010 75 g, 2 h 24 to 28 wGA

Abbreviations: ACOG = American College of Obstetricians and Gynecologists; ADA = American Diabetes Association; ADIPS = Australasian Diabetes in Pregnancy Society; BMI = body mass index; CC = Carpenter Coustan; DM = diabetes mellitus; Dx = diagnosis; FPG = fasting plasma glucose; g = grams; GDM = gestational diabetes mellitus; h = hours; HAPO = Hyperglycemia and Adverse Pregnancy Outcome; HbA1c = hemoglobin A1c; HIP = hyperglycemia in pregnancy; HIV = human immunodeficiency virus; Hx = history; IADPSG = International Association of Diabetes and Pregnancy Study Groups; IQR = interquartile range; mg/dl = milligram per deciliter; min = minute; mmol/L = millimole per liter; IWC = International Workshop Conference; LGA = large for gestational age; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; SD = standard deviation; kg/m^2 = kilograms per meter squared; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus; Tx = treatment; wGA = weeks' gestational age; wk(s) = week(s); WHO = World Health Organization; yr = year(s); +ve =positive

Appendix B Table 8. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2

Author, Year, Country	1a. Was a consecutive or random sample of patients enrolled?	1b. Did the study avoid inappropriate exclusions (if no, <5% yes, 5-10% or NR is unclear, >10% no)?	1c. Was the study a low risk of bias?	1d. Is the study applicable to the review?	2a. If a threshold was used, was it pre-specified?	2b. Was the index test performed as intended (e.g. venous sample)?	2c. Was the study a low risk of bias?	2d. Is the study applicable to the review?
Agarwal[87], 2000, UAE	Unclear	No (+ve OGCT or +ve Hx only)	No	Unclear	Yes	Yes	Yes	Yes
Agarwal[88], 2001, UAE	Unclear	No (+ve OGCT or +ve Hx only)	No	Unclear	Yes	Yes	Yes	Yes
Agarwal[86], 2006, UAE	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes
Agarwal[89], 2018, India	Yes	Yes	Yes	No (non-VHDI country)	Yes	Yes	Yes	Yes
Ayach[90], 2006, Brazil	Yes	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes
Benaiges[91], 2017, Spain	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Benhalima[92], 2018, Belgium	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bhavadharini[93], 2017, India	Yes	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes
Braga[94], 2019, Brazil	Unclear	Unclear	Unclear	No (non-VHDI country)	No (none pre-specified)	Yes	No	Yes
Cetin[95], 1997, Turkey	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes
Chevalier[96], 2011, France	Yes	No (+ve OGCT only)	No	Yes	Unclear	Yes	Unclear	Yes
De Los Monteros[97], 1999, Mexico	Yes	Yes	Yes	No (non-VHDI country)	Yes	Yes	Yes	Yes
Dickson, 2019[38], South Africa	Yes	Yes	Yes	No (non-VHDI country)	Yes	Yes	Yes	Yes

Appendix B Table 8. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2

Author, Year, Country	1a. Was a consecutive or random sample of patients enrolled?	1b. Did the study avoid inappropriate exclusions (if no, <5% yes, 5-10% or NR is unclear, >10% no)?	1c. Was the study a low risk of bias?	1d. Is the study applicable to the review?	2a. If a threshold was used, was it pre-specified?	2b. Was the index test performed as intended (e.g. venous sample)?	2c. Was the study a low risk of bias?	2d. Is the study applicable to the review?
Ho[99], 2017, China	Yes	No (excluded those with missing data-39% of sample, & +ve OGCT only)	No	No (non-VHDI country)	Yes	Yes	Yes	Yes
Hughes[100], 2014, New Zealand	Yes	No (excluded those with missing data, 77% of sample)	No	Yes	Yes	Yes	Yes	Yes
Kauffman[101], 2006, US	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Khalafallah[102], 2016, Australia	Yes	Unclear	Unclear	Yes	Unclear	Yes	Unclear	Yes
Lamar[103], 1999, US	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Lekva[104], 2018, Norway	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Navid[105], 2014, Pakistan	No (convenience sampling)	Unclear	No	No (non-VHDI country)	Yes	Yes	Yes	Yes
Odsaeter[106], 2016, Norway	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Olagbuji[107], 2017, Nigeria	Yes	Yes	Yes	No (non-VHDI country)	Yes	Yes	Yes	Yes
Perea-Carrasco[108], 2002, Spain	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Perucchini[109], 1999, Switzerland	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pezeshki[110], 2019, Iran	Unclear	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes
Poo[111], 2018, Singapore	Yes	Yes	Yes	Unclear	Unclear	Yes	Unclear	Yes
Poomalar[112], 2013, India	Unclear	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes

Appendix B Table 8. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2

Author, Year, Country	1a. Was a consecutive or random sample of patients enrolled?	1b. Did the study avoid inappropriate exclusions (if no, <5% yes, 5-10% or NR is unclear, >10% no)?	1c. Was the study a low risk of bias?	1d. Is the study applicable to the review?	2a. If a threshold was used, was it pre-specified?	2b. Was the index test performed as intended (e.g. venous sample)?	2c. Was the study a low risk of bias?	2d. Is the study applicable to the review?
Rajput[113], 2012, India	Yes	Yes	Yes	No (non-VHDI country)	Yes	Yes	Yes	Yes
Saadati[114], 2016, Iran	Unclear	Yes	Unclear	No (non-VHDI country)	No (none pre-specified)	Yes	No	Yes
Sacks[115], 2003, US	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Saeedi[116], 2018, Sweden	Yes	No (did not exclude DM, excluded GDM Dx <28wGA)	No	Unclear	Unclear	No (converted capillary to venous values)	No	Unclear
Sevket[118], 2014, Turkey	Yes	Unclear	Unclear	Unclear	Yes	Yes	Yes	Yes
Sham[119], 2014, India	Yes	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes
Sharma[120], 2018, India	Unclear	Yes	Unclear	No (non-VHDI country)	Unclear	Yes	Unclear	Yes
Siricharoenthai[121], 2019, Thailand	Yes	No (OGCT +ve only)	No	No (non-VHDI country)	Unclear	Yes	Unclear	Yes
Soumya[122], 2015, India	Yes	Unclear	Unclear	No (non-VHDI country)	Unclear	Yes	Unclear	Yes
Sermer[117], 1998, Canada	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Naylor[36], 1997, Canada	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes
Trujillo[123], 2014, Brazil	Yes	Yes	Yes	No (non-VHDI country)	Unclear	Yes	Unclear	Yes
Uncu[124], 1995, Turkey	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Unclear	Yes

Appendix B Table 8. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2

Author, Year, Country	1a. Was a consecutive or random sample of patients enrolled?	1b. Did the study avoid inappropriate exclusions (if no, <5% yes, 5-10% or NR is unclear, >10% no)?	1c. Was the study a low risk of bias?	1d. Is the study applicable to the review?	2a. If a threshold was used, was it pre-specified?	2b. Was the index test performed as intended (e.g. venous sample)?	2c. Was the study a low risk of bias?	2d. Is the study applicable to the review?
Veres[125], 2015, Romania	Unclear	No (high-risk population)	No	Unclear	Unclear	Yes	Unclear	Yes
Weerakiet[126], 2006, Thailand	Yes	No (high-risk population)	No	No (non-VHDI country)	Yes	Yes	Yes	Yes
Wu[127], 2018, China	Unclear	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes
Zhu[128], 2013 (a), China	Yes	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes
Zhu[129], 2013 (b), China	Yes	Unclear	Unclear	No (non-VHDI country)	Yes	Yes	Yes	Yes

Abbreviations: Dx = diagnose; OGCT = glucose challenge test; GDM = gestational diabetes mellitus; Hx = history; VHDI = very high development index; wGA = weeks' gestational age; +ve = positive

Appendix B Table 9. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2, Continued

Author, Year, Country	3a. Is the reference standard likely to correctly classify the target audience?	3b. Was the reference standard intended to be given to everyone, or at least a random sample (>10%)?	3c. Was the study a low risk of bias?	3d. Is the study applicable to the review?	4a. Was there an appropriate interval between the index test reference standard?	4b. Did all patients receive the same reference standard and according to criteria?	4c. Were all (≥80%) patients included in the analysis?	4d. Did they avoid excluding GDM cases from screening in ref standard and analysis (<10%)?	4e. Was the study a low risk of bias?	Quality Rating
Agarwal[87], 2000, UAE	Unclear	Yes	Unclear	Yes	Yes	Unclear	Yes	Yes	Unclear	Fair
Agarwal[88], 2001, UAE	Unclear	Yes	Unclear	Yes	Yes	Unclear	Yes	Yes	Unclear	Fair
Agarwal[86], 2006, UAE	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Unclear	Fair
Agarwal[89], 2018, India	Unclear	Yes	Unclear	Yes	Yes	Unclear	Yes	Yes	Unclear	Good
Ayach[90], 2006, Brazil	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Benaiges[91], 2017, Spain	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Benhalima[92], 2018, Belgium	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Bhavadharini[93], 2017, India	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Braga[94], 2019, Brazil	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Cetin[95], 1997, Turkey	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Chevalier[96], 2011, France	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No (excluded GDM Dx by OGCT >200mg/dl)	No	Fair
De Los Monteros[97], 1999, Mexico	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Dickson[38], 2019, South Africa	Yes	Yes	Yes	Yes	Yes	Yes	No (60.8% of recruited	Yes	No	Fair

Appendix B Table 9. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2, Continued

Author, Year, Country	3a. Is the reference standard likely to correctly classify the target audience?	3b. Was the reference standard intended to be given to everyone, or at least a random sample (>10%)?	3c. Was the study a low risk of bias?	3d. Is the study applicable to the review?	4a. Was there an appropriate interval between the index test reference standard?	4b. Did all patients receive the same reference standard and according to criteria?	4c. Were all (≥80%) patients included in the analysis?	4d. Did they avoid excluding GDM cases from screening in ref standard and analysis (<10%)?	4e. Was the study a low risk of bias?	Quality Rating
							were analyzed)			
Ho[99], 2017, China	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Hughes[100], 2014, New Zealand	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Kauffman[101], 2006, US	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Khalafallah[102], 2016, Australia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Lamar[103], 1999, US	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Good
Lekva[104], 2018, Norway	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Navid[105], 2014, Pakistan	Unclear	Yes	Unclear	Yes	Unclear	Unclear	Yes	Yes	Unclear	Fair
Odsaeter[106], 2016, Norway	Unclear	Yes	Unclear	Unclear	Yes	Unclear	No (73-79% analyzed)	Yes	No	Fair
Olagbuji[107], 2017, Nigeria	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Good
Perea-Carrasco[108], 2002, Spain	Yes	Yes	Yes	Yes	Unclear	Unclear	Unclear	Yes	Unclear	Fair
Perucchini[109], 1999, Switzerland	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Pezeshki[110], 2019, Iran	Yes	Yes	Yes	Yes	Yes	No (20-24 wGA or 24-28 wGA)	Yes	Yes	No	Fair
Poo[111], 2018, Singapore	Yes	Yes	Yes	Yes	Yes	Yes	No (79% analyzed)	Yes	No	Fair

Appendix B Table 9. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2, Continued

Author, Year, Country	3a. Is the reference standard likely to correctly classify the target audience?	3b. Was the reference standard intended to be given to everyone, or at least a random sample (>10%)?	3c. Was the study a low risk of bias?	3d. Is the study applicable to the review?	4a. Was there an appropriate interval between the index test reference standard?	4b. Did all patients receive the same reference standard and according to criteria?	4c. Were all (≥80%) patients included in the analysis?	4d. Did they avoid excluding GDM cases from screening in ref standard and analysis (<10%)?	4e. Was the study a low risk of bias?	Quality Rating
Poomalar[112], 2013, India	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Unclear	Fair
Rajput[113], 2012, India	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Good
Saadati[114], 2016, Iran	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Sacks[115], 2003, US	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Unclear	Good
Saeedi[116], 2018, Sweden	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Fair
Sevket[118], 2014, Turkey	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Sham[119], 2014, India	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Sharma[120], 2018, India	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Siricharoenthai[121], 2019, Thailand	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Soumya[122], 2015, India	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Sermer[117], 1998, Canada	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Naylor[36], 1997, Canada	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Trujillo[123], 2014, Brazil	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Uncu[124], 1995, Turkey	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Veres[125], 2015, Romania	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Fair

Appendix B Table 9. Quality Assessment of Studies on Accuracy of Screening Tests (KQ4), QUADAS-2, Continued

Author, Year, Country	3a. Is the reference standard likely to correctly classify the target audience?	3b. Was the reference standard intended to be given to everyone, or at least a random sample (>10%)?	3c. Was the study a low risk of bias?	3d. Is the study applicable to the review?	4a. Was there an appropriate interval between the index test reference standard?	4b. Did all patients receive the same reference standard and according to criteria?	4c. Were all (≥80%) patients included in the analysis?	4d. Did they avoid excluding GDM cases from screening in ref standard and analysis (<10%)?	4e. Was the study a low risk of bias?	Quality Rating
Weerakiet[126], 2006, Thailand	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Good
Wu[127], 2018, China	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear	Fair
Zhu[128], 2013 (a), China	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Zhu[129], 2013 (b), China	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good

Abbreviations: Dx = diagnose; OGCT = glucose challenge test; GDM = gestational diabetes mellitus; Hx = history; wGA = weeks' gestational age; +ve = positive

Appendix B Table 10. Quality Assessment of Studies on Accuracy of Risk-Based Scoring Systems (KQ4), PROBAST

Author, Year, Country	1.1 Were appropriate data sources used?	1.2 Were all inclusions and exclusions of participants appropriate?	1.3 Risk of bias	2.1 Were predictors defined and assessed in a similar way for all participants?	2.2 Were predictor assessments made without knowledge of outcome data?	2.3a Are all predictors available at the time the model is intended to be used?	2.3b Were all predictors that are intended to be used in the model actually collected and used?	2.3c Are all predictors available for all participants (<20% missing for any)?	2.4 Risk of bias	3.1 Was the outcome determined appropriately and according to criteria?	3.2 Was a prespecified or standard outcome definition used?
Ayach[90], 2006, Brazil	Yes	No (excluded 22% with missing data)	Unclear	PY	PN	Yes	Yes	Yes	Unclear	Yes	Yes
Gobl[98], 2012, Austria	Yes	NI	Unclear	Yes	PN	Yes	Yes	Yes	Unclear	PY	Yes
Naylor[36], 1997, Canada	Yes	Yes	Low	Yes	NI	Yes	Yes	Yes	Unclear	Yes	Yes

Abbreviations: PY = probably yes; PN = probably no; NI = no information

Appendix B Table 11. Quality Assessment of Studies on Accuracy of Risk-Based Scoring Systems (KQ4), PROBAST, Continued

Author, Year, Country	3.3 Were predictors excluded from the outcome definition?	3.4 Was the outcome defined and determined in a similar way for all participants?	3.5 Was the outcome determined without knowledge of predictor information?	3.6 Was the time interval between predictor assessment and outcome determination appropriate?	3.7 Risk of bias	4.1 Were there a reasonable number of participants with the outcome?	4.2 Were continuous and categorical predictors handled appropriately?	4.3 Were all enrolled participants included in the analysis; if many are missing, was this handled appropriately? (80% analyzed as threshold)	4.4 Were relevant model performance measures evaluated appropriately?	4.5 Risk of Bias	Quality Rating
Ayach[90], 2006, Brazil	PY	Yes	NI	PY	Low	PN	Yes	Yes	PN	High	Fair
Gobl, 2012[98],	Yes	PY	NI	PY	Low	PY	Yes	Yes	Yes	Low	Good
Naylor[36], 1997, Canada	Yes	Yes	NI	PY	Low	PY	Yes	Yes	PN	Unclear	Good

Abbreviations: PY = probably yes; PN = probably no; NI = no information

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Arbib[189], 2017 RCS(NR) Israel Aug 2007 – Dec 2012	309 **G1:** OAV on CC, n=32 **G2:** NGT, n=277	**G1:** 34.5 ±4.6 **G2:** 33.1 ±4.8 NR NR NR & NR	**Inclusion:** Women with a normal 50g OGCT (<140mg/dL) followed by a 3rd trimester OGTT, done at physician discretion (6.2% of OGCT -ve), who delivered a live-born fetus, with a BW >500g at or beyond 28 wGA **Exclusion:** Multiple gestations, any evidence of major fetal malformations or chromosomal abnormalities and those without complete data on their glucose test results	3h, 100g OGTT CC, 1982 (at physician discretion, 1-step) 3rd trimester	Macrosomia (>4,000g), LGA, induction of labor, cesarean section, shoulder dystocia, neonatal hypoglycemia (not defined), respiratory distress syndrome, hyperbilirubinemia (neonatal jaundice) N/A N/A
Benhalima[190], 2013 RCS(1) Belgium 2005 – 2010	6,505 **G1:** 2-step 100g IADPSG, n=160 **G2:** NGT, n=6345	**G1:** 31.6 ± 4.7 **G2:** 30.9 ± 4.8 **G1:** 23.3 ± 3.7 **G2:** 23.7 ± 4.4 **G1:** Black/Minority Ethnic (BME) group: 17.4%; Caucasian: 82.6% **G2:** Black/Minority Ethnic (BME) group: 9.5%; Caucasian: 90.5% NR & NR	**Inclusion:** Women screened by 5th IWC (CC) criteria in a hospital **Exclusion:** NR	1 h, 50g OGCT (≥ 140 mg/dL) 3h, 100g OGTT CC, 1982 (universal, 2-step) 24-28 wGA	Gestational hypertension (≥140/90 mmHg), preeclampsia (hypertension + proteinuria or in combination with reduced growth or HELLP-syndrome), cesarean section (planned + emergency combined), macrosomia (>4000 g), LGA, shoulder dystocia, NICU admission, preterm delivery (<37 wGA), 5 min Apgar score (<7) N/A N/A

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Berkus[191], 1995 PCS(NR) U.S. 1987 – 1988	660 **G1:** OAV on CC, n=87 **G2:** OGCT +ve, n=573	**G1:** 29.0 ± 6.0 **G2:** 26.0 ± 6.0 **BMI >27.3kg/m^2:** **G1:** 20.8% **G2:** 16.5% NR NR & NR	**Inclusion:** Nonhypertensive gravidas, singleton pregnancy, non-diabetic undergoing 3h OGTT, attended clinics in San Antonio area, screened +ve on OGCT (≥140 mg/dL) **Exclusion:** Women with 2+ abnormal OGTT values by NDDG criteria	1 h, 50g OGCT (≥ 140 mg/dL) 3 h, 100 g OGTT NDDG, 1979 (**selective**, 2-step) NR (24-28 wGA if by ACOG)	Macrosomia (>4,000 g), LGA N/A N/A
Biri[192], 2009 RCS(1) Turkey Jan 2004 - Dec 2006	1,900 **G1:** OAV, n=142 **G2:** OGCT +ve, n=326 **G3:** OGCT – ve, n=1432 G2 & 3 combined for analysis	**G1:** 32.1 ± 4.6 **G2:** 30.9 ± 4.9 **G3:** 29.6 ± 4.6 NR NR NR & NR	**Inclusion:** Singleton pregnancies, screened at study centre **Exclusion:** Pre-pregnancy DM, multiple gestations	1 h, 50 g OGCT (≥ 140 mg/dL) 3 h, 100 g OGTT NDDG, 1979 (universal, 2-step) 24-28 wGA	Preeclampsia (not defined), cesarean delivery, macrosomia (>4,000 g), hypoglycemia (<40 mg/dL), hyperbilirubinemia, LGA, SGA, 5 min Apgar score (continuous), preterm delivery (not defined) N/A N/A

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Chico[193], 2005 RCS(1) Spain Jan 1999 - Dec 2001	5,826 **G1:** OAV on CC, n=59 **G2:** NGT, n=5767	**G1:** 33.3 ± 4.0 **G2:** 32.8 ± 4.0 NR NR NR & NR	**Inclusion:** All pregnancies handled in 2 yr study period **Exclusion:** None	1 h, 50 g OGCT (≥140 mg/dL) 3 h, 100 g OGTT NDDG, 1979 (universal, 2-step) 24-28 wGA (High-risk screened in 1st trimester; OAV at 24-28 wGA rescreened 3-4 wks later)	Cesarean delivery, maternal weight gain, macrosomia (>4000 g), hypoglycemia (need for i.v. glucose), hyperbilirubinemia (jaundice), stillbirth, LGA, SGA, 1 min and 5 min Apgar score (continuous N/A N/A
Corrado[194], 2009 RCS(NR) Italy Jan 1996 - Dec 2005	776 **G1:** OAV on CC, n=152 (of 161) **G2:** OGCT +ve, n=624 (of 686)	**G1:** 31.2 ± 5.1 **G2:** 30.1 ± 4.9 **G1:** 25.0 ± 5.1 **G2:** 24.2 ± 4.4 **Caucasian:** 100.0% **G1:** NR & 35.5% **G2:** NR & 27.7%	**Inclusion:** Caucasian, +ve OGCT (≥135mg/dL) and underwent OGTT **Exclusion:** Multiple gestations, diagnosed with GDM and treated (insulin/diet)	1 h, 50 g OGCT (≥ 135 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-28 wGA	Hypertensive disorders of pregnancy (preeclampsia & gestational hypertension), cesarean delivery, macrosomia (>4000 g), hypoglycemia (<30 mg/dL), 1 min and 5 min Apgar scores (continuous) N/A **Age, BMI**, parity, weight gain in pregnancy, HOMA-IR and family history of diabetes mellitus

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, **used in analysis)**
Davis[195], 2018 RCS(1) U.S. Jan 2006 – Dec 2010	5,666 **G1:** 2-step 100g IADPSG, n=181 **G2:** OGCT +ve, n=544 **G3:** OGCT –ve, n=4,941 G2 & 3 combined for main analysis; adjusted analysis is for G1 vs G3	NR Weight **G1:** 157.2 ± 40.9 lbs **G2:** 148 ± 34.3 lbs **G3:** 146.9 ± 33.9 lbs **G1:** White: 74.0%; Black: 12.7%; Other: 9.4%; Unknown: 3.9% **G2:** White: 75.2%; Black: 9.4%; Other: 11.9%; Unknown: 3.5% **G3:** White: 70.8%; Black: 19.1%; Other: 7.0%; Unknown: 3.1% NR & NR	**Inclusion:** Women that underwent a OGCT <130mg/dL or ≥130 mg/dL and <180 mg/dL, and clinically indicated OGTT **Exclusion:** Women with OGCT values between 130-135 mg/dL without OGTT due to cut-off of 135 mg/dL used by some physicians, multiple gestations, preexisting DM, delivered at a different hospital, missing key independent variables, out of range gestational ages (<0, or >43 wGA), no glucose testing done	1 h, 50g OGCT (≥130 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-28 wGA (75% of women)	LGA, macrosomia (>4000 g), cesarean delivery (primary), hypertensive disorders of pregnancy (preeclampsia or gestational hypertension), shoulder dystocia, SGA, excessive gestational weight gain (IOM), preterm delivery (<37 wGA), maternal birth trauma (lacerations, 3rd or 4th degree) **Subgroup (data not shown):** only including women screened between 24-28 wGA. **Outcomes (data not shown):** GDM classification and delivery outcomes (no significant differences observed vs. total cohort) **Race, marital status, maternal education, mother's age at delivery, gestational age at delivery, prepregnancy weight, and adjusted total maternal weight gain**
Derks, 2019 PCS(1) U.S.	1,045 **G1:** OAV on CC, n=36 **G2:** OGCT +ve, n=92	**G1:** 33.4 ± 3.9 **G2:** 34.0 ± 4.3 **G3:** 32.0 ± 5.1 Pre-pregnancy BMI **G1:** 25.4 ± 4.2	**Inclusion:** singleton live birth in Project Viva cohort with data for their early teens (56% of cohort sample)	1 h, 50g OGCT (≥140mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step)	Childhood overweight (at 13 years old, 85th-<95th percentile), childhood obesity (≥85th percentile) N/A

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Derks, 2019 Continued. Apr 1999 – Jul 2002 (& 13 year follow-up for offspring)	**G3:** OGCT – ve, n=917	**G2:** 25.2 ± 5.0 **G3:** 24.4 ± 5.0 Offspring ethnicity (Maternal ethnicity NR) **G1:** Black: 17%; Hispanic: 3%; Asian: 6%; White: 61%; Other:14% **G2:** Black: 10%; Hispanic: 7%; Asian: 2%; White: 74%; Other: 8% **G3:** Black: 15%; Hispanic: 4%; Asian: 3%; White: 66%; Other: 12% NR & NR	**Exclusion:** T1DM, T2DM, no prenatal glycemic screening data or adolescent data available	26-28 wGA	N/A
Ethridge[197], 2014 RCS(1) U.S. Jan 2007 – Jun 2012	8,052 **G1:** 2-step 100g IADPSG, n=281 **G2:** OGCT +ve, n=772 **G3:** OGCT – ve, n=6,999	**G1:** 28.54 **G2:** 27.54 **G3:** 24.69 **G1:** 35.57 **G2:** 32.74 **G3:** 32.30 **G1:** Black: 30.2%; Caucasian: 47.0%; Hispanic: 16.0% **G2:** Black: 28.8;	**Inclusion:** Singleton gestation between Jul 2007 and Jun 2012, and had glucose screening or glucose tolerance testing completed after 24 wGA **Exclusion:** Abnormal glucose screen without subsequent glucose tolerance test, missing	1 h, 50g OGCT (≥ 135 mg/dL) 3 h, 100g OGTT CC, 1982 (universal, 2-step) >24 wGA	LGA, macrosomia (>4000g), NICU admission, hypertensive disorder of pregnancy (gestational hypertension, preeclampsia, eclampsia, or hemolysis, elevated liver enzymes and low platelet count), cesarean section (primary), stillbirth, shoulder dystocia, 1 min and 5 min Apgar score (<7), maternal birth trauma (perineal laceration, 3rd or 4th degree)

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, **used in analysis)**
Ethridge, 2014 Continued.	G2 & 3 combined for main analysis	Caucasian: 46.1%; Hispanic: 17.1% **G3:** Black:47.5%; Caucasian: 35.3%; Hispanic: 13.5% NR & NR	outcome data, **or preterm delivery**		**Subgroup (data not shown):** Only using data from patients receiving OGTT <34 wGA N/A
Heetchuay[198], 2017 RCS(1) Thailand Jan 2009 – Jun 2015	1,185 **G1:** OAV on 1 or 2-step CC, n=395 (of 444) **G2:** NGT, n=790	**G1:** 31.8 ± 4.9 (<35 yrs: 68.9%; ≥35 yrs: 31.1%) **G2:** 30.8 ± 5.6 (<35 yrs: 69.4%; ≥35 yrs: 30.6%) **G1:** <18.5: 8.9%; 18.5-24.9: 66.0%; 25.0-29.9: 21.0%; 30.0-34.9: 3.3%; ≥35: 0.8% **G2:** <18.5: 9.9%; 18.5-24.9: 67.3%; 25.0-29.9: 18.5%; 30.0-34.9: 3.4%; ≥35: 0.9% **G1:** NR & 36.5% **G2:** NR & 30.8%	**Inclusion:** Women with OAV on the 100g OGTT. Control group selected by systemic random sampling method from women with normal values on the 100g OGTT(1:2 ratio); all delivered at hospital **Exclusion:** Overt DM, multifetal pregnancy, incomplete data for the 100g OGTT result, incomplete data of adverse pregnancy outcomes	1 h, 50 g OGCT (≥ 140 md/dL) 3 h, 100 g CC, 1982 (universal, 1 or 2-step) 24-28 wGA If risk factors, early as possible	Cesarean section, gestational hypertension, preeclampsia-eclampsia, macrosomia (>4,000 g), LGA, SGA, shoulder dystocia, hypoglycemia, hyperbilirubinemia, respiratory distress syndrome, NICU admission, stillbirth, preterm delivery (<37 wGA), 1 min and 5 min Apgar score (<7) N/A **Maternal age, gestational age at birth (wks), multiparous status, strong family Hx of T2DM (for outcomes significant in unadjusted, except for macrosomia)**

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, **used in analysis)**
Hillier[199], 2007 RCS(2 regions) U.S. 1995-2000	8,896 **G1:** OAV on CC, n=288 **G2:** OGCT +ve, n=999 **G3:** OGCT –ve, n=7,609 G2 & 3 combined for main analysis	NR (overall: <18 yrs: 2.7%; 18-25 yrs: 29.9%; 26-30 yrs: 23.2%; 31-35 yrs: 30.0%; ≥36 yrs: 14.2%) NR NR (overall: Caucasian: 43.5%; Hawaiian: 21.8%; Filipino: 13.1%; Japanese: 6.1%; Pacific Islander: 3.7%; Chinese: 2.6%; Hispanic: 2.2%; Black: 1.9%; Samoan:1.8%; Other: 3.4% NR & NR	**Inclusion:** singleton births, data on mother-child pairs 5-7 yrs postpartum (having weight data) **Exclusion:** Preexisting DM	1 h, 50 g OGCT (≥ 140 mg/dL) 3 h, 100 g OGTT NDDG, NR (1979) (universal, 2-step) NR (24-28 wGA if by NDDG)	Macrosomia (>4,000g) at birth, childhood (5-7 yrs) obesity (age and sex-adjusted >85th and >95th percentile) **Subgroup:** macrosomic babies vs non-macrosomic babies, **Outcome:** childhood obesity **Maternal weight gain, maternal age, parity, ethnicity, macrosomia at birth, infant's sex, infant birth weight (not for macrosomia)**
Hirst[200], 2012 PCS(1) Viet Nam NR	2,538 (92% of eligible) **G1:** 1-step 75g IADPSG but not OAV on 3hr 75g CC, 386 **G2:** NGT, n=2,152	**G1:** 29.37 ±4.89 **G2:** 27.85 ±4.73 **G1:** 21.10 ±2.99 **G2:** 20.45 ±2.63 **G1:** Vietnamese: 95.9% **G1:** Vietnamese: 95.1%	**Inclusion:** Receiving antenatal care through outpatient departments, age >18, confirmed gestation between 24-32 wGA, singleton pregnancy, planned to deliver in the hospital, not known to have diabetes **Exclusion:** NR	2 h, 75 g OGTT CC, 1982 (no 3h value) (universal, 1-step) 24-32 wGA (mean 28 ± 1.7)	LGA, neonatal hypoglycemia (glucose infusion or <46 mg/dL), hyperbilirubinemia (jaundice requiring phototherapy), NICU admission (intensive neonatal care), perinatal death, preeclampsia (blood pressure >140/90 mm Hg on at least two occasions and proteinuria >300 g in 24 h), cesarean section (primary),

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, **used in analysis)**
Hirst, 2012 Continued.		**G1:** 0.26% & 9.6% **G2:** 0.28% & 5.8%			induction of labor, SGA, preterm delivery (<37 wGA), maternal birth trauma (perineal laceration involving the anal sphincter) N/A **Age, BMI at OGTT, height at OGTT, indoor partner's smoking status, family Hx of diabetes, famliy Hx of hypertension, gestational age at OGTT, baby's sex, parity** (not in cesarean section model)**, hospitalisation prior to delivery** (not in preeclampsia model)**, mean arterial blood pressure at the 1st antenatal care visit** (not in preeclampsia model)
Kaymak[201], 2011 RCS(1) Turkey Jan – Jun 2009	960 **G1:** OAV on CC, n=80 **G2:** OGCT +ve, n=401 **G3:** OGCT – ve, n=479 G2 & 3 combined for main analysis	**G1:** 29.4± 5.3 **G2:** 27.4± 5.5 **G3:** 25.2± 4.8 **BMI >27kg/m^2:** **G1:** 33.0% **G2:** 24.0% **G3:** 22.0% NR NR & NR	**Inclusion:** patients undergoing 50g OGCT between 24-28 wGA; G1 was random selection **Exclusion:** multiple pregnancy, preexisting systemic disease that may complicate pregnancy, did not deliver at the study institution	1 h, 50 g OGCT (>140 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-28 wGA	LGA, hypertensive disorders in pregnancy (persistent elevation of blood pressure > 20 wGA with or without proteinuria), primary cesarean delivery, neonatal hypoglycemia, sholder dystocia, hyperbilirubinemia, neonatal mortality, SGA, NICU admission, macrosomia (>4,000g), preterm delivery (<37 wGA), 5 min Apgar score (<7)

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Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Kaymak, 2011 Continued.					N/A N/A
Kim[202], 2002 PCS(1) South Korea NR	699 **G1:** OAV (1h) on NDDG, n=16 **G2:** OAV (2h) on NDDG, n=35 **G3:** OAV (3h) on NDDG, n=71 **G4:** OGCT +ve, n=577 G1, 2 & 3 combined for main analysis	**G1:** 29.5 ± 4.4 **G2:** 30.2 ± 3.3 **G3:** 32.3 ± 3.8 **G4:** 30.7 ± 3.9 **G1:** 21.0 ± 3.0 **G2:** 20.7 ± 2.6 **G3:** 21.8 ± 2.8 **G4:** 21.4 ± 2.9 NR NR & NR	**Inclusion:** singleton pregnancy; antenatal care at Ajou University Hospital Department of Obstetrics and Gynecology, completed all testing, delivery at hospital **Exclusion:** known DM, GDM diagnosis	1 h, 50 g OGCT (>130 mg/dL) 3 h, 100 g OGTT NDDG, NR (1979) (universal, 2-step) 28-32 wGA	Preeclampsia (presence of hypertension and proteinuria irrespective of the presence of Edema), cesarean delivery (for cephalopelvic disproportion or fetal distress), LGA, hypoglycemia (<35 mg/dL), perinatal death, respiratory distress syndrome, SGA, preterm delivery (<37 wGA), 1 min and 5 min Apgar (<7) N/A N/A
Kim[203], 2019 PCS(2) South Korea Aug 2014 – Oct 2016 (recruitment)	1,969 **G1:** 2-step 75g IADPSG, n=131 **G2:** OGCT +ve, n=529 **G1:** OGCT – ve, n=1309	**G1:** 34.7± 3.8 **G2+G3:** 34.3± 3.9 **G1:** 22.0± 3.1 **G2+G3:** 21.0± 2.8 Korean: 100.0% NR & NR	**Inclusion:** Singleton pregnancy, had initial prenatal visit <24 wGA and scheduled to receive prenatal obstetric care and deliver at study hospitals **Exclusion:** Multiple pregnancies, overt or pre-	1 h, 50 g OGCT (>140 mg/dL) 2 h, 75 g OGTT CC, 1982 (universal, 2-step) 24-28 wGA	Preeclampsia (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg on two or more occasions and proteinuria ≥1+ on a dipstick test or urine protein level ≥300 mg during a 24-hour period), labor induction, primary cesarean delivery, LGA, macrosomia (>4,000g), SGA,

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, **used in analysis)**
Kim, 2019 Continued.	G2 & 3 combined for main analysis		gestational DM, delivery planned at another hospital, last menstrual period was not definitive, ultrasound evaluation not performed between 6-24 wks		shoulder dystocia or birth injury, neonatal hypoglycemia (≤30 mg/dL in the first 24 hours after birth or ≤45 mg/dL after the first 24 hours after birth), hyperbilirubinemai (phototherapy), NICU admission, preterm delivery (<37 wGA) N/A **Maternal age, parity, height, BMI at delivery, gestational age at delivery, baby's sex**
Koivunen, 2020 RCS (6) Finland 2008-2009	3,208 **G1:** 1-step 75g IADPSG (FPG or 2hr), not OAV on CC, n=389 **G2:** OGTT – ve, n=2,692 **G3**: OGTT- (2 hr 7.8-8.5 mmol/L), n=127	**G1:** 30.0 ± 5.7 **G2:** 29.4 ± 5.3 **G3:** 30.0 ± 5.5 **G1:** 26.9 ± 4.7 **G2:** 25.5 ± 4.3 **G3:** 25.4 ± 4.6 NR NR & NR	**Inclusion:** women with an OGTT performed >24 wGA **Exclusion:** women with pre-gestational DM, multiple pregnancies, Dx with GDM in early pregnancy (<24 wGA), non-GDM women receiving insulin Tx, women Dx with GDM without an OGTT, women low-risk for GDM (primiparous: age <25 y, BMI <25 kg/m^2, no family Hx of DM; or if multiparous: age <40 y, BMI <25 kg/m^2, no previous Hx of fetal macrosomia)	2 h, 75 g OGTT OAV on CC, 1982 (selective, 1-step) 24-40 wGA (mean 27.5 ± 2.5)	LGA (>90th percentile), SGA, preterm delivery (<37 wGA), pregnancy-induced hypertension (gestational hypertension or pre-eclampsia), cesarean delivery, induced delivery

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Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Landon[205], 2011 Secondary analysis of RCT, Landon 2009, NR) U.S. Oct 2002 - Nov 2007	1,368 **G1:** OGCT +ve (incl. NGT on OGTT (n=675) and OAV on OGTT (n=256), all had FPG <95), n=931 **G2:** OGCT –ve (<120 mg/dL), n=437 Analysis compared NGT on OGTT & OGCT –ve (n=1,112) vs. OAV on OGTT (n=256)	**G1:** 27.4 ± 5.5 **G2:** 25.1 ± 5.3 **G1:** 30.1 ± 5.3 **G2:** 29.9 ± 5.8 **G1:** Black: 12.4%; Hispanic: 58.3%; White or other: 29.3 **G2:** Black: 12.8%; Hispanic: 58.6%; White or other: 28.6% NR & NR	**Inclusion:** Enrolled between 24-30 wGA **Exclusion:** Preexisting diabetes, abnormal results before 24 wGA, prior GDM, Hx of stillbirth, multifetal gestation, asthma, CHT, corticosteriod use, known fetal anomaly, likely preterm delivery, fasting >95 mg/dL on OGTT	1 h, 50 g OGCT (>135 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-30 wGA (mean 28 wGA)	LGA, shoulder dystocia, hypertensive disorders of pregnancy, hypoglycemia (NR), hyperbilirubinemia (NR) N/A N/A

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Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Lapolla[206], 2007 PCS(5) Italy NR	510 **G1:** OAV on CC, n=48 **G2:** OGCT +ve, n=128 **G3:** OGCT –ve, n=334 G2 & 3 combined for main analysis; adjusted values are for G1 vs G3	**G1:** 32.5 ± 4.4 **G2:** 31.7 ± 4.9 **G3:** 30.9 ± 4.7 **G1:** 23.7 ± 4.7 **G2:** 22.8 ± 3.9 **G3:** 22.4 ± 4.2 NR NR & NR	**Inclusion:** attending study center for routine prenatal care, screened for GDM **Exclusion:** Those who smoke, chronic hypertension, with conditions known to affect glucose metabolism, those without data	1 h, 50 g OGCT (>140 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-27 wGA	Cesarean delivery, macrosomia (>4,000 g), LGA, SGA N/A **Maternal age, BMI, HbA1c, plasma glucose at t 0min and 60 min (for LGA)**
Lapolla[207], 2011 RCS(1) Italy 1998 - 2008	1,927 **G1:** 2-step 100g IADPSG but not OAV on CC, n=112 **G2:** NGT, n=1,815	**G1:** 32.4 ± 4.5 **G2:** 32.2 ± 4.5 **G1:** 23.7 ± 4.3 **G2:** 23.3 ± 4.2 NR NR & NR	**Inclusion:** Singleton pregnancies, followed up at study hospital in 1998-2008 **Exclusion:** NR	1 h, 50 g OGCT (>140 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step-1 or 2 abnormal values) 24-28 wGA (High-risk screened at 1st visit)	Gestational hypertension, cesarean delivery, macrosomia (>4,000 g), LGA, SGA, maternal morbidity (preeclampsia, eclampsia and mortality) N/A N/A
Lee, 2020 PCS(1)	2,529 **G1:** 2-step 75g IADPSG but	**G1:** 34.3 ± 3.5 **G2:** 34.1 ± 3.8 **G3:** 33.1 ± 3.7 Pre-pregnancy BMI	**Inclusion:** women with a singleton pregnancy **Exclusion:** multiple gestations, giving birth at	1 h, 50 g OGCT (>140 mg/dL) 2 h, 75 g OGTT	Cesarean delivery, LGA, macrosomia (>4000g), preterm delivery (<37 wGA), shoulder dystocia, maternal birth trauma, apgar score <7 at 1 min, apgar

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Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Lee, 2020 Continued. South Korea Mar 2013 – Nov 2017	not 2hr 75g CC, n=52 **G2:** OGCT +ve, n=498 **G3:** OGCT – ve, n=1,979	**G1:** 22.1 ± 3.6 **G2:** 20.7 ± 2.8 **G3:** 20.6 ± 2.8 NR **G1:** NR & 25.0% **G2:** NR & 29.5% **G3:** NR & 26.2%	another hospital, receiving OGTT at other clinics	CC, 1982 (universal, 2-step) 24-28 wGA	score <7 at 5 min, NICU admission, neonatal jaundice (phototherapy) N/A **Maternal age, parity, pre-pregnancy BMI**
Martinez-Cruz, 2019 RCS(1) Mexico Jan 2010 – Dec 2014	564 **G1:** 1-step 75g IADPSG (on FPG or 2hr value only) but not 1-step 75g CC, n=282 **G2:** OGTT – ve, n=282	**G1:** 29.9 ± 7.2 **G2:** 30.4 ± 6.5 Pre-gestational BMI **G1:** 27.3 ± 4.6 **G2:** 27.1 ± 4.0 Mexican women: 100.0% **G1:** 1.8% & 59.6% **G2:** 0.4% & 44.3%	**Inclusion:** singleton pregnancy, maternal age >18 years, referred to for prenatal care and delivery, gestational age 22-28 wks **Exclusion:** women with two or more abnormal OGTT values, pre-gestational DM, autoimmune, immunosuppressive, kidney or heart diseases	2 h, 75 g OGTT CC, 1982 (universal, 1-step) **G1:** 22.5 ± 6.7 **G2:** 22.1 ± 5.9	LGA, macrosomia (>4000g), gestational hypertension, preeclampsia (hypertension associated with proteinuria after wGA 20), cesarean delivery, preterm delivery (20-36.6 wGA) Subgroup: BMI categories (>30 kg/m^2 vs <30 kg/m^2) Matched non-GDM patients 1:1 for maternal age and pre-gestational BMI

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Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Murat Seval[210], 2016 RCS(1) Turkey Dec 2008 – Dec 2011	2,337 **G1:** OAV on 1 or 2-step CC, n=90 (n=18 with risk factors) **G2:** NGT, n=2,247 (n=90 with risk factors)	**G1:** 30.5± 5.8 **G2:** 26.9± 5.2 NR NR NR & NR	**Inclusion:** women attending the study hospital for antenatal care, screened for GDM and outcome data **Exclusion:** All types of pre-gestational DM, fasting glucose value >125 mg/dL, known fetal malformations, stillbirths	1 h, 50 g OGCT (>140 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-28 wGA Patients with risk factors were given OGTT without OGCT (5% of patients)	Macrosomia (>4000 g), cesarean section rate, NICU admission, preterm delivery (<37 wGA) N/A N/A
Park[211], 2015 RCS(1) South Korea Jan 2006 – Aug 2012	131 **G1:** OAV on CC, n=38 **G2:** OGCT +ve, n=93	**G1:** 33.6 ± 4.0 **G2:** 32.8 ± 3.5 Median (range) **G1:** 22.4± 19.8-25.0 **G2:** 20.9± 19.6-23.7 Korean: 100.0% **G1:** 2.6% & NR **G2:** 1.1% & NR	**Inclusion:** Women that underwent a 100g OGTT after a +ve OGCT and delivered at the study hospital from Jan 2006 to Aug 2012 **Exclusion:** multiple pregnancies, pre-gestational DM, non-Korean ethnicity, receiving insulin therapy for GDM, registered at the study hospital after the 1st trimester	1 h, 50 g OGCT (>140 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-28 wGA	Cesarean section (not repeat), excessive gestational weight gain (above IOM recommendations; data not shown), preterm delivery , macrosomia (NR), SGA (NR), LGA (NR) N/A N/A

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Retnakaran[212], 2008 Retnakaran[220], 2010 PCS (Multicenter, n = NR) Canada 2003 - Sep 2007	350 **G1:** OAV on 1-step NDDG, n=91 (19 had OGCT-ve) **G2:** OGCT +ve, n=166 **G3:** OGCT & OGTT –ve, n=93 G2 & G3 combined for unjusted analysis; adjusted is for G1 vs G3	**G1:** 34.2 ± 4.2 **G2:** 33.8 ± 4.2 **G3:** 34.0 ± 4.4 Median (range) **G1:** 23.5 ± 21.8-27.7 **G2:** 23.5 ± 21.1-27.5 **G3:** 23.0 ± 21.5-26.1 **G1:** White: 71.4%; Asian: 19.8%; Other: 8.8% **G2:** White: 79.5%; Asian: 9.0%; Other: 11.5% **G3:** White: 79.6%; Asian: 7.5%; Other: 12.9% **G1:** 12.1%* & 52.8% **G2:** 3.6%* & 50.6% **G3:** 0.0%* & 41.9% *previous GDM/macrosomic infant	**Inclusion:** Attending outpatient obstetrics clinics in late second trimester, before or after their 50g OGCT, 3-month postpartum OGTT **Exclusion:** NR **c)** OAV on NDDG, FPG ≥5.8mmol/L were excluded	1 h, 50 g OGCT (>140 mg/dL) 3 h, 100 g OGTT NDDG, 1979 (all women had OGTT) 24-28 wGA	3mo postpartum: glucose intolerance (pre-diabetes [IGT, IFG, IGT/IFG] or diabetes, Dx by 75g OGTT) 3mo postpartum: metabolic syndrome (defined by IDF or AHA/NHLBI) cholesterol, LDL cholesterol, HDL cholesterol, triglycerides) **a+b) Subgroup:** IGT subdivided into OAV on 1h vs 2 or 3h. **Outcome:** a)metabolic syndrome b)cardiovascular risk **Months postpartum, family Hx of DM, weight gain in pregnancy preceding OGTT, pre-pregnancy BMI, age, ethnicity (Asian, other), Hx of GDM** **a) postpartum breastfeeding, cesarean delivery** **b) Age, ethnicity, family Hx of DM, breast-feeding, waist circumference at 3mo postpartum (repeated with BMI at 3mo postpartum rather than waist circumference)**

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Rust[213], 1996 RCS(1) U.S. NR	283 **G1:** OAV on CC, n=78 **G2:** OGCT +ve, n=205	**G1:** 23.7 ± NR **G2:** 22.7 ± NR **G1:** 25.5 ± NR **G2:** 24.8 ± NR NR NR & NR	**Inclusion:** +ve on OGCT; underwent 3 h 100 g OGTT **Exclusion:** Delivery outside study hospital	1 h, 50 g OGCT (>140 mg/dL) 3 h, 100 g OGTT NDDG,1979 (universal, 2-step) Early 3rd trimester	Cesarean delivery, LGA, hypoglycemia N/A N/A
Sermer[214], 1995 PCS(3) Canada Sep 1989 - Mar 1992	3,637 **G1:** OAV on 1-step NDDG (NR) **G2:** NGT (NR)	NR NR NR NR & NR	**Inclusion:** ≥24 yrs at delivery; no Hx of preexisting DM; examined by physician before 24 wGA gestation **Exclusion:** Delivery <28 wks	1 h, 50 g OGCT (>140 mg/dL) 3 h,100 g OGTT NDDG, 1979 28 wGA (±7 d)	Preeclampsia (increase in blood pressure 30 and 15 mmHg and >0.3 g/day protein), macrosomia (>4000 g), cesarean section, fetal trauma (cephalhematoma, peripheral nerve injury, fracture of the clavicle or a long bone, fracture of the skull, or other trauma as deened noteworthy by the attendant and/or neonatologist), hypoglycemia (iv glucose)(NR), respiratory distress syndrome (NR) N/A N/A
Shang[215], 2014 RCS(1)	5,504 **G1:** 2-step 75g IADPSG but not OAV	**G1:** 29.31 ± 3.20 **G2:** 29.41 ± 3.28 NR	**Inclusion:** Singleton pregnancy visiting the study hospital for prenatal care and delivery	1 h, 50 g OGCT (>140 mg/dL) 3 h, 75 g OGTT	Cesarean delivery, preeclampsia, macrosomia (≥4000g), preterm delivery (<37 wGA) N/A

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, used in analysis)
Shang, 2014 Continued. China Dec 2008 – Dec 2011	on 3hr 75g CC, n=158 **G2:** NGT, n=5,346	Chinese: 100.0% **G1:** 0.6% & NR **G2:** 0.3% & NR	**Exclusion:** Hx of DM, hyperthyroidism, endocrine complications	CC, 1982 (1 or 2 abnormal; universal, 2-step) 24-28 wGA	N/A
Vambergue[216], 2000 PCS(15) France Feb - Sep 1992	239 **G1:** OAV on CC, n=131 **G2:** OGCT – ve, n=108 (1:1 for OAV group)	**G1:** 28.8 ± 5.8 **G2:** 27.0 ± 5.2 **G1:** 24.8 ± 4.8 **G2:** 23.0 ± 3.9 **G1:** French: 86.9%; Non-French nationality: 13.1% **G2:** French: 91.5% ; Non-French nationality: 8.5% G1: NR & 22% G2: NR & NR	**Inclusion:** Attendance at public maternity unit **Exclusion:** Twin pregnancies, pre-pregnancy high blood pressure, asthma, haemochromatosis, pre-pregnancy diabetes or GDM	1 h, 50 g OGCT (>130 mg/dL) 3 h, 100 g OGTT CC, 1982 (universal, 2-step) 24-28 wGA	Pregnancy-induced hypertension (gestational hypertension or preeclampsia), cesarean delivery, shoulder dystocia, macrosomia (>4000g), hypoglycemia (treated), hyperbilirubinemia, perinatal mortality, LGA, respiratory distress syndrome, transfer to neonatal intensive care unit, SGA, preterm delivery (<37 wGA), 1 min and 5 min Apgar score (<7) N/A 1st degree family Hx of DM, obstetric Hx of malformations, mortality, macrosomia, glycosuria, hydramnios, eclampsia, preeclampsia, **pre-pregnancy obesity (>27kg/m^2)**, **maternal age (>35yrs)**, **multiparity, education level (reported for LGA only)**

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, **used in analysis)**
Wang[217], 2013 RCS(1) China Mar 2006 – Jun 2011	7,217 **G1:** OAV on NDDG, n=225 **G2:** OGCT +ve, n=1,021 **G3:** OGCT –ve, n=5,971 G1 & 2 combined for main analysis; adjusted data only for G1 vs G3 Secondary analysis: **G1:** OAV on CC, n=289 **G2:** OGCT +ve, n=799 **G3:** OGCT –ve, n=5,971 G1 & 2 combined for main analysis; adjusted data only for G1 vs G3	**G1:** 31.0± 4.5 **G2:** 30.0± 4.5 **G3:** 28.2± 4.5 **G1:** 28.2± 4.0 **G2:** 27.1± 3.7 **G3:** 26.7± 3.5 Taiwanese: 100.0% NR & NR	**Inclusion:** Women given a 50g OGCT and delivered at the study hospital **Exclusion:** Multifetal pregnancies, pre-pregnancy DM, incomplete 100g OGTT results	1 h, 50 g OGCT (140 mg/dL) 3 h, 100 g OGTT NDDG, 1979 (universal, 2-step) 24-28 wGA	Hypertensive disorders in pregnancy (transient hypertension of pregnancy or chronic hypertension identified in the latter half of pregnancy) or preeclampsia (BP of >140/90 mmHg after the 20th wk of gestation in a woman with previously normal BP and who have proteinuria [>0.3 g/day or >1+ on a urine dipstick], with or without pathological edema), cesarean section, macrosomia (>4000g), NICU admission, shoulder dystocia (aOR only), preterm delivery (<37 wGA), maternal birth trauma (perineal laceration, 3rd or 4th degree)(aOR only) N/A **Maternal age, BMI at entry, gestational week receiving 50g GCT, nulliparous status, chronic hypertension (only for OAV vs OGCT –ve)**

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Waters[218], 2016 PCS (secondary analysis of U.S. and Canada (North American HAPO centers) NR	5,898 **G1:** 1-step 75g IADPSG but not 75g 2hr CC, n=878 **G2:** NGT, n=5,020	**G1:** 31.0 ± 5.6 **G2:** 30.1 ± 5.8 **G1:** 31.5 ± 6.4 **G2:** 28.2 ± 4.9 **G1:** White: 42.3%; Black: 7.6%; Hispanic: 39.1%; Asian: 8.7%; Other: 2.4% **G2:** White: 52.2%; Black: 8.7%; Hispanic: 30.8%; Asian: 5.8%; Other: 2.5% **G1:** NR & 29.7% **G2:** NR & 20.5%	**Inclusion:** underwent 75g OGTT between 24-32 wGA, participating in HAPO from North American countries **Exclusion:** <18 yrs old, delivery planned at another hospital, date of last menstrual period not definitive, no ultrasound estimation from 6-24 wGA of gestational age, unable to complete OGTT within 24-32 wGA, multiple pregnancy, conception was achieved using gonadotropin ovulation induction or in vitro fertilization, underwent glucose testing before recruitment or received a diagnosis of DM during this pregnancy, glucose measurements outside HAPO after enrollment, had DM before pregnancy requiring medication, participated in another study that may interfere with HAPO, known to be HIV-positive or to have hep B or C, previous participation in HAPO, unable to converse without an interpreter	2 h, 75 g OGTT CC, 1982 (universal, 1-step) 24-32 wGA	LGA, primary cesarean delivery, neonatal hypoglycemia (symptoms, treatment or lab thresholds), preeclampsia (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg on two or more occasions a minimum of 6 h apart and proteinuria of 1+ or more on a dipstick test or a protein level in the urine ≥300 mg for a 24-h period), shoulder dystocia or birth injury, NICU admission (>24 h, or by the death of the baby or transfer to another hospital), hyperbilirubinemia (phototherapy after birth, at least one laboratory report of a bilirubin concentration ≥20 mg/dL (342 mmol/L), or readmission for hyperbilirubinemia), preterm delivery (<37 wGA) N/A **Field center**, **age**, **height**, **BMI**, **gestational age at OGTT**, **smoking**, **alcohol use**, **hospitalization before delivery**, **family Hx of DM**, **mean arterial pressure at OGTT**, **parity**, **baby's sex**, Hx of high BP, maternal UTI

Appendix B Table 12. Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year Study Design (number of centers) Country Dates of study	Women Analyzed, *n* Groups, *n*	Maternal Age, *mean ± SD/ median ± IQR (yr)* BMI, *mean ± SD/ median ± IQR (kg/m^s)* Ethnicity Previous GDM & Family Hx of T2DM (%)	Inclusion/Exclusion Criteria	Diagnostic Test Criteria Timing of diagnostic test	Outcomes Subgroup Analysis Adjustments for Confounders (tested, **used in analysis)**
Wei[219], 2014 RCS(1) China Jan 2005 – Dec 2012	22,804 **G1:** 2-step 75g IADPSG but not OAV on 3hr 75g NDDG, n=1,175 **G2:** NGT, n=21,629	NR NR NR NR & NR	**Inclusion:** Women who delivered at the university hospital **Exclusion:** Pre-pregnancy DM, no 50g OGCT or OGTT during pregnancy	1 h, 50 g OGCT 3 h, 75 g OGTT NDDG, 1979 (universal, 2-step, **1 or 2 abnormal**) 24-28 wGA	Cesarean section (all pregnancies), macrosomia (only in singeton pregnancies), gestational hypertension, neonatal hypoglycemia, perinatal death N/A N/A N/A

Abbreviations: ACOG = American College of Obstetricians and Gynecologists; AHA/NHLBI = American Heart Association/National Heart Lung and Blood Institute; aOR = adjusted odds ratio; BMI = body mass index; BP = blood pressure; BW = birth weight; CC = Carpenter Coustan; CHT = chronic hypertension; DM = diabetes mellitus; Dx = diagnosis; g = grams; FPG = fasting plasma glucose; G = group; GDM = gestational diabetes mellitus; HAPO = Hyperglycemia and Adverse Pregnancy Outcome; HbA1c = hemoglobin A1c; HDL = high density lipoprotein; HIV = human immunodeficiency virus; Hx = history; IADPSG = International Association of Diabetes in Pregnancy Study Groups; IDF = International Diabetes Federation; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; IOM = Institute of Medicine; IWC = International Workshop Conference; LDL = low density lipoprotein; LGA = large for gestational age; mg/dl = milligram per deciliter; min(s) = minute(s); mmHg = millimeter of mercury; mo(s) = month(s); N/A = not applicable; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; NICU = neonatal intensive care unit; NR = not reported; OAV = one abnormal value; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; PCS = prospective cohort study; RCS = retrospective cohort study; SGA = small for gestational age; UTI = urinary tract infection; wGA = weeks' gestational age; yr(s) = year(s)

Appendix B Table 13. Quality Assessment of Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year, Study design	Representativeness of exposed cohort	Selection of non-exposed cohort (e.g., same, location NGT population)	Ascertainment of exposure	Outcome of interest not present at start of study	No impact on care by knowledge of glycemic status	Controls for key confounders	Assessment of outcome	Follow up long enough for outcomes to occur	Adequacy of cohort follow up	Quality rating (not considering confounding)
Berkus, 1995[191], PCS	Somewhat representative (screened for risk factors)	Selected population (OGCT+ve)	Secure record	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Derks 2019[196], PCS	Truly representative	Represents NGT population	Secure record	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Hirst[200], 2012, PCS	Truly representative	Represents NGT population	Secure record	Yes	Unclear	Yes (for adjusted data)	Record linkage	Yes	Yes	Fair
Kim[202], 2002, PCS	Somewhat representative (24% excluded from no delivery or data)	Selected population (OGCT+ve)	Secure record	Yes	No (OAV were monitored more closely during care)	No	Record linkage	Yes	Yes	Fair
Kim[203], 2019, PCS	Somewhat representative (23% of pregnant women at hospitals participated)	Represents NGT population	Secure record	Yes	Unclear	Yes (for adjusted data)	Record linkage	Yes	Yes	Fair
Landon[205], 2011, PCS	Somewhat representative (32% of eligible declined participation; all had OGTT FPG <95)	Selected population (OGCT 120 to 135 missing)	Secure record	Yes	Yes (blinded)	No	Blinded outcome assessment	Yes	Yes	Good
Lapolla[206], 2007, PCS	Somewhat representative (20% excluded without data; no smoking, no chronic hypertension)	Represents NGT population	Secure record	Yes	Unclear	Yes (for LGA)	Record linkage	Yes	Yes	Fair
Lee 2020[208], PCS	Truly representative	Represents NGT population	Secure record	Yes	Unclear	Yes	Record linkage	Yes	Yes	Fair
Waters[218], 2016, PCS	Somewhat representative (44% of eligible had data; 1-step 2-hr CC used so a few women may	Represent NGT population (although 1-step CC so may have	Secure record	Yes	Yes (blinded)	Yes (for adjusted data)	Blinded outcome assessment	Yes	Yes (no for cesarean or preeclamp	Good (Fair for cesarean or preeclampsia)

Appendix B Table 13. Quality Assessment of Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year, Study design	Representativeness of exposed cohort	Selection of non-exposed cohort (e.g., same, location NGT population)	Ascertainment of exposure	Outcome of interest not present at start of study	No impact on care by knowledge of glycemic status	Controls for key confounders	Assessment of outcome	Follow up long enough for outcomes to occur	Adequacy of cohort follow up	Quality rating (not considering confounding)
	have been IADPSG who would have met 3 hr criteria w/ CC)	less glycemia)							sia with 85%)	
Retnakaran[212], 2008, PCS	Somewhat representative (<70% of cohort had 3 mo postpartum data [and # eligible NR]; 42-52% family hx of DM	Selected population (had to agree to do OGTT; adjusted results for OAV vs OGCT-ve only)	Secure record	Unclear (women not tested early or prior to pregnancy for preexisting IGT/IFG,T2DM)	Unclear	Yes (for OAV vs. OGCT-ve)	Record linkage	Unclear (3 mos postpartum)	Yes	Fair
Sermer[214], 1995, PCS	Somewhat representative (having data)	Selected population (GCT+ve)	Secure record	Yes	Yes (blinded)	No (for our comparisons of interest)	Blinded outcome assessment; no sample sizes or measures of variance by group reported	Yes	Yes	Good
Vambergue[216], 2000, PCS	Somewhat representative (excluded those with pre-pregnancy high BP; n eligible NR) chosen 1:1 with exposure group)	Selected population (chosen 1:1 with exposure group; # eligible NR)	Secure record	Yes	Yes (all GDM patients sent to diabetologist)	Yes (for LGA adjusted; no adjusted data for macrosomia or Apgar scores)	Blinded outcome assessors	Yes	Yes	Good
Arbib[189], 2016, RCS	Selected population (women that were OGCT –ve, then screened in 3rd trimester by physician discretion)	Represents NGT population	Secure record	Unclear (some outcomes could be more apparent, i.e. macrosomia and LGA by 3rd trimester)	Unclear	Yes (for cesarean delivery)	Record linkage	Yes	Yes	Fair

Appendix B Table 13. Quality Assessment of Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year, Study design	Representativeness of exposed cohort	Selection of non-exposed cohort (e.g., same, location NGT population)	Ascertainment of exposure	Outcome of interest not present at start of study	No impact on care by knowledge of glycemic status	Controls for key confounders	Assessment of outcome	Follow up long enough for outcomes to occur	Adequacy of cohort follow up	Quality rating (not considering confounding)
Benhalima [190], 2013, RCS	Somewhat representative (low-risk population, only included those who received screening at the study hospital, 53% of pregnancies)	Represents NGT population	Secure record	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Biri[192], 2009, RCS	Somewhat representative	Represents NGT population	Secure record	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Chico[193], 2005, RCS	Somewhat representative	Represents NGT population	Secure record	Yes	Yes (all GDM patients sent to endocrinologist)	No	Record linkage	Yes	Yes	Fair
Corrado[194], 2009, RCS	Somewhat representative (only recruited Caucasian women)	Selected population (OGCT+ve)	Secure record	Yes	Unclear	Yes (for adjusted data)	Record linkage	Yes	Yes	Fair
Davis[195], 2018, RCS	Somewhat representative (excluded women missing key variables)	Represents NGT population	Secure record	Yes	Unclear	Yes (except for excessive gestational weight gain and SGA with significant differences between groups)	Record linkage	Yes	Yes	Fair
Ethridge[197], 2014, RCS	Somewhat representative (excluded missing outcome data or OGCT +ve without OGTT results)	Represents NGT population	Secure record	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Heetchuay [198], 2017, RCS	Somewhat representative (OAV on CC by 1- or 2-step, and excluded	Represents NGT population (some not	Secure records	Yes	Unclear	Yes (except for macrosomia with	Record linkage	Yes	Yes	Fair

Appendix B Table 13. Quality Assessment of Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year, Study design	Representativeness of exposed cohort	Selection of non-exposed cohort (e.g., same, location NGT population)	Ascertainment of exposure	Outcome of interest not present at start of study	No impact on care by knowledge of glycemic status	Controls for key confounders	Assessment of outcome	Follow up long enough for outcomes to occur	Adequacy of cohort follow up	Quality rating (not considering confounding)
	those missing data, ~10%)	given OGCT, 1-step, and some given OGCT and OGTT, 2-step)				significant differences between groups)				
Hillier[199], 2007, RCS	Somewhat repesentative (required wieght data at 5-7 yrs)	Represents NGT population	Secure records	Yes	Unclear	Yes (obesity)	Record linkage	Yes	Yes	Fair
Kaymak[201], 2011, RCS	Truly representative	Represents NGT population	Secure records	Yes	Unclear	No (not for our groups of interest)	Record linkage	Yes	Yes	Fair
Koivunen, 2020[204], RCS	Somewhat representative (in population at risk and excluded missing data and those with GDM by OGTT <24 wGA)	Represents those without OAV but excluding low risk	Secure records	Yes	Unclear	No (not for our groups of interest)	Record linkage	Yes	Yes	Fair
Lapolla[207], 2011, RCS	Somewhat representative (IADPSG group not GDM by 1 or 2 abnormal CC)	Selected population (NGT is not OAV on CC)	Secure records	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Martinez-Cruz, 2019[209], RCS	Somewhat representative (IADPSG group on FPG or 2hr values only and not GDM by 1-step CC)	Represents NGT population	Secure records	Yes	Unclear	Yes (matched 1:1 for maternal age and pre-gestational BMI)	Record linkage	Yes	Yes	Fair
Murat Seval[210], 2016, RCS	Truly representative	Represents NGT population	Secure records	Yes	Unclear (some SMBG in all patients in routine care)	No	Record linkage	Yes	Yes	Fair

Appendix B Table 13. Quality Assessment of Studies on Associations of Outcomes for More vs. Less Inclusive GDM Criteria (KQ5)

Author, Year, Study design	Representativeness of exposed cohort	Selection of non-exposed cohort (e.g., same, location NGT population)	Ascertainment of exposure	Outcome of interest not present at start of study	No impact on care by knowledge of glycemic status	Controls for key confounders	Assessment of outcome	Follow up long enough for outcomes to occur	Adequacy of cohort follow up	Quality rating (not considering confounding)
Park[211], 2015, RCS	Somewhat representative (women registered in 1st trimester)	Selected population (OGCT +ve)	Secure records	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Rust[213], 1996, RCS	Truly representative	Selected population (OGCT +ve)	Secure records	Yes	Yes (GDM referred to diabetes center)	No (not for our groups of interest)	Blinded outcome assessment	Yes	Yes	Good
Shang[215], 2014, RCS	Somewhat representative (IADPSG group not GDM by 1 or 2 abnormal CC)	Represents NGT population	Secure records	Yes	Unclear	No	Record linkage	Yes	Yes	Fair
Wang[217], 2013, RCS	Somewhat representative (excluded those with no OGTT data, if 1hr value <FPG value, or those OGCT +ve but no OGTT. "Of 7513 singleton pregnancies, 20.5% (n=1542) were associated with complete 100g OGTT results")	Represents NGT population	Secure records	Yes	Unclear	Yes (for adjusted data)	Record linkage	Yes	Yes	Fair
Wei[219], 2014, RCS	Somewhat representative (IADPSG group not GDM by 1 or 2 abnormal NDDG)	Represents NGT population	Secure records	Yes	Unclear	No	Record linkage	Yes	Yes	Fair

Abbreviations: CC = Carpenter Coustan; DM = diabetes mellitus; FPG = fasting plasma glucose; g = grams; GDM = gestational diabetes mellitus; hr = hour; IADPSG = International Association of Diabetes and Pregnancy Study Groups; LGA = large for gestational age; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; NR = not reported; OAV = one abnormal value; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; PCS = prospective cohort study; RCS = retrospective cohort study; SGA = small for gestational age; SMBG = self-monitoring of blood glucose; yr(s) = year(s); +ve = positive; -ve = negative

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Bevier[221], 1999 RCT NR U.S.	NR 103 83 (35 vs. 48)	G1: 27.4 ± 5.4 G2: 26.3 ± 6.0 Weight (kg) G1: 68.2 ± 11.4 G2: 72.4 ± 12.0 G1: HBA1c at 28 weeks: 4.7+/-0.7 G2: HBA1c at 28 weeks: 4.7+/-0.5 G1: White: 6.0% Black: 0.0% Hispanic: 94.0% G2: White: 4.0% Black: 2.0% Hispanic: 94.0% G1: 9.0% & 31.0% G2: 19.0% & 48.0%	Inclusion: OGCT+ve and OGTT-ve OGCT (≥140 mg/dL), 100 g OGTT at 24–28 wks with O'Sullivan and Mahan criteria Exclusion: Hypertension; collagen disease; chronic renal disease; cardiac or pulmonary disease; Rh sensitization; Hx of preterm labor or SGA	Preeclampsia, shoulder dystocia, SGA, cesarean delivery, induction of labor, macrosomia/LGA, 1 min and 5 min Apgar score (continuous)	G1: Diet (3 meals and 3 snacks; 40% carbohydrates, 20% protein, 40% fat), SMBG, and insulin if needed; RBG weekly and HbA1 testing at 28 and 32 wks; insulin initiation if FPG >90mg/dl or 1hr postprandial >120mg/dl on 3+ occasions; insulin n=1/35 G2: Regular RBG with insulin if needed; HbA1c testing at 28 and 32 wks; repeat OGTT at 30-32 wks; insulin initiated if RBG >120mg/dl; insulin n=4/48
Bonomo[222], 2005 RCT 1997 to 2002 Italy	NR 300 300 (150 vs. 150; 21 women were replaced post-randomization)	G1: 31.1 ± 4.7 G2: 30.7 ± 5.1 G1: 23.1 ± 4.4 G2: 23.0 ± 4.5 At diagnostic OGTT (mmol/L): G1: fasting 4.68 ± 0.45; 2h 6.00 ± 0.57	Inclusion: Caucasian; OGCT+ve and OGTT-Ve; singleton pregnancies 50g OGCT (>140 mg/dL at 24-28 wGA), and a normal 100g OGTT within 7 days of screening and repeated at 30-34 wGA if negative (values under fasting, 1h, 2h, and 3h by CC criteria).	Cesarean delivery (all and emergency), hypoglycemia (<1.7mmol/l on 2+ consecutive occasions), hyperbilirubinemia (plasma ≥205 µmol/l), NICU admission, macrosomia, LGA, SGA, 5 min Apgar score (continuous)	G1: Diet to maintain 24–30 kcal/kg per day based on pre-pregnancy weight (3 meals, 2–3 snacks; 50–55% carbohydrates, 25–30% protein, 20-25% fat); clinic visits every 2 weeks with glucose testing and discussion of diet/compliance, daily home urine testing for ketones; BG targets were FPG <5.1 mmol/l and 2hr postprandial <6.7 mmol/l

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Bonomo, 2005 Continued.		G2: fasting 4.77 ± 0.52 Caucasian: 100.0% NR & NR	If standard risk factors, screening done at booking. Exclusion: Normal OGCT; one abnormal OGTT value; GDM under CC criteria		G2: No special care, diet or treatment
Crowther[41], 2005 RCT, multi-center Sept 1993 to June 2003 Australia	NR 1000 1000 (490 vs. 510; 506 vs 524 infants)	G1: 30.9 ± 5.4 G2: 30.1 ± 5.5 G1: 26.8 (23.3–31.2) G2: 26.0 (22.9–30.9) OGTT results (mmol/L): G1: fasting 4.8 ± 0.7; 2h (median, IQR) 8.6 (8.1-9.3) G2: fasting 4.8 ± 0.6; 2h (median, IQR) 8.5 (8.1-9.1) G1: White: 73.0% Asian: 19.0% Other: 9.0% G2: White: 78.0% Asian: 14.0% Other: 8.0% NR & NR	Inclusion: Singleton or twin pregnancy; 16–30 wGA; prenatal clinic attendance; ≥1 risk factors for GDM or OGCT+ve; 75-g OGTT at 24-34 wGA with fasting <7.8 mmol/L and 2h 7.8-11.0 mmol/L Risk factors or 50g OGCT (≥140 mg/dL), then on 75 g OGTT at 24–34 wGA by WHO 1985 (glycemic response intermediate between normal and diabetic), until 1998 when WHO classified any glucose level above normal as GDM Exclusion: More severe glucose impairment; Hx of GDM; active chronic systemic disease (except essential hypertension)	Induction of labor, caesarean delivery (elective & emergency), preeclampsia (defined as hypertension-blood pressure of at least 140/90 mmHg on two occasions more than 4 hours apart), shoulder dystocia, hypoglycemia (requiring IV therapy), hyperbilirubinemia (jaundice requiring phototherapy), stillbirth, neonatal death, neonatal nursery, macrosomia, bone fracture, nerve palsy, RDS, LGA, SGA, 5 min Apgar score (<7); quality of life 6 wks and 3 months after enrollment (SF-36)	G1: Ongoing obstetric care; dietary advice; SMBG four times daily then once daily after targets met; glucose targets were FPG 3.5-5.5 mmol/l, preprandial ≤5.5 mmol/l and 2hr postprandial ≤7.0mmol/l; insulin initiated if two capillary-blood glucose results ≥5.5mmol/l on FPG or postprandial ≥7.0 mmol/l at 35 wGA or less; if ≥35 wGA and postprandial ≥8.0 mmol/l or one capillary BG value ≥9.0 mmol/l G2: Routine clinical care, further assessment/ treatment at the discretion of the clinician

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Gillman[240], 2010 CCT (4-5 year follow up of Crowther, 2005) 1997 to 2007 Australia	1030 (total children from Crowther, 2005 RCT) 351 eligible 241 with South Australian surveillance data on with height weight data at age 4-5 years 199 analyzed (94 vs 105)	G1: 30.3 G2: 28.9 G1: 27.7 G2: 25.3 OGTT results (mmol/L): G1: fasting 4.9; 2h 8.4 G2: fasting 4.8; 2h 8.6 G1: White: 85.1% Asian: 11.7% Aboriginal/Other: 3.2% G2: White: 89.5% Asian: 8.6% Aboriginal/Other: 1.9% NR & NR Children Female sex: G1: 50.0% G2: 47.6% Birth weight, g: G1: 3346 G2: 3585 Macrosomia: G1: 5.3% G2: 52.4% LGA: G1: 10.6% G2: 22.9%	Inclusion: Same as Crowther, 2005 plus South Australian children; livebirths; available data Exclusion: Same as Crowther, 2005 plus twins; missing height and weight data	Child obesity (>85th percentile) at age 4-5 years	G1: Same as Crowther, 2005 G2: Same as Crowther, 2005

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Deveer[226], 2013 CCT (reclassified from RCT) NR Turkey	NR 100 100 (50 vs. 50)	G1: 29.46 ± 5.82 G2: 31.22 ± 5.58 G1: 28.01 ± 3.60 G2: 29.10 ± 4.83 GCT values (mg/dL): G1: 155 (140-180) G2: 151.50 (140-180) NR	Inclusion: +ve OGCT, -ve OGTT, tested between 24-28 wGA 50g OGCT (140-180mg/dl), and OGTT results not meeting CC criteria Exclusion: Pre-existing diabetes, prior GDM, a Hx of stillbirth, multiple gestation, active chronic systemic disease	LGA, macrosomia, SGA, primary cesarean delivery, NICU admission, antenatal preeclampsia (elevation in blood pressure together with proteinuria), neonatal birth injury, perinatal death, maternal birth trauma (perineal trauma), preterm delivery (<37 wGA), 5 min Apgar score (<7)	G1: Medical nutrition therapy from dietician, with diet tailored to BMI: 20-25 kg/m^2 given 30kcal/kg/day; 25-30 kg/m^2 given 25 kcal/kg/day; ≥30 kg/m^2 given 15-20kcal/kg/day; 45% carbohydrate, 20% protein, 35% fat; followed weekly for first month post-diagnosis and then every two weeks until delivery; BG targets were FPG 95mg/dl and 2hr postprandial 140mg/dl G2: Routine antenatal care
Fadl[227], 2015 RCT Feb 2008 to Dec 2011 Sweden	NR 72 72 69 (33 vs 36; 67 infants)	G1: 32.6± 5.9 G2: 30.6± 5.5 G1: 31.3± 6.4 G2: 32.6± 5.9 OGTT results (mmol/L): G1: fasting 5.7± 0.6; 2h 10.6± 0.54 G2: fasting 5.7± 0.7; 2h 10.7± 0.5 G1: Non-Nordic origin: 36.4% G2: Non-Nordic origin: 22.2% NR & NR	Inclusion: women that underwent an OGTT before 34 wGA Criteria for OGTT: 1st degree family Hx of diabetes, prior LGA babies, previous GDM, BMI ≥30kg/m^2 or a RBG >9.0mmol/L 75g OGTT (28-32 wGA) with capillary FPG <7.0 mmol/L or capillary 2h ≥10.0 mmol/L and <12.2 mmol/L If RBG >9.0 mmol/L OGTT done in early pregnancy with repeat at 28-32 wGA if normal Exclusion: twin pregnancy	LGA, macrosomia, neonatal hypoglycemia, pre-eclampsia, gestational hypertension, cesarean delivery, induction of labor, perinatal mortality, brachial plexus injury, hyperbilirubinemia, NICU admission, respiratory disorder, shoulder dystocia, APGAR scores, preterm birth, severe maternal hypoglycemia (requiring assistance of another person)	G1: Dietary advice; home BG monitoring four times daily with instruction to keep in target range (FPG between 4-5 mmol/L; post-prandial values <6.5 mmol/L), insulin initiated if three values in one week exceeded target; insulin=66.7% G2: Conventional prenatal care

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Garner[223], 1997 RCT Sept 1991 to May 1994 Canada	326 300 299 (149 vs 150)	G1: 30.7 ± 4.8 G2: 30.7 ± 4.6 Pre-pregnancy weight (kg) G1: 68.91 ± 16.87 G2: 71.23 ± 19.78 75 g OGCT screening (mg/dL): G1: 180.0 ± 25.2 G2: 183.6 ± 32.4 91% Caucasian G1: NR & 50.3% G2: NR & 44.0%	Inclusion: Women with GDM diagnosed between 24–32 wGA; otherwise low-risk pregnancy 75g OGCT (≥144 mg/dL) and 75g OGTT at 24-28 wGA assessed by Hatem et al. criteria (FPG 4.8 mmol/ l, 1-h 10.9 mmol/ l and 2-h 9.6 mmol/l) Exclusion: Multiple gestation; maternal-fetal blood group incompatibility; known congenital anomaly; prior evidence of placenta previa or abruptio placentae; significant maternal disease; long-term medical therapy; imminent delivery	Caesarean delivery, hypoglycemia, hyperbilirubinemia, birth injury (fracture and neurologic sequelae, intracranial hemorrhage), macrosomia (>4000 & 4500 g), stillbirth, neonatal death	G1: Tertiary care center follow up with obstetrician and endocrinologist; dietary counseling, calorie-restricted diet of 35 kcal/kg ideal body weight per day to meet glucose targets of FPG <80 mg/dL and 1h post-prandial level <140 mg/dL; bi-weekly fetal monitoring; BG daily self-monitoring, insulin initiated if 2+ instances of BG values above targets; insulin=24.2% G2: Routine obstetric care by primary provider; unrestricted healthy diet by Canada Food Guide; twice weekly BG self-monitoring; no fetal monitoring unless indicated **Note**: women from G2 with persistently elevated FG >140 mg/dL or 1h post-prandial >200 mg/dL (T2DM) transferred to treatment arm; given diet, insulin, monitoring; analyzed with control group in ITT (n=16; 10.6%) G1 had 13 (8.7%)

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Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Malcolm[241], 2006 CCT (7-11 year follow up of Garner, 1997) Canada	89 (of 299 in Garner 1997) IFG n=80 (50 vs 30) IGT n=71 (46 vs 25) BMI n=85	Age at follow up: G1: 40.9 ±4.5 G2: 41.0 ± 4.2 Age at delivery: G1: 31.3 ± 4.5 G2: 30.9 ± 3.6 Pre-pregnancy weight (kg): G1: 66.5 ± 13.9 G2: 74.8 ± 24.0 BMI at follow up G1: 28.4 ± 6.20 G2: 30.0 ± 7.70 G1: Caucasian: 94.5% Black: 0.0% East Indian: 1.8% Other: 3.6% G2: Caucasian: 85.3% Black: 5.9% East Indian: 2.9% Other: 5.9% G1: NR & 41.5% Child Age at follow up: G1: 9.0 ± 0.8 G2: 9.3 ± 0.7 Female sex G1: 25% G2: 19%	Same as Garner, 1997	Child impaired glucose tolerance (≥7.8 and < 11.1 mmol/ l) of fasting tolerance (FPG 6.0–6.9 mmol/ l); T2DM (≥7.0 mmol/ l or a 2-h glucose ≥ 11.1 mmol/ l); >95th percentile); at age 7-11 years	G1: Same as Garner, 1997 G2: Same as Garner, 1997

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Malcolm, 2006 Continued.		Birthweight, g: G1: 3333 ± 654 G2: 3546 ± 720			
Hughes[228], 2018 RCT Oct 2015 to May 2016 New Zealand	67 47 (24 & 23) 44 (23 & 21)	Age at expected delivery date: G1: 30.5 (28.0-34.5) G2: 32.0 (29.5-36.0) BMI at baseline: G1: 29.6 (24.1-35.6) G2: 30.3 (27.1-38.4) HbA1c at booking: G1: 42 (41-45) G2: 42 (41-45) G1: European: 21% Maori: 0% Pacific:17% Asian: 58% Other: 4% G2: European: 13% Maori: 9% Pacific: 13% Asian: 57% Other: 9% NR & NR	Inclusion: HbA1c 5.9%-6.4% at booking; ongoing pregnancy with gestational age <14 wGA; age ≥ 18 Exclusion: pre-existing diabetes; fetus with lethal congenital anomalies; multiple pregnancy	Pre-eclampsia (new-onset or worsening hypertension after 20 weeks' gestation and the coexistence of one or more of the following new-onset conditions: proteinuria (protein/creatinine ratio 30 mg/mmol), other maternal organ dysfunction or fetal growth restriction), induction of labor, cesarean delivery (total and emergency), preterm delivery, shoulder dystocia, birth trauma, neonatal death (≥20wGA to 28 d after delivery), LGA, SGA, NICU admission, hypoglycemia (<2.2 mmol/l; requiring dextrose gel; requiring IV dextrose), hyperbilirubinemia (jaundice requiring phototherapy)	G1: Offered outpatient visits every 3-6 wks at local diabetes clinic in combination with follow-up from their lead maternity carer (community midwife or obstetrician); received ongoing lifestyle education, home blood glucose monitoring (before and after each meal), and medication as required (metformin and/or insulin) to maintain capillary BG levels within target range: FBG <5.0 mmol/L (90 mg/dL), 1hr postprandial <7.4 mmol/L (133.3 mg/dL), 2hr postprandial <6.5 mmol/L (188 mg/dL); insulin initiation at discretion of attending physician; metformin=14, insulin=15 (17/23, 73.9% of total women, some overlap) G2: Standard care with their lead maternity caregiver and 75g OGTT screening at 24 wGA; New Zealand criteria used: FBG ≥5.5 mmol/L (99 mg/dL) or 2hr BG ≥9.0 mmol/L (162 mg/dL); metformin=3, insulin=11 (11/22, 50.0% of total women, some overlap)

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Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Kokanali[229], 2014 RCT NR Turkey	NR 201 (99 vs 102) 201	Age at delivery: G1: 27.89 ± 5.79 G2: 27.91 ± 5.81 Pre-gestational BMI: G1: 26.41 ± 2.74 G2: 26.69 ± 3.35 NR NR G1: 12.1% & 30.3% G2: 15.7% & 28.4%	Inclusion: women between 24-28 wGA 50g GCT value between 140 and 200 mg/dL and one abnormal value (OAV) on 100g OGTT at 24-28 wGA by CC diagnostic criteria Exclusion: smokers, women with systemic diseases, multiple gestations, Hx of uterine operations	Cesarean delivery (emergency), preeclampsia (elevation in blood pressure together with proteinuria), macrosomia, LGA, SGA, NICU admission, neonatal hypoglycemia (blood glucose level below 40mg/dl within 2 hours from birth), preterm delivery (<37 wGA), 5 min Apgar score (<7), neonatal birth injury	G1: Personalized dietary advice from dietician (22-35 kcal/kg according to BMI); 40% carbohydrates, 30% proteins, 30% fat across 3 meals and 3 snacks; daily routine activity; blood glucose monitoring; BG targets were FPG <95mg/dl and 1hr postprandial <140mg/dl); insulin initiation if any one abnormal G2: Routine antenatal care
Landon[42], 2009 RCT, multi-center Oct 2002 to Nov 2007 US	19,655 eligible by inclusion criteria but 44% met exclusion criteria % 18% declined 7298 completed OGTT 958 (485 vs. 473) Varies by outcome (931 for most except hypoglycemia [n=738; 77%])	G1: 29.2 ± 5.7 G2: 28.9 ± 5.6 BMI at entry: G1: 30.1 ± 5.0 G2: 30.2 ± 5.1 Glucose level after 50g OGCT (mg/dL): G1: 159.0 ± 15.3 G2: 159.7 ± 15.5	Inclusion: Women between 24 weeks 0 days and 30 weeks 6 days gestation; 50g OGCT value between 135 and 200 mg/dL at 24-31 wGA OGTT fasting glucose <95 mg/dL and 2 or 3 timed measurements above CC thresholds Exclusion: Abnormal GCT result before 24 wGA; pre-existing diabetes; prior GDM; Hx of stillbirth; multifetal gestation; asthma;	Induction of labor, caesarean delivery (total and after excluding cases of abnormal presentation, placenta previa, oligohydramnios, and previous cesarean delivery) , preeclampsia (elevation in blood pressure (defined by gestational hypertension) together with proteinuria =300 mg of protein or more in a 24-hour urine collection or a result of 2+ or greater on a dipstick test when a 24-hour collection was not available; elevated blood pressure with either elevated liver enzyme levels (aspartate aminotransferase level ≥70 U	G1: Nutritional counseling and dietary therapy; daily BG self-monitoring; insulin initiated if most FPG ≥95 mg/dL or 2h ≥120 mg/dL between visits; insulin=37/485, (7.6%) G2: Usual prenatal care; BG testing per provider; treatment initiated if RBG ≥160mg/dl or FPG ≥95mg/dl; insulin=2/473 (0.4%)

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Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Landon, 2009 Continued.		Glucose level on OGTT (mg/dL): G1: fasting 86.6 ± 5.7; 1h 191.8 ± 21.9; 2h 173.7 ± 21.8; 3h 137.3 ± 29.0 G2: fasting 86.3 ± 5.7; 1h 193.4 ± 19.3; 2h 173.3 ± 19.6; 3h 134.1 ± 31.5 G1:White: 25.4% Black: 11.5% Hispanic: 57.9% Asian: 4.5% Other: 0.6% G2: White: 25.2% Black: 11.4% Hispanic: 56.0% Asian: 5.9% Other: 1.5% G1: 0.0% (exclusion criteria) & NR G2: 0.0% (exclusion criteria) & NR	chronic hypertension; corticosteroid use; known fetal anomaly; imminent or preterm delivery likely due to maternal disease or fetal condition	per liter) or thrombocytopenia (platelet count <100,000 per cubic millimeter) was also diagnosed as preeclampsia), gestational hypertension (systolic pressure of 140 mm Hg or more or a diastolic pressure of 90 mm Hg or more on two occasions at least 4 hours apart, or one elevated blood-pressure value subsequently treated with medication), hypertensive disorders of pregnancy (preeclampsia or hypertension), shoulder dystocia, hypoglycemia (glucose value o<35mg/dl 2 hrs after birth), hyperbilirubinemia (value greater than the 95th percentile for any given point after birth), stillbirth or neonatal death, birth injury (brachial plexus palsy or clavicular, humeral or skull fracture), NICU admission, RDS, LGA, SGA, macrosomia, preterm delivery (<37 wGA)	

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Berggren[234], 2012 CCT (Secondary analysis of Landon 2009)	958 from Landon, 2009 RCT) 768 analyzed by subgroups Hispanic or Non-Hispanic White (371 vs 397)	Mild treated GDM: Hispanic (n=274): 29.5 ± 5.7 Non-Hispanic White (n=123): 29.2 ± 5.9 Mild Untreated GDM: Hispanic (n=255):29.5 ± 5.6 Non-Hispanic White (n=116): 28.5 ± 5.0 BMI at enrollment Mild treated GDM: Hispanic (n=274): 29.5 ± 5.7 Non-Hispanic White (n=123): 29.2 ± 5.9 Mild Untreated GDM: Hispanic (n=255):29.5 ± 5.6 Non-Hispanic White (n=116): 28.5 ± 5.0 BMI at enrollment Mild treated GDM: Hispanic: 30.3 ± 4.4 Non-Hispanic White: 29.7 ± 5.5 BMI at enrollment	Same as Landon, 2009. Insulin use: Mild Treated GDM, Hispanic: 1.2% Mild Treated GDM, Non-Hispanic White: 2.3%	Hyperbilirubinemia, hypoglycemia, SGA, LGA, macrosomia, hypertensive disorders of pregnancy, NICU admission, preterm delivery (<37 wGA) All adjusted models were within group not between.	Same as Landon, 2009

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Berggren, 2012 Continued.		Mild Untreated GDM: Hispanic: 30.2 ± 4.3 Non-Hispanic White: 30.6 ± 6.2 OGCT (mg/dl): Mild Treated GDM: Hispanic: 159.0 ± 15.1 Non-Hispanic White: 157.1 ± 14.3 Mild Untreated GDM: Hispanic: 160.6 ± 15.5 Non-Hispanic White: 159.5 ± 15.9 Dx OGTT (mg/dl) Mild Treated GDM Hispanic: FPG 86.9 ± 5.6; 1hr 192.1 ± 23.8; 2hr 172.7 ± 22.6; 3hr 140.3 ± 28.3			

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Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Berggren, 2012 Continued.		Non-Hispanic White: FPG 85.5 ± 6.1; 1hr 189.2 ± 19.1; 2hr 174.8 ± 20.2; 3hr 133.3 ± 27.4 (p=0.02 at 3hr for Hispanic vs non-Hispanic white) Mild Untreated GDM Hispanic: FPG 86.3 ± 5.8; 1hr 193.8 ± 18.3; 2hr 172.5 ± 21.1; 3hr 136.7 ± 29.2 Non-Hispanic White: FPG 86.3 ± 5.6; 1hr 192.1 ± 21.9; 2hr 172.6 ± 16.4; 3hr 128.6 ± 32.2 (p=0.02 at 3hr for Hispanic vs non-Hispanic white) Hispanic: 48.3% Non-Hispanic White: 51.7% 0% (exclusion criteria) & NR			
Harper[236], 2016 CCT (Secondary analysis of Landon, 2009)	958 (from Landon, 2009 RCT) 931 analyzed by subgroups meeting NDDG or CC criteria	NDDG criteria(n=560): 29.3 ± 5.6 CC criteria(n=398): 28.7 ± 5.7 NDDG criteria: 30.1 ± 5.1 CC criteria: 30.2 ± 5.1	Same as Landon, 2009 Mutually exclusive groups meeting NDDG vs CC criteria (but all FPG <95 mg/dL)	Hypertensive disorders of pregnancy, shoulder dystocia, cesarean delivery, LGA, SGA, macrosomia (chosen based on effectiveness in main RCT)	Same as Landon, 2009. Insulin use by group: NDDG criteria, treated: 8.3% NDDG criteria, untreated: 0.8% CC criteria, treated: 7.2% CC criteria, untreated: 0.0%

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Harper 2016, Continued.		OGCT (mg/dl) NDDG criteria: 161.3 ± 15.9 CC criteria: 156.7 ± 14.3 (p<0.001) Dx OGTT (mg/dl) NDDG criteria: FPG 87.0 ± 5.5; 1hr 198.6 ± 21.1; 2hr 181.6 ± 20.4; 3hr 142.2 ± 30.6 CC criteria: FPG 85.7 ± 5.9; 1hr 184.1 ± 16.9; 2hr 162.0 ± 14.9; 3hr 126.6 ± 27.3 (all time points were significantly different at p<0.001) NDDG criteria: African American: 11.3%; Caucasian: 24.1%; Hispanic: 57.5%; Other: 7.1% CC criteria: African American: 11.8%; Caucasian: 26.9%; Hispanic: 56.3%; Other: 5.0% 0% (exclusion criteria) & NR			

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Palatnik[237], 2015 CCT (Secondary analysis of Landon, 2009) Palatnik, 2015 Continued.	958 (from Landon, 2009) 932 analyzed by subgroups of gestational age at treatment initiation	Group by gestational age at initiation of Tx (wGA) 24-26 (n=116): 28.7 ± 5.5 27 (n=170): 29.0 ± 5.6 28 (n=193): 29.1 ± 5.5 29 (n=221): 29.2 ± 5.9 30+ (n=258): 29.2 ± 5.6 24-26: 30.0 ± 4.8 27: 31.0 ± 5.5 28: 304 ± 5.2 29: 29.9 ± 4.7 30+: 29.7 ± 5.0 OGCT (mg/dl): 24-26: 158.9 ± 15.4 27: 158.9 ± 15.3 28: 158.4 ± 15.3 29: 160.2 ± 15.5 30+: 159.8 ± 15.5 Dx OGTT (mg/dl): 24-26: FPG 87.2 ± 5.9; 1hr 194.1 ± 21.2; 2hr 177.2 ± 22.6; 3hr 136.2 ± 30.5 27: FPG 86.3 ± 5.7; 1hr 194.4 ± 18.7; 2hr 173.8 ± 18.6; 3hr 131.1 ± 29.3 28: FPG 86.4 ± 5.6; 1hr 190.9 ± 23.6; 2hr 171.8 ± 19.5; 3hr 136.5 ± 30.7	Inclusion: Same as Landon, 2009 plus data available	NICU admission, LGA, cesarean delivery, hypertensive disorders of pregnancy	Same as Landon, 2009

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Palatnik, 2015 Continued.		29: FPG 85.7 ± 6.1; 1hr 193.5 ± 20.0; 2hr 174.0 ± 21.3; 3hr 136.3 ± 30.1 30+: FPG 86.8 ± 5.4; 1hr 191.3 ± 20.0; 2hr 172.5 ± 21.4; 3hr 137.5 ± 30.5 24-26: Black: 13.8% Hispanic: 69.8%; White: 13.8%; Other: 2.6% 27:Black: 12.9%; Hispanic: 65.9%; White: 15.3%; Other :5.9% 28: Black: 8.3%; Hispanic: 65.3%; White: 20.7%; Other: 5.7% 29: Black: 11.3%; 50.2%; 33.5%; 5.0% 30+: Black: 12.0%; Hispanic: 45.0%; White: 33.3%; Other: 9.7% (p<0.001 for ethnicity across all groups) 0& (exclusion criteria) & NR			
Casey[235], 2015 CCT (Secondary analysis of Landon 2009)	958 (from Landon, 2009 958 analyzed by BMI subgroups	Same as Landon, 2009 NR by BMI group	Same as Landon, 2009	LGA	Same as Landon, 2009

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Landon[239], 2015 CCT (5-10 year followup of Landon, 2009) Feb 2012 to Sep 2013	905 (from Landon, 2009 RCT meeting revised criteria) 666 contacted 500 (264 vs. 236) for childhood obesity; 390 (210 vs 180) for metabolic impairment and diabetes in childhood	Maternal Age at entry: G1 (n=264): 29.2 ± 5.2 G2 (n=236): 28.7 ± 5.5 BMI at entry: G1: 30.2 ± 5.1 G2: 30.6 ± 5.4 50g OGCT (mg/dL): G1: 158.2 ± 15.3 G2: 158.4 ± 15.4 Dx OGTT (mg/dL): G1: FPG 86.9 ± 5.7; 1hr 191.0 ± 21.2; 2hr 172.5 ± 21.4; 3hr 138.2 ± 29.1 G2: FPG 86.5 ± 5.6; 1hr 192.9 ± 19.1; 2hr 172.5 ± 18.5; 3hr 133.7 ± 31.6 G1: NHB: 10.6% NHW: 31.8% Hispanic: 54.6% Other: 3.0% G2: NHB: 11.4% NHW: 27.5% Hispanic: 55.9% Other: 5.1% Child Female sex: G1: 47.0% G2: 48.7%	Same as Landon, 2009 plus enrollment at a center still participating in MFMU Network at time of follow up study (12/16 centers; 94% of original RCT patients) Exclusion: Same as Landon, 2009	Child diabetes; obesity ($\geq$85th and 95th percentile), cardiovascular risk factors, impaired fasting glucose at age 5-10 years	Same as Landon, 2009

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Landon, 2015 Continued.		Birth weight, g: G1: 3283 +/-491.4 G2: 3468.3 +/- 546.4 Macrosomia: G1: 4.6% G2: 13.6% LGA: G1: 6.4% G2: 15.7%			
Casey[238], 2019 CCT (5-10 year follow up of Landon, 2009) Feb 2012 to Sep 2013 U.S.	905 (total from Landon, 2009 RCT) 666 contacted 483 participated in followup study on maternal outcomes 457 analyzed (243 vs. 214)	Age at follow up: G1: 36 (33-40) G2: 36 (32-40) Age at entry: G1: 29 (26-33) G2: 29 (25-33) BMI pre-pregnancy: G1: 25.9 (22.9-29.4) G2: 25.7 (22.6-28.9) BMI at entry: G1: 29.7 (26.3-33.2) G2: 29.7 (27.0-33.0) 50g OGCT (mg/dL): G1: 155 (145-170) G2: 157 (145-170) Dx OGTT (mg/dL): G1: FPG 88 (84-91); 1h 190 (181-203); 2h 170 (160-182); 3h 144 (120-155)	Inclusion: Same as Landon, 2009 plus enrollment at a center still participating in MFMU Network at time of followup study (12/16 centers; 94% of original RCT patients) Exclusion: Same as Landon, 2009	Maternal impaired fasting glucose (≥100mg/dl); metabolic syndrome (three or more of the following five criteria were met: (1) a waist circumference greater than 88 cm, (2) serum triglycerides150 mg/dL or greater or current treatment for hyperlipidemia, (3) high-density lipoprotein (HDL) cholesterol less than 50 mg/dL, (4) a systolic blood pressure of 130 mmHg or greater or a diastolic blood pressure 85 mm Hg or greater or current treatment for hypertension, and (5) a fasting serum glucose of 100 mg/dL or more or current treatment for diabetes (oral agent or insulin); diabetes (currently treated for or +ve 75g OGTT by ADA criteria);	Same as Landon, 2009

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Casey, 2019 Continued.		G2: FPG 88 (83-91); 1h 194 (185-203), 2h 171 (160-182); 3h 141 (114-156) G1: White: 33.7% Black: 10.7% Hispanic: 52.7% Other: 2.9% G2: White: 27.1% Black: 10.3% Hispanic: 58.4% Other: 4.2% G1: 0.0% (exclusion criteria) & NR G2: 0.0% (exclusion criteria) & NR		obesity (BMI >30 kg/m^2) up to 10 years post-pregnancy	
Osmundson[230], 2016 RCT May 2012 to Jun 2014 U.S.	121 95 83 (42 vs 41; 74 for our outcomes)	G1: 32.4 ± 5.1 G2: 34.3 ± 5.2 Pre-pregnancy BMI: G1: 27.2 (24.8-33.2) G2: 27.4 (22.6-32.7) NR HBA1c (%) G1: 5.8 (5.7-5.9) G2: 5.8 (5.7-5.9) G1: Caucasian: 17.1% Asian: 39.0% Hispanic: 41.5% Black: 2.4%	Inclusion: HbA1c between 5.7-6.4% before 14 wGA Exclusion: Pre-gestational diabetes, chronic corticosteroid use, multifetal gestation, <18 years old, prior pregnancy with shoulder dystocia or birth injury possibly attributed to diabetes (clavicular, humeral or brachial plexus injury), or macrosomia	Induction of labor, cesarean delivery, primary cesarean delivery, excessive maternal weight gain, pre-eclampsia (BP ≥140/90 with 300 mg of protein on a 24-hour urine collection), gestational hypertension (BP ≥140/90), macrosomia, hyperbilirubinemia (requiring treatment), hypoglycemia (<36mg/dl), perinatal mortality (not reported: LGA, shoulder dystocia, birth injury (clavicular, humeral, or brachial plexus injury)	G1: Dietary counselling with Certified Diabetes Educator; carbohydrate goal of 15g at breakfast, 15-30g at snacks, 45-55g at lunch & dinner; food diary; SMBG four times daily for goal fasting <92 mg/dL, 1h postprandial <135 mg/dL; insulin initiated if >20% of self-monitored BG elevated, visits every two weeks by CDE or obstetric provider; 75g OGTT [IADPSG] at 26-28 wks with negatives continuing dietary but reduced SMBG; insulin=14/39 (35.9%)

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Osmundson, 2016 Continued.		G2: Caucasian: 12.2% Asian: 36.6% Hispanic: 48.8% Black: 2.4% G1: 21.4% & NR G2: 12.2% & NR		Subgroups: By pre-pregancy BMI (non-obese vs. obese=BMI ≥30kg/m2); outcomes: induction of labor, cesarean delivery, macrosomia	G2: Routine prenatal care with screening OGTT at 26-28 wks; insulin initiation if GDM at OGTT and target values exceeded on >2 occasions; insulin= 10/38 (26.3%)
Simmons[231], 2018 RCT Jul 2015 to Apr 2016 Australia	21 21 20 (11 vs 9)	G1: 29 ± 5 G2: 30 ± 7 G1: 32.3 ± 7.8 G2: 33 ± 7.0 Early (<20wGA) OGTT results (mmol/L): G1: fasting 5.1 ± 0.4; 1h 8.0 ± 1.7; 2h 7.0 ± 1.9 G2: fasting 5.2 ± 0.3; 1h 8.4 ± 1.6; 2h 6.8 ± 1.7 G1: Caucasian: 63.6% G2: Caucasian: 50.0% G1: NR & 36.4% G2: NR & 30.0%	Inclusion: consecutive pregnant women < 20 wGA, with a singleton pregnancy, aged ≥18 years and referred for an OGTT based on the presence of risk factors for GDM (ADIPS) 75g OGTT (<20 wGA) with IADPSG criteria Exclusion: inability to understand English, or a presence of a major active medical disorder	Hypertensive disorders of pregnancy (pregnancy induced hypertension or preeclampsia), induction of labor, cesarean delivery (total and priamry), NICU admission, hypoglycemia (≤2.2mmol/L), LGA, SGA, stillbirth, shoulder dystocia	G1: Group education, SMBG and saw a dietitian. FBG and 2 h glucose targets were < 5.3mmol/l and <6.8 mmol/l respectively. If values exceeded on >2 occasions women were offered metformin or insulin; insulin and/or metformin=4/11 (36.0%) G2: Routine prenatal care with screening at 24-28 wGA; insulin if GDM at OGTT and target values exceeded on >2 occasions; insulin and/or metformin=4/10 (40.0%)
Vinter[232], 2018 CCT (secondary analysis of RCT on prevention of GDM using lifestyle intervention,	90 90 allocated (36 vs. 54) 90	Median age (IQR): G1: 29 (27-34) G2: 30 (27-32) Pre-pregnancy or 1st measured weight in pregnancy:	Inclusion: singleton pregnancy, 18-40 years old, BMI 30-40 kg/m^2 (pre-pregnancy or 1st measured weight in pregnancy)	Hypertensive disorders in pregnancy, preeclampsia (proteinuria and persistently elevated blood pressure, ≥140/90 mmHg, on more than one occasion), maternal hypertension (persistently elevated blood pressure, ≥140/90 mmHg, on more than one occasion),	G1: Lifestyle intervention: 4 diet counseling sessions with a trained dietician, encouraged to perform 30-60 min daily exercise with a free full membership to a fitness center for 6 months until delivery (included closed exercise classes with a physiotherapist 1h weekly)

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Vinter, 2018 Continued. for obese women with mild GDM early in pregnancy) Oct 2007 to Oct 2010 Denmark		G1: 34.3 (32.3-39.2) G2: 34.6 (32.7-37.3) 1st trimester OGTT (mmol/L), median (IQR): G1: venous fasting 5.30 (5.10-5.45); capillary 2h 6.25 (5.80-7.20) G2: venous fasting 5.20 (5.20-5.40); capillary 2h 6.70 (5.90-7.55) G1: Caucasian: 100% G2: Caucasian: 100% G1: NR & NR G2: NR & NR	75g OGTT diagnosed retrospectively in early pregnancy (12-15 wGA) by modified WHO 2013 criteria (venous FPG ≥5.1 mmol/L and/or 2h capillary ≥8.5 mmol/L), but not meeting Danish criteria for GDM (2h capillary ≥9.0 mmol/L) at any time (12-15, 28-30 or 34-36 wGA) (96% had early GDM based on FPG) Exclusion: prior serious obstetric complications, major medical disorders including pregestational DM, alcohol abuse, non-Danish speaking, and meeting Danish criteria for GDM or NGT	cesarean delivery (total, emergency and planned), shoulder dystocia, preterm delivery, macrosomia, LGA, NICU admission, excessive weight gain (≥9 kg as per Institue of Medicine)	G2: Routine care Note: During pregnancy, both groups were monitored with fasting blood samples, OGTTs, sonographic fetal biometry, and measurements of maternal weight and blood pressure
Yang[233], 2014 RCT Dec 2010 to Oct 2012 China	1,371 948 (242 excluded because of protocol deviations from renovations; 6 women	G1: 29.9 ± 3.5 G2: 29.7 ± 3.2 Pre-pregnancy BMI: G1: 22.9 ± 3.6 G2: 23.4 ± 3.9 OGCT (mmol/L) G1: 9.0 (8.4-9.8) G2: 8.9 (8.3-9.8)	Inclusion: Women with confirmed GDM 50g OGCT (≥140mg/dL), and 75g OGTT at 24-28 wks diagnosed by IADPSG criteria (2-step) for GDM	Macrosomia, LGA, neonatal hypoglycemia (capillary blood glucose <1.7 mmol/l), shoulder dystocia or birth trauma, bone fracture, stillbirth or neonatal death, induction of labor, cesarean delivery, preeclampsia (SBP/DBP ≥140/90	G1: Shared care delivered by doctors and nurses; group education sessions at 27, 29, 33 weeks; individualized dietary advice and physical activity counseling based on BMI; self-monitoring of BG four times daily for two weeks then daily to meet targets (fasting 3.5-5.1, 2h post-prandial ≤7 mmol/L up to 36 weeks then ≤8 mmol/L after 36 weeks); insulin as

Appendix B Table 14. Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, year Study Design Dates of study Country	Women Eligible, n Women Randomized, n Women Analyzed*, n	Maternal Age, mean± SD (yr) BMI, mean ± SD; median (IQR) (kg/m^s) Glucose Levels, mean ± SD Race Previous GDM & Family Hx of T2DM (%)	Inclusion/ Exclusion Criteria	Outcomes of Interest	Interventions
Yang, 2014 Continued.	delivered outside hospital) 700	OGTT results (mmol/L): G1: fasting 5.1 ± 0.6; 1h 10.1 ± 1.4; 2h 8.4 ± 1.2 G2: fasting 5.0 ± 0.5; 1h 10.0 ± 1.3; 2h 8.4 ± 1.4 G1: Han chinese: 97.0% Others: 3.0% G2: Han chinese: 97.0% Others: 3.1% NR & NR	Exclusion: OGTT meeting criteria for DM, younger than 18 yrs old, non-singleton pregnancy, maternal-fetal ABO blood type incompatibility, maternal diseases (i.e. chronic hypertension, thyrotoxicosis, pre-pregnancy diabetes), use of long-term medications that might affect glucose metabolism	mmHg with proteinuria, +or more), pregnacy induced hypertension (SBP/DBP ≥140/90 mmHg), 1 min Apgar score (<7), preterm delivery (<37 wGA) Subgroups: By GDM diagnostic criteria (IADPSG only; IADPSG & WHO 1999); outcomes: Macrosomia, LGA, Hypertensive disorders in pregnancy	needed (target values exceeded 2+ times in 2-week interval or 2h post-prandial >9.0 mmol/L once during 1-week period) (n=339); insulin=4/339 (1.2%) G2: Usual care; offered group education class on diet and physical activity by a diabetes educator; insulin treatment if HbA1c ≥6.5% during 34 wk follow-up (n=361); insulin=1/361 (0.3%)

Abbreviations: ACOG = American College of Obstetricians and Gynecologists; BG = blood glucose; BMI = body mass index; CC = Carpenter Coustan; CCT = controlled clinical trial; CDE = certified diabetes educator; Dx = diagnosis; FPG = fasting plasma glucose; g = grams; G = group; GDM = gestational diabetes mellitus; HAPO = Hyperglycemia and Adverse Pregnancy Outcome; HBGM = home blood glucose monitoring; HbA1c = hemoglobin A1c; hr(s) = hour(s); Hx = history; IADPSG = International Association of Diabetes and Pregnancy Study Groups; IQR = interquartile range; IWC = International Workshop Conference; kcal/kg = kilocalorie per kilogram; LGA = large for gestational age; MFMU = Maternal-Fetal Medicine Units; mg/dl = milligram per deciliter; min(s) = minute(s); mmol/L = millimole per liter; MNT = medical nutrition therapy; N/A = not applicable; NDDG = National Diabetes Data Group; NICU = neonatal intensive care unit; NR = not reported; OAV = one abnormal value; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; RBG = random blood glucose; RDS = respiratory distress syndrome; SGA = small for gestational age; ST = short term; Tx = treatment; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus; wGA = weeks' gestational age; WHO = World Health Organization; wk(s) = week(s); yr(s) = year(s)

Appendix B Table 15. Quality Ratings of Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, Year	Sequence Generation	Allocation Concealment	Comparable at baseline	Blinding of Participants and Providers	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Outcome Reporting	Other	Quality Rating
Bevier[221], 1999	Unclear	Unclear	Low	None; Unclear (objective outcomes)	NR; Unclear (objective outcomes)	Unclear (19% and uneven)	Low	Low	Fair
Bonomo[222], 2005	Unclear (replaced 21 women after randomization)	Unclear	Low	None; Unclear (objective outcomes)	NR; Unclear (objective outcomes)	Low	Low	Low	Fair
Crowther[41], 2005	Low	Unclear (assigned some OGCT+ve into routine care group)	Low (women in the intervention group were older and were less likely to be white or primiparous)	Low (blinded to OGTT results; CG told they did not have GDM & some NGT women assigned)	Unclear ("research assistant extracted data" but providers of UC group blinded to glucose value)	Low	Low	Low	Good
Deveer[226], 2013 (CCT)	High (days of week)	High (days of week)	Unclear (only report 4 variables)	NR; Unclear (objective outcomes)	NR; Unclear (objective outcomes)	Low	Low	Low	Fair
Fadl[227], 2015	Low	Low	Low	Low (CG blinded to OGTT results)	Unclear (data extractor NR; but providers of UC group blinded to glucose value objective outcomes)	Low	Unclear (shoulder dystocia, APGAR scores and preterm deliveries reported in methods but not results)	Low	Good (Fair for outcomes with potential SOR)
Garner[223], 1997	Low	Unclear	Low	Unclear (patients aware of GDM status & SMBG results; providers not given SMBG results for CG)	Unclear (objective outcomes)	Low	Unclear (no prespecified outcomes)	Low	Fair
Hughes[228], 2018	Low	Low	Unclear (older age in controls; few variables compared)	Unclear (objective outcomes)	Unclear (objective outcomes)	Low	Low	Low	Fair
Kokanali[229], 2014	Low	Unclear (coin toss)	Low	Unclear (NR)	Unclear (NR)	Low	Low	Low	Fair (blinding NR, allocation

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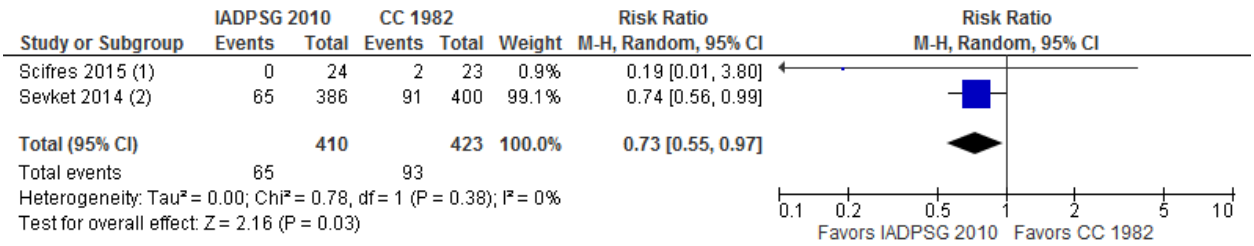
Author, Year	Sequence Generation	Allocation Concealment	Comparable at baseline	Blinding of Participants and Providers	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Outcome Reporting	Other	Quality Rating
									concealment NR)
Landon[42], 2009	Low	Low	Low	Low (blinded OGTT and NGT group >2:1 assigned to CG)	Low (blinded for hypertension and shoulder dystocia)	Low (Unclear for hypoglycemia 77% followup)	Low	Low	Good
Osmundson[230], 2016	Low	Low	Low	Unclear (no blinding; objective outcomes)	Unclear (NR; objective outcomes)	Unclear (22% loss to followup for most outcomes)	Unclear (no results for LGA or birth injury used ClinicalTrials.gov for hypoglycemia, hyperbilirubinemia, mortality, pre-eclampsia)	Low	Fair (no blinding, significant loss to followup, and potential selective outcome reporting)
Simmons[231], 2018	Low	Unclear	Low (IG higher systolic BP 111 vs 101)	Low (participant, midwifery, obstetric, diabetes clinic, and research staff were kept blinded to all numeric results and only knew if a woman had been referred for GDM treatment)	Unclear (research staff not blinded to treatment status; objective outcomes)	Unclear (1 drop-out each arm)	Low	Low	Good
Vinter[232], 2018 (CCT)	High (for this analysis; unequal groups sizes 36 vs 54)	Low	Unclear (characteristics seem similar but unmeasured confounders possible)	Low (intervention not blinded but this is secondary analysis for those retrospectively dx with mild GDM (96% FPG; all	Unclear; open label	Low	Low (same outcomes as prespecified for original RCT)	Low	Fair (not randomized for this comparison)
Vinter, 2018 Continued.				venous plasma measurements including fasting glucose were blinded to the clinicians).					

Appendix B Table 15. Quality Ratings of Studies on Treatment of Gestational Diabetes (KQs 6 and 7)

Author, Year	Sequence Generation	Allocation Concealment	Comparable at baseline	Blinding of Participants and Providers	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Outcome Reporting	Other	Quality Rating
				Patients dx with GDM as per usual Danish guidelines told and excluded from study.					
Yang[233], 2014	Unclear (by the time sequence of visits to the clinic and a list of priori computer-generated random assignment)	Unclear (NR)	Low	Unclear (states women blinded but methods NR; providers not blinded; objective outcomes)	Unclear (research team not blinded but objective outcomes and hypertension cases reviewed by masked clinician)	Low	Unclear (Macrosomia and hypertensive disorders of pregnancy prespecfied; several other outcomes reported but stated as post hoc and does not appear to be biased reporting)	Low	Fair (unclear sequence generation; no blinding or patients or providers)

Abbreviations: BP = blood pressure; CCT = controlled clinical trial; CG = control group; Dx = diagnosed; FPG = fasting plasma glucose; GDM = gestational diabetes mellitus; IG = intervention group; LGA = large for gestational age; NGT = normal glucose tolerance; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; RCT = randomized controlled trial; SMBG = self-monitoring blood glucose; SOR = selective outcome reporting; UC = usual care; vs = versus; +ve = positive

Appendix C Figure 1. Meta-Analysis of Trials: Primary Cesarean Deliveries, IADPSG vs. CC Screening Strategies (KQ3)

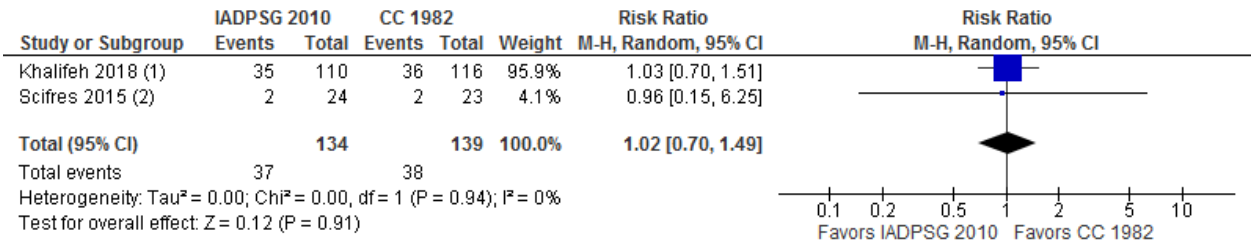


Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 2. Meta-Analysis of Trials: Gestational Hypertension, IADPSG vs. CC Screening Strategies (KQ3)

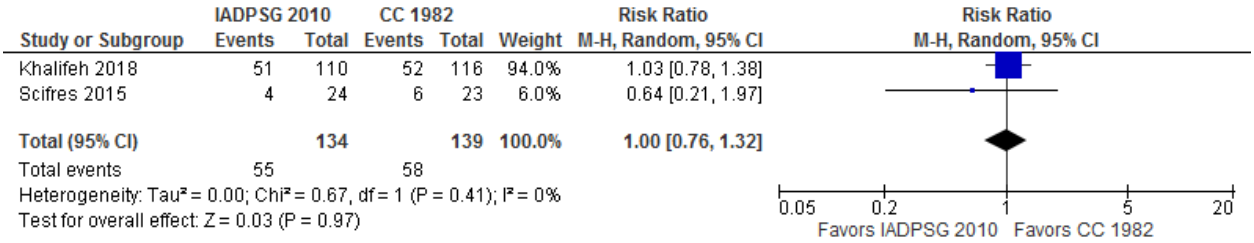
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 3. Meta-Analysis of Trials: Total Cesarean Deliveries, IADPSG vs. CC Screening Strategies (KQ3)



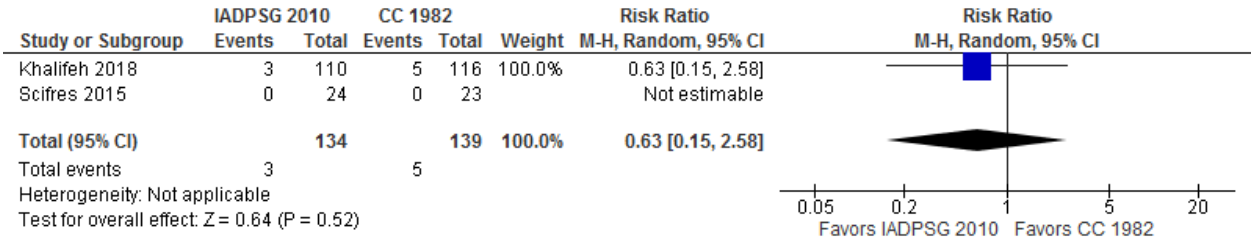
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 4. Meta-Analysis of Trials: Induction of Labor, IADPSG vs. CC Screening Strategies (KQ3)



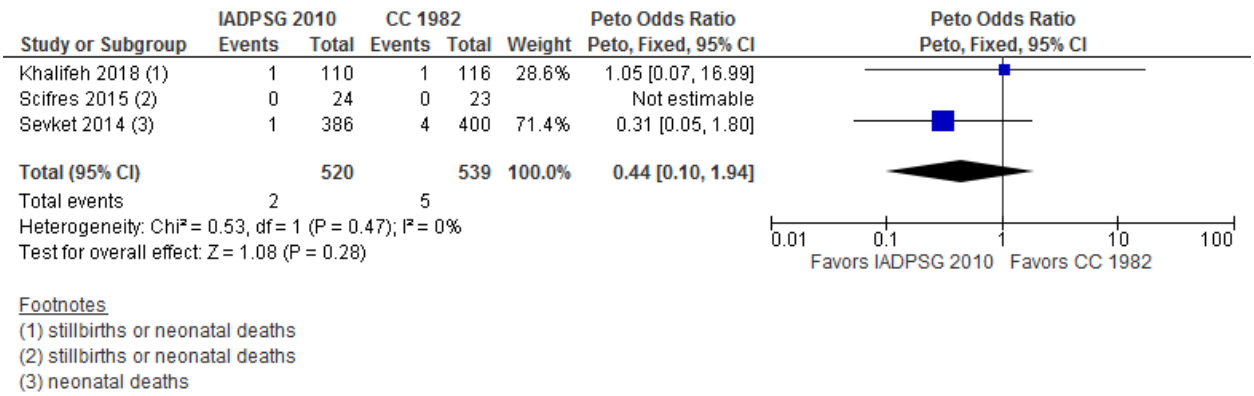
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 5. Meta-Analysis of Trials: Maternal Birth Trauma, IADPSG vs. CC Screening Strategies (KQ3)



Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

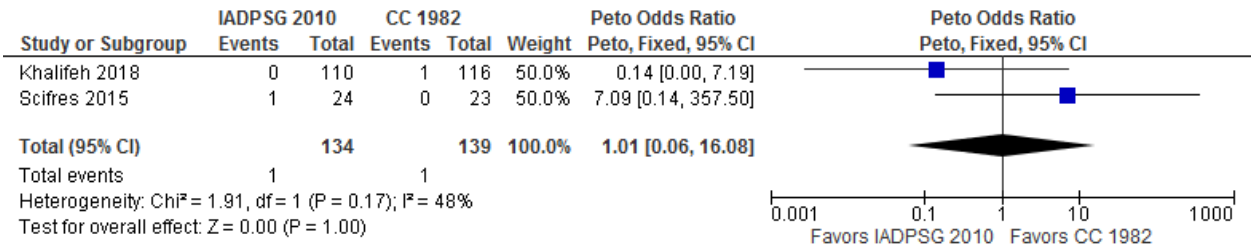
Appendix C Figure 6. Meta-Analysis of Trials: Mortality, IADPSG vs. CC Screening Strategies (KQ3)



Footnotes
(1) stillbirths or neonatal deaths
(2) stillbirths or neonatal deaths
(3) neonatal deaths

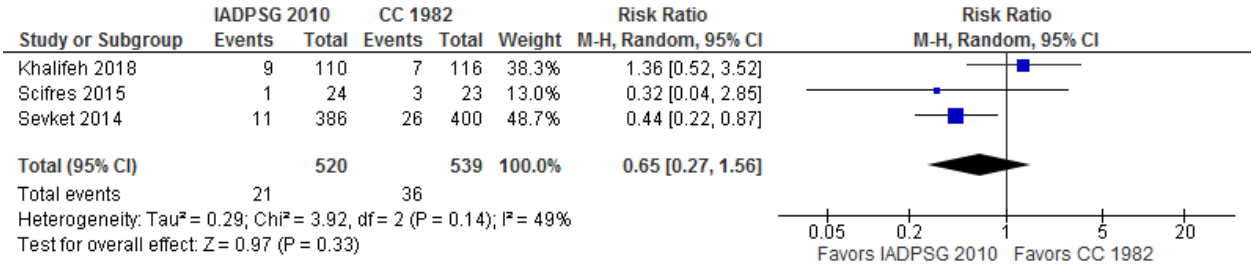
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question

Appendix C Figure 7. Meta-Analysis of Trials: Shoulder Dystocia, IADPSG vs. CC Screening Strategies (KQ3)



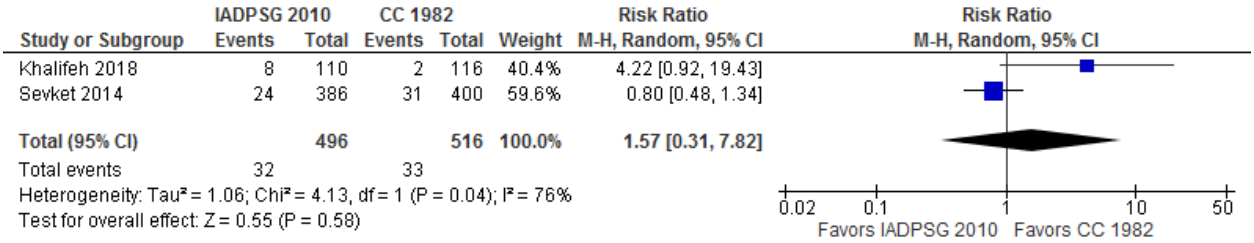
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question

Appendix C Figure 8. Meta-Analysis of Trials: Macrosomia >4,000 g, IADPSG vs. CC Screening Strategies (KQ3)



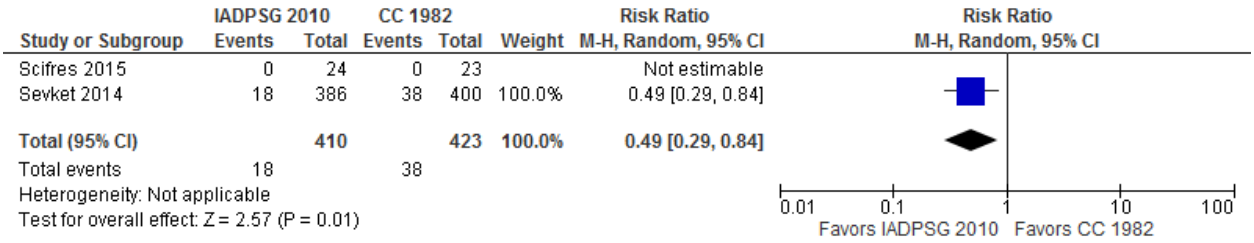
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 9. Meta-Analysis of Trials: Neonatal Hyperbilirubinemia, IADPSG vs. CC Screening Strategies (KQ3)



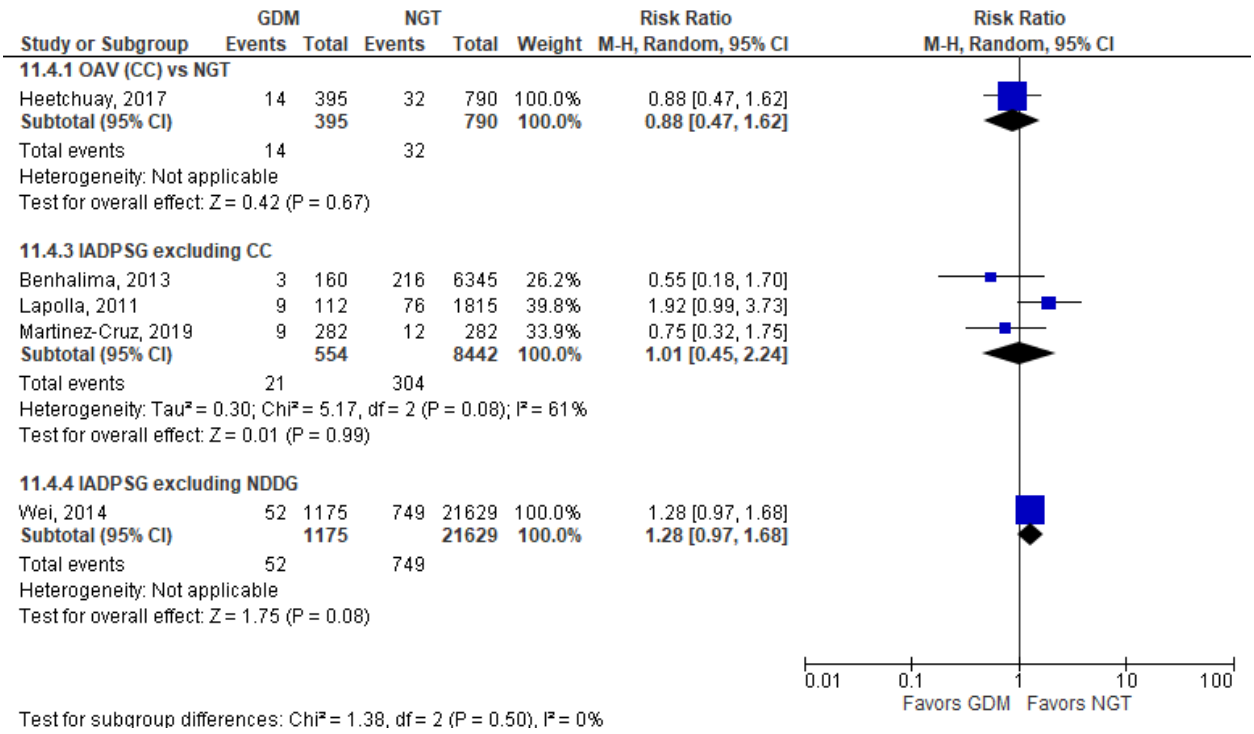
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 10. Meta-Analysis of Trials: NICU Admissions, IADPSG vs. CC Screening Strategies (KQ3)



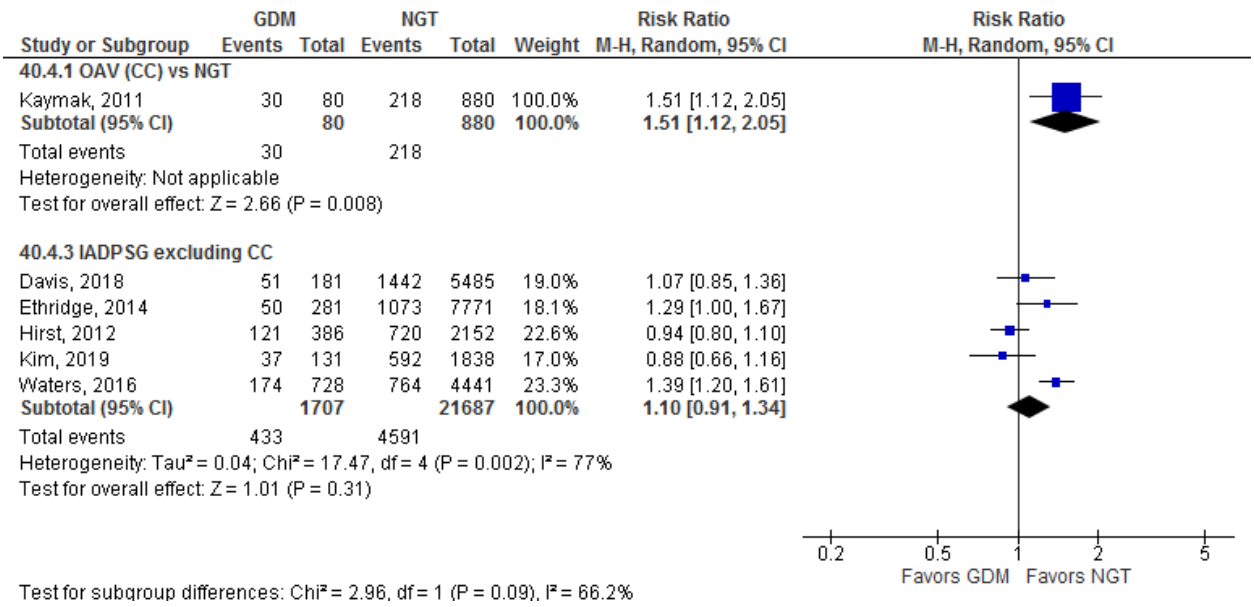
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NICU = neonatal intensive care unit

Appendix C Figure 11. Forest Plot for Association Between More Inclusive GDM and Gestational Hypertension (KQ5)



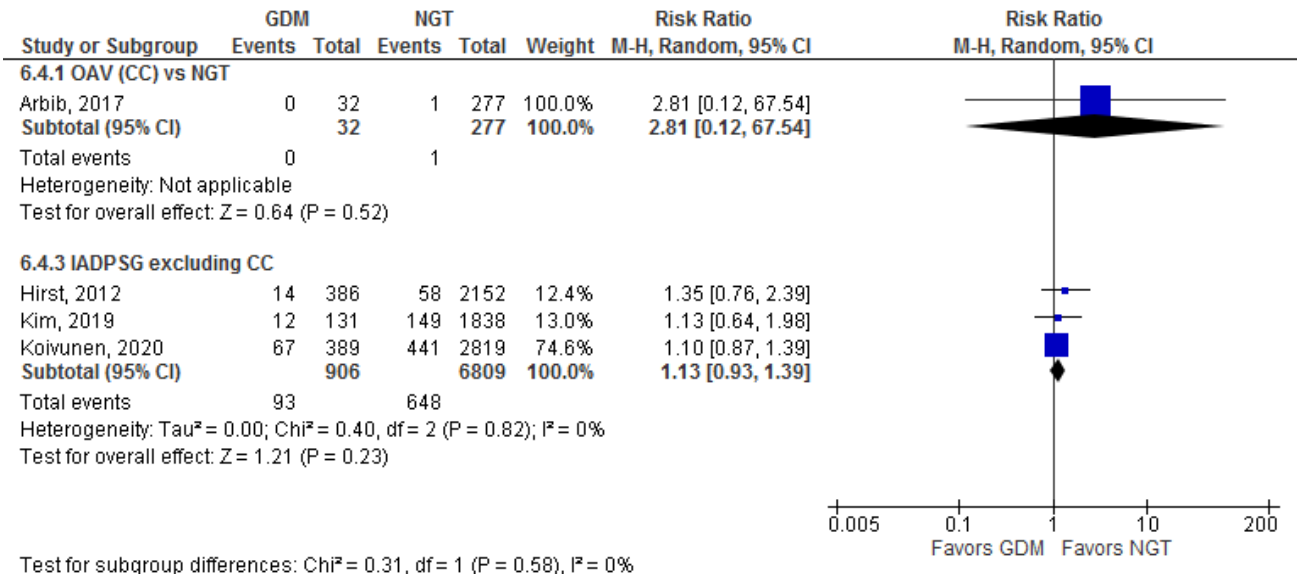
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Appendix C Figure 12. Forest Plot for Association Between More Inclusive GDM and Primary Cesarean Deliveries (KQ5)



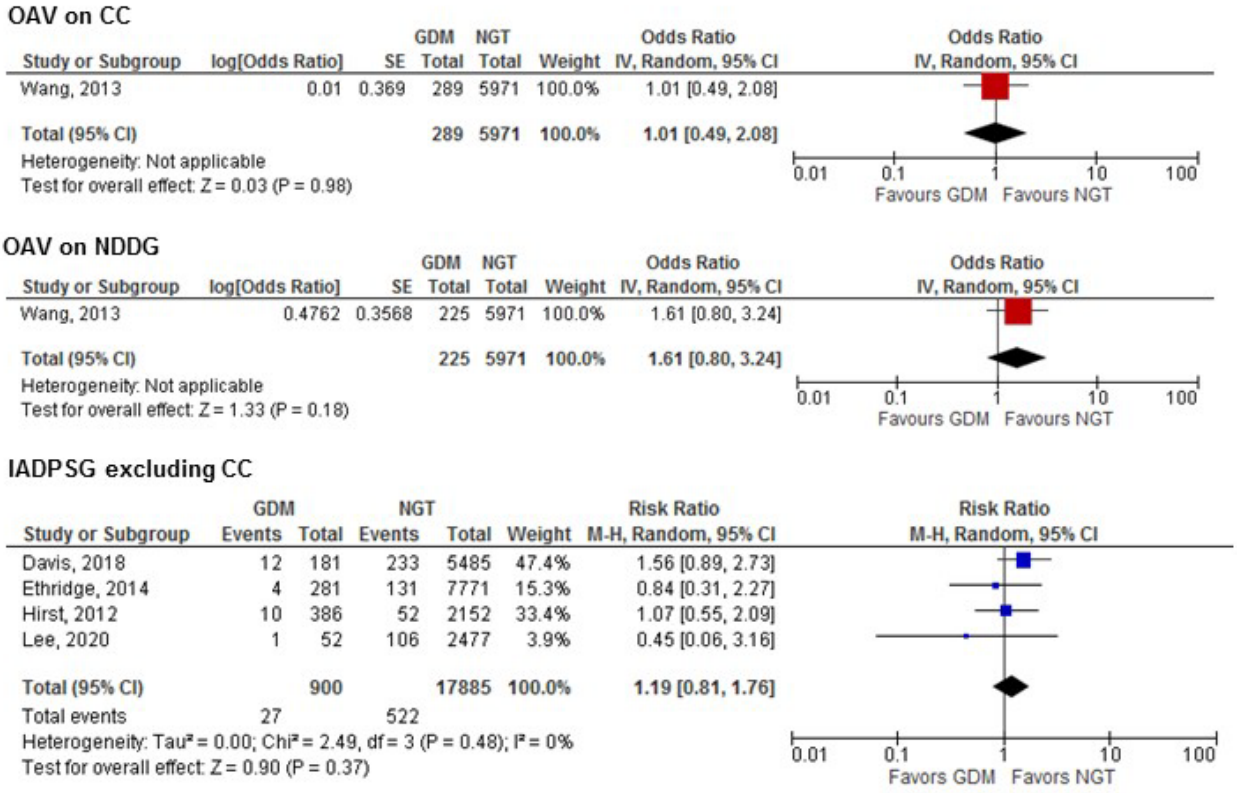
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Appendix C Figure 13. Forest Plot for Association Between More Inclusive GDM and Induction of Labor (KQ5)



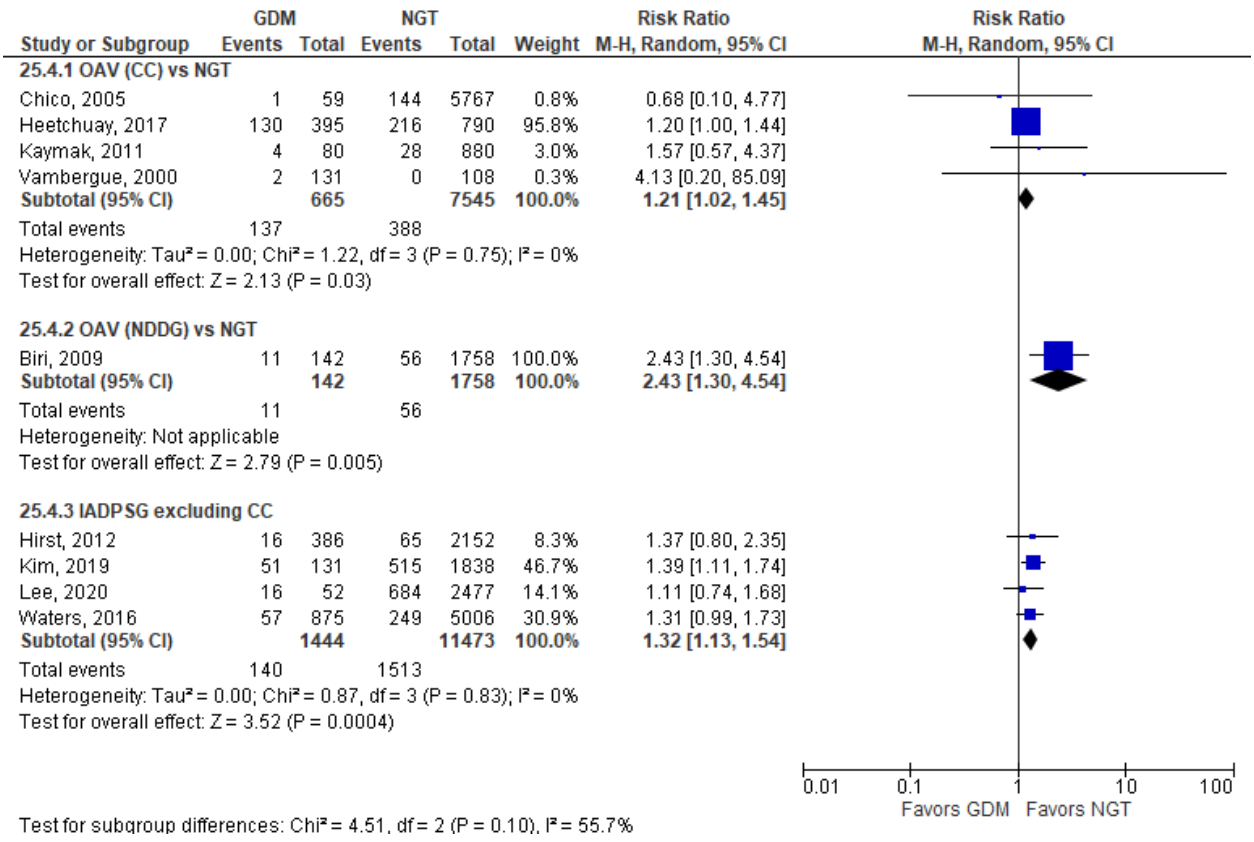
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Appendix C Figure 14. Forest Plots for Association Between More Inclusive GDM and Maternal Birth Trauma (KQ5)



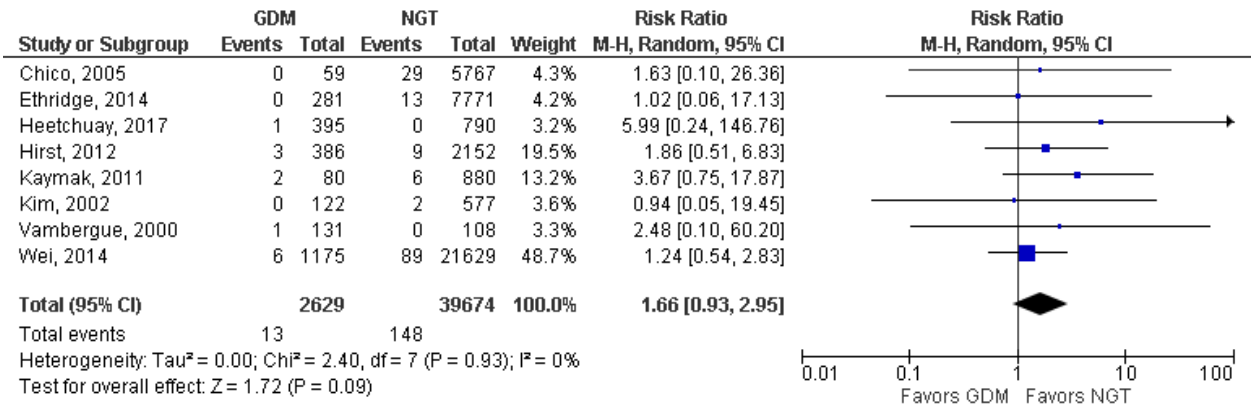
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; IV = inverse variance; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value; SE = standard error

Appendix C Figure 15. Forest Plots for Association Between More Inclusive GDM and Hyperbilirubinemia (KQ5)



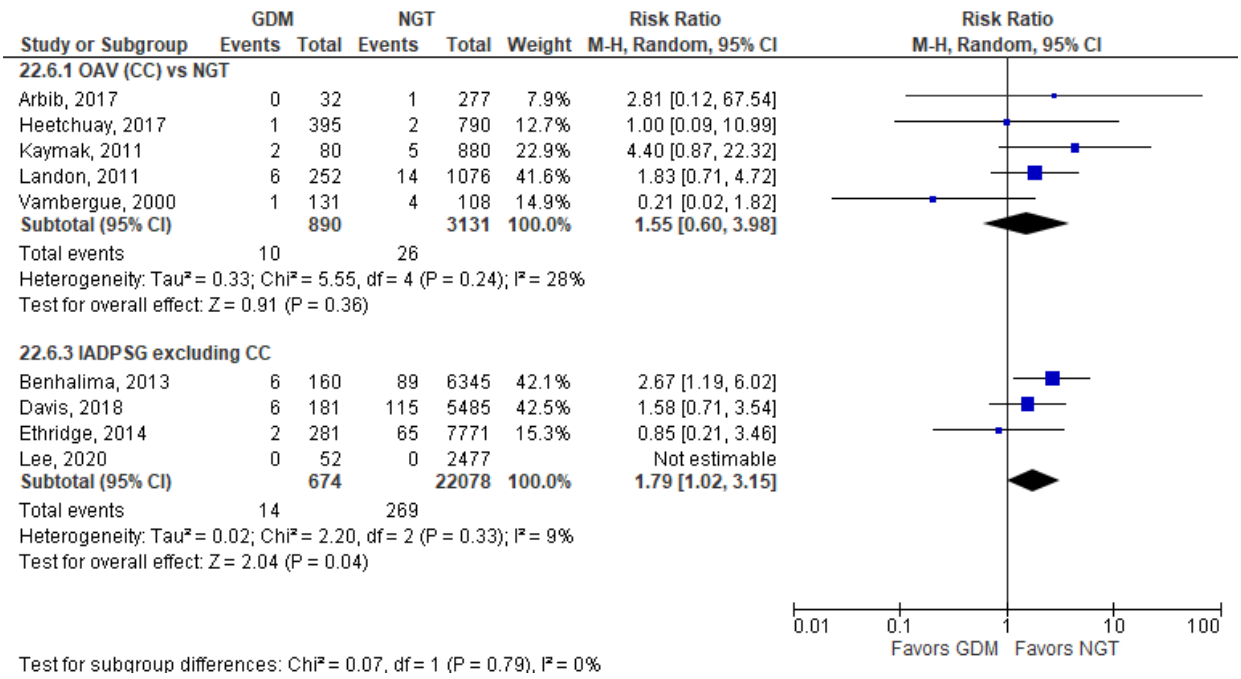
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Appendix C Figure 16. Meta-Analysis for Association Between More Inclusive GDM and Mortality, All Comparisons (KQ5)



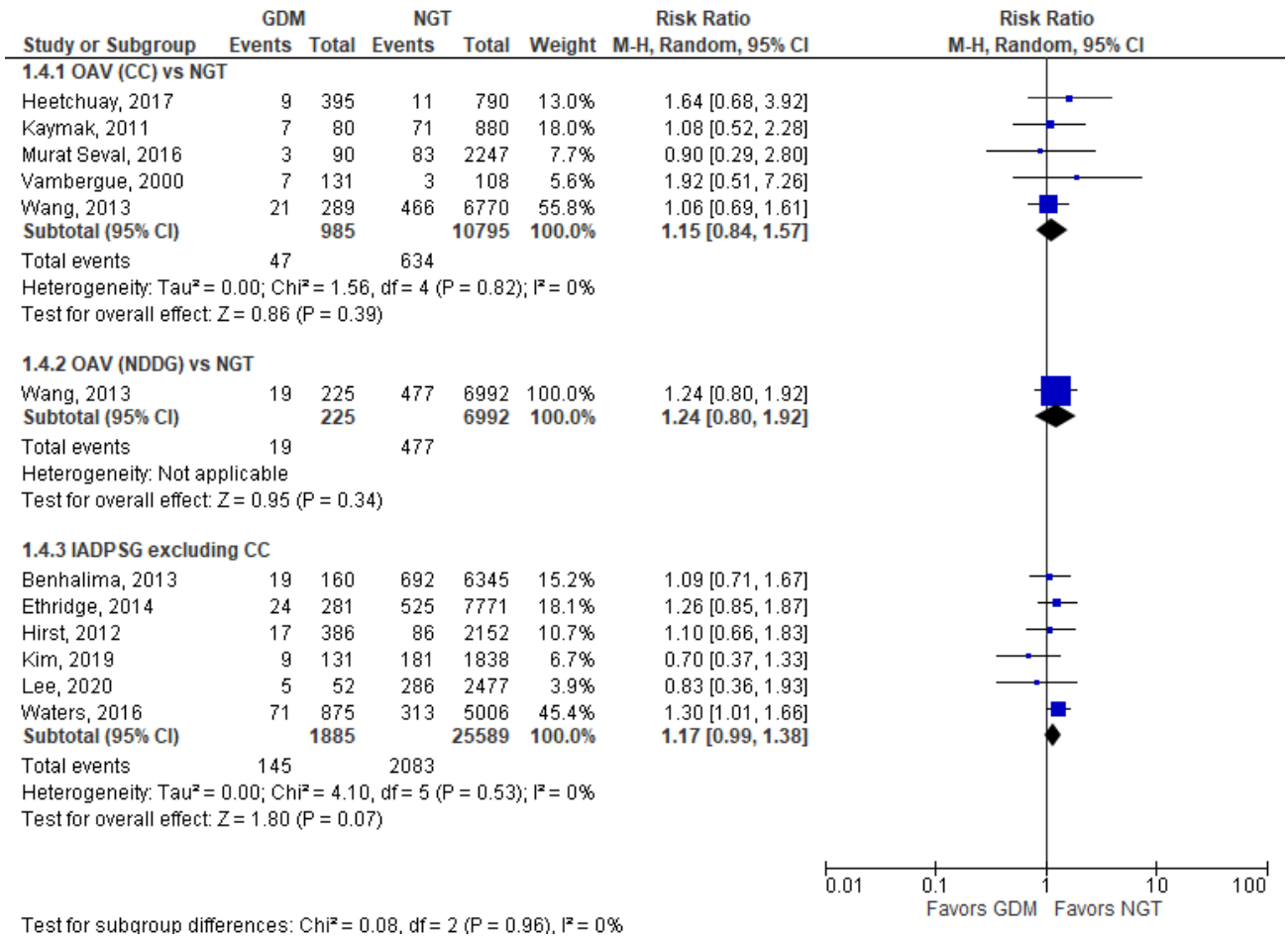
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel; NGT = normal glucose tolerance

Appendix C Figure 17. Forest Plots for Association Between More Inclusive GDM and Shoulder Dystocia (KQ5)



Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NGT = normal glucose tolerance; OAV = one abnormal value

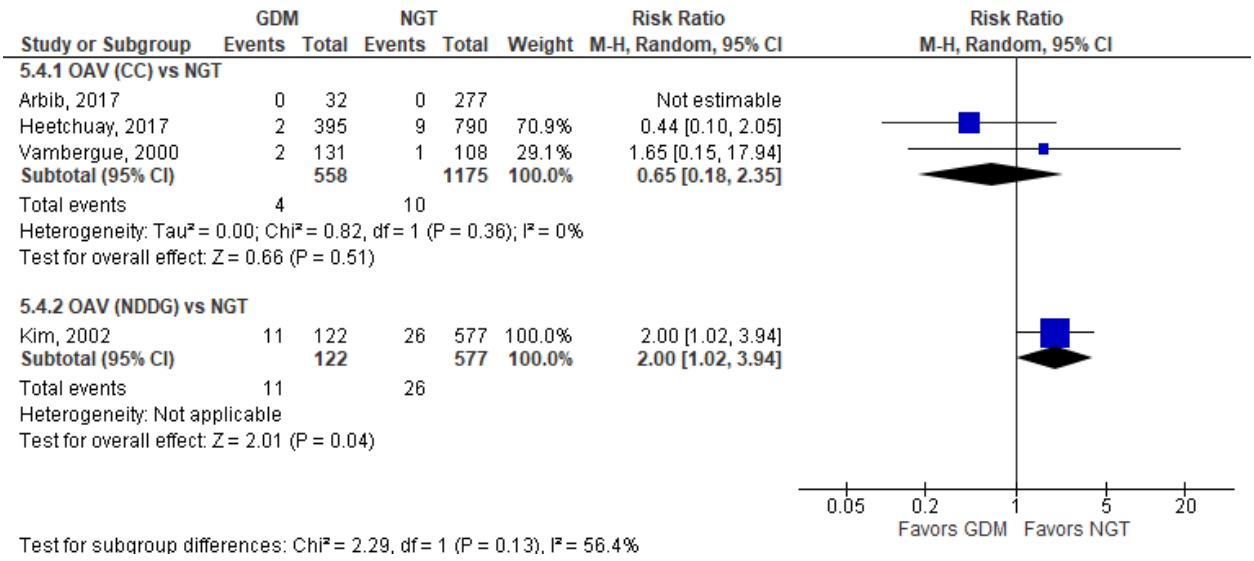
Appendix C Figure 18. Forest Plots for Association Between More Inclusive GDM and NICU Admissions (KQ5)*



Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

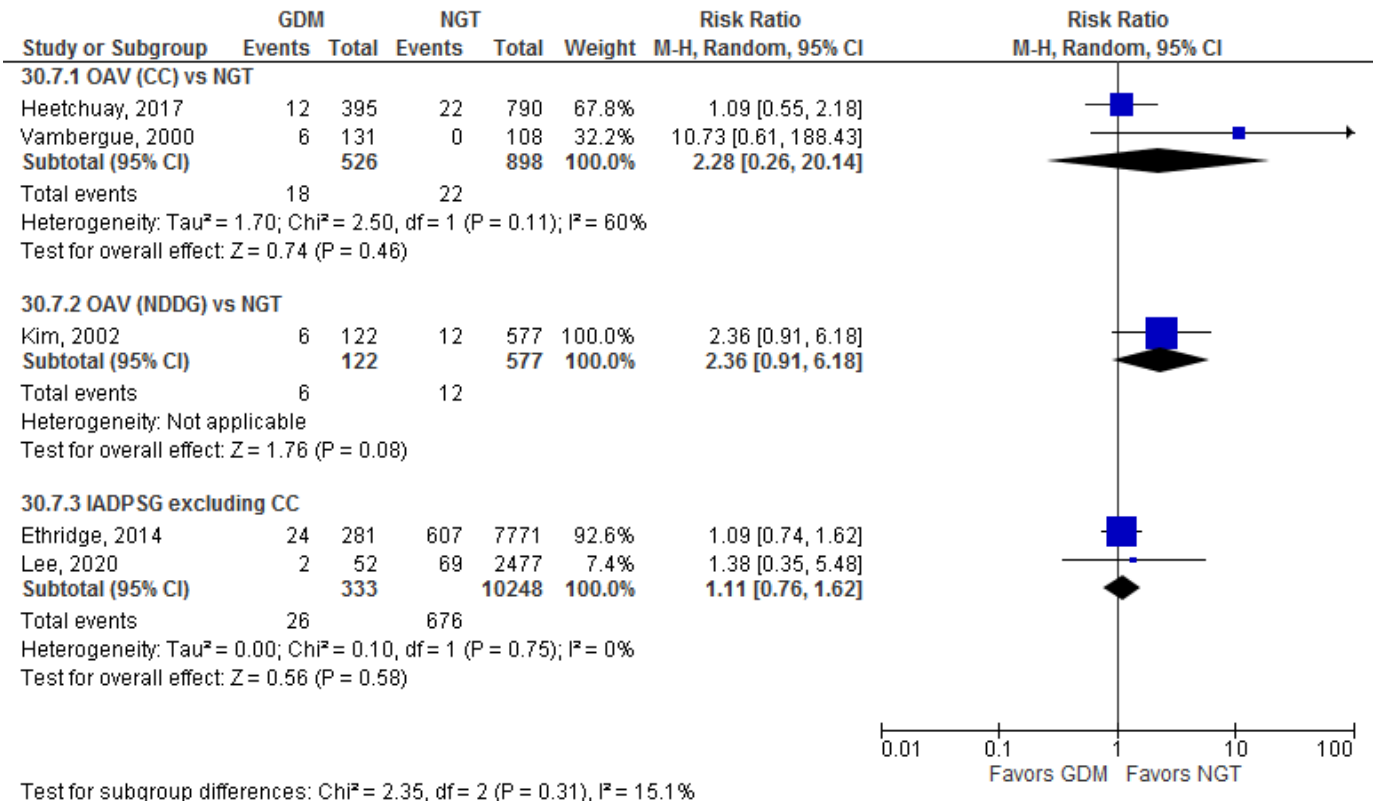
***Four studies[74,77,90,93] examining IADPSG excluding CC performed adjusted analyses (N=12,419; aOR 1.02 [95% CI, 0.81 to 1.28]; I^2=0%)

Appendix C Figure 19. Forest Plots for Association Between More Inclusive GDM and Respiratory Distress Syndrome (KQ5)



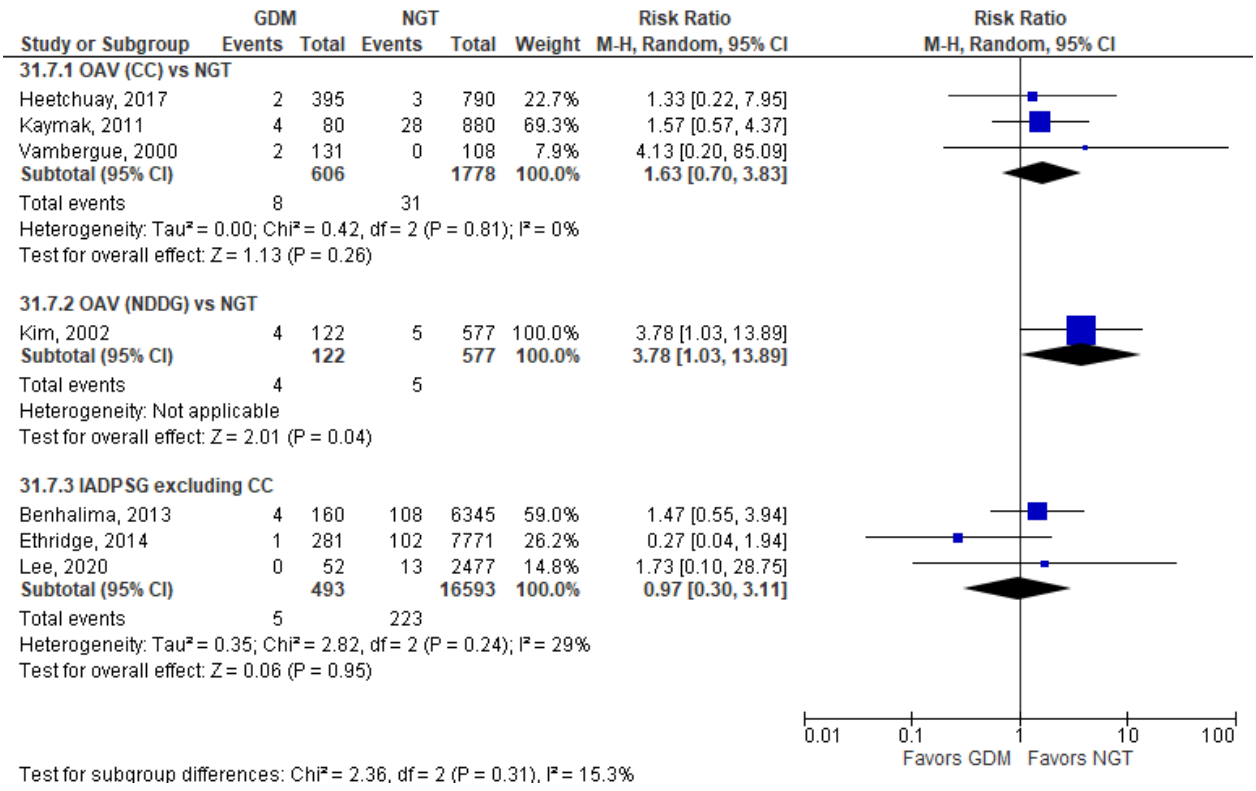
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Appendix C Figure 20. Forest Plots for Association Between More Inclusive GDM and APGAR Scores Below 7 at 1 Minute (KQ5)



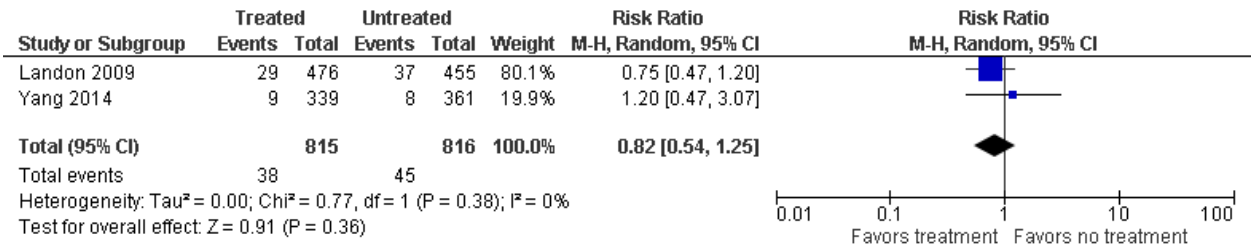
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Appendix C Figure 21. Forest Plots for Association Between More Inclusive GDM and APGAR Scores Below 7 at 5 Minutes (KQ5)



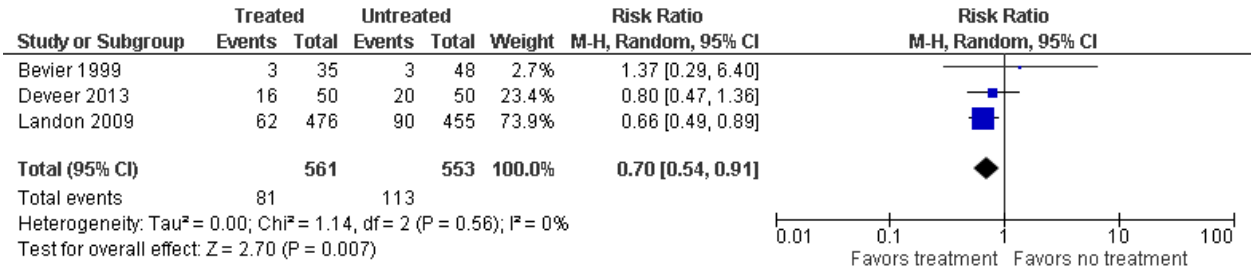
Abbreviations: CC = Carpenter Coustan; CI = confidence interval; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Groups; KQ = key question; M-H = Mantel-Haenszel; NDDG = National Diabetes Data Group; NGT = normal glucose tolerance; OAV = one abnormal value

Appendix C Figure 22. Meta-Analysis of Trials: Gestational Hypertension, Treated vs. Untreated GDM (KQ6)



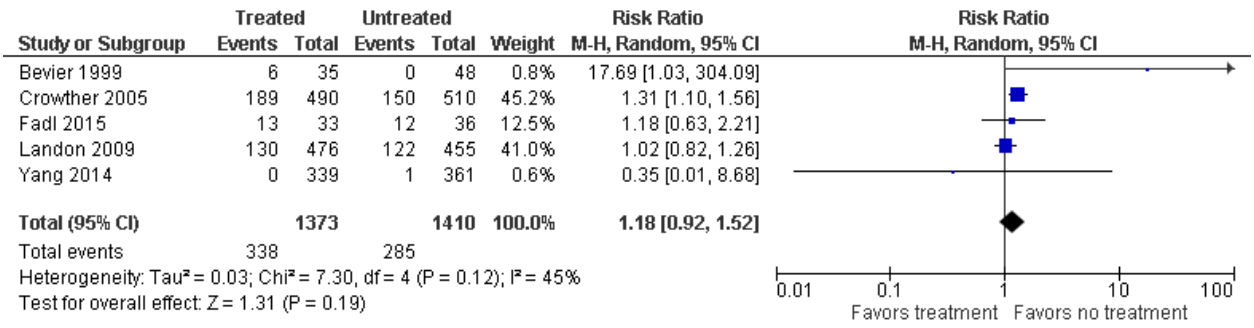
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 23. Meta-Analysis of Trials: Primary Cesarean Delivery, Treated vs. Untreated GDM (KQ6)



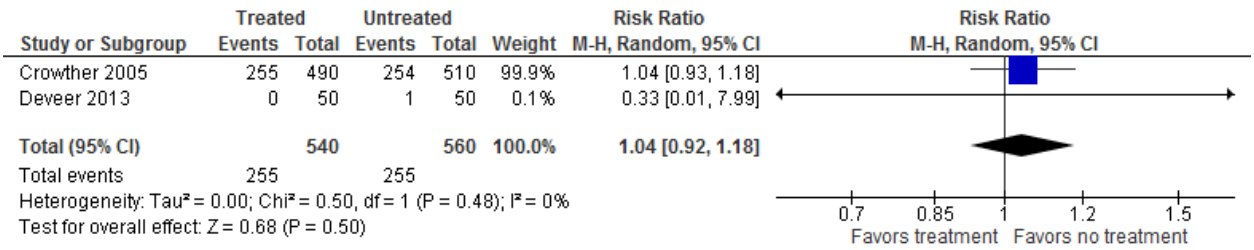
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 24. Meta-Analysis of Trials: Induction of Labor, Treated vs. Untreated GDM (KQ6)



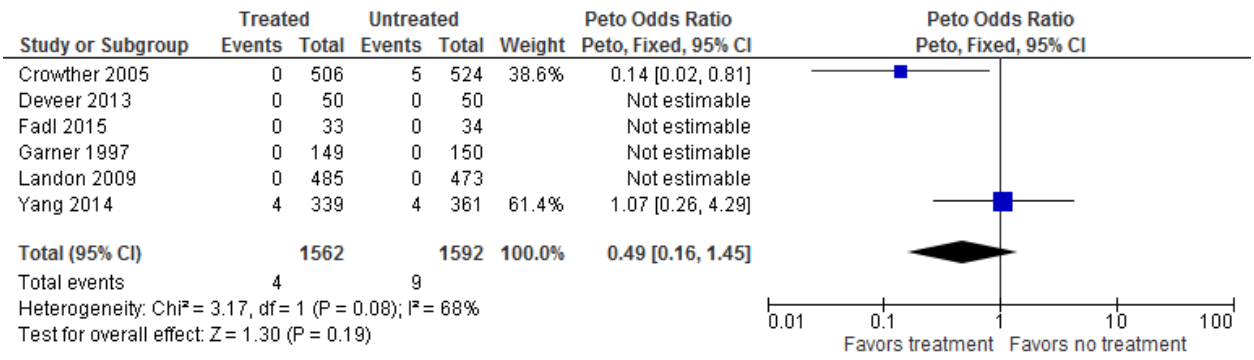
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 25. Meta-Analysis of Trials: Maternal Birth Trauma, Treated vs. Untreated GDM (KQ6)



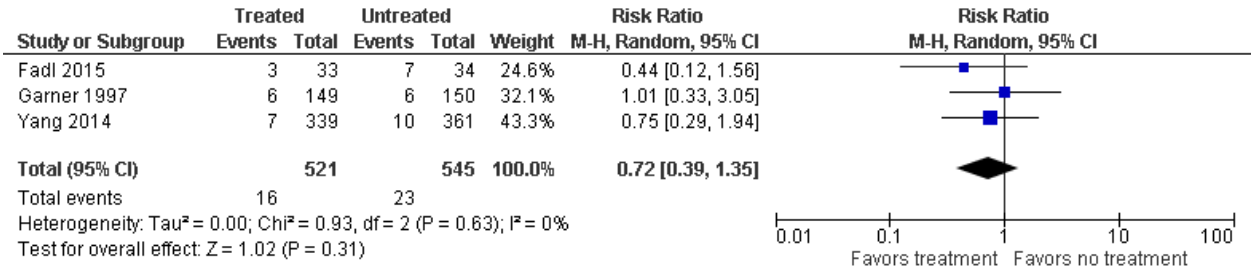
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 26. Meta-Analysis of Trials: Mortality, Treated vs. Untreated GDM (KQ6)



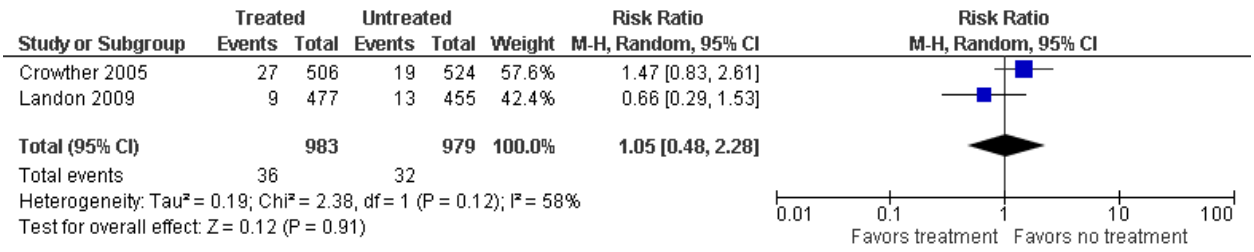
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 27. Meta-Analysis of Trials: Macrosomia (>4,500 g), Treated vs. Untreated GDM (KQ6)



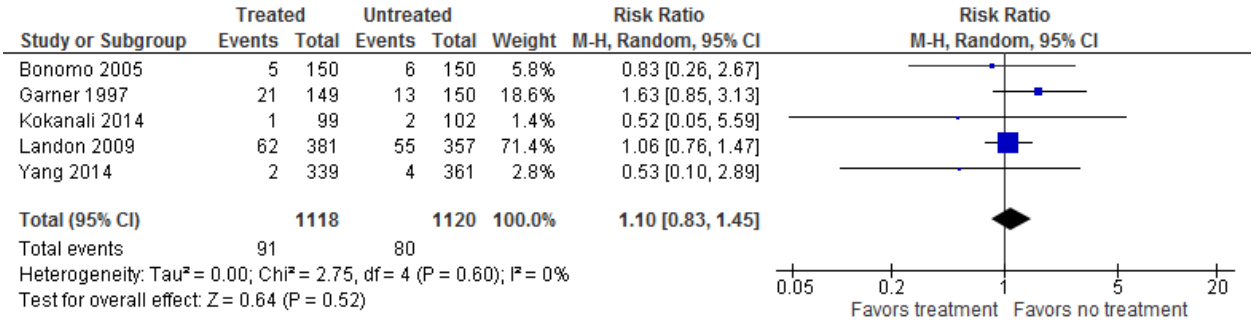
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 28. Meta-Analysis of Trials: Respiratory Distress Syndrome, Treated vs. Untreated GDM (KQ6)



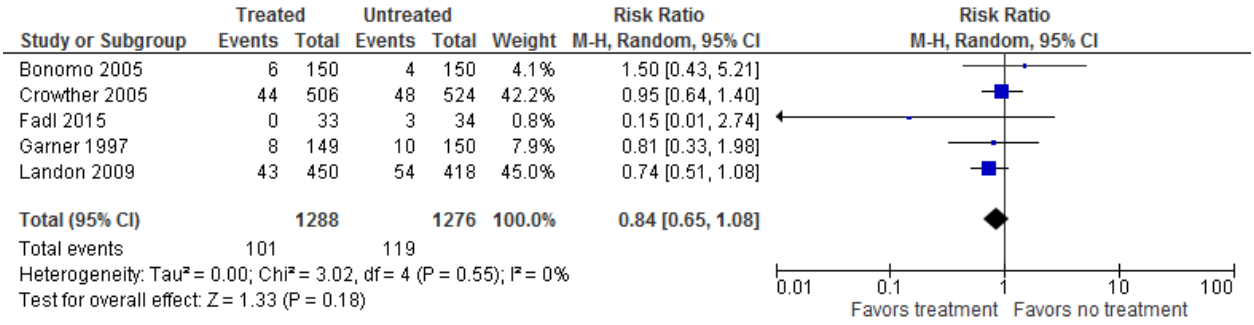
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 29. Meta-Analysis of Trials: Any Hypoglycemia, Treated vs. Untreated GDM (KQ6)



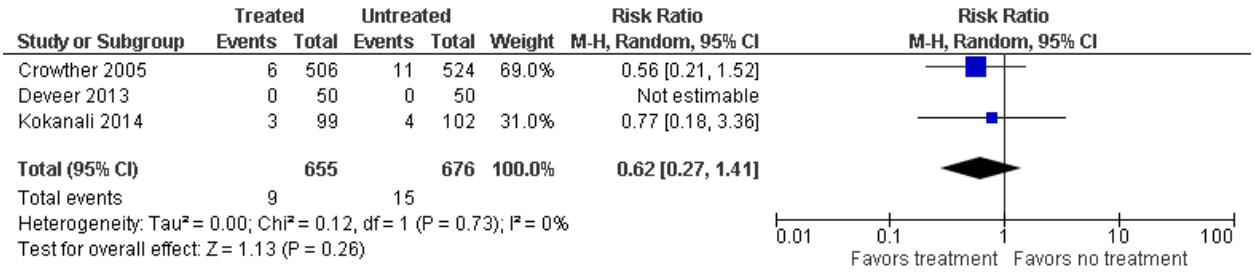
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 30. Meta-Analysis of Trials: Hyperbilirubinemia, Treated vs. Untreated GDM (KQ6)



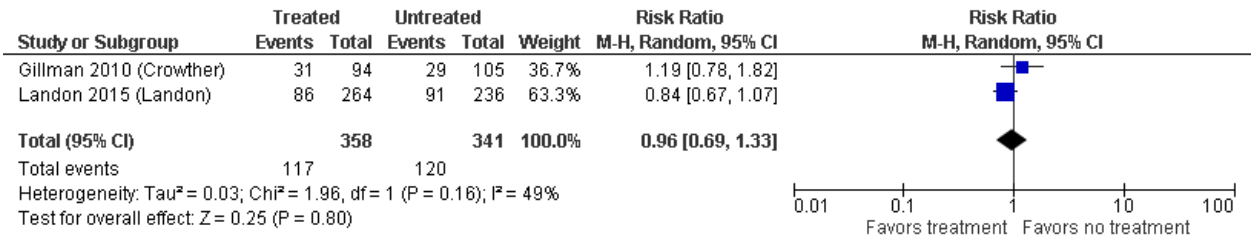
Abbreviations: CI = confidence interval; GDM = gestational diabetes mellitus; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 31. Meta-Analysis of Trials: 5 Minute Apgar Score Less Than 7, Treated vs. Untreated (KQ6)



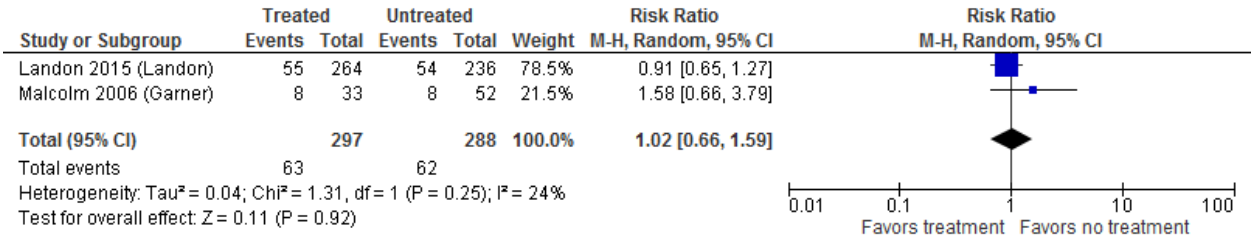
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 32. Meta-Analysis of Trials: Childhood Overweight or Obesity (BMI ≥85th Percentile), Treated vs. Untreated (KQ6)



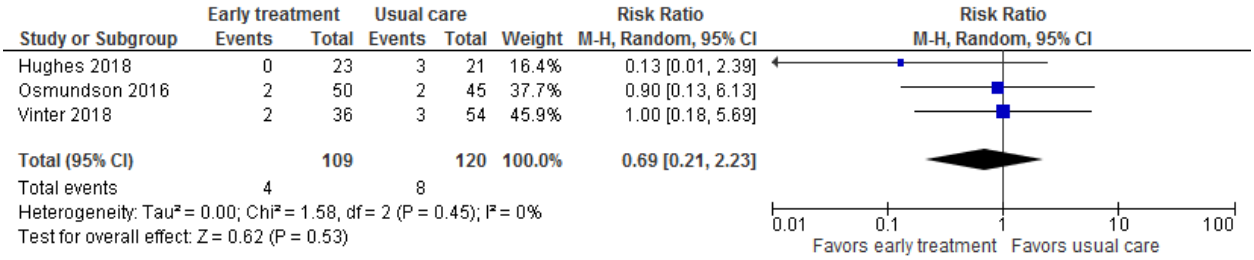
Abbreviations: BMI = body mass index; CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 33. Meta-Analysis of Trials: Childhood Obesity (BMI ≥95th Percentile), Treated vs. Untreated (KQ6)



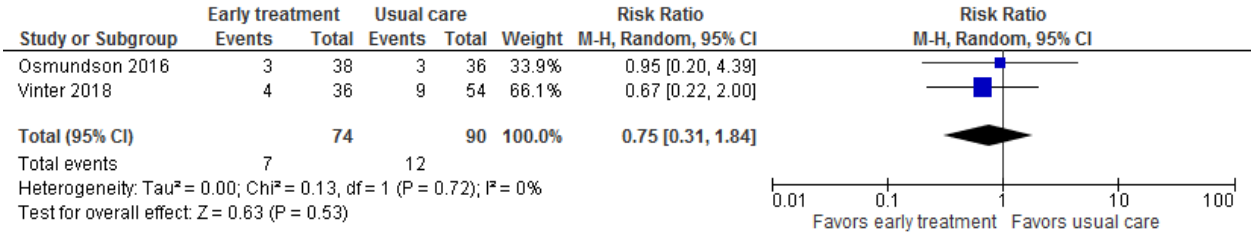
Abbreviations: BMI = body mass index; CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 34. Meta-Analysis of Trials: Preeclampsia, Early Treatment vs. Usual Care (KQ6)



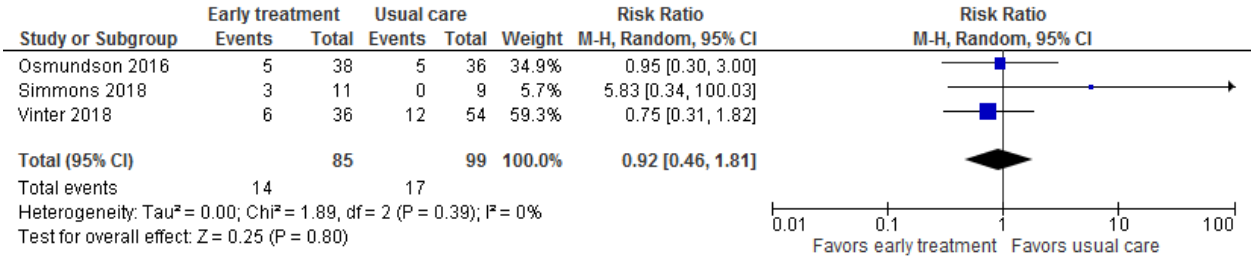
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel
Data for Osmundson were reported at ClincialTrials.gov

Appendix C Figure 35. Meta-Analysis of Trials: Gestational Hypertension, Early Treatment vs. Usual Care (KQ6)



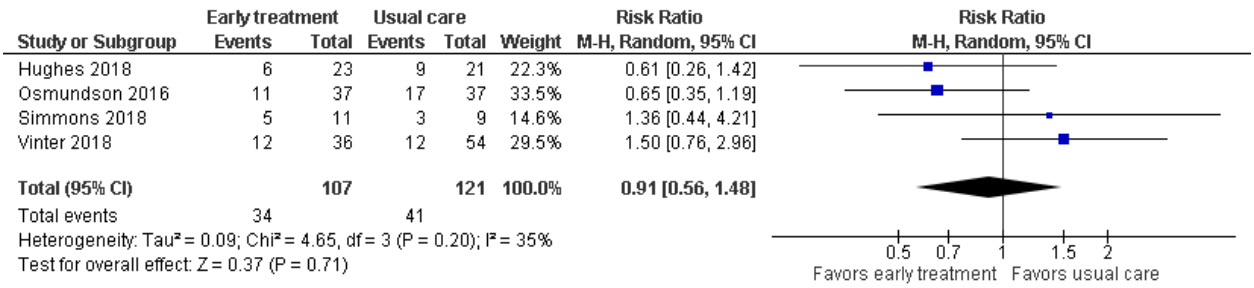
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 36. Meta-Analysis of Trials: Hypertensive Disorders of Pregnancy, Early Treatment vs. Usual Care (KQ6)



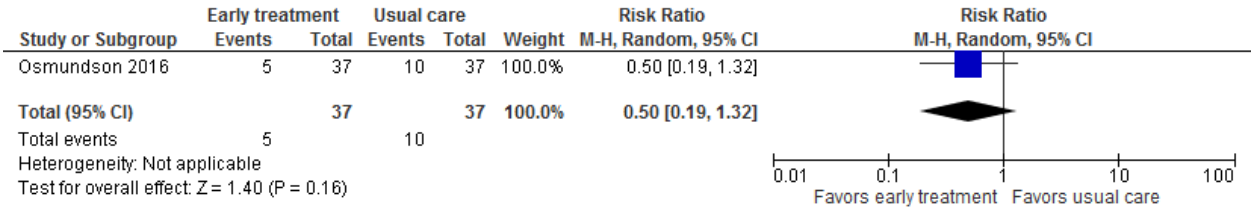
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel
Data for Osmundson are adding data for pre-eclampsia from ClincialTrials.gov with data in primary publication on Gestational hypertension.

Appendix C Figure 37. Meta-Analysis of Trials: Cesarean Delivery, Early Treatment vs. Usual Care (KQ6)



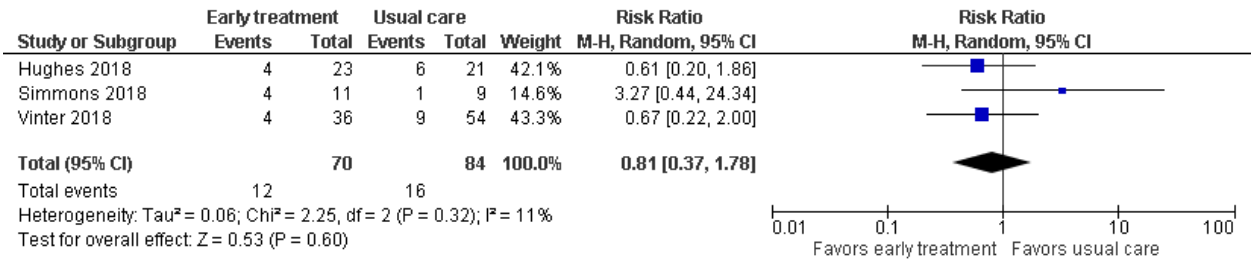
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 38. Forest Plot of Trial: Primary Cesarean Delivery, Early Treatment vs. Usual Care (KQ6)



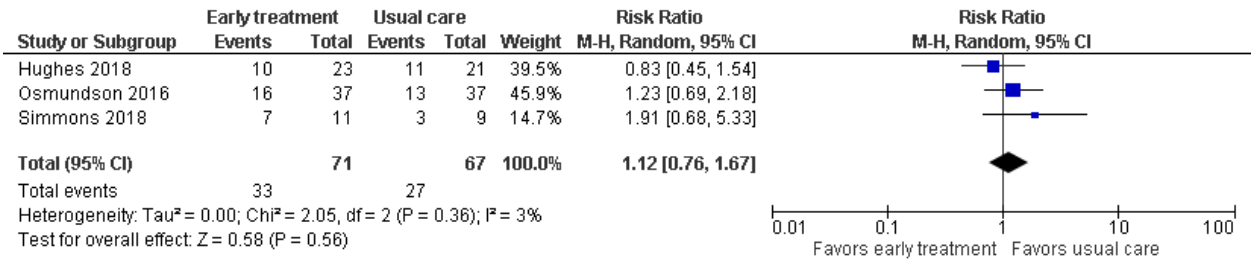
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 39. Meta-Analysis of Trials: Emergency Cesarean Delivery, Early Treatment vs. Usual Care (KQ6)



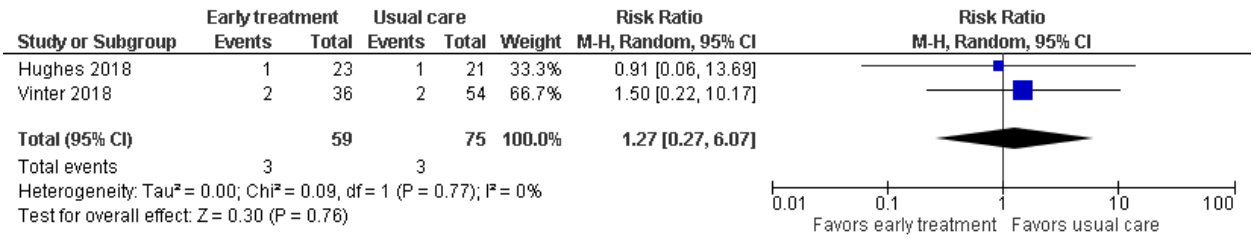
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 40. Meta-Analysis of Trials: Induction of Labor, Early Treatment vs. Usual Care (KQ6)



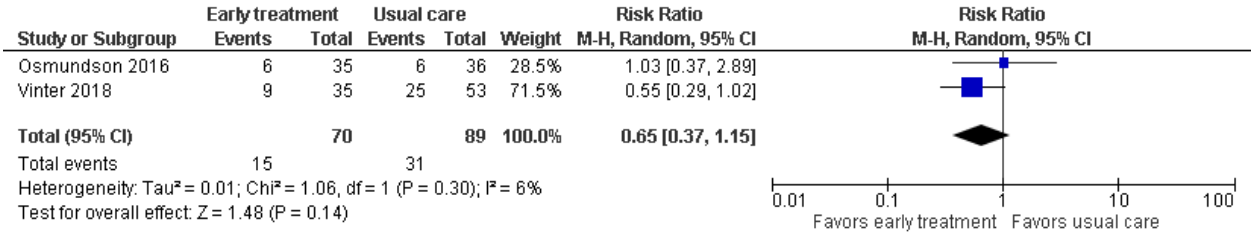
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 41. Meta-Analysis of Trials: Preterm Delivery, Early Treatment vs. Usual Care (KQ6)



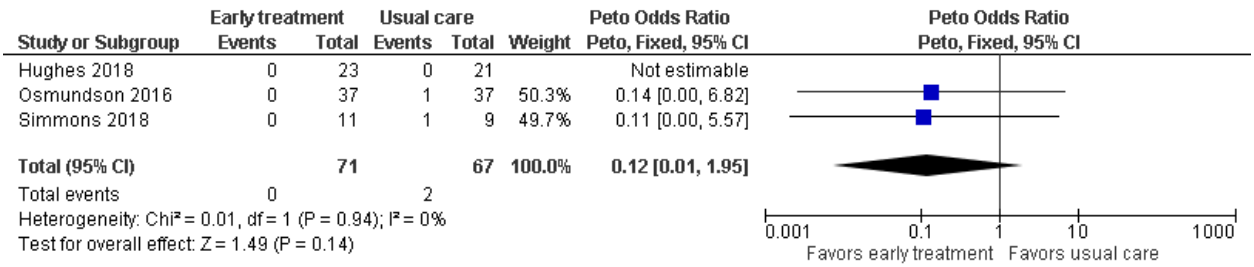
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 42. Meta-Analysis of Trials: Excessive Gestational Weight Gain, Early Treatment vs. Usual Care (KQ6)



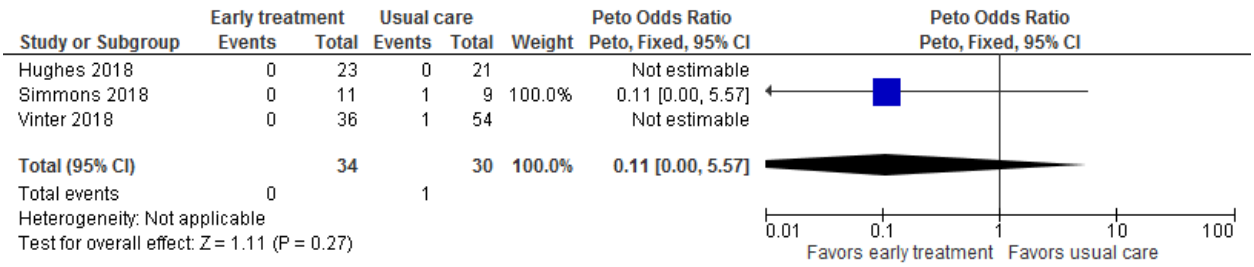
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 43. Meta-Analysis of Trials: Mortality, Early Treatment vs. Usual Care (KQ6)



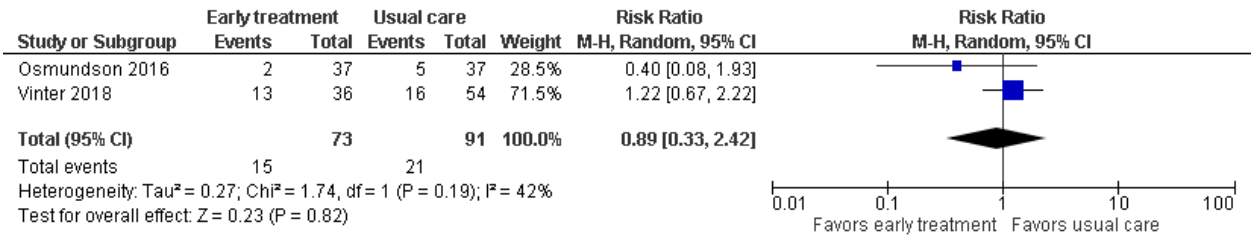
Abbreviations: CI = confidence interval; KQ = key question
Data for Osmundson were reported at ClincialTrials.gov

Appendix C Figure 44. Meta-Analysis of Trials: Shoulder Dystocia, Early Treatment vs. Usual Care (KQ6)



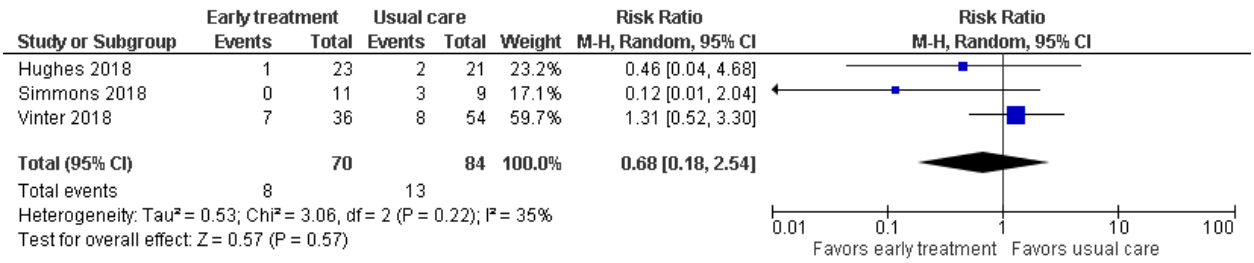
Abbreviations: CI = confidence interval; KQ = key question

Appendix C Figure 45. Meta-Analysis of Trials: Macrosomia (>4,000 g), Early Treatment vs. Usual Care (KQ6)



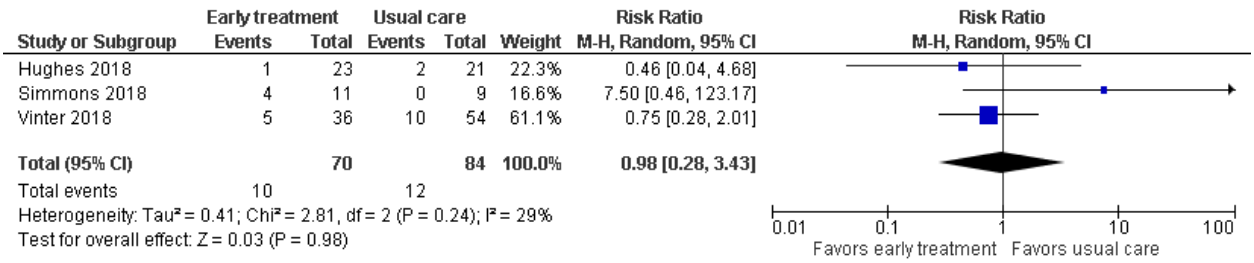
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 46. Meta-Analysis of Trials: Large for Gestational Age, Early Treatment vs. Usual Care (KQ6)



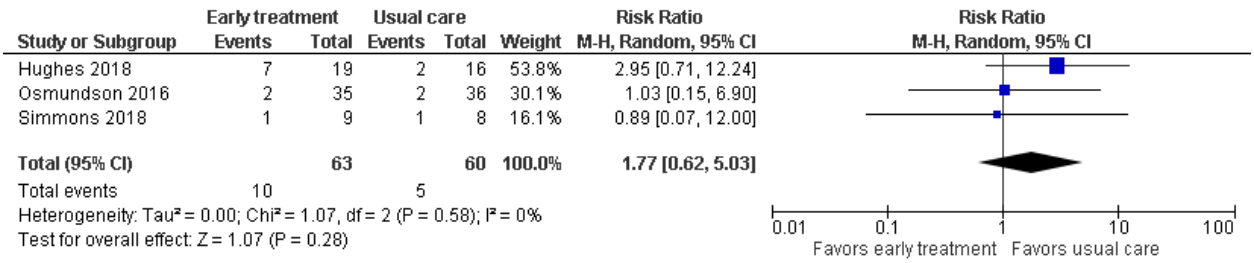
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 47. Meta-Analysis of Trials: NICU Admission, Early Treatment vs. Usual Care (KQ6)



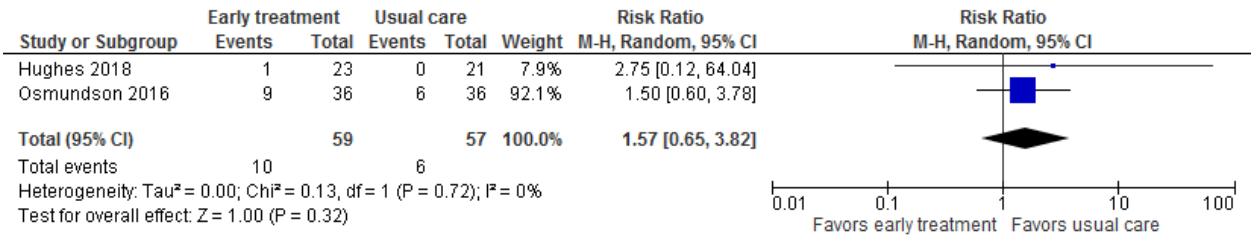
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel; NICU = neonatal intensive care unit

Appendix C Figure 48. Meta-Analysis of Trials: Any Hypoglycemia, Early Treatment vs. Usual Care (KQ6)



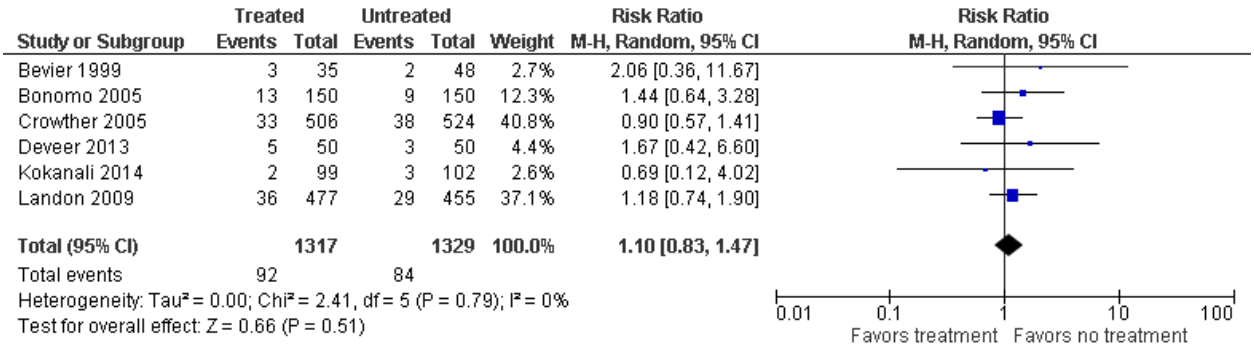
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel
Data for Osmundson are from ClincialTrials.gov.

Appendix C Figure 49. Meta-Analysis of Trials: Hyperbilirubinemia, Early Treatment vs. Usual Care (KQ6)



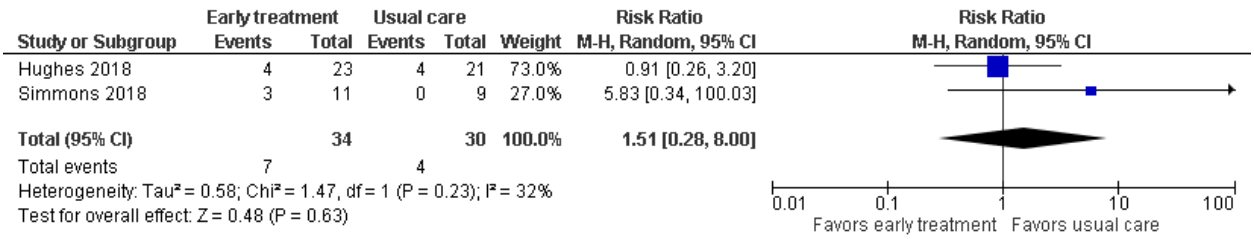
Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel
Data for Osmundson are from ClincialTrials.gov

Appendix C Figure 50. Meta-Analysis of Trials: Small for Gestational Age, Treated vs. Untreated (KQ7)



Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix C Figure 51. Meta-Analysis of Trials: Small for Gestational Age, Early Treatment vs. Usual Care (KQ7)



Abbreviations: CI = confidence interval; KQ = key question; M-H = Mantel-Haenszel

Appendix D Table 1. Evidence on Harms From Observational Studies on Screening vs. No Screening for GDM (KQ2)

Outcome Group	Author, Year, Country Sample Size Study Design Quality	Outcome	Results (GDM vs. no GDM Unless Stated Otherwise)	Study Analysis
Psychosocial Harms Associated with Screening	Rumbold, 2002,[77] Australia N=212 (21 with GDM) Prospective cohort Fair	Anxiety (Short-form STAI range 6-24) & Depressive symptoms (EPDS ≥12) A. Harms of screening in OGCT-ve: Before screening (mixed sample) vs after screening (before OGTT) vs. late in pregnancy B. Harms of False Positives (FP) & GDM Dx (OGCT-ve vs FPs vs GDM late in pregnancy)	A. Across time in OGCT-ve Anxiety: Before: 10 ± 3.0, n=158 After: 11 ± 3.0, n=124 Late pregnancy: 11 ±4.0, n=95 Depressive symptoms: Before: 33/158 (21%) After: 21/124 (17%) Late pregnancy: 17/95 (18%) B. Across time in OGCT –ve, OGCT +ve (FP) & GDM Dx Anxiety: Before: 10 ± 3.0, n=158 After: OGCT-ve 11 ± 3.0, n=124 OGCT+ve 11 ±4, n=62 Late in pregnancy: OGCT-ve 11 ± 4, n=95 OGCT+ 12 ±4, n=29 GDM 11± 4, n=21 Depressive symptoms: Before: 33/158 (21%) After: OGCT-ve 21/124 (17%) OGCT+ve 11/62 (18%) Late in pregnancy: OGCT-ve 17/95 (18%) OGCT+ 6/29 (21%) GDM 4/21 (19%) Nonsignificant differences across any comparisons over time	No adjustments
	Kerbel, 1997,[73] Canada N=813 (False positive 88 vs negative or	Harms of false positives (FP) State anxiety (STAI 20-80) (MID 5 points)	Change from baseline (12-24 wks) to 32 weeks (after OGTT) in False positive vs no GDM: State Anxiety: FP (n=88): 0.88 ± 9.7 vs. perceived test negative/not tested (n=725) 0.16 ±11.4 (p=0.57) (p=0.55 after adjusting for potentially confounding variables).	Multivariate linear regression model. Not adjusted for BMI. Powered for 5 point difference in state anxiety.

Appendix D Table 1. Evidence on Harms From Observational Studies on Screening vs. No Screening for GDM (KQ2)

Outcome Group	Author, Year, Country Sample Size Study Design Quality	Outcome	Results (GDM vs. no GDM Unless Stated Otherwise)	Study Analysis
Psychosocial Harms Associated with Screening, Continued.	perceived negative 725) Prospective cohort Fair	Depressive symptoms CES-D (0-60)	Depressive symptoms: FP: 0.95 ± 4.1 vs perceived -ve/not tested 0.13 ± 5.7 (p=0.093) Still nonsignificant after adjustment (p value NR)	
Psychosocial Harms Associated with Receiving a GDM Diagnosis	Daniells, 2003,[71] Australia N=100 (50 with GDM) Prospective double cohort (50 GDM vs 50 NGT) Fair	Mean STAI scores on State anxiety (range 20-80) ("reactive") Trait anxiety (range 20-80) ("intrinsic") Assessed in 3rd trimester (~30 wks; after screening/Dx), antepartum (~36 wks) and 6 wks postpartum	State Anxiety: Wk 30: GDM 40.6 ± 13.3 vs. NGT 34.2 ±9.9 (p= 0.007) Wk 36: GDM 33.7 ±10.9 vs NGT 35.3 ±9.1 (p 0.43) 6 wks Postpartum: GDM 31.7 ± 10.6 vs NGT 34.1 ±10.9 (p=0.28) Higher State anxiety right after diagnosis, but attenuated by delivery and remained into postpartum period Subgroups: At 36 wk no difference (p=0.87) in State anxiety between GDM treated vs not with insulin At 30 wk no difference (p=0.64) in State Anxiety between groups from Australia vs. not No difference when based on age (p value NR) or country of origin Trait Anxiety: Wk 30: GDM 39.5 ± 10.3 vs NGT 38.3 ± 10.2 (p=0.58) Wk 36: GDM 36.0 ±9.0 vs NGT 37.8 ±10.4 (p= 0.35) 6 wks postpartum: GDM 34.4± 10.5 vs NGT 36.7± 9.5 (p=0.24)	Scale 20-80 (higher more anxiety). Not adjusted for variables; age and BMI higher in GDM vs. no-GDM, p=0.02.
Cesarean Deliveries Associated with a GDM Diagnosis	Naylor, 1996,[75] Canada N=3,778 (143 with GDM) Prospective cohort	Risk for cesarean, accounting for macrosomia	Cesarean: GCT- 20.2% (585/2940) GCT+ 23.9% (136/580) Untreated borderline GDM 29.6% (34/115) GDM 33.6% (48/143) Macrosomia >4000g: GCT- 13.7% (395/2940)	A stratified analysis (2x3x4) was used to examine the effects of macrosomia (present/absent) on mode of delivery (cesarean, other interventions, spontaneous vaginal) after controlling for glucose tolerance (the four groups). This categorical bivariate analysis was followed by a multivariate logistic regression, including

Appendix D Table 1. Evidence on Harms From Observational Studies on Screening vs. No Screening for GDM (KQ2)

Outcome Group	Author, Year, Country Sample Size Study Design Quality	Outcome	Results (GDM vs. no GDM Unless Stated Otherwise)	Study Analysis
Cesarean Deliveries Associated with a GDM Diagnosis, Continued.	Good		GCT+ 14.0% (80/580) Untreated borderline GDM 28.7% (33/115) GDM 10.5% (15/143) Stratified analysis: Overall, macrosomia was associated with an increased rate of cesarean delivery after controlling for the level of glucose tolerance (P<.001 by stratified analysis) (Table 4). However, among women with treated GDM, cesarean delivery births were equally common whether the neonate was macrosomic (33% [5/15]) or not (33.6% [43/128]). (Macrosomia had no impact on patients with known treated GDM) Multivariable, vs negative screenees: GDM: aOR for cesarean 1.6 (95% CI 1.0-2.5) (same in models for 4000, 4500, birth weight) FPs: 1.2 (0.9-1.5), Borderline GDM 1.2 (0.7-2.0)	maternal characteristics associated with cesarean delivery (P<.05) on univariate comparisons (maternal age, race, parity, body mass index, history of preeclampsia, current preeclampsia, gestational age, and previous cesarean delivery, breech, dystocia, previous cesarean, fetal distress) to assess whether macrosomia was an independent risk factor for cesarean delivery. Sensitivity analysis using >4500 g and birth weight vs. >4000 g macrosomia. Indications for cesarean delivery assessed via hospital discharge data (92% complete) (previous cesarean, breech presentation, dystocia, fetal distress)
Hospital Experiences Potentially Impacting Breastfeeding Outcomes	Oza-Frank, 2017,[76] U.S. N=157,187 (14,409 with GDM) Cross-sectional Good	CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) survey based on Baby-Friendly Hospital Initiative Practices	Women with GDM were *less* likely to report: • Breastfeeding in the first hour (aOR, 0.83 [95% CI, 0.73 to 0.94]) • Feeding only breast milk in the hospital (aOR, 0.73 [95% CI, 0.65 to 0.82]) • Feeding on demand (aOR, 0.86 [95% CI, 0.74 to 0.99]) Women with GDM were significantly *more* likely to report: • Receiving a pump (aOR 1.28 [95% CI, 1.07 to 1.53]) • Receiving a formula gift pack (aOR, 1.17 [95% CI, 1.03 to 1.34]). (Receiving a pump was the only positive practice) No significant difference in aOR for: • Hospital staff gave me information about breastfeeding • My baby stayed in the same room with me at the hospital • I breastfed my baby in the hospital • Hospital staff helped me learn how to breastfeed • The hospital gave me a telephone number to call for help with breastfeeding	Weighted multivariable logistic regression. Adjusted models: maternal age, maternal race, maternal education, Medicaid status, prepregnancy BMI, parity, mode of delivery, gestational age, pregnancy intention, NICU admission, and proportion of women delivering multiples. Current U.S. maternity care practices do not universally include all 10 BFHI steps, and the level to which individual hospitals implement any, some, or all steps may vary widely, which may contribute to the observed disparities by GDM.

Appendix D Table 1. Evidence on Harms From Observational Studies on Screening vs. No Screening for GDM (KQ2)

Outcome Group	Author, Year, Country Sample Size Study Design Quality	Outcome	Results (GDM vs. no GDM Unless Stated Otherwise)	Study Analysis
Hospital Experiences Potentially Impacting Breastfeeding Outcomes, Continued.			• My baby used a pacifier in the hospital	
	Doughty, 2018,[72] U.S. N=1,733 (107 with GDM) Cross-sectional Good	U.S. Infant Feeding Practices Study II (consumer opinion panel; secondary analysis from prenatal and neonatal questionnaires) on Hospital experiences (neonatal factors and hospital experiences that could affect exclusive breastfeeding); Problems with breastfeeding in 1st 2 wks (17 questions regardless of breastfeeding); Delayed onset of lactation (>72 hrs)	GDM vs noGDM differences: • Newborn staying in the mother's hospital room (except for doctor visits, bathing, or other treatments; among infants with no NICU stay) (43.7% vs 58.7%; aOR 0.55, 95% CI [0.36, 0.85]) • Mother reporting that the newborn had trouble sucking (43.9% vs 32.1%; aOR 1.66, 95% CI [1.08, 2.54]) • Baby not interested in breastfeeding (13.1 vs. 7.3%; aOR 2.06, 95% CI [1.07, 3.98] (when using inverse probability-weighting, not interested in breastfeeding changed aOR 1.97, 0.97 to 4.01) • (Perceived delay in lactation): Took too long for milk to come in 20.5% vs 1.9% p=0.05 No differences in • Getting help with breastfeeding within 1 hr of delivery (15% vs. 23.4%; aOR 0.64 (0.36 to 1.15), • Delayed onset of lactation [>72hrs postpartum) (29.9% vs 23.7%; aOR 1.26, 0.79 to 2.01) or • Other breastfeeding problems (not specified; aOR 0.23 (0.05 to 0.99) • Baby fed sugar (8.8% vs 11.8%, p=0.35, not adjusted) • Baby given a pacifier (51% v 56.5%, p=0.28, not adjusted) • Tried to breastfeed within 1 hour (54.7% vs 59.8% p=0.3, not adjusted) Some other reasons from prenatal sample: Less likely to say only breastfeeding is the best way to feed a newborn (59% vs 71%) More likely to say that their doctors believed infants should be formula fed (aOR 2.82, 95% CI [1.17-6.79]).	Multivariable logistic regression models: maternal age, race/ethnicity, and BMI regardless of significance; other variables maternal age, race (White vs. non-White), education, income, parity, marital status, Supplemental Nutrition Program for Women, Infants and Children (WIC) participation, smoking status, and employment status, gestational weight gain, type of delivery, medication during labor, infant birth weight, gestational age, birth weight category, and sex.
	Loewenberg Weisband, 2017,[74] U.S.	Mediation analysis to assess whether hospital supplementation	Intending to exclusively BF: GDM 51.9% vs nonGDM 63.0%; aOR 0.71; 95% CI, 0.51–0.99 Supplementation (water, formula or sugar if breastfed): 63.5% vs 46.4% p<0.001; aOR 1.86 95% CI 1.27-2.72	Logistic regression for crude and adjusted associations between GDM history and exclusive breastfeeding intention. Multivariable logistic regression for .

Appendix D Table 1. Evidence on Harms From Observational Studies on Screening vs. No Screening for GDM (KQ2)

Outcome Group	Author, Year, Country Sample Size Study Design Quality	Outcome	Results (GDM vs. no GDM Unless Stated Otherwise)	Study Analysis
Hospital Experiences Potentially Impacting Breastfeeding Outcomes, Continued.	N=2,263 (160 with GDM) Prospective cohort Fair Moderate (some lack of representativeness in sample)	mediated the association between exclusive breastfeeding intention and (any) breastfeeding duration, by GDM.	Duration of any breastfeeding: 21.4 ± 21.2 wks vs 24.6 ± 20.8 wks (p=0.04) Not having exclusive breastfeeding intentions was associated with increased odds of hospital supplementation in both women with GDM and women with NDM (GDM: aOR 3.52; 95% CI [1.44–8.57], NDM: aOR 3.66; 95% CI [2.93–4.56]). Breastfeeding duration was similar by exclusive breastfeeding intentions (GDM aOR 22.3 95% CI 16.6 to 28.0 vs no GDM 20.7 95% CI 19.1-22.3) and by hospital supplementation (GDM 13.1 95% CI 5.8 to 20.4 vs no GDM 10.1 95% CI 8.3 to 11.8), regardless of GDM Hospital supplementation partially mediated the association between exclusive breastfeeding intentions and duration in NDM women (total effect: 14.54, indirect effect 2.03, p < 0.001), but it did not mediate the association in women with GDM (total effect: 14.76, indirect effect 1.31, p = 0.22). Differences in supplementation between these groups were primarily driven by differences in intentions to breastfeed exclusively	association between breastfeeding intention and hospital supplementation. Mediation analysis to assess whether hospital supplementation mediated the association between exclusive breastfeeding intention and breastfeeding duration, also by GDM. Potential confounders considered: maternal age (years), race/ethnicity (White, Black, Hispanic, or other), marital history (currently married versus not currently married), mother received WIC support while pregnant (yes versus no), household income as a percentage of federal poverty level (<185%, 185–349%, ‡350%), smoking during third trimester (yes versus no), planning to go back to work (yes versus no), first birth (yes versus no), and prepregnancy body mass index (BMI; kg/m2) by using self-reported height and weight (as a continuous variable or grouped as a three-level categorical variable— Normal weight: 18.5 kg/m^2 to <25 kg/m^2; Overweight 25 kg/m^2 to <30 kg/m2; Obese ‡30 kg/m^2) according to Institute of Medicine criteria. All analyses were adjusted for prepregnancy BMI; none for delivery/infant complications

Abbreviations: aOR = adjusted odds ratio; BMI = body mass index; CDC = Centers for Disease Control and Prevention; CESD = Center for Epidemiological Studies Depression; CG = control group; Dx = diagnosis; EPDS = Edinburgh Postnatal Depression Scale (EPDS); GDM = gestational diabetes mellitus; hr(s) = hour(s); IG = intervention group; IGT = impaired glucose tolerance; IQR = interquartile range; kg = kilogram; mo(s) = month(s); NGT = normal glucose intolerance; NICU = neonatal intensive care unit; NR = not reported; OGCT = oral glucose challenge test; OGTT = oral glucose tolerance test; PPD = postpartum depression; RCT = randomized controlled trial; RR = risk ratio; SD = standard deviation; STAI = State-Trait Anxiety Inventory; wk(s) = week(s); WIC = Women, Infants and Children Program.

Appendix D Table 2. Supplemental Analyses on Effects From Trials Comparing Different GDM Screening Strategies (KQ3)

Outcome	Comparison	Number of Studies	Proportion of Events in Group 1* (or incidence % [95% CI])	Proportion of Events in Group 2 (or incidence % [95% CI])	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Pre-eclampsia	IADPSG vs CC	3[80-82]	16/520	34/539	0.66 [0.15 to 2.98]; 76%	
	• IADPSG vs CC *(profile likelihood)*	3[80-82]	16/520	34/539	0.61 [0.13 to 4.13]; 59%	
	• IADPSG vs CC *(good quality studies and only one to define outcome)*	1[81]	1/24	0/23	2.88 [0.12 to 67.29]; NA	
	Early vs usual timing with CC	1[79]	62/459	44/463	1.42 [0.99 to 2.05]; NA	
Gestational hypertension	IADPSG vs CC	1[82]	57/386	60/400	0.98 [0.70 to 1.38]; NA	
	• IADPSG vs CC *(good quality studies and only one to define outcome)*	1[81]	0/24	0/23	Not estimable	
	Early vs usual timing with CC	1[79]	74/459	58/463	1.29 [0.94 to 1.77]; NA	
Hypertensive disorders of pregnancy	IADPSG vs WHO 1999	1[78]	14/249	15/253	0.95 [0.47 to 1.92]; NA	
	Early vs usual timing with CC	1[79]	136/459	151/463	0.91 [0.75 to 1.10]; NA	
Total cesarean deliveries	IADPSG vs CC	2[80,81]	37/134	38/139	1.02 [0.70 to 1.49]; 0%	
	• IADPSG vs CC *(good quality studies)*	1[81]	2/24	2/23	0.96 [0.15 to 6.25]; NA	
	IADPSG vs CC	2[81,82]	65/410	91/423	0.73 [0.55 to 0.97]; 0%	-0.063 [-0.115 to -0.112]

Appendix D Table 2. Supplemental Analyses on Effects From Trials Comparing Different GDM Screening Strategies (KQ3)

Outcome	Comparison	Number of Studies	Proportion of Events in Group 1* (or incidence % [95% CI])	Proportion of Events in Group 2 (or incidence % [95% CI])	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Primary cesarean deliveries	• IADPSG vs CC *(good quality studies)*	1[81]	0/24	2/23	0.19 [0.01 to 3.80]; NA	
	IADPSG vs. WHO 1999	1[78]	66/249	64/253	1.05 [0.78 to 1.41]; NA	
	Early vs usual timing with CC	1[79]	79/459	93/463	0.86 [0.65 to 1.12]; NA	
Induction of Labor	IADPSG vs CC	2[80,81]	55/134	58/139	1.00 [0.76 to 1.32]; 0%	
	• IADPSG vs CC *(good quality studies)*	1[81]	4/24	6/23	0.64 [0.21 to 1.97]; NA	
	Early vs usual timing with CC	1[79]	212/454	229/458	0.93 [0.82 to 1.07]	
Preterm delivery	IADPSG vs CC	2	27/496	42/516	0.75 [0.30 to 1.93]; 72%	
	IADPSG vs CC *(profile likelihood)*	2	27/4960	42/516	0.73 [0.25 to 2.44]; 42%	
	• IADPSG vs CC *(good quality studies)*	1[81]	0/24	0/23	Not estimable	
	IADPSG vs WHO 1999	1[78]	16/249	18/253	0.90 [0.47 to 1.73]; NA	
Maternal birth trauma	IADPSG vs CC	1	3/110	5/116	0.63 [0.15 to 2.58]; NA	
	• IADPSG vs CC *(good quality studies)*	1[81]	0/24	0/23	Not estimable	
Excessive gestational weight gain	IADPSG vs CC	1[81]	10/24	10/23	0.96 [0.49 to 1.86]; NA	

Appendix D Table 2. Supplemental Analyses on Effects From Trials Comparing Different GDM Screening Strategies (KQ3)

Outcome	Comparison	Number of Studies	Proportion of Events in Group 1* (or incidence % [95% CI])	Proportion of Events in Group 2 (or incidence % [95% CI])	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Perinatal mortality	IADPSG vs CC	2[80,82]	2/496	5/516	Peto odds ratio: 0.44 [0.10 to 1.94]; 0%	
	• IADPSG vs CC *(good quality studies)*	1[81]	0/24	0/23	Not estimable	
	IADPSG vs NDDG	1[54]	0.33 [0.22 to 0.51]	0.32 [0.20 to 0.52]	0.63 [0.21 to 1.91] (not adjusted due to few events)	
Birth injury	IADPSG vs NDDG	1[54]	3.5 [3.1 to 4.0]	3.2 [2.8 to 3.8]	1.09 [0.79 to 1.49]	
Shoulder dystocia	IADPSG vs CC	2[80,81]	1/134	1/139	Peto odds ratio: 1.01 [0.06 to 16.08]; 48%	
	• IADPSG vs CC *(good quality studies)*	1[81]	1/24	0/23	7.09 [0.14 to 357.50]; NA	
	IADPSG vs. WHO 1999 (includes birth injury)	1[78]	1/249	0/253	3.05 [0.12 to 74.46]; NA	
	Early vs usual timing with CC	1[79]	30/459	32/463	0.96 [0.49 to 1.86];]; NA	
Macrosomia >4000 grams	IADPSG vs CC	3[80-82]	21/520	36/539	0.65 [0.27 to 1.56]; 49%	
	• IADPSG vs CC *(profile likelihood)*	3[80-82]	21/520	36/539	0.64 [0.22 to 1.77]; 25%	
	• IADPSG vs CC *(good quality studies)*	1[81]	1/24	3/23	0.32 [0.04 to 2.85]; NA	
	Early vs usual timing with CC	1[79]	25/459	21/463	1.20 [0.68 to 2.11]	
Large for gestational age	IADPSG vs CC	3	15/520	34/539	0.46 [0.25 to 0.83]; 0%	-0.032 [-0.057 to -0.008]
	• IADPSG vs CC *(good*	1[81]	1/24	3/23	0.32 [0.04 to 2.85]	

Appendix D Table 2. Supplemental Analyses on Effects From Trials Comparing Different GDM Screening Strategies (KQ3)

Outcome	Comparison	Number of Studies	Proportion of Events in Group 1* (or incidence % [95% CI])	Proportion of Events in Group 2 (or incidence % [95% CI])	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Large for gestational age, Continued.	*quality studies)*					
	IADPSG vs. WHO 1999	1[78]	7/249	3/253	2.37 [0.62 to 9.06]; NA	
	Early vs usual timing with CC	1[79]	27/459	26/463	1.05 [0.62 to 1.77]; NA	
Neonatal hypoglycemia	IADPSG vs CC	2	15/496	31/516	0.52 [0.28 to 0.95]; 0%	-0.027 [-0.05 to -0.005]
	• IADPSG vs CC *(good quality studies)*	1[81]	0/24	0/23	Not estimable	
	IADPSG vs WHO 1999	1[78]	3/249	4/253	0.76 [0.17 to 3.37]; NA	
	Early vs usual timing with CC	1[79]	22/459	19/463	1.17 [0.64 to 2.13]; NA	
Neonatal hyperbilirubin-emia	IADPSG vs CC	2[80,82]	32/496	33/516	1.57 [0.31 to 7.82]; 76%	
	• IADPSG vs CC *(profile likelihood)*	2[80,82]	32/496	33/516	0.95 [0.29 to 10.53]; 0%	
	Early vs usual timing with CC	1[79]	90/459	72/463	1.26 [0.95 to 1.67]; NA	
Admission to NICU	IADPSG vs CC	1[81]	18/386	38/400	0.49 [0.29 to 0.84]; NA	-0.037 [-0.079 to -0.006]
	• IADPSG vs CC *(good quality studies)*	1[81]	0/24	0/23	Not estimable	
APGAR score <7 at 5 minutes	IADPSG vs CC	1[80]	1/110	2/116	0.53 [0.05 to 5.73]; NA	

Abbreviations: CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes in Pregnancy Study Groups; NA = not applicable; NDDG = National Diabetes Data Group; NICU = neonatal intensive care unit; vs = versus; WHO = World Health Organization

Appendix D Table 3. Evidence for Accuracy of Oral Glucose Challenge Test Screening (KQ4)

Diagnostic criteria	Criteria (OGCT)	Author, Year	Country	Timing (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
CC	130 mg/dL	De Los Monteros, 1999[97]	Mexico	24-28	445	11.7	90.4	80.9	82.0
		Poomalar 2013[112]	India	22-28[b]	500	7.2	75.0	86.4	85.6
		Sham, 2014[a 119]	India	24-28	89	13.5	100.0	24.7	34.8
	135 mg/dL	De Los Monteros, 1999[97]	Mexico	24-28	445	11.7	88.4	86.1	86.3
		Perucchini, 1999[109]	Switzerland	24-28	520	10.2	60.4	88.0	85.2
		Poomalar, 2013[112]	India	22-28[b]	500	7.2	75.0	90.1	89.0
		Sham, 2014[c 119]	India	24-28	89	13.5	100.0	31.2	40.4
	140 mg/dL	Ayach, 2006[90]	Brazil	24-28	341	3.8	76.9	86.6	86.2
		De Los Monteros, 1999[97]	Mexico	24-28	445	11.7	88.5	87.0	87.2
		Navid, 2014[105]	Pakistan	24-28	100	4.0	1.00	84.4	85.0
		Perucchini, 1999[109]	Switzerland	24-28	520	10.2	58.5	91.0	87.7
		Poomalar, 2013[112]	India	22-28[b]	500	7.2	75.0	92.0	90.8
		Sermer, 1998[117]	Canada	25-27	3836	6.9	67.4	83.5	82.4
		Sham, 2014[d 119]	India	24-28	89	13.5	100.0	44.2	51.7
		Weerakiet, 2006[126]	Thailand	21-27	359 (with risk factors	16.7	90.0	61.0	65.9
IADPSG	130 mg/dL	Benhalima, 2018[92]	Belgium	24-26	1811	12.6	72.4	70.2	70.5
		Olagbuji, 2017[107]	Nigeria	24-31	280	16.4	47.8	84.2	78.2
	135 mg/dL	Benhalima, 2018[92]	Belgium	24-26	1811	12.6	66.2	76.1	74.8
		Olagbuji, 2017[107]	Nigeria	24-31	280	16.4	39.1	88.0	80.0
	140 mg/dL	Benhalima, 2018[92]	Belgium	24-26	1811	12.6	59.7	81.0	78.3
		Olagbuji, 2017[107]	Nigeria	24-31	280	16.4	37.0	93.2	83.9
NDDG	130 mg/dL	De Los Monteros, 1999[97]	Mexico	24-28	445	9.7	90.7	79.4	80.4
	135 mg/dL	De Los Monteros, 1999[97]	Mexico	24-28	445	9.7	88.5	84.2	84.7
		Uncu, 1995[124]	Turkey	24-28	42	33.0	78.6	46.4	57.1
	140 mg/dL	Cetin, 1997[95]	Turkey	24-28	274	6.2	64.7	87.5	86.1
		De Los Monteros, 1999[97]	Mexico	24-28	445	9.7	88.4	85.3	85.6
		Lamar, 1999[103]	United States	24-28	136	3.7	80.0	82.4	82.4
		Perea-Carrasco, 2002[108]	Spain	24-28	642	16.4	98.1	75.0	76.9
		Sermer, 1998[117]	Canada	25-27	3836	3.8	76.6	82.2	82.0
		Uncu, 1995[124]	Turkey	24-28	42	33.0	78.6	53.6	61.9

Appendix D Table 3. Evidence for Accuracy of Oral Glucose Challenge Test Screening (KQ4)

Diagnostic criteria	Criteria (OGCT)	Author, Year	Country	Timing (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
Sacks	130 mg/dL	De Los Monteros, 1999[97]	Mexico	24-28	445	13.9	88.7	82.2	83.1
	135 mg/dL	De Los Monteros, 1999[97]	Mexico	24-28	445	13.9	83.9	87.2	86.7
	140 mg/dL	De Los Monteros, 1999[97]	Mexico	24-28	445	13.9	82.3	88.0	87.2

Abbreviations: CC = Carpenter Coustan; IADPSG = International Association of Diabetes and Pregnancy Study Groups; mg/dl = milligrams per deciliter; NDDG = National Diabetes Data Group; OGCT = oral glucose challenge test

[a]Used a 131 mg/dL cutoff.

[b]Some up to 37 weeks' GA.

[c]Used a 135.5 mg/dL cutoff.

[d]Used a 141 mg/dL cutoff.

Appendix D Table 4. Evidence for Accuracy of Fasting Plasma Glucose Screening (KQ4)

Diagnostic criteria	Criteria (FPG)	Author, Year	Country	Timing (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
CC	67 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	0.0	3.3
	69 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	1.3	3.5
	70 mg/dL	Agarwal, 2000[a87]	United Arab Emirates	24-28	1276 (+ hx)	31.0	99.2	7.0	35.7
					368 (+ OGCT)	31.8	99.1	4.4	34.5
	70.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	2.6	3.8
	71.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	3.9	4.1
	72.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	16.9	6.8
	73.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	19.5	7.3
	75 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	38.2	11.3
	76 mg/dL	Agarwal, 2006[b86]	United Arab Emirates	24-28	4528	14.7	99.2	10.8	22.5
		Agarwal, 2000[a87]	United Arab Emirates	24-28	1276 (+ hx)	31.0	73.2	17.0	42.2
					368 (+ OGCT)	31.8	98.3	12.4	39.7
	76.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	100.0	32.5	10.1
	77.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	91.7	37.7	10.9
	78.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	91.7	40.3	11.4
	79 mg/dL	Agarwal, 2000[a87]	United Arab Emirates	24-28	1276 (+ hx)	31.0	94.7	32.4	51.7
					368 (+ OGCT)	31.8	96.6	27.9	49.7
		Agarwal, 2006[b86]	United Arab Emirates	24-28	4528	14.7	97.0	29.4	38.4
		Perucchini, 1999[109]	Switzerland	24-28	520	10.2	100.0	39.0	45.2
	79.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	91.7	46.8	12.8
	80 mg/dL	Poomalar, 2013[112]	India	22-28	500	7.2	88.0	94.0	93.6
	80.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	91.7	50.6	56.1
	81.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	83.3	55.8	14.4
	82.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	75.0	62.3	15.5
	83.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	66.7	67.5	16.3
	85 mg/dL	Agarwal, 2006[b86]	United Arab Emirates	24-28	4528	14.7	89.7	53.0	57.9
		Agarwal, 2000[a87]	United Arab Emirates	24-28	1276 (+ hx)	31.0	88.1	52.6	63.6
					368 (+ OGCT)	31.8	91.5	51.4	64.1
		Poomalar, 2013[112]	India	22-28	500	7.2	88.0	95.0	94.5
		Sham, 2014[119]	India	24-28	89	13.5	66.7	71.4	17.1
	86 mg/dL	Poomalar, 2013[112]	India	22-28	500	7.2	80.0	96.0	94.8
	86.5 mg/dL	Perucchini, 1999[109]	Switzerland	24-28	520	10.2	81.1	76.0	76.5
		Sham, 2014[119]	India	24-28	89	13.5	66.7	72.7	17.4
	87.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	66.7	75.3	17.9

Appendix D Table 4. Evidence for Accuracy of Fasting Plasma Glucose Screening (KQ4)

Diagnostic criteria	Criteria (FPG)	Author, Year	Country	Timing (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
CC, Continued.	88 mg/dL	Agarwal, 2006[b86]	United Arab Emirates	24-28	4528	14.7	84.7	70.6	72.5
	88.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	66.7	81.8	19.3
	89.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	66.7	84.4	19.8
	90 mg/dL	Agarwal, 2006[b86]	United Arab Emirates	24-28	4528	14.7	82.6	76.1	76.9
		Agarwal, 2000[a87]	United Arab Emirates	24-28	1276 (+ve hx)	31.0	82.1	74.8	77.0
					368 (+ve OGCT)	31.8	84.6	72.1	76.1
		Poomalar, 2013[112]	India	22-28	500	7.2	72.0	97.0	95.2
		Sham, 2014[119]	India	24-28	89	13.5	66.7	66.7	66.7
	90.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	66.7	87.0	20.4
	91.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	66.7	89.6	20.9
	92 mg/dL	Kauffman, 2006[101]	Unites States	24-28	123	20.3	76.0	89.8	87.0
		Chevalier, 2011[a96]	France	24-28	1383	23.9	26.4	95.2	78.8
	92.5 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	50.0	96.1	21.7
	94 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	41.7	97.4	21.7
	95 mg/dL	Chevalier, 2011[a96]	France	24-28	1383	23.9	19.4	97.7	79.0
		Poomalar, 2013[112]	India	22-28	500	7.2	61.0	100.0	97.2
	95.5 mg/dL	Agarwal, 2006[b86]	United Arab Emirates	24-28	4528	14.7	69.0	89.8	87.1
		Agarwal, 2000[a87]	United Arab Emirates	24-28	1276 (+ hx)	31.0	73.5	94.0	87.6
					368 (+ OGCT)	31.8	79.5	90.8	87.2
	96 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	41.7	98.7	22.0
	98 mg/dL	Sham, 2014[119]	India	24-28	89	13.5	33.3	98.7	21.7
IADPSG	72 mg/dL	Zhu, 2013a[128]	China	24-28	24854	12.7	97.3	12.4	23.2
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	95.0	9.0	24.0
	74 mg/dL	Zhu, 2013a[128]	China	24-28	24854	12.7	95.8	18.3	28.1
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	93.0	14.0	27.8
	76 mg/dL	Agarwal, 2018[89]	India	80% 24-28	6520	18.3	97.8	28.6	41.3
	76 mg/dL	Zhu, 2013a[128]	China	24-28	24854	12.7	93.5	26.0	34.6
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	89.0	22.0	33.7
	77.5 mg/dL	Agarwal, 2018[89]	India	80% 24-28	6520	18.3	95.6	43.9	53.3
		Zhu, 2013a[128]	China	24-28	24854	12.7	91.1	35.5	42.5
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	84.0	29.0	38.6

Appendix D Table 4. Evidence for Accuracy of Fasting Plasma Glucose Screening (KQ4)

Diagnostic criteria	Criteria (FPG)	Author, Year	Country	Timing (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
IADPSG, Continued.	78.5 mg/dL	Pezeshki, 2019[110]	Iran	24-48	356	8.4	63.3	73.0	72.2
	79 mg/dL	Agarwal, 2018[89]	India	80% 24-28	6520	18.3	92.6	55.7	62.4
		Saeedi, 2018[c116]	Sweden	24-28	3616	11.7	96.0	57.0	61.6
		Zhu, 2013a[128]	China	24-28	24854	12.7	87.8	45.8	51.1
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	78.0	38.0	45.0
	79.5 mg/dL	Pezeshki, 2019[110]	Iran	20-24	356	8.4	76.7	76.1	76.1
	80 mg/dL	Trujillo, 2014[123]	Brazil	24-28	4926	18.0	96.9	55.0	62.5
	81 mg/dL	Dickson, 2019[38]	South Africa	24-28	589	7.0	98.0	80.0	81.0
		Zhu, 2013a[128]	China	24-28	24854	12.7	83.7	56.3	59.8
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	71.0	48.0	52.0
	82 mg/dL	Lekva, 2018[104]	Norway	14-16	985	24.5	44.1	97.9	91.5
	83 mg/dL	Saeedi, 2018[c116]	Sweden	24-28	3616	11.7	95.0	67.0	70.3
		Zhu, 2013a[128]	China	24-28	24854	12.7	78.9	67.0	68.5
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	63.0	58.0	58.9
	84.5 mg/dL	Sharma, 2018[120]	India	<20	246	6.5	93.8	74.3	75.6
	85 mg/dL	Agarwal, 2018[89]	India	80% 24-28	6520	18.3	82.1	81.6	81.7
		Trujillo, 2014[123]	Brazil	24-28	4926	18.0	92.5	78.4	80.9
		Zhu, 2013a[128]	China	24-28	24854	12.7	74.1	76.4	76.1
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	55.0	68.0	65.7
	86.5 mg/dL	Saeedi, 2018[c116]	Sweden	24-28	3616	11.7	91.0	85.0	85.7
		Zhu, 2013a[128]	China	24-28	24854	12.7	69.1	84.1	82.2
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	47.0	76.0	70.9
	88 mg/dL	Zhu, 2013a[128]	China	24-28	24854	12.7	64.7	90.8	87.5
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	39.0	83.0	75.3
	90 mg/dL	Agarwal, 2018[89]	India	80% 24-28	6520	18.3	70.1	97.9	92.8
		Saeedi, 2018[c116]	Sweden	24-28	3616	11.7	88.9	96.0	95.2
		Trujillo, 2014[123]	Brazil	24-28	4926	18.0	88.3	95.1	93.9
		Zhu, 2013a[128]	China	24-28	24854	12.7	59.8	96.0	91.4
		Zhu, 2013b[129]	China	Median (SD) 13.4 (3.5)	17186	17.5	31.0	89.0	78.9
HAPO 2.0	79 mg/dL	Saeedi, 2018[116]	Sweden	24-28	3616	7.2	96.0	54.0	58.1
	83 mg/dL	Saeedi, 2018[116]	Sweden	24-28	3616	7.2	96.0	64.0	67.1
	86.5 mg/dL	Saeedi, 2018[116]	Sweden	24-28	3616	7.2	93.0	81.0	82.2

Appendix D Table 4. Evidence for Accuracy of Fasting Plasma Glucose Screening (KQ4)

Diagnostic criteria	Criteria (FPG)	Author, Year	Country	Timing (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
HAPO 2.0 Continued.	90 mg/dL	Saeedi, 2018[116]	Sweden	24-28	3616	7.2	91.0	92.0	91.9
	94 mg/dL	Saeedi, 2018[116]	Sweden	24-28	3616	7.2	89.0	98.0	97.1
NDDG	93 mg/dL	Kauffman, 2006[101]	United States	24-28	123	13.0	81.3	87.9	87.0
Sacks	70 mg/dL	Sacks, 2003[115]	United States	Mean (SD) 10.7 (4.9)	4507	6.7	100.0	2.0	8.6
	75 mg/dL	Sacks, 2003[115]	United States	Mean (SD) 10.7 (4.9)	4507	6.7	97.0	9.0	14.9
	80 mg/dL	Sacks, 2003[115]	United States	Mean (SD) 10.7 (4.9)	4507	6.7	89.0	25.0	29.3
	85 mg/dL	Sacks, 2003[115]	United States	Mean (SD) 10.7 (4.9)	4507	6.7	74.0	52.0	53.5
	90 mg/dL	Sacks, 2003[115]	United States	Mean (SD) 10.7 (4.9)	4507	6.7	52.0	78.0	76.3
	95 mg/dL	Sacks, 2003[115]	United States	Mean (SD) 10.7 (4.9)	4507	6.7	34.0	92.0	88.1

Abbreviations: CC = Carpenter Coustan; FPG = fasting plasma glucose; Hx = history (clinical); HAPO = Hyperglycemia and Adverse Pregnancy Outcomes Study Group; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NDDG = National Diabetes Data Group; OGCT = oral glucose challenge test; SD = standard deviation.

[a]High-risk population (In Agarwal 2000, all referred for OGTT had either a positive OGCT (+OGCT) or were referred on clinical grounds (+hx); in Chevalier 2011, all had post-load glycaemia >130 mg/dL on 50 g GCT)
[b]Used 75g glucose load, 2 hour testing interval
[c]Modified IADPSG criteria due to absence of a 1-hour value

Appendix D Table 5. Evidence for Accuracy of Hemoglobin A1c Screening vs. OGTT Both at 24-28 wGA, (KQ4)

Diagnostic Criteria	Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
CC	≥4.5%	Agarwal, 2001[88]	United Arab Emirates	HbA1c: 27.1 ± 6.1 OGTT: NR	337 (+ve Hx) 93 (+ve GCT)	27.0	98.3	4.5	29.6
	≥5.0%	Agarwal, 2001[88]	United Arab Emirates	HbA1c: 27.1 ± 6.1 OGTT: NR	337 (+ve Hx) 93 (+ve GCT)	27.0	92.1	27.6	44.8
	≥5.1%	Braga, 2019[94]	Brazil	24-28	176	44.3	70.9	71.6	71.0
		Veres, 2015[125]	Romania	24-28	132 (+ Hx)	19.7	100.0	79.3	83.3
	≥5.5%	Agarwal, 2001[88]	United Arab Emirates	HbA1c: 27.1 ± 6.1 OGTT: NR	337 (+ve Hx) 93 (+ve GCT)	27.0	72.8	66.0	67.8
	≥5.7%	Ho, 2017[99]	China	HbA1c: 22-29 OGTT: 21-36	1989 (+ve GCT)	29.0	45.2	84.1	72.8
		Veres, 2015[125]	Romania	24-28	132 (+ Hx)	19.7	57.4	91.5	84.8
	≥6.0%	Agarwal, 2001[88]	United Arab Emirates	HbA1c: 27.1 ± 6.1 OGTT: NR	337 (+ve Hx) 93 (+ve GCT)	27.0	34.2	91.0	75.8
CC 75g 2h	≥5.5%	Rajput, 2012[113]	India	24-28	607	7.1	85.7	61.1	62.9
	≥5.95%	Rajput, 2012[113]	India	24-28	607	7.1	28.6	97.2	92.3
NDDG	≥4.5%	Siricharoenthai, 2019[121]	Thailand	28.9 ± 5.2	114 (+ve GCT)	30.7	100.0	7.6	36.0
	≥5.8%	Siricharoenthai, 2019[121]	Thailand	28.9 ± 5.2	114 (+ve GCT)	30.7	17.1	100.0	74.6
	≥7.2%	Uncu, 1995[124]	Turkey	24-28	42	33.3	64.0	64.0	64.3
IADPSG	≥4.6%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	95.9	4.6	15.4
		Sevket, 2014[118]	Turkey	24-28	339	15.6	96.2	23.0	34.5
	≥4.7%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	95.9	10.0	20.2
	≥4.8%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	81.6	18.0	25.6
	≥4.9%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	73.5	31.4	36.5
	≥5.0%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	69.4	51.9	54.2
	≥5.1%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	61.2	67.6	66.9
	≥5.2%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	55.1	79.7	76.7
		Rajput, 2012[113]	India	24-28	607	23.7	83.1	40.5	50.7
		Sevket, 2014[118]	Turkey	24-28	339	15.6	64.2	67.5	67.0
	≥5.3%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	34.7	88.4	82.1
		Soumya, 2015[122]	India	24-28	500	9.0	95.6	51.0	55.0

Appendix D Table 5. Evidence for Accuracy of Hemoglobin A1c Screening vs. OGTT Both at 24-28 wGA, (KQ4)

Diagnostic Criteria	Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
IADPSG, Continued.	≥5.4%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	26.5	95.4	87.3
	≥5.5%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	22.4	98.2	89.2
	≥5.6%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	12.2	99.0	88.8
	≥5.7%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	10.2	99.5	89.0
		Sevket, 2014[118]	Turkey	24-28	339	15.6	26.4	90.5	80.5
		Soumya, 2015[122]	India	24-28	500	9.0	73.3	75.6	75.4
	≥5.8%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	8.2	99.7	89.0
	≥5.9%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	6.1	99.7	88.5
	≥6.0%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	4.1	99.7	88.1
		Rajput, 2012[113]	India	24-28	607	23.7	11.9	97.1	76.9
	≥6.1%	Khalafallah, 2016[102]	Australia	25.7 ± 3.3	480	11.9	2.0	99.7	88.1
		Soumya, 2015[122]	India	24-28	500	9.0	46.7	95.0	90.6

Abbreviations: CC = Carpenter Coustan; GCT = glucose challenge test; Hx = history; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NDDG = National Diabetes Data Group; OGTT = oral glucose tolerance test

Appendix D Table 6. Evidence for Accuracy of Hemoglobin A1c Screening, Early HbA1c and OGTT 24-28 wGA (KQ4)

Diagnostic Criteria	Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
NDDG	≥4.5%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	99.3	2.4	15.1
	≥4.6%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	98.7	4.2	16.6
	≥4.7%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	98.0	6.7	18.7
	≥4.8%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	96.7	10.1	21.5
	≥4.9%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	92.8	17.9	27.7
	≥5.0%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	84.9	27.1	34.7
	≥5.1%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	78.9	39.7	44.8
	≥5.2%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	73.0	53.7	56.2
	≥5.3%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	64.5	64.2	64.2
	≥5.4%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	53.9	74.6	71.8
	≥5.5%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	44.1	82.9	77.8
	≥5.6%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	32.9	89.3	81.9
	≥5.7%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	25.7	92.5	83.8
	≥5.8%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	19.7	94.9	85.1
	≥5.9%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	14.5	97.5	86.6
	≥6.0%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	10.5	98.6	87.0
	≥6.1%	Benaiges, 2017[91]	Spain	HbA1c: ≤12 OGTT: 24-28	1158	13.1	7.2	99.4	87.3
IADPSG	≥4.0%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	100.0	0.7	16.1
	≥4.1%	Wu, 2018[127]	China	HbA1c: 12-16	690	15.5	100.0	2.1	17.2

Appendix D Table 6. Evidence for Accuracy of Hemoglobin A1c Screening, Early HbA1c and OGTT 24-28 wGA (KQ4)

Diagnostic Criteria	Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
IADPSG, Continued.		Wu, 2018 Continued.		OGTT: 24-28					
	≥4.2%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	99.1	3.6	18.4
	≥4.3%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	96.3	5.8	19.9
	≥4.4%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	89.7	11.0	23.2
	≥4.5%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	85.0	17.0	27.5
	≥4.6%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	76.6	27.6	35.2
	≥4.7%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	66.4	39.1	43.3
	≥4.8%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	54.2	53.0	53.2
	≥4.9%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	39.3	69.1	64.5
	≥5.0%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	28.0	82.8	74.3
	≥5.1%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	21.5	89.5	79.0
	≥5.2%	Poo, 2018[111]	Singapore	HbA1c: <14 OGTT: 24-28	151	11.3	82.4	71.6	72.8
		Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	15.0	95.2	82.8
	≥5.3%	Pezeshki, 2019[110]	Iran	HbA1c: 1st trimester OGTT: 24-28	356	8.4	80.0	80.0	80.1
		Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	8.4	98.1	84.2
	≥5.4%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	5.6	99.3	84.8
	≥5.6%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	4.7	99.8	85.1
	≥5.7%	Wu, 2018[127]	China	HbA1c: 12-16 OGTT: 24-28	690	15.5	1.9	100.0	84.8
	≥5.8%	Wu, 2018[127]	China	HbA1c: 12-16	690	15.5	0.9	100.0	84.6

Appendix D Table 6. Evidence for Accuracy of Hemoglobin A1c Screening, Early HbA1c and OGTT 24-28 wGA (KQ4)

Diagnostic Criteria	Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	Number Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
IADPSG, Continued.		Wu, 2018 Continued.		OGTT: 24-28					

Abbreviations: CC = Carpenter Coustan; HbA1c = hemoglobin A1c; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NDDG = National Diabetes Data Group; OGTT = oral glucose tolerance test; wGA = weeks' gestational age

Appendix D Table 7. Evidence for Accuracy of Hemoglobin A1c Screening, HbA1c vs. IADPSG Criteria at Various Timepoints (KQ4)

Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	N Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
≥4.0%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	100.0	0.6	13.9
≥4.2%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	100.0	3.6	16.5
≥4.4%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	97.4	8.2	20.2
	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22 & 32-36	628	7.2	100.0	0.5	11.8
≥4.6%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	93.3	20.3	30.1
	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22 & 32-36	628	7.2	97.8	2.4	9.2
≥4.7%	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22 & 32-36	628	7.2	95.6	16.5	22.1
			HbA1c: 18-22 OGTT: 18-22	677	2.4	100.0	16.6	18.6
≥4.8%	Hughes, 2014[100]	New Zealand	<20	974	17.5	100.0	3.0	22.7
	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22	677	2.4	87.5	30.3	31.6
	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	83.1	36.7	42.9
≥4.9%	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22	677	2.4	68.8	51.2	51.7

Appendix D Table 7. Evidence for Accuracy of Hemoglobin A1c Screening, HbA1c vs. IADPSG Criteria at Various Timepoints (KQ4)

Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	N Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
≥5.0%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	66.2	56.2	57.5
≥5.2%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	51.3	76.4	73.1
	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22 & 32-36	628	7.2	13.3	95.2	89.3
			HbA1c: 18-22 OGTT: 18-22	677	2.4	12.5	94.7	92.8
≥5.3%	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22 & 32-36	628	7.2	8.9	97.8	91.4
			HbA1c: 18-22 OGTT: 18-22	677	2.4	6.3	97.4	95.3
≥5.4%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	31.8	88.4	80.8
≥5.6%	Saadati, 2016[114]	Iran	<20	158	29.1	40.0	80.0	68.4
	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	18.5	94.3	84.2
≥5.8%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	11.3	97.9	86.3
	Odsaeter, 2016[106]	Norway	HbA1c: 18-22 OGTT: 18-22 & 32-36	628	7.2	0.0	100.0	92.8
			HbA1c: 18-22 OGTT: 18-22	677	2.4	0.0	100.0	97.6
≥5.9%	Hughes, 2014[100]	New Zealand	<20	974	17.5	18.8	98.4	84.5

Appendix D Table 7. Evidence for Accuracy of Hemoglobin A1c Screening, HbA1c vs. IADPSG Criteria at Various Timepoints (KQ4)

Threshold (HbA1c)	Author, Year	Country	Timing of Index & Timing of OGTT (Weeks' Gestation)	N Analyzed	Prevalence (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
≥6.0%	Hughes, 2014[100]	New Zealand	<20	974	17.5	13.5	99.2	84.3
	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	8.7	99.1	87.0
≥6.1%	Hughes, 2014[100]	New Zealand	<20	974	17.5	9.9	99.7	84.1
≥6.2%	Hughes, 2014[100]	New Zealand	<20	974	17.5	5.9	99.9	83.5
	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	4.6	99.2	86.6
≥6.3%	Hughes, 2014[100]	New Zealand	<20	974	17.5	4.0	99.9	83.2
≥6.4%	Hughes, 2014[100]	New Zealand	<20	974	17.5	3.3	100.0	83.2
	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	2.6	99.5	86.6
≥6.6%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	2.1	99.6	86.6
≥6.8%	Bhavadharini, 2017[93]	India	HbA1c: 19.5 ± 7.6 Early FPG (dx): 1st trimester OGTT: 2nd/3rd trimester	1459	13.4 (n=33 1st trimester; n=162 2nd/3rd trimester)	1.0	99.7	86.5

Abbreviations: CC = Carpenter Coustan; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NDDG = National Diabetes Data Group; OGTT = oral glucose tolerance test

Appendix D Table 8. Supplemental Analysis for Association Between More Inclusive GDM and Pregnancy Outcomes (KQ5)

Outcome	Comparison	Number of Studies	Number of Events and Patients (n/N) Exposed	Number of Events and Patients (n/N) Control	Relative Risk [95% CI]; I^2	Absolute Risk Difference [95% CI]
Pre-eclampsia	OAV (CC) vs NGT	1[198]	18/395	20/790	1.80 [0.96 to 3.36]; NA	
	OAV (NDDG) vs NGT	3[192,202,214]	8/264	46/2335 (data and numbers per group were not provided by one study (n=3,637)[214]	OR 1.65 [1.09 to 2.50]; 0% (RR 1.62 [1.09 to 2.41])	0.015 [0.002 to 0.039]
	• OAV (NDDG) vs NGT *(only blinded studies)*	1[214]	NR	NR	OR 1.80 [1.10 to 2.95]; NA (RR, 1.77 [1.1 to 2.82]) (using CER 0.023 from 2 studies in above)	
	IADPSG (excluding CC) vs NGT	7[190,200,203,207,209,215,218]	185/1961	829/22198	1.93 [1.34 to 2.77]; 69%	0.0328 [-0.0044 to 0.0700]
	• IADPSG (excluding CC) vs NGT *(profile likelihood)*	7[190,200,203,207,209,215,218]	185/1961	829/22198	1.92 [1.28 to 3.05]; 63.5%	
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	4[190,203,207,218]	140/1135	624/14418	2.15 [1.30 to 3.58]; 71%	
	• IADPSG (excluding CC) vs NGT *(only blinded studies)*	1[218]	109/732	285/4420	2.31 [1.88 to 2.84]; NA	
	IADPSG (excluding CC) vs NGT *(adjusted)*	3 [200,203,218]	1249	8410	aOR 1.99 [1.10 to 3.58]; 56%	
	IADPSG (excluding CC) vs NGT *(adjusted; profile likelihood)*	3[200,203,218]	1249	8410	aOR 1.77 [1.30 to 3.49]; 0%	
Gestational hypertension	OAV (CC) vs NGT	1[198]	13/395	32/790	0.88 [0.47 to 1.62]; NA	
	IADPSG (excluding CC) vs NGT	3[190,207,209]	21/554	304/8442	1.01 [0.45 to 2.24]; 61%	
	IADPSG (excluding CC) vs NGT (profile likelihood)	3[190,207,209]	21/554	304/8442	1.05 [0.39 to 2.36]; 38.8%	

Appendix D Table 8. Supplemental Analysis for Association Between More Inclusive GDM and Pregnancy Outcomes (KQ5)

Outcome	Comparison	Number of Studies	Number of Events and Patients (n/N) Exposed	Number of Events and Patients (n/N) Control	Relative Risk [95% CI]; I^2	Absolute Risk Difference [95% CI]
Gestational hypertension, Conitnued.	IADPSG (excluding NDDG) vs NGT	1[219]	52/1175	749/21629	1.28 [0.97 to 1.68]; NA	
Hypertensive disorders of pregnancy	OAV (CC) vs NGT	5[194,201,205,216,217]	95/904	391/9458	2.09 [1.53 to 2.86]; 40%	0.050 [0.030 to 0.070]
	• OAV (CC) vs NGT *(profile likelihood)*	5[194,201,205,216,217]	95/904	391/9458	2.08 [1.49 to 3.01]; 31%	
	• OAV (CC) vs NGT *(only VHDI studies)*	4[194,201,205,216]	75/615	188/2688	1.98 [1.34 to 2.94]; 46%	
	• OAV (CC) vs NGT *(only blinded studies)*	2[205,216]	43/383	90/1184	1.55 [1.07 to 2.25]; 0%	
	OAV (CC) vs NGT *(adjusted)*	2[194,217]	441	6595	aOR 2.14 [1.44 to 3.17]; 0%	
Hypertensive disorders of pregnancy, Continued.	OAV (NDDG) vs NGT	1[217]	17/225	210/6992	2.52 [1.56 to 4.05]; NA	0.046 [0.019 to 0.080]
	OAV (NDDG) vs NGT (*adjusted)*	1[217]	225	5971	aOR 2.09 [1.21 to 3.61]; NA	
	IADPSG (excluding CC) vs NGT	4[195,197,204,209]	101/1133	1200/16357	1.15 [0.93 to 1.41]; 0%	
	IADPSG (excluding CC) vs NGT *(only VHDI studies)*	3[195,197,204]	70/851	1166/16075	1.22 [0.96 to 1.53]; 0%	
	IADPSG (excluding CC) vs NGT *(adjusted)*	1[195]	181	5485	aOR 1.41 [0.79 to 2.52]; NA	
Total cesarean deliveries	OAV (CC) vs NGT	10[189,193,194,198,206,210,211,213,216,217]	525/1312	5308/17343	1.29 [1.13, 1.47]; 52%	0.078 [0.034 to 0.123]
	• OAV (CC) vs NGT *(profile likelihood)*	10[189,193,194,198,206,210,211,213,216,217]	525/1312	5308/17343	1.29 [1.12 to 1.49]; 50%	
	• OAV (CC) vs NGT *(only VHDI studies)*	8[189,193,194,206,210,211,213,216]	217/628	2783/9783	1.32 [1.10, 1.60]; 48%	
	• OAV (CC) vs NGT *(only blinded studies)*	3[193,213,216]	56/268	1485/6080	1.32 [0.99, 1.75]; 0%	

Appendix D Table 8. Supplemental Analysis for Association Between More Inclusive GDM and Pregnancy Outcomes (KQ5)

Outcome	Comparison	Number of Studies	Number of Events and Patients (n/N) Exposed	Number of Events and Patients (n/N) Control	Relative Risk [95% CI]; I^2	Absolute Risk Difference [95% CI]
Total cesarean deliveries, Continued.	• OAV (CC) vs NGT *(removing Arbib [third trimester only])*	9[193,194,198,206,210,211,213,216,217]	515/1280	5249/17066	1.28 [1.12, 1.47]; 57%	
	OAV (CC) vs NGT *(adjusted)*	1[194] 1[217]	152 289	624 5971	aOR 2.20 [1.55 to 3.12]; NA	
	OAV (NDDG) vs NGT	4[192,202,214,217]	217/489	3399/9327 (data and numbers per group were not provided by one study (n=3,637)[214]	OR 1.48 [1.27 to 1.72]; 0% (RR 1.28 [1.17 to 1.39)	0.092 [0.056 to 0.129]
	• OAV (NDDG) vs NGT *(only VHDI studies)*	3[192,202,214]	264	2335	OR 1.42 [1.18 to 1.71]; 0% (RR 1.24 [1.11 to 1.37]	
	• OAV (NDDG) vs NGT *(only blinded studies)*	1[214]	NR	NR	OR 1.40 [1.10 to 1.78]; NA (RR 1.27 [1.06 to 1.42]	
	OAV (NDDG) vs NGT*(adjusted)*	1[217]	225	5971	aOR 1.18 [0.89 to 1.56]; NA	
	IADPSG (excluding CC) vs NGT	6[190,204,207-209,215]	532/1153	7004/19084	1.20 [1.05 to 1.38]; 77%	0.0695 [0.0131 to 0.1258]
	IADPSG (excluding CC) vs NGT *(profile likelihood)*	6[190,204,207-209,215]	532/1153	7004/19084	1.20 [1.04 to 1.39]; 68.3%	
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	4[190,204,207,208]	196/713	3443/13456	1.27 [1.07 to 1.52]; 48%	
	IADPSG (excluding CC) vs NGT *(adjusted)*	2[204,208]	441	5169	1.02 [0.49 to 2.12]; NA	
	IADPSG (excluding NDDG) vs NGT	1[219]	732/1175	10689/21629	1.26 [1.20 to 1.32]; NA	0.129 [0.100 to 0.157]
Primary cesarean deliveries	OAV (CC) vs NGT	1[201]	30/80	218/880	1.51 [1.12, 2.05]; NA	0.127 [0.017 to 0.237]
	IADPSG (excluding CC) vs NGT	5[195,197,200,203,218]	433/1707	4591/21687	1.10 [0.91, 1.34]; 77%	

Appendix D Table 8. Supplemental Analysis for Association Between More Inclusive GDM and Pregnancy Outcomes (KQ5)

Outcome	Comparison	Number of Studies	Number of Events and Patients (n/N) Exposed	Number of Events and Patients (n/N) Control	Relative Risk [95% CI]; I^2	Absolute Risk Difference [95% CI]
Primary cesarean deliveries, Continued.	• IADPSG (excluding CC) vs NGT *(profile likelihood)*	5[195,197,200,203,218]	433/1707	4591/21687	1.11 [0.90 to 1.34]; 68%	
	• IADPSG (excluding CC) vs NGT *(only VHDI countries)*	4[195,197,203,218]	312/1321	3871/19535	1.16 [0.95, 1.42]; 69%	
	• IADPSG (excluding CC) vs NGT *(only blinded studies)*	1[218]	174/728	764/4441	1.39 [1.20, 1.61]; NA	
	IADPSG (excluding CC) vs NGT *(adjusted)*	4[195,200,203,218]	1426	13916	aOR 0.94 [0.69 to 1.28; 73%	
	• IADPSG (excluding CC) vs NGT *(adjusted; profile likihood)*	4[195,200,203,218]	1426	13916	aOR 0.95 [0.68 to 1.27]; 59%	
	• IADPSG (excluding CC) vs NGT *(adjusted VHDI studies)*	3[195,203,218]	1040	11764	aOR 1.00 [0.69 to 1.45]; 67%	
	• IADPSG (excluding CC) vs NGT *(adjusted blinded studies)*	1[218]	728	4441	aOR 1.31 [1.07 to 1.60; NA	
Induction of Labor	OAV (CC) vs NGT	1[189]	0/32	1/277	2.81 [0.12 to 67.54]; NA	
	IADPSG (excluding CC) vs NGT	3[200,203,204]	93/906	648/6809	1.13 [0.93 to 1.39]; 0%	
	IADPSG (excluding CC) vs NGT *(only VHDI studies)*	2[203,204]	79/520	590/4657	1.11 [0.89 to 1.37]; 0%	
	IADPSG (excluding CC) vs NGT *(adjusted)*	3[200,203,204]	906	6682	aOR 1.15 [0.91 to 1.46]; 0%	
Preterm delivery	OAV (CC) not NGT	6[198,201,210,211,216,217]	97/1023	760/10888	1.42 [1.14 to 1.77]; 0%	0.018 [-0.032 to 0.068]
	• OAV (CC) not NGT *(only VHDI studies)*	4[201,210,211,216]	26/339	25/3328	1.27 [0.64 to 2.52]; 42%	
	• OAV (CC) not NGT *(only blinded studies)*	1[216]	7/131	4/108	1.44 [0.43 to 4.80]; NA	
	OAV (CC) vs NGT *(adjusted)*	1[217]	289	5971	aOR 1.53 [1.03 to 2.27[; NA	

Appendix D Table 8. Supplemental Analysis for Association Between More Inclusive GDM and Pregnancy Outcomes (KQ5)

Outcome	Comparison	Number of Studies	Number of Events and Patients (n/N) Exposed	Number of Events and Patients (n/N) Control	Relative Risk [95% CI]; I^2	Absolute Risk Difference [95% CI]
Preterm delivery, Continued.	OAV (NDDG) not NGT	3[192,202,217]	32/489	534/9327	1.37 [0.97 to 1.94]; 0%	0.012 [-0.0043 to 0.029]
	•OAV (NDDG) not NGT *(only VHDI studies)*	2[192,202]	10/264	43/2335	1.46 [0.57 to 3.75]; 32%	
	OAV (NDDG) not NGT *(adjusted)*	1[217]	225	5971	aOR 1.37 [0.86 to 2.18]; NA	
	IADPSG (excluding CC) vs NGT	9[190,195,200,203,204,208,209,215,218]	220/2617	3322/31764	1.19 [0.97 to 1.46]; 45%	0.0076 [-0.0084 to 0.0236]
	• IADPSG (excluding CC) vs NGT *(profile likelihood)*	9[190,195,200,203,204,208,209,215,218]	220/2617	3322/31764	1.20 [0.98 to 1.44]; 0%	
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	6[190,195,203,204,208,218]	152/1791	2682/23984	1.26 [1.03 to 1.53]; 23%	0.0125 [-0.0036 to 0.0287]
	• IADPSG (excluding CC) vs NGT *(only blinded studies)*	1[218]	68/878	301/5020	1.29 [1.00 to 1.66]; NA	
	IADPSG (excluding CC) vs NGT *(adjusted)*	5[195,200,203,208,218]	1628	16474	aOR 1.43 [1.16 to 1.75]; 0%	
Maternal birth trauma	OAV (CC) not NGT	1[217]	289	5971	aOR 1.01 [0.49 to 2.08]; NA	
	OAV (NDDG) vs NGT	1[217]	225	5971	aOR 1.61 [0.80 to 3.24]; NA	
	IADPSG (excluding CC) vs NGT	4[195,197,200,208]	27/900	522/17885	1.19 [0.81 to 1.76]; 0%	
	• IADPSG (excluding CC) vs NGT *(only VHDI*)	3[195,197,208]	17/514	470/15733	1.19 [0.67 to 2.10]; 16%	
	IADPSG (excluding CC) vs NGT *(adjusted*)	2[195,200]	462	13256	aOR [1.05 [0.59 to 1.86]; 0%	
Excessive gestational weight gain	IADPSG (excluding CC) vs NGT	1[195]	63/181	1748/5485	1.09 [0.89 to 1.34]; NA	

Abbreviations: aOR = adjusted odds ratio; CC = Carpenter Coustan; CI = confidence interval; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NA = not applicable; NGT = normal glucose tolerance; NDDG = National Diabetes Data Group; OAV = one abnormal value; OGCT = oral glucose challenge test

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
Mortality: All outcomes	All studies	8[193,197,198,200-202,216,219]	13/2629	148/39674	1.66 [0.93 to 2.95]; 0%	
	• All studies *(only blinded studies)*	2[193,216]	1/190	29/5875	1.95 [0.24 to 15.91]; 0%	
	• All studies *(only VHDI studies)*	5[193,197,201,202,216]	3/673	50/15103	2.17 [0.74 to 6.37]; 0%	
Mortality: Neonatal death	OAV (CC) vs NGT	1[201]	2/80	6/880	3.67 [0.75 to 17.87]; NA	
Mortality: Stillbirth	OAV (CC) vs NGT	2[193,198]	1/454	29/6557	2.86 [0.35 to 23.32]; 0%	
	IADPSG (excluding CC) vs NGT	1[197]	0/281	13/7771	1.02 [0.06 to 17.13]; NA	
Mortality: Perinatal death	OAV (CC) vs GCT-ve	1[216]	1/131	0/108	2.48 [0.10 to 60.20]; NA	
	OAV (NDDG) vs NGT	1[202]	0/122	2/577	0.94 [0.05 to 19.45]; NA	
	• IADPSG (excluding CC) vs NGT	1[200]	3/386	9/2152	1.86 [0.51 to 6.83]; NA	
	• IADPSG (excluding CC) vs NGT (*adjusted)*	1[200]	386	2152	aOR 1.68 [0.44 to 6.41]; NA	
	• IADPSG (excluding NDDG) vs NGT	1[219]	6/1175	89/21629	1.24 [0.54 to 2.83]; NA	
Birth injury	OAV (NDDG) vs NGT	1[214]	3,637		OR 1.10 [0.60 to 2.02]; NA (RR not estimable)	
Shoulder dystocia or birth injury	IADPSG (excluding CC) vs NGT	2[203,218]	28/1006	101/6858	1.70 [1.13 to 2.57]; 0%	0.011 [0.001, 0.022]
	IADPSG (excluding CC) vs NGT *(adjusted)*	2[203,218]	28/1006	101/6858	aOR: 1.64 [0.80 to 3.38]; 24%	
Shoulder dystocia	OAV (CC) vs NGT	5[189,198,201,205,216]	10/890	26/3131	1.55 [0.60 to 3.98]; 28%	
Shoulder dystocia, Continued.	• OAV (CC) vs NGT *(only blinded studies)*	1[205] 1[216]	6/252 1/131	14/1076 4/108	1.83 [0.71 to 4.72]	

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
					0.21 [0.02 to 1.82]	
	• OAV (CC) vs NGT *(only VHDI studies)*	4[189,201,205,216]	9/495	24/2341	1.60 [0.50 to 5.17]; 44%	
	• OAV (CC) vs NGT *(removing Arbib)*	4[198,201,205,216]	10/858	25/2854	1.41 [0.56 to 4.31]; 45%	
	OAV (CC) vs NGT *(adjusted)*	1[217]	289	5971	aOR 0.88 [0.12 to 6.45]; NA	
	OAV (NDDG) vs NGT	1[217]	225	5971	aOR 2.21 [0.51 to 9.58]; NA	
	IADPSG (excluding CC) vs NGT	4[190,195,197,208]	14/674	269/22078	1.79 [1.02 to 3.15]; 9%	0.0054 [-0.0083 to 0.0191]
	IADPSG (excluding CC) vs NGT*(adjusted)*	1[195]	181	5485	aOR [1.29 [0.40 to 4.19]; NA	
Macrosomia >4000g	OAV (CC) vs NGT	10[189,193,194,198,199,201,206,210,216,217]	125/1564	1697/26522	1.47 [1.16 to 1.87]; 18%	0.026 [-0.008 to 0.059]
	• OAV (CC) vs NGT *(only blinded studies)*	2[193,216]	24/190	296/5975	1.65 [0.82 to 3.36]; 16%	
	• OAV (CC) vs NGT *(only VHDI studies)*	8[189,193,194,199,201,206,210,216]	107/880	1621/18962	1.36 [1.11 to 1.67]; 0%	
	• OAV (CC) vs NGT *(removing Arbib)*	9[193,194,198,199,201,206,210,216,217]	121/1532	1664/26245	1.51 [1.17 to 1.96]; 24%	
	OAV (CC) vs NGT (*adjusted)*	1[194] 1[217]	152 289	624 5971	aOR 2.00 [1.13 to 3.54]; NA aOR 0.33 [0.05 to 2.18]; NA	
	OAV (NDDG) vs NGT	4[191,192,214,217]	454	9323	OR 1.85 [1.44 to 2.38]; 3.2%	0.048 [0.025 to 0.074]

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
Macrosomia >4000g, Continued.				(data and numbers per group were not provided by one study (n=3,637)[214]	(RR 1.76 [1.40 to 2.19])	
	• OAV (NDDG) vs NGT *(only VHDI countries)*	3[191,192,214]	229	2331	OR 1.80 [1.39 to 2.34]; 0% (RR 1.71 [1.36 to 2.16])	0.044 [0.022 to 0.072]
	• OAV (NDDG) vs NGT *(only blinded studies)*	1[214]	NR	NR	OR 1.70 [1.20 to 2.41]; NA (RR 1.63 [1.18 to 2.22])	0.039 [0.011 to 0.076]
	OAV (NDDG) vs NGT *(adjusted)*	1[217]	225	5971	aOR 2.06 [0.80 to 5.30]; NA	
	IADPSG (excluding CC) vs NGT	8[190,195,197,203,207-209,215]	127/1357	2156/31359	1.70 [1.35 to 2.14]; 37%	0.0357 [0.0099 to 0.0614]
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	6[190,195,197,203,207,208]	101/917	1745/25731	1.76 [1.32 to 2.35]; 51%	
	IADPSG (excluding CC) vs NGT *(adjusted)*	3[195,203,208]	364	8758	aOR 2.21 [1.49 to 3.29]; 0%	
	IADPSG (not NDDG) vs NGT	1[219]	170/1151	1428/21286	2.20 [1.90 to 2.55]; NA	0.081 [0.060 to 0.101]; NA
Large for gestational age	OAV (CC) vs NGT	8[189,193,198,201,205,206,213,216]	152/1075	506/9562	1.64 [1.25 to 2.15]; 49%	0.047 [0.018 to 0.076]
	• OAV (CC) vs NGT *(profile likelihood)*	7[189,193,198,201,205,206,213,216]	152/1075	506/9562	1.62 [1.24 to 2.19]; 33%	
	• OAV (CC) vs NGT *(only blinded studies)*	4[189,198,201,206]	67/520	218/7153	1.65 [0.96 to 2.82]; 61%	
	• OAV (CC) vs NGT *(only VHDI countries)*	7[189,193,201,205,206,213,216]	105/680	453/8772	1.62 [1.16 to 2.26]; 56%	

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
Large for gestational age, Continued.	• OAV (CC) vs NGT *(removing Arbib)*	7[193,198,201,205,206,213,216]	141/1043	418/9285	1.75 [1.31 to 2.33]; 47%	
	OAV (CC) vs NGT *(adjusted)*	3[198,206,216]	574	1232	aOR 1.91 [1.33 to 2.75]; 0%	
	OAV (NDDG) vs NGT	3[191,192,202]	52/351	266/2908	1.68 [1.28 to 2.21]; 0%	0.053 [-0.0013 to 0.106]
	IADPSG (excluding CC) vs NGT	10[190,195,197,200,203,204,207-209,218]	435/2851	3465/35987	1.69 [1.42 to 2.01]; 64%	0.0595 [0.0337 to 0.0853]
	• IADPSG (excluding CC) vs NGT *(profile likelihood)*	10[190,195,197,200,203,204,207-209,218]	435/2851	3449/35860	1.69 [1.39 to 2.02]; 61.3%	
	• IADPSG (excluding CC) vs NGT *(only blinded studies)*	1[218]	134/877	394/5003	1.94 [1.62 to 2.33]; NA	
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	8[190,195,197,203,204,207,208,218]	356/2183	3180/33426	1.79 [1.50 to 2.15]; 63%	
	IADPSG (excluding CC) vs NGT *(adjusted)*	6[195,200,203,204,208,218]	2016	18605	aOR 1.73 [1.41 to 2.11]; 42%	
	• IADPSG (excluding CC) vs NGT *(adjusted; profile likelihood)*	4[195,200,203,218]	1574	13934	aOR 1.70 [1.29 to 2.25]; 26%	
	• IADPSG (excluding CC) vs NGT *(adjusted & only VHDI)*	5[195,203,204,208,218]	1630	16453	aOR 1.85 [1.53 to 2.23]; 19%	
NICU admissions	OAV (CC) vs NGT	5[198,201,210,216,217]	47/958	634/10795	1.15 [0.84 to 1.57]; 0%	
	OAV (CC) vs NGT *(only VHDI studies)*	3[201,210,216]	17/301	157/3235	1.15 [0.65 to 2.02]; 0%	
	OAV (CC) vs NGT *(adjusted)*	1[217]	289	5971	aOR 1.11 [0.70 to 1.76]; NA	

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
NICU admissions, Continued.	OAV (NDDG) vs NGT	1[217]	19/225	477/6992	1.24 [0.80 to 1.92]; NA	
	OAV (NDDG)) vs NGT *(adjusted)*	1[217]	225	6992	aOR 1.33 [0.82 to 2.16]; NA	
	IADPSG (excluding CC) vs NGT	6[190,197,200,203,208,218]	145/1885	2083/25589	1.17 [0.99 to 1.38]; 0%	0.0091 [-0.0031 to 0.0214]
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	5[190,197,203,208,218]	128/1499	1997/23437	1.17 [0.98 to 1.40]; 1%	
	• IADPSG (excluding CC) vs NGT *(only blinded studies)*	1[218]	71/875	313/5006	1.30 [1.01 to 1.66]; NA	
	IADPSG (excluding CC) vs NGT *(adjusted)*	4[200,203,208,218]	1444	10975	aOR 1.02 [0.81 to 1.28]; 0%	
Respiratory distress syndrome	OAV (CC) vs NGT	3[189,198,216]	4/558	10/1175	0.65 [0.18 to 2.35]; 0%	
	• OAV (CC) vs NGT *(only VHDI studies)*	2[189,216]	2/163	1/385	1.65 [0.15 to 17.94]; NA (no events in 1 study)	
	OAV (NDDG) vs NGT	1[202]	11/122	25/577	2.00 [1.02 to 3.94]	0.045 [-0.0085 to 0.099]
Hypoglycemia	OAV (CC) vs NGT	7[189,193,194,198,201,213,216]	76/927	331/8651	1.61 [1.20 to 2.15]; 0%	0.019 [0.0022 to 0.040]
	• OAV (CC) vs NGT *(only VHDI studies)*	6[189,193,194,201,213,216]	52/532	308/7861	1.46 [1.04 to 2.05]; 0%	
	• OAV (CC) vs NGT *(only blinded studies)*	3[193,213,216]	34/268	236/6080	1.25 [0.79 to 1.97]; 0%	
	• OAV (CC) vs NGT *(only unblinded studies)*	4[189,194,198,201]	42/659	95/2571	1.91 [1.31 to 2.77]; 0%	

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
Hypoglycemia, Continued.					Subgroup effects for blinding p=0.16	
	• OAV (CC) vs NGT *(with defined outcome)*	3[193,194,216]	34/342	242/6499	1.34 [0.85 to 2.11]; 0%	
	• OAV (CC) vs NGT *(without defined outcome)*	4[189,198,201,213]	42/585	89/2152	1.82 [1.25 to 2.65]; 0% Subgroup effects for defined outcome p=0.30	
	• OAV (CC) vs NGT *(removing Arbib)*	6[193,194,198,201,213,216]	75/895	330/8374	1.58 [1.18 to 2.11]; 0%	
	OAV (CC) vs NGT (*adjusted)*	1[198]	395	790	aOR 1.79 [0.97 to 3.34]; NA	
	OAV (NDDG) vs NGT	2[192,202]	7/264	11/2335	6.64 [2.52 to 17.49]; 0% Sermer 1995 (n=3637): no association found for IV for hypoglycemia (data NR)[214]	0.020 [0.002 to 0.038]
	• OAV (NDDG) vs NGT *(with defined outcome)*	2[192,202]	7/264	11/2335	6.64 [2.52 to 17.49]; 0% Sermer 1995 (n=3637): no association found for IV for hypoglycemia (data NR)[214]	

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
Hypoglycemia, Continued.	• OAV (NDDG) vs NGT *(only blinded studies)*	1[214]	3637		Sermer 1995 (n=3637): no association found for IV for hypoglycemia (data NR)[214]	
	IADPSG (excluding CC) vs NGT	3[200,203,218]	37/1392	91/8996	2.51 [1.72 to 3.68]; 0%	0.016 [0.0072 to 0.025]
	• IADPSG (excluding CC) vs NGT *(with defined outcome)*	3[200,203,218]	37/1392	91/8996	2.51 [1.72 to 3.68]; 0%	
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	2[203,218]	28/1006	76/6844	2.48 [1.35 to 4.65]; 21%	
	• IADPSG (excluding CC) vs	1[218]	25/875	67/5006	2.13 [1.36 to 3.34]; NA	
	• NGT *(only blinded studies)*					
	IADPSG (excluding CC) vs NGT *(adjusted)*	3[200,203,218]	1392	8996	aOR 2.48 [1.64 to 3.74]; 0%	
	IADPSG (excluding NDDG) vs NGT	1[219]	30/1175	254/21629	2.17 [1.50 to 3.15]; NA	0.014 [0.005 to 0.023]
Hyperbilirubinemia	OAV (CC) vs NGT *(removing Arbib)*	4[193,198,201,216]	137/665	388/7545	1.21 [1.02 to 1.45]; 0%	
	• OAV (CC) vs NGT *(with Arbib)*	5[189,193,198,201,216]	138/697	388/7822	1.34 [0.84 to 2.13]; 15%	
	• OAV (CC) vs NGT *(only VHDI studies)*	4[189,193,201,216]	8/302	172/7032	1.95 [0.64 to 5.97]; 24%	
	• OAV (CC) vs NGT *(only blinded studies)*	2[193,216]	3/190	144/5875	1.15 [0.22 to 5.94]; 0%	

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
Hyperbilirubinemia, Continued.	OAV (CC) vs NGT *(adjusted)*	1[198]	395	790	aOR 1.16 [0.88 to 1.53]; NA	
	OAV (NDDG) vs NGT	2[192,214]	142	1758 (data and numbers per group were not provided by one study (n=3,637)[214]	OR 2.04 [1.47 to 2.84]; 0% (RR 1.97 [1.45 to 2.68])	0.031 [0.014 to 0.054]
	• OAV (NDDG) vs NGT *(only blinded studies)*	1[214]	3637 (NR by group)		OR 1.90 [1.30 to 2.87]; NA (RR 1.85 [1.29 to 2.63]; NA)	
	IADPSG (excluding CC) vs NGT	4[200,203,208,218]	140/1444	1513/11473	1.32 [1.13 to 1.54]; 0%	0.0213 [-0.0040 to 0.0467]
	• IADPSG (excluding CC) vs NGT *(only VHDI studies)*	3[203,208,218]	124/1058	1448/9321	1.32 [1.12 to 1.55]; 0%	
	• IADPSG (excluding CC) vs NGT (only blinded studies)	1[218]	57/875	249/5006	1.31 [0.99 to 1.73]; NA	
	IADPSG (excluding CC) vs NGT *(adjusted)*	4[200,203,208,218]	1444	10975	aOR 1.38 [1.11 to 1.70]; 0%	
	IADPSG (excluding CC) vs NGT *(adjusted and only VHDI)*	3[203,208,218]	1058	8823	aOR 1.37 [1.09 to 1.73]; 0%	
APGAR score <7 at 1 minute	OAV (CC) vs NGT	1[198] 1[216]	12/395 6/131	22/790 0/108	1.09 [0.55 to 2.18]; NA 10.73 [0.61 to 88.43]; NA	
	OAV (NDDG) vs NGT	1[202]	6/122	12/577	2.36 [0.91 to 6.18]; NA	

Appendix D Table 9. Supplemental Analysis for Association Between More Inclusive GDM and Fetal/Neonatal Outcomes (KQ5)

Outcome	Comparisons	Number of Studies	Number of Events and Patients (n/N) (Only N for ORs and MDs): GDM	Number of Events and Patients (n/N) (Only N for ORs and MDs): Control	Relative Effects [95% CI]; I^2 (RR unless otherwise stated)	Absolute Risk Difference [95% CI]
APGAR score <7 at 1 minute, Continued.	IADPSG (excluding CC) vs NGT	2[197,208]	26/333	676/10248	1.11 [0.76 to 1.62]; 0%	
APGAR score <7 at 5 minutes	OAV (CC) vs NGT	3[198,201,216]	8/606	31/1778	1.63 [0.70 to 3.83]; 0%	
	• OAV (CC) vs NGT *(only VHDI studies)*	2[201,216]	6/211	28/988	1.73 [0.66 to 4.57]; 0%	
	• OAV (CC) vs NGT *(only blinded studies)*	1[216]	2/131	0/108	4.13 [0.20 to 85.09]; NA	
	OAV (NDDG) vs NGT	1[202]	4/122	5/577	3.78 [1.03 to 13.89]; NA	0.024 [-0.0084 to 0.057]
	IADPSG (excluding CC) vs NGT	3[190,197,208]	5/493	223/16593	0.97 [0.30 to 3.11]; 29%	
	IADPSG (excluding CC) vs NGT *(adjusted)*	1[208]	0/52	9/1979	aOR 0.79 [0.31 to 2.01]; NA	

Abbreviations: aOR = adjusted odds ratio; CC = Carpenter Coustan; IADPSG = International Association of Diabetes and Pregnancy Study Groups; NA = not applicable; NGT = normal glucose tolerance; NDDG = National Diabetes Data Group; OAV = one abnormal value; OGCT = oral glucose challenge test; VHDI = very high development index

Appendix D Table 10. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Pregnancy Outcomes (KQ6)

Outcome	Comparisons	Number of Studies	#Events/ Treated	#Events/ Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Preeclampsia	All studies	6[42,221,226,227,229,233]	42/1032	48/1052	0.99 [0.46 to 2.16]; 59%	
	• Profile likelihood	6[42,221,226,227,229,233]	42/1032	48/1052	0.96 [0.46 to 2.39]; 48%	
	• Removing OGTT-ve studies	4[42,227,229,233]	38/947	47/954	0.81 [0.35 to 1.91]; 70%	
	• Removing studies with minimal intervention in UC	4[42,226,227,229]	22/658	39/643	0.55 [0.33 to 0.92]; 0%	-0.017 [-0.052 to 0.017]
	• Removing studies with some early treatment	5[42,221,226,229,233]	39/999	43/1016	1.11 [0.44 to 2.84]; 67%	
	• Removing nonVHDI studies	5[42,221,226,227,229]	24/693	40/691	0.60 [0.35 to 1.01]; 3%	
	• Only blinded studies	2[42,227]	15/509	30/491	0.49 [0.27 to 0.90]; 0%	-0.030 [-0.055 to -0.005]
	• Removing CCT	5[42,221,227,229,233]	40/982	48/1002	0.90 [0.41 to, 2.01]; 64%	
	• Removing study with no outcome definition (Bevier)	5[42,226,227,229,233]	40/997	47/1004	0.91 [0.40 to 2.09]; 65%	
Gestational hypertension	All studies	2[42,233]	38/815	45/816	0.82 [0.54 to 1.25]; 0%	
	• Removing nonVHDI studies/with minimal intervention	1[42]	29/476	37/455	0.75 [0.47 to 1.20]; NA	
	• Only blinded studies	1[42]	29/476	37/455	0.75 [0.47 to 1.20]; NA	
Hypertensive disorders of pregnancy	All studies	3[41,42,233]	126/1305	171/1326	0.85 [0.50 to 1.43]; 80%	
	• Only blinded and VHDI studies	2[41,42]	99/966	155/965	0.64 [0.51 to 0.81]; 0%	
	Subgroup: gestational age at timing of treatment	1[237]	24-26 wGA: 7/68 27 wGA: 4/77 28 wGA: 15/102 29 wGA: 7/109 ≥30 wGA: 8/119	24-26 wGA: 6/43 27 wGA: 19/88 28 wGA: 8/87 29 wGA: 10/106	24-26 wGA: 0.74 [0.27 to 2.05]; NA 27 wGA: 0.24 [0.09 to 0.68]; NA 28 wGA: 1.60 [0.71 to 3.59]; NA 29 wGA:	27 wGA: -0.164 [-0.263 to -0.0647]

Appendix D Table 10. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Pregnancy Outcomes (KQ6)

Outcome	Comparisons	Number of Studies	#Events/ Treated	#Events/ Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Hypertensive disorders of pregnancy, Continued.				≥30 wGA: 19/130	0.68 [0.27 to 1.72]; NA ≥30 wGA: 0.46 [0.21 to 1.01]; NA Subgroup effect: p=0.06	
	Subgroup: Hispanic vs Non-Hispanic white	1[234]	Hispanic: 23/274 Non-Hispanic white: 11/123	Hispanic: 37/255 Non-Hispanic white: 13/116	Hispanic: 0.58 [0.35 to 0.95];NA Non-Hispanic white: 0.80 [0.37 to 1.71]; NA Subgroup effect: p=0.49	Hispanic: -0.061 [-0.115 to -0.0069]
	Subgroup: Meeting NDDG 1979 vs meeting CC 1982 criteria	1[236]	NDDG: 25/280 CC: 16/196	NDDG: 35/262 CC: 27/193	NDDG: 0.67 [0.41 to, 1.09]; NA CC: 0.58 [0.32 to 1.05]; NA Subgroup effect: p=0,73	
Cesarean delivery	All studies	8[41,42,221-223,227,229,233]	638/1771	684/1812	0.95 [0.83 to 1.08]; 43%	
	• Profile likelihood	8[41,42,221-223,227,229,233]	638/1771	684/1812	0.96 [0.82 to 1.08]; 34%	
	• Removing OGTT-ve studies	6[41,42,223,227,229,233]	589/1586	630/1614	0.95 [0.82 to 1.10]; 54%	
	• Removing studies with minimal intervention in UC	5[41,42,222,227,229]	364/1248	411/1253	0.89 [0.79 to 1.00]; 0%	
	• Removing studies with some early treatment	6[41,42,221,223,229,233]	587/1588	634/1626	0.93 [0.79 to 1.09]; 60%	
	• Removing nonVHDI studies	7[41,42,221-223,227,229]	399/1432	451/1451	0.89 [0.80 to 1.00]; 0%	
	• Only blinded studies	3[41,42,227]	287/999	326/1001	0.88 [0.77 to 1.01]; 2%	
	• Cesarean delivery, defined as total/all	3[41,42,221]	285/1001	330/1013	0.87 [0.73 to 1.03]; 29%	
Cesarean delivery, Continued.	**Subgroup:** gestational age at timing of treatment	1[237]	24-26 wGA: 23/68 27 wGA: 22/77 28 wGA: 29/102 29 wGA: 26/109 ≥30 wGA: 28/120	24-26 wGA: 15/43 27 wGA: 32/88 28 wGA: 28/87 29 wGA: 33/107 ≥30 wGA: 46/130	24-26 wGA: 0.97 [0.57 to 1.64]; NA 27 wGA: 0.79 [0.50 to 1.23]; NA 28 wGA: 0.88 [0.57 to 1.36]; NA 29 wGA: 0.77 [0.50 to 1.20]; NA ≥30 wGA: 0.66 [0.44 to 0.98] Subgroup effect: p=0.80	≥30 wGA: -0.121 [-0.232 to -0.008]

Appendix D Table 10. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Pregnancy Outcomes (KQ6)

Outcome	Comparisons	Number of Studies	#Events/ Treated	#Events/ Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
	Subgroup: meeting NDDG versus meeting CC criteria	1[236]	NDDG: 78/280 CC: 50/196	NDDG: 79/262 CC: 75/193	NDDG: 0.92 [0.71 to 1.20]; NA CC: 0.66 [0.49 to 0.88]; NA Subgroup effect: p=0.09	CC: -0.134 [-0.225 to -0.041]
Primary cesarean delivery	All studies	3[42,221,226]	81/561	113/553	0.70 [0.54 to 0.91]; 0%	-0.0525 [-0.103 to -0.0024]
	• Removing OGTT-ve studies/only blinded studies	1[42]	62/476	90/455	0.66 [0.49 to 0.89]; NA	-0.058 [-0.115 to -0.020]
	• Removing studies with minimal intervention in UC	2[42,226]	78/526	110/505	0.69 [0.53 to 0.89]; 0%	-0.068 [-0.114 to -0.223]
	• Removing Landon (broader definition)	2[221,226]	19/85	23/98	0.85 [0.51 to 1.39]; 0%	
	• Removing CCT	2[42,221]	65/511	93/503	0.68 [0.51 to 0.90]; 0%	-0.038 [-0.123 to 0.048]
Emergency cesarean delivery	All studies	1[41]	80/490	103/510	0.81 [0.62 to 1.05]; NA	
Induction of Labor	All studies	5[41,42,221,227,233]	338/1373	285/1410	1.18 [0.92 to 1.52]; 45%	
	• Profile likelihood	5[41,42,221,227,233]	338/1373	285/1410	1.18 [0.93 to 1.51]; 13%	
	• Removing OGTT-ve studies	4[41,42,227,233]	332/1338	285/1362	1.17 [0.98 to 1.39]; 21%	
	• Removing studies with minimal intervention in UC & no blinding	3[41,42,227]	332/999	284/1001	1.17 [0.97 to 1.41]; 39%	
	• Removing studies with some early treatment	4[41,42,221,233]	325/1340	273/1374	1.19 [0.87 to 1.62]; 59%	
	• Removing nonVHDI studies	4[41,42,221,227]	338/1034	284/1049	1.19 [0.92 to 1.55]; 56%	
Preterm delivery	All studies	4[42,226,229,233]	69/965	92/968	0.75 [0.56 to 1.01]; 0%	
	• Removing OGTT-ve studies	3[42,229,233]	68/915	88/918	0.77 [0.57 to 1.04]; 0%	
Preterm delivery, Continued.	• Removing studies with minimal intervention in UC/nonVHDI	3[42,226,229]	51/626	64/607	0.78 [0.55 to 1.10]; 0%	

Appendix D Table 10. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Pregnancy Outcomes (KQ6)

Outcome	Comparisons	Number of Studies	#Events/ Treated	#Events/ Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
	• Only blinded studies	1[42]	45/477	53/455	0.81 [0.56 to 1.18]; NA	
	Subgroup: Hispanic vs Non-Hispanic white (Berggren 2012, secondary analysis of Landon 2009)	1[234]	Hispanic: 24/274 Non-Hispanic white: 14/123	Hispanic: 23/255 Non-Hispanic white: 14/116	Hispanic: 0.97 [0.56 to 1.68]; NA Non-Hispanic white: 0.94 [0.47 to 1.89]; NA Subgroup effect: p=0.95	
Maternal birth trauma	All studies	2[41,226]	255/540	255/560	1.04 [0.92 to 1.18]; 0%	
	• Only blinded study/without OGTT-ve	1[41]	255/490	254/510	1.04 [0.93 to 1.18]; NA	
Long-term maternal development of metabolic impairment (Impaired fasting glucose)	All studies	1[238]	66/243	54/214	1.08 [0.79 to 1.47]; NA	
Long-term maternal development of T2DM (5-10 years)	All studies	1[238]	21/243	17/214	1.09 [0.59 to 2.01]; NA	
Long-term maternal development of metabolic syndrome (5-10 years)	All studies	1[238]	73/243	69/214	0.93 [0.71 to 1.22]; NA After adjustment for race-ethnicity and time since diagnosis: 0.95 [0.73 to 1.25]	
Long-term maternal obesity (≥30kg/m^2)	All studies	1[238]	98/243	79/214	1.09 [0.87 to 1.38]; NA	

Abbreviations: CC = Carpenter Coustan; CCT = controlled clinical trial; CI = confidence interval; GDM = gestational diabetes mellitus; NA = not applicable; NDDG = National Diabetes Data Group; OGTT = oral glucose tolerance test; UC = usual care; VHDI = very high development index; wGA = weeks' gestational age; -ve = negative

Appendix D Table 11. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Fetal/Neonatal Outcomes (KQ6)

Outcome	Comparison	Number of studies	#Events/ # Treated	# Events/ #Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Mortality	All studies	2	4/845	9/885	Peto OR 0.49 [0.16 to 1.45]; 68%	
Birth injury	All studies	3	3/1015	10/1013	Peto OR 0.33 [0.11, 0.99]	-0.002 [-0.006 to -0.002]
Shoulder dystocia	All studies	3	15/1017	36/1027	0.42 [0.23 to 0.77]; 0%	-0.013 [-0.043 to 0.016]
	• Removing OGTT-ve studies	2	14/982	34/979	0.41 [0.22 to 0.76]; 0%	-0.013 [-0.045 to 0.019]
	• Removing studies with minimal intervention in UC/no blinding/nonVHDI	2[41,42]	14/982	34/979	0.41 [0.22 to 0.76]; 0%	-0.020 [-0.034 to -0.007]
	• Removing nonVHDI studies	3[41,42,221]	15/1017	36/1027	0.42 [0.23 to 0.77]; 0%	-0.020 [-0.033 to -0.007]
	Subgroup: Meeting NDDG vs meeting CC criteria (Harper 2016, secondary analysis of Landon, 2009)	1[236]	NDDG: 5/280 CC: 2/196	NDDG: 15/262 CC: 3/193	NDDG: 0.31 [0.11 to 0.85]; NA CC: 0.66 [0.11 to 3.89]; NA Subgroup effect: 0.47	NDDG: -0.039 [-0.072 to -0.007]
Macrosomia >4000g	All studies	8[41,42,221-223,226,229,233]	164/1805	330/1839	0.53 [0.41 to 0.68]; 42%	-0.089 [-0.120 to -0.059]
	• Profile likelihood	8[41,42,221-223,226,229,233]	164/1805	330/1839	0.53 [0.40 to 0.67]; 15%	
	• Removing OGTT-ve studies	5[41,42,223,229,233]	154/1570	292/1591	0.56 [0.43 to 0.71]; 43%	-0.084 [-0.109 to -0.059]
	• Removing studies with minimal intervention in UC	5[41,42,222,226,229]	101/1282	227/1280	0.46 [0.37 to 0.57]; 0%	-0.095 [-0.123 to -0.066]
	• Removing studies with some early treatment	7[41,42,221,223,226,229,233]	156/1655	314/1689	0.53 [0.39 to 0.71]; 42%	-0.096 [-0.130 to -0.062]
	• Removing nonVHDI studies	7[41,42,221-223,226,229]	126/1466	267/1478	0.50 [0.36 to 0.68]; 45%	-0.096 [-0.131 to -0.060]
	• Only blinded studies	2[41,42]	77/983	175/978	0.44 [0.34 to 0.57]; 0%	-0.097 [-0.126 to -0.068]

Appendix D Table 11. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Fetal/Neonatal Outcomes (KQ6)

Outcome	Comparison	Number of studies	#Events/ # Treated	# Events/ #Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Macrosomia >4000g, Continued.	• Removed Bevier (macrosomia or LGA)	7[41,42,222,223,226,229,233]	163/1770	318/1791	0.54 [0.42, 0.69]; 38%	-0.083 [-0.109 to -0.057]
	Subgroup: Hispanic vs non-Hispanic white (Berggren 2012-secondary analysis of Landon 2009)	1[234]	Hispanic: 20/274 Non-Hispanic white: 5/123	Hispanic: 40/255 Non-Hispanic white: 17/116	Hispanic: 0.47 [0.28 to 0.77] Non-Hispanic White: 0.28 [0.11 to 0.73] Subgroup effect: p=0.35	Hispanic: -0.084 [-0.138 to -0.030] Non-Hispanic White: -0.106 [-0.179 to -0.033]
	Subgroup: Meeting NDDG versus meeting CC criteria (Harper 2016, secondary analysis of Landon, 2009)	1[236]	NDDG: 16/281 CC: 12/196	NDDG: 41/261 CC: 24/193	NDDG: 0.36 [0.21 to 0.63]; NA CC: 0.49 [0.25 to 0.96]; NA Subgroup effect: 0.49	NDDG: -0.10 [-0.152 to -0.048] CC: -0.063 [-0.121 to -0.0057]
Macrosomia >4500g	All studies	3[223,227,233]	16/521	23/545	0.72 [0.39 to 1.35]; 0%	
	• Removing studies with minimal intervention in UC and no blinding	1[227]	3/33	7/34	0.44 [0.12 to 1.56]; NA	
	• Removing studies with some early treatment	2[223,233]	13/488	16/511	0.85 [0.41 to 1.75]; 0%	
	• Removing nonVHDI studies	2[223,227]	9/182	13/184	0.70 [0.31 to 1.62]; 0%	
Large for gestational age	All studies	7[41,42,222,226,227,229,233]	174/1654	322/1675	0.56 [0.47 to 0.66]; 0%	-0.084 [-0.108 to -0.061]
	• Removing OGTT-ve studies	5[41,42,227,229,233]	163/1454	290/1475	0.58 [0.48 to 0.69]; 0%	-0.081 [-0.106 to -0.056]
	• Removing studies with minimal intervention in UC and nonVHDI	6[41,42,222,226,227,229]	130/1315	250/1314	0.53 [0.44 to 0.65]; 0%	-0.088 [-0.114 to -0.062]
	• Removing studies with some early treatment	5[41,42,226,229,233]	158/1471	285/1491	0.57 [0.48 to 0.69]; 0%	-0.083 [-0.108 to -0.058]
	• Only blinded studies	3[41,42,227]	109/1016	197/1012	0.56 [0.45 to 0.69]; 0%	-0.085 [-0.124 to -0.046]
	Subgroup: gestational age at		24-26 wGA: 8/69 27 wGA: 5/77	24-26 wGA: 6/43	24-26 wGA: 0.83 [0.31 to 2.23]; NA	≥30 wGA: -0.104 [-0.177 to -0.031]

Appendix D Table 11. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Fetal/Neonatal Outcomes (KQ6)

Outcome	Comparison	Number of studies	#Events/ # Treated	# Events/ #Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Large for gestational age, Continued.	timing of treatment	1[237]	28 wGA: 8/103 29 wGA: 7/109 ≥30 wGA: 6/120	27 wGA: 12/88 28 wGA: 14/86 29 wGA: 14/107 ≥30 wGA: 20/130	27 wGA: 0.48 [0.18 to 1.29]; NA 28 wGA: 0.48 [0.21 to 1.08]; NA 29 wGA: 0.49 [0.21 to 1.17]; NA ≥30 wGA: 0.33 [0.14 to 0.78]; NA Subgroup effect: p=0.75	
	Subgroup: BMI category	1[235]	<25kg/m^2: 1/73 25-29.9 kg/m^2: 11/187 30-34.9 kg/m^2: 13/153 35-39.9 kg/m^2: 4/53 ≥40 kg/m^2: 4/19	<25kg/m^2: 2/70 25-29.9 kg/m^2: 22/181 30-34.9 kg/m^2: 30/151 35-39.9 kg/m^2: 13/57 ≥40 kg/m^2: 3/20	<25kg/m^2: 0.48 [0.04 to 5.17]; NA 25-29.9 kg/m^2: 0.48 [0.24 to 0.97]; NA 30-34.9 kg/m^2: 0.43 [0.23 to 0.79]; NA 35-39.9 kg/m^2: ≥40 kg/m^2: 0.33 [0.12 to 0.95]; NA ≥40 kg/m^2: 1.40 [0.6 to 5.46] Subgroup effect: p=0.56	25-29.9 kg/m^2: -0.063 [-0.121 to -0.004] 30-34.9 kg/m^2: -0.114 [-0.191 to -0.036] 35-39.9 kg/m^2: -0.153 [-0.283 to -0.023]
	Subgroup: Hispanic vs Non-Hispanic white	1[234]	Hispanic: 22/274 Non-Hispanic white: 6/123	Hispanic: 38/255 Non-Hispanic white: 16/116	Hispanic: 0.54 [0.33 to 0.89]; NA Non-Hispanic white: 0.35 [0.14 to 0.87]; NA Subgroup effect: p=0.42	Hispanic: -0.069 [-0.123 to -0.015] Non-Hispanic white: -0.089 [-0.163 to -0.016]
	Subgroup: meeting NDDG versus meeting CC criteria	1[236]	NDDG: 17/281 CC: 17/196	NDDG: 41/261 CC: 25/193	NDDG: 0.39 [0.22 to 0.66]; NA CC: 0.67 [0.37 to 1.20]; NA Subgroup effect: p=0.17	NDDG: -0.097 [-0.149 to -0.044]
NICU admissions	All studies	5[42,222,226,227,229]	63/809	84/791	0.73 [0.53 to 0.99]; 0%	-0.020 [-0.045, 0.0051]
	• Removing OGTT-ve studies	3[42,227,229]	50/609	61/591	0.79 [0.55 to 1.13]; 0%	-0.018 [-0.050 to 0.013]

Appendix D Table 11. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Fetal/Neonatal Outcomes (KQ6)

Outcome	Comparison	Number of studies	#Events/ # Treated	# Events/ #Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
NICU admissions, Continued.	• Removing studies with some early treatment	3[42,226,229]	57/626	76/607	0.72 [0.52 to 1.00]; 0%	
	• Only blinded studies	2[42,227]	44/510	54/489	0.78 [0.53 to 1.14]	
	Subgroup: gestational age at timing of treatment	1[237]	24-26 wGA: 10/69 27 wGA: 9/77 28 wGA: 7/101 29 wGA: 9/108 ≥30 wGA: 8/119	24-26 wGA: 7/43 27 wGA: 13/89 28 wGA: 12/87 29 wGA: 13/107 ≥30 wGA: 8/129	24-26 wGA: 0.89 [0.37 to 2.16]; NA 27 wGA: 0.80 [0.36 to, 1.77]; NA 28 wGA: 0.50 [0.21 to 1.22]; NA 29 wGA: 0.69 [0.31 to 1.54]; NA ≥30 wGA: 1.08 [0.42 to 2.80]; NA Subgroup effect: p=0.81	
	Subgroup: Hispanic vs Non-Hispanic white	1[234]	Hispanic: 20/274 Non-Hispanic white: 8/123	Hispanic: 21/255 Non-Hispanic white: 13/116	Hispanic: 0.89 [0.49 to 1.60]; NA Non-Hispanic white: 0.58 [0.25 to 1.35]; NA Subgroup effect: p=0.42	
Respiratory distress syndrome	All studies (both VHDI, both with Tx initiation mid-pregnancy)	2[41,42]	36/983	32/979	1.05 [0.48 to 2.28]; 58%	
	• Profile likelihood	[41,42]	36/983	32/979	1.13 [0.39 to 2.56]; 5%	
Any Hypoglycemia	All studies	5[42,222,223,229,233]	91/1118	80/1120	1.10 [0.83 to 1.45]; 0%	
	• Removing OGTT-ve studies and with early treatment	4[42,223,229,233]	86/968	74/970	1.12 [0.83 to 1.49]; 0%	
	• Removing studies with minimal intervention in UC	3[42,222,229]	68/630	63/609	1.02 [0.75 to 1.41]; 0%	
	• Removing nonVHDI studies	4[42,222,223,229]	89/779	76/759	1.12 [0.84 to 1.49]; 0%	

Appendix D Table 11. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM at 24 Weeks' Gestation or Later, Fetal/Neonatal Outcomes (KQ6)

Outcome	Comparison	Number of studies	#Events/ # Treated	# Events/ #Untreated	Relative Risk [95% CI]; I^2 (unless stated otherwise)	Absolute Risk Difference [95% CI]
Any Hypoglycemia, Continued.	• Only blinded studies	1[42]	62/381	55/357	1.06 [0.76 to 1.47]; NA	
	• Removing study without definition of outcome	4[42,222,229,233]	70/969	67/970	1.00 [0.73 to 1.37]; 0%	
	Subgroup: Hispanic vs Non-Hispanic white	1[234]	Hispanic: 34/274	Hispanic: 30/255	Hispanic: 1.05 [0.67 to 1.67]; NA	
			Non-Hispanic white: 15/123	Non-Hispanic white: 13/116	Non-Hispanic white: 1.09 [0.54 to 2.19]; NA Subgroup effect: p=0.94	
Hyperbilirubinemia	All studies (all VHDI)	5[41,42,222,223,227]	101/1288	119/1276	0.84 [0.65 to 1.08]; 0%	
	• Removing OGTT-ve studies	4[41,42,223,227]	95/1138	115/1126	0.82 [0.63, 1.06]; 0%	
	• Removing studies with minimal intervention in UC	4[41,42,222,227]	93/1139	109/1126	0.84 [0.65 to 1.10]; 0%	
	• Removing studies with some early treatment	3[41,42,223]	95/1105	112/1092	0.83 [0.64, 1.08]; 05	
	• Only blinded studies	2[41,42,227]	87/956	102/942	0.83 [0.64 to 1.09]; 0%	
	Subgroup: Hispanic vs Non-Hispanic white	1[234]	Hispanic: 27/274 Non-Hispanic white: 11/123	Hispanic: 31/255 Non-Hispanic white: 12/116	Hispanic: 0.81 [0.50 to 1.32]; NA Non-Hispanic white: 0.86 [0.40 to 1.88]; NA Subgroup effect: p=0.89	
APGAR score <7 at 1 minute	All studies	1[233]	0/339	7/361	0.07 [0.00 to 1.24]; NA	
APGAR score <7 at 5 minutes	All studies	2	9/605	15/626	0.62 [0.27 to 1.41]; 0%	
	• Only blinded studies	1[41]	6/506	11/524	0.56 [0.21 to 1.52]; NA	

Abbreviations: BMI = body mass index; CC = Carpenter Coustan; CI = confidence interval; g = grams; GDM = gestational diabetes mellitus; NA = not applicable; NDDG = National Diabetes Data Group; OGTT = oral glucose tolerance test; UC = usual care; -ve = negative

Appendix D Table 12. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM in Early Pregnancy, Pregnancy Outcomes (KQ6)

Outcome	Comparison	Number of studies	Number of events and patients (n/N) Early treated	Number of events and patients (n/N) Usual care	Relative Effects [95% CI]; I^2	Absolute risk difference [95% CI]
Preeclampsia	All studies	3[228,230,232]	4/109	8/120	0.69 [0.21, 2.23]; 0%	
	Removing CCT	2[228,230]	2/73	5/66	0.47 [0.07, 2.92]; 19%	
Gestational hypertension	All studies	2[230,232]	7/74	12/90	0.75 [0.31, 1.84]; 0%	
	Removing CCT	1[230]	3/38	3/36	0.95 [0.20, 4.39]; NA	
Hypertensive disorders of pregnancy	All studies	3[230-232]	14/85	17/99	0.92 [0.46, 1.81]; 0%	
	Removing CCT	2[230,231]	8/49	5/45	1.49 [0.31, 7.19]; 30%	
Cesarean delivery	All studies	4[228,230-232]	34/107	41/121	0.91 [0.56, 1.48]; 35%	
	Removing CCT	3[228,230,231]	22/71	29/67	0.72 [0.46, 1.13]; 0%	
	Subgroup: Obese vs non-obese	1[230]	≥30kg/m^2: 3/11 <30kg/m^2: 8/26	≥30kg/m^2: 10/16 <30kg/m^2: 7/21	≥30kg/m^2: 0.44 [0.15, 1.23]; NA <30kg/m^2: 0.92 [0.40, 2.13]; NA Subgroup effect: p=0.27	
Primary cesarean delivery	All studies	1[230]	5/37	10/37	0.50 [0.19, 1.32]; NA	
	Subgroup: Obese vs non-obese	1[230]	≥30kg/m^2: 0/11 <30kg/m^2: 5/26	≥30kg/m^2: 5/16 <30kg/m^2: 5/21	≥30kg/m^2: 0.13 [0.01, 2.12]; NA <30kg/m^2: 0.81 [0.27, 2.42]; NA Subgroup effect: p=0.23	
Emergency cesarean delivery	All studies	3[228,231,232]	12/70	16/84	0.81 [0.37, 1.78]; 11%	
	Removing CCT	2[228,231]	8/34	7/30	1.14 [0.23, 5.74]; 52%	
Induction of Labor	All studies	3[228,230,231]	33/71	27/67	1.12 [0.76, 1.67]; 3%	
	Subgroup: Obese vs non-obese	1[230]	≥30kg/m^2: 6/11 <30kg/m^2: 10/26	≥30kg/m^2: 5/16 <30kg/m^2: 8/21	≥30kg/m^2: 1.75 [0.71, 4.32]; NA <30kg/m^2: 1.01 [0.49, 2.10]; NA Subgroup effect: p=0.36	
Preterm delivery	All studies Removing CCT	2[228,232] 1[228]	3/59 1/23	3/75 1/21	1.27 [0.27, 6.07]; 0% 0.91 [0.06, 13.69]; NA	
Excessive gestational weight gain	All studies	2[230,232]	15/70	31/89	0.65 [0.37, 1.15]; 6%	
	Removing CCT	1[230]	6/35	6/36	1.03 [0.37, 2.89]; NA	

Abbreviations: CCT = controlled clinical trial; GDM = gestational diabetes mellitus; kg/m^2 = kilograms per meter squared; NA = not applicable

Appendix D Table 13. Supplemental Analysis Including Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM in Early Pregnancy, Fetal/Neonatal Outcomes (KQ6)

Outcome	Comparison	Number of Studies	Number of Events and Patients (n/N) Early treated	Number of Events and Patients (n/N) Usual care	Relative Effects [95% CI]; I^2 (RR unless otherwise)	Absolute Risk Difference [95% CI]
Mortality	All studies	3[228,230,231]	0/71	2/67	Peto OR 0.12 [0.01 to 1.95]	
Birth injury	All studies	1[228]	0/23	0/21	Not estimable	
Shoulder dystocia	All studies	3[228,231,232]	0/70	2/84	Peto OR 0.11 [0.00 to 5.57	
Macrosomia >4000g	All studies	2[230,232]	15/73	21/91	0.89 [0.33, 2.42]; 42%	
	• Profile likelihood	2[230,232]	15/73	21/91	1.08 [0.27 to 2.23]; 0%	
	• Removing CCT	1[230]	2/37	5/37	0.40 [0.08, 1.93]; NA	
	Subgroup: Obese vs non-obese	1[230]	≥30kg/m^2: 0/11 <30kg/m^2: 2/26	≥30kg/m^2: 2/16 <30kg/m^2: 3/21	≥30kg/m^2: 0.28 [0.01, 5.39]; NA <30kg/m^2: 0.54 [0.10, 2.93] Subgroup effect: p=0.71	
Macrosomia >4500g	All studies (CCT)	1[232]	0/36	3/54	0.21 [0.01, 3.99]; NA	
Large for gestational age	All studies	3[228,231,232]	8/70	13/84	0.68 [0.18, 2.54]; 35%	
	• Removing CCT	2[228,231]	1/34	5/30	0.27 [0.04, 1.61]; 0%	
NICU admissions	All studies	3[228,231,232]	10/70	12/84	0.98 [0.28, 3.43]; 29%	
	• Removing CCT	2[228,231]	5/34	2/30	1.66 [0.10, 27.18]; 58%	
Any Hypoglycemia	All studies	3[228,230,231]	10/63	6/60	1.77 [0.62, 5.03]; 0%	
Hyperbilirubinemia	All studies	2[228,230]	10/59	6/57	1.57 [0.65 to 3.82]; 0%	

Abbreviations: CCT = controlled clinical trial; CI = confidence interval; g = grams; kg/m^2 =kilograms per meter squared; NA = not applicable; NICU = neonatal intensive care unit; OGTT = oral glucose tolerance test; OR = odds ratio; RR = relative risk; VHDI = Very High Development Index country

Appendix D Table 14. Supplemental Analysis With Subgroup Analysis, From Trials of Treatment vs. No Treatment for GDM in Early Pregnancy, Harms (KQ7)

Outcome	Comparison	Number of Studies	Number of Events and Patients (n/N) Intervention Treated	Number of Events and Patients (n/N) Intervention Untreated	Relative Effects (RR) [95% CI]; I^2	Absolute Risk Difference [95% CI]
Small for gestational age	All studies	6[41,42,221,222,226,229]	92/1317	84/1329	1.10 [0.83 to 1.47]; 0%	
	• Removing OGTT-ve studies	3[41,42,229]	71/1082	70/1081	1.01 [0.73, 1.39]; 0%	
	• Removing studies with minimal intervention in UC	5[41,42,222,226,229]	89/1282	82/1281	1.08 [0.81, 1.45]; 0%	
	• Removing studies with some early treatment	5[41,42,221,226,229]	79/1167	75/1179	1.06 [0.78, 1.44]; 0%	
	• Only blinded studies	2[41,42]	69/983	67/979	1.03 [0.74 to 1.42]; 0%	
	Subgroup: Hispanic vs Non-Hispanic white	1[234]	Hispanic: 20/274 Non-Hispanic white: 10/123	Hispanic: 13/255 Non-Hispanic white: 9/116	Hispanic: 1.43 [0.73 to 2.82]; NA Non-Hispanic white: 1.05 [0.44 to 2.49]; NA Subgroup effect: p=0.58	
	Subgroup: meeting NDDG versus meeting CC criteria	1	NDDG: 22/381 CC: 14/196	NDDG: 17/261 CC: 12/193	NDDG: 1.20 [0.65 to 2.21]; NA CC: 1.15 [0.55 to 2.42]; NA Subgroup effect: p=0.93	
Low birthweight	All studies	1[233]	14/339	14/361	1.06 [0.52 to 2.20]; NA	
Severe Hypoglycemia	All studies	3[41,42,227]	60/1014	58/1013	1.02 [0.60 to 1.76]; 58%	

Abbreviations: CC = Carpenter Coustan; CI = confidence interval; NA = not applicable; NDDG = National Diabetes Data Group; OGTT = oral glucose tolerance test; RR = relative risk; UC = usual care

Appendix D Table 15. Comparisons of Findings for Total and Primary Cesarean Deliveries and Macrosomia From GDM Treatment Trials (KQ7)

Timing of treatment	Author, Year; Sample Size	Total and Primary Cesarean Delivery Rates, % (events/N) and Relative Risk [95% CI] Treated	Total and Primary Cesarean Delivery Rates, % (events/N) and Relative Risk [95% CI] Untreated	Total and Primary Cesarean Delivery Rates, % (events/N) and Relative Risk [95% CI] RR	Macrosomia (>4,000 g) Rate (unless otherwise noted), % (events/N) and Relative Risk [95% CI] Treated	Macrosomia (>4,000 g) Rate (unless otherwise noted), % (events/N) and Relative Risk [95% CI] Untreated	Macrosomia (>4,000 g) Rate (unless otherwise noted), % (events/N) and Relative Risk [95% CI] RR
Treatment at >24 weeks' gestation	Bevier, 1999[221]; 83	14.3% (5/35) 8.6% (3/35)	25.0% (12/48) 6.3% (3/48)	0.57 [0.22 to 1.47] 1.37 [0.29 to 6.40]	2.9% (1/35)	25.0% (12/48)	0.11 [0.02 to 0.84]
	Bonomo, 2005[222]; 300	29.0% (44/150)	28.0% (42/150)	1.05 [0.73 to 1.50]	5.3% (8/150)	10.7% (16/150)	0.50 [0.22 to 1.13]
	Crowther, 2005[41]; 1000	31.0% (152/490)	32.0% (164/510)	0.96 [0.80 to 1.16]	10.0% (49/506)	21.0% (110/524)	0.46 [0.34 to 0.63]
	Garner, 1997[223]; 299	20.1% (30/149)	18.6% (28/150)	1.08 [0.68 to 1.71]	16.1% (24/149)	18.7% (28/150)	0.86 [0.53 to 1.42]
	Landon, 2009[42]; 931	26.9% (128/476) 13.0% (62/476)	33.8% (154/455) 19.8% (90/455)	0.79 [0.65 to 0.97] 0.66 [0.49 to 0.89]	5.9% (28/477)	14.3% (65/454)	0.41 [0.27 to 0.63]
	Deveer, 2013[226]; 100	NR 32% (16/50)	NR 40% (20/50)	0.80 [0.47 to 1.36]	2.0% (1/50)	20.0% (10/50)	0.10 [0.01 to 0.75]
	Fadl, 2015[227]; 69	21.2% (7/33)	22.2% (8/36)	0.95 [0.39 to 2.34]	>4,500g: 9.1% (3/33)	>4,500 g: 20.6% (7/34)	0.44 [0.12 to 1.56]*
	Kokanali, 2014[229]; 201	33.3% (33/99)	42.2% (43/102)	0.79 [0.55 to 1.13]	15.1% (15/99)	25.5% (26/102)	0.59 [0.34 to 1.05]
	Yang, 2014[233]; 700	70.5% (239/339)	64.5% (233/361)	1.09 [0.99 to 1.21]	11.2% (38/339)	17.5% (63/361)	0.64 [0.44 to 0.93]
	Pooled estimate			Total cesarean: 0.95 [0.83, 1.08] Primary: 0.70 [0.54 to 0.91]			0.53 [0.41 to 0.68]
Early Treatment	Vinter 2018[232]; 90	33.3% (12/36)	22.2% (12/54)	1.50 [0.76 to 2.96]	36% (13/36)	30% (16/54)	1.22 [0.67 to 2.22]
	Osmundson, 2016[230]; 74	29.7% (11/37) 13.5% (5/37)	46.0% (17/37) 27% (10/37)	0.65 [0.35 to 1.19] 0.50 [0.19 to 1.32]	5.4% (2/37)	13.5% (5/37)	0.40 [0.08 to 1.93]
	Hughes 2016[228]; 44	26.1% (6/23)	42.8% (9/21)	0.61 [0.26 to 1.42]	LGA: 4.3% (1/23)	LGA: 9.5% (2/21)	0.46 [0.04 to 4.68]

Appendix D Table 15. Comparisons of Findings for Total and Primary Cesarean Deliveries and Macrosomia From GDM Treatment Trials (KQ7)

Timing of treatment	Author, Year; Sample Size	Total and Primary Cesarean Delivery Rates, % (events/N) and Relative Risk [95% CI] Treated	Total and Primary Cesarean Delivery Rates, % (events/N) and Relative Risk [95% CI] Untreated	Total and Primary Cesarean Delivery Rates, % (events/N) and Relative Risk [95% CI] RR	Macrosomia (>4,000 g) Rate (unless otherwise noted), % (events/N) and Relative Risk [95% CI] Treated	Macrosomia (>4,000 g) Rate (unless otherwise noted), % (events/N) and Relative Risk [95% CI] Untreated	Macrosomia (>4,000 g) Rate (unless otherwise noted), % (events/N) and Relative Risk [95% CI] RR
Early Treatment, Continued.	Simmons 2018[231]; 20	5/11	3/9	1.36 [0.44 to 4.21]	LGA: 0% (0/11)	LGA: 33.3% (3/9)	0.12 [0.01 to 2.04]
	Pooled estimate			Total cesarean: 0.91 [0.56 to 1.48] Primary cesarean: NA			Macrosomia: 0.89 [0.33 to 2.42] LGA: 0.27 [0.04 to 1.61]

Abbreviations: CI = confidence interval; g = grams; LGA =large for gestational age; NR=not reported; RR = relative risk

Appendix D Table 16. Relationship Between Predictive Values and Prevalence of GDM for 50 g OGCT Test Accuracy

Screening Test	Prevalence	Positive Predictive Value	Negative Predictive Value
50 g OGCT ≥140 mg/dL by CC 1982 Sensitivity=82%; Specificity=82%	7%	26%	98%
	15%	45%	96%
	25%	60%	93%
50 g OGCT ≥135 mg/dL by CC 1982 Sensitivity=93%; Specificity=79%	7%	25%	99%
	15%	44%	98%
	25%	60%	97%
50 g OGCT ≥130 mg/dL by CC 1982 Sensitivity=90%; Specificity=81% (median)	7%	26%	99%
	15%	46%	98%
	25%	61%	96%
50 g OGCT ≥140 mg/dL by IADPSG 2010 Sensitivity=48%; Specificity=87% (median)	7%	22%	96%
	15%	39%	90%
	25%	55%	83%
50 g OGCT ≥135 mg/dL by IADPSG 2010 Sensitivity=53%; Specificity=82% (median)	7%	18%	96%
	15%	34%	91%
	25%	50%	84%
50 g OGCT ≥130 mg/dL by IADPSG 2010 Sensitivity=60%; Specificity=77% (median)	7%	16%	96%
	15%	32%	92%
	25%	47%	85%
50 g OGCT ≥140 mg/dL by NDDG 1979 Sensitivity=85%; Specificity=81%	7%	25%	99%
	15%	44%	97%
	25%	60%	94%
50 g OGCT ≥135 mg/dL by NDDG 1979 Sensitivity=84%; Specificity=65% (median)	7%	15%	98%
	15%	30%	96%
	25%	44%	92%
50 g OGCT ≥130 mg/dL by NDDG 1979 Sensitivity=91%; Specificity=79%	7%	25%	99%
	15%	43%	98%
	25%	59%	96%
50 g OGCT ≥140 mg/dL by Sacks 1989 Sensitivity=82%; Specificity=88%	7%	34%	98%
	15%	55%	97%
	25%	69%	94%
50 g OGCT ≥135 mg/dL by Sacks 1989 Sensitivity=84%; Specificity=87%	7%	33%	99%
	15%	53%	97%
50 g OGCT ≥135 mg/dL by Sacks 1989, Continued.	25%	68%	94%
50 g OGCT ≥130 mg/dL by Sacks 1989 Sensitivity=89%; Specificity=92%	7%	27%	99%
	15%	47%	98%
	25%	62%	96%

Abbreviations: CC = Carpenter Coustan; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes and Pregnancy Study Group**;** NDDG = National Diabetes Data Group; OGCT = oral glucose challenge test

Appendix D Table 17. Relationship Between Predictive Values and Prevalence of GDM for Fasting Plasma Glucose Screening Tests

Screening Test	Prevalence	Positive Predictive Value	Negative Predictive Value
FPG ≥76 mg/dL by CC 1982 Sensitivity=median 98%; Specificity=median 17%	7%	8%	99%
	15%	17%	98%
	25%	28%	97%
FPG ≥79 mg/dL by CC 1982 Sensitivity=96%; Specificity=35%	7%	10%	99%
	15%	21%	98%
	25%	33%	96%
FPG ≥80 mg/dL by CC 1982 Sensitivity=median 90%; Specificity=median 72%	7%	20%	99%
	15%	36%	98%
	25%	52%	96%
FPG ≥85 mg/dL by CC 1982 Sensitivity=88%; Specificity=73%	7%	20%	99%
	15%	37%	97%
	25%	52%	95%
FPG ≥86 mg/dL by CC 1982 Sensitivity=median 80%; Specificity=median 76%	7%	20%	98%
	15%	37%	96%
	25%	53%	92%
FPG ≥90 mg/dL by CC 1982 Sensitivity=81%; Specificity=82%	7%	25%	98%
	15%	44%	96%
	25%	60%	93%
FPG ≥92 mg/dL by CC 1982 Sensitivity=median 67%; Specificity=median 90%	7%	33%	97%
	15%	54%	94%
	25%	69%	89%
FPG ≥95.5 mg/dL by CC 1982 Sensitivity=58%; Specificity=98%	7%	69%	97%
	15%	84%	93%
	25%	91%	88%
FPG ≥76 mg/dL by IADPSG 2010 Sensitivity=median 96%; Specificity=median 27%	7%	9%	99%
	15%	19%	97%
	25%	30%	95%
FPG ≥77.5 mg/dL by IADPSG 2010 Sensitivity=median 93%; Specificity=median 40%	7%	10%	99%
	15%	21%	97%
	25%	34%	95%
FPG ≥79 mg/dL by IADPSG 2010 Sensitivity=median 93% Specificity=median 56%	7%	14%	99%
	15%	27%	98%
	25%	41%	96%
FPG ≥83 mg/dL by IADPSG 2010 Sensitivity=median 87%; Specificity=median 67%	7%	17%	99%
	15%	32%	97%
	25%	47%	94%
FPG ≥85 mg/dL by IADPSG 2010 Sensitivity=median 82%; Specificity=median 78%	7%	22%	98%
	15%	40%	96%
	25%	56%	93%
FPG ≥86.5 mg/dL by IADPSG 2010 Sensitivity=median 80%; Specificity=median 85%	7%	28%	98%
	15%	48%	96%
	25%	63%	93%
FPG ≥90 mg/dL by IADPSG 2010 Sensitivity=79%; Specificity=96%	7%	60%	98%
	15%	78%	96%
	25%	87%	93%

Abbreviations: CC = Carpenter Coustan; FPG = fasting plasma glucose; GDM = gestational diabetes mellitus; IADPSG = International Association of Diabetes in Pregnancy Study Groups