- Gestational Diabetes Gestational Diabetes (GDM) Guideline (2016)

Gestational Diabetes

GDM: Full Recommendations and Supporting Evidence (2016)

Recommendations

Below you will find a list of recommendations in the Gestational Diabetes Mellitus (GDM) Evidence-Based Nutrition Practice Guideline organized by nutrition care process and topic.

The project started with a review of the 2008 recommendations. Selected recommendations were reviewed. The **Summary of Changes 2016** provides an overview of the recommendation revisions and updates.

To see the Recommendation Summary, just click on the Recommendation title. Also view the Executive Summary of Recommendations or print the 2016 guideline in PDF (Link to be Added) format.

Screening and Referral

GDM: Referral to an RDN

Nutrition Assessment

GDM: Nutrition Assessment

GDM: Assessment of Food/Nutrition-related History GDM: Assessment of Anthropometric Measurement GDM: Assessment of Biochemical Data, Medical Tests, and Procedures GDM: Assessment of Nutrition-Focused Physical Findings and Client History

Nutrition Diagnosis

None.

Nutrition Intervention

GDM: Medical Nutrition Therapy

GDM: Medical Nutrition Therapy (MNT) GDM: Frequency and Duration of MNT

GDM: Calories

GDM: Macronutrients

GDM: Macronutrient Requirements GDM: Carbohydrate Prescription GDM: Carbohydrate and Post Prandial Breakfast Glycemia

GDM: Vitamins and Minerals

GDM: Dietary Vitamin and Mineral Intake GDM: Vitamin and Mineral Supplementation

GDM: Meal and Snack Distribution

GDM: High-Intensity Sweeteners

GDM: Alcohol

GDM: Physical Activity

Nutrition Monitoring and Evaluation

GDM: Nutrition Monitoring and Evaluation

<u>Gestational Diabetes</u>
<u>Gestational Diabetes</u> (GDM) Guideline (2016)

Recommendations Summary

GDM: Referral to an RDN 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> Section below. Fvidence

Recommendation(s)

GDM: Referral to an RDN

Pregnant women who are diagnosed with <u>gestational diabetes mellitus</u> (GDM), should be referred to a <u>registered dietitian nutritionist</u> (RDN) for <u>medical nutrition therapy</u> (MNT). Individualized <u>MNT</u> is important in helping pregnant women with <u>GDM</u> achieve and maintain normal glycemic levels and appropriate weight gain, while meeting essential nutrients for pregnancy to promote positive maternal and fetal outcomes.

Rating: Strong Imperative

- Risks/Harms of Implementing This Recommendation
- There are no potential risks or harms associated with the application of this recommendation.
- Conditions of Application
- It is preferable to refer to an RDN who has experience in working with patients who have diabetes or who specialize in diabetes

management [e.g., Certified Diabetes Educator (CDE)].

- Potential Costs Associated with Application
- Costs of MNT sessions and reimbursement vary. However, MNT is essential for improved outcomes.
- Recommendation Narrative

The recommendation *GDM*: *Referral of Women with GDM to an RDN* is based on the American Diabetes Association's (ADA) Standards of Medical Care in Diabetes 2016 and the Endocrine Society's *Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline* (Blumer et al, 2013) provide support for the recommendation as follows:

- In Management of Diabetes in Pregnancy, the ADA makes the following clinical practice recommendation for women with <u>gestational diabetes mellitus</u> (GDM) (ADA 2016):

 "Lifestyle change is an essential component of management of <u>GDM</u> and may suffice for treatment for many women. Medications should be added if needed to achieve glycemic targets. Rating: Level of Evidence: A"

 Summary of support for the recommendation:

 "After diagnosis, treatment starts with <u>MNT</u>, <u>physical activity</u> and weight management depending on pregestational weight and glucose monitoring aiming for the targets recommended by the Fifth International Workshop-Conference on GDM."
 "CDM is characterized by increased rick of margregomia and bitth complications and an increased rick."
 - "GDM is characterized by increased risk of <u>macrosomia</u> and birth complications and an increased risk of maternal diabetes after pregnancy. Although there is some heterogeneity, many <u>randomized</u> <u>controlled trials</u> suggest that the risk of GDM may be reduced by diet, exercise, and lifestyle •

counseling The Endocrine Society's *Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline* (Blumer et al, 2013) make the following recommendations:

• Management of Elevated Blood Glucose

• "2.3b. We recommend that the initial treatment of gestational diabetes should consist of <u>MNT</u> and daily moderate exercise for 30 minutes or more. Rating: 1/+++ (Strong recommendation / Moderate quality evidence)"

- exercise for 30 minutes or more. Rating: 1/+++ (Strong recommendation / Moderate quality evidence)"
 Summary of support for the recommendation:

 "Lifestyle therapy for GDM results in a lower incidence of reduced birth weight, <u>large-for-gestational-age</u> births, and preeclampsia. Both aerobic exercise and non-weight-bearing exercise have been shown to lower blood glucose levels in women with gestational diabetes."
 Nutrition therapy and weight gain targets for women with overt or gestational diabetes
 "4.1. "We recommend medical nutrition therapy for all pregnant women with overt or gestational diabetes to help achieve and maintain desired glycemic control while providing essential nutrient requirements. Rating: 1/++ (Strong recommendation / Low quality evidence)"
 Summary of support for the recommendation:

 "Although nutrition intervention for overt diabetes and GDM is a fundamental treatment modality, there is a paucity of evidence-based data on this topic. Nevertheless, nutrition therapy has been shown to improve glycemic control for people living with overt diabetes and for women with GDM."
- Recommendation Strength Rationale

This topic was not included in the <u>EAL systematic review</u>. The Academy of Nutrition and Dietetics and the GDM Expert workgroup concur with the American Diabetes Association's *Standards of Medical Care in Diabetes 2016* recommendaton rating for "Management of Diabetes in Pregnancy (GDM)" and *The Endocrine Society's Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline* recommendation ratings for "Nutrition Therapy and Weight Gain Targets for Women with Overt or GDM" and "Management of Elevated Blood Glucose."

Minority Opinions

None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

References

- <u>References not graded in Academy of Nutrition and Dietetics Evidence Analysis Process</u>

 - American Diabetes Association (ADA). Classification and diagnosis of diabetes. Sec. 2. In Standards of Medical Care in Diabetes 2016. *Diabetes Care* 2016; 39 (Suppl. 1): S13–S22.
 ADA. Management of diabetes in pregnancy. Sec.12. In Standards of Medical Care in Diabetes 2016. *Diabetes Care* 2016; 39 (Suppl. 1): S94–S98.
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<u>Gestational Diabetes</u>
Gestational Diabetes (GDM) Guideline (2016)

Recommendations Summary

GDM: Nutrition Assessment 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> Evidence Section below.

Recommendation(s)

GDM: Assessment of Food/Nutrition-related History of Women with GDM

The <u>registered dietitian nutritionist</u> (RDN) should assess the food and nutrition-related history of women with <u>gestational diabetes mellitus</u> (GDM) including, but not limited to:

- Food, beverage and nutrient intake including:
 - <u>Calorie</u> intake
 Types and amount of <u>carbohydrate</u> (including <u>fiber</u>), fat, <u>protein</u>; with special attention to high calorie, low-nutrient dense foods such as desserts, candy, <u>sugar-sweetened beverages</u>

 - Serving sizes
 Meal and snack patterns, including frequency and duration

 Recent changes

 - Receive Granges
 Preferences, avoidance, intolerances, allergies including:

 In relationship to gastrointestinal discomforts (e.g., nausea, vomiting, heartburn, constipation, ptyalism)
 Reaction to or changes in food tastes/smells related to pregnancy
 - Cultural and religious considerations.
- \odot 2017 Academy of Nutrition and Dietetics (A.N.D.), Evidence Analysis Library. Printed on: 03/30/17 from: http://www.andéal.org

- Appetite and changes in appetite
 Eating environment and meals eaten away from home

Eating environment and meals eaten away from home
Diet history and behavior: previous diets and diet adherence, disordered eating
Factors affecting access to food: Psychosocial/economic issues (e.g., social support) impacting nutrition therapy
Method of food preparation, food safety
Pharmacologic therapy (including insulin or oral glucose-lowering agent)
Substance use: <u>Alcohol</u>, tobacco, caffeine, recreational drugs
Use of <u>dietary supplements</u>, prenatal vitamins, over-the-counter medications, complementary and/or herbal
Knowledge, beliefs or attitudes: Motivation, readiness to change, self-efficacy; willingness and ability to make lifestyle changes
<u>Physical activity</u> and function: Exercise patterns, functionality for activities of daily living, sleep patterns.
Assessment of these factors is needed to effectively determine <u>nutrition diagnoses</u> and formulate a nutrition care plan. Inability to achieve optimal intrake may contribute to poor outcomes. optimal nutrient intake may contribute to poor outcomes.

Rating: Consensus Imperative

GDM: Assessment of Anthropometric Measurement of Women with GDM

The <u>RDN</u> should assess the following anthropometric measurements in women with <u>GDM</u>, including but not limited to:

- Height, current weight, pre-pregnancy weight and <u>body mass index</u> (BMI)
 Weight changes during pregnancy.

Assessment of these factors is needed to effectively determine nutrition diagnoses and formulate a nutrition care plan.

Rating: Consensus

Imperative

GDM: Assessment of Biochemical Data, Medical Tests, and Procedures of Women with GDM

The <u>RDN</u> should evaluate available data of women with <u>GDM</u> and recommend as indicated: Biochemical data, medical tests and procedures including, but not limited to:

- Glycemic tests: Glucose challenge test (GCT), oral glucose tolerance test (OGTT), glycosylated hemoglobin (A1C), fasting glucose,
- rańdom glucose Use of self-monitoring blood glucose (SMBG) meters and urinary ketones, if recommended
 Maternal and fetal testing (e.g., ultrasounds, biophysical profile, non-stress testing)
 Nutritional anemia profile (e.g., hemoglobin, hematocrit, folate, B12, iron)
 Vitamin D and other micronutrient levels, as appropriate

- Thyroid function

Kidney function.
 Assessment of these factors is needed to effectively determine <u>nutrition diagnoses</u> and formulate a nutrition care plan.

Rating: Consensus Imperative

GDM: Assessment of Nutrition-Focused Physical Findings and Client History of Women with GDM

The <u>RDN</u> should evaluate available data regarding the client history and nutrition-focused physical findings of women with <u>GDM</u> including, but not limited to:

Patient/Family/Client Medical/Health history

- Age

- Age
 Single or multiple fetuses
 Weeks of gestation; estimated date of delivery (EDD); method of delivery
 Previous obstetric history including GDM
 Risk factors for developing GDM or diabetes, including family history of diabetes
 General health; vital signs
 Pertinent medical and dental history including other diseases, conditions and illnesses
 Gastrointestinal discomforts: Nausea, vomiting, diarrhea, constipation, heartburn and ptyalism
- <u>Health literacy</u> and numeracy
 Education and occupation

Social history: Psychological/socioeconomic factors (e.g., social support).
 Assessment of these factors is needed to effectively determine <u>nutrition diagnoses</u> and formulate a nutrition care plan.

Rating: Consensus Imperative

• Risks/Harms of Implementing This Recommendation

There are no potential risks or harms associated with the application of these recommendations.

- Conditions of Application

 - <u>RDN</u>s should be appropriately trained to conduct a nutrition-focused physical exam
 If necessary data are not available, the RDN should use professional judgment to request or obtain addition data
 Women who have complicating conditions such as renal disease or eating disorders may require more indepth or specialized nutrition assessments [American Diabetes Association (ADA), 2016]
 RDNs should be alert to psychosocial stressors, such as family and household strain, verbal or physical abuse, exposure to discrimination, <u>food insecurity</u>, unemployment, low resources, major or catastrophic life events and anxiety about the current pregnancy. Such stressors may indicate need for further screening and referral to a mental health professional for early treatment to prevent adverse pregnancy outcomes (Kaiser and Campbell, 2014).
- Potential Costs Associated with Application

Accessibility and costs of additional testing should be considered.

Recommendation Narrative

The purpose of the <u>nutrition assessment</u> is to identify nutrition-related problems, their causes and their significance. Relevant data is verified and interpreted by the <u>RDN</u> through an ongoing, non-linear and dynamic process of collecting data and continual analysis of the patient or client's status, compared to specified criteria (eNCPT, 2016). Nutritional assessment encompasses changes in anthropometric, biochemical and clinical indicators throughout the course of pregnancy (Kaiser and Campbell, 2014). Data are obtained from the patient or client through interview, observation and measurements or may come from the medical record or other health care providers. Nutrition assessment findings are then documented in nutrition diagnosis statements and nutrition intervention goal setting (eNCPT, 2016).

Nutrition assessment is organized under five domains (categories). These are: Food/Nutrition-Related History; Anthropometric Measurements; Biochemical Data, Medical Tests, and Procedures; Nutrition-Focused Physical Findings; Client History (eNCPT, 2016). The last two are combined in the narrative below.

Food or Nutrition-Related History

Food and nutrition-related history pertinent to diabetes and pregnancy include:

- Dietary history includes a thorough review of usual food intake, pattern of intake (timing, meals and snacks) and previous history of diet adherence (ADA, 2013)

- Educational knowledge, such as nutrition and meal-planning skills, barriers to dietary compliance, such as lack of family support, daily schedule or economic issues, etc. (ADA, 2013)
 Macronutrient (especially <u>carbohydrate</u> and <u>fiber</u>) and micronutrient dietary intake (ADA, 2013)
 Vitamin and mineral supplement use (prenatal and non-prenatal) or use of natural remedies, such as herbs or alternative therapies (ADA, 2013)
 Food allergies or intolerances (ADA, 2013)
 Use of alcebel tobacce caffeine or other substances [Joelin Diabetes Captor & Joelin Clinic (Joelin), 2011]

- Use of alcohol, tobacco, caffeine or other substances [Joslin Diabetes Center & Joslin Clinic (Joslin), 2011]
 Medications: Prescription (diabetes-related, non-diabetes-related); over the counter medications (ADA, 2013)
 Screening for other nutrition risks (e.g., eating disorders, pica, adolescence, low literacy, low income, psychosocial issues)
- (Shields and Tsay, 2015) Exercise pattern: Type, frequency, duration [American College of Obstetricians and Gynecologists (ACOG), 2015; Joslin, . 2011]
- Finally, language, cultural background, ethnic or religious beliefs should be taken into consideration (Shields and Tsay, 2015

Anthropométric Measurements

- Anthropometric measurements pertinent to diabetes and pregnancy include:

 Height, weight, weight history, pre-pregnancy weight and <u>BMI</u> should be assessed at the initial visit and weight should be tracked at each visit to determine if the <u>gestational weight gain</u> (GWG) is appropriate (within range), based on IOM revised guidelines for weight gain during pregnancy (IOM, 2009) (Shields and Tsay, 2015; Joslin, 2011; Kaiser and Campbell, 2014)
 While the total amount of weight gained in normal-term pregnancies varies in women (IOM, 2009), the IOM recommends that women achieve <u>GWG</u> within the range identified for their pre-pregnant BMI for singleton or multiple pregnancies, as appropriate (Kaiser and Campbell, 2014; IOM, 2009)
 Inappropriate weight gain (excess or inadequate weight gain) may require further assessment of food and kcal intake and adjustment in the <u>nutrition prescription</u> (ADA, 2016).

 Biochemical Data, Medical Tests and Procedures

- Clinical data related to medical tests pertinent to diabetes and pregnancy include:

 Glycemic tests, including GCT, <u>OGTT</u>, A1c, fasting and random glucose and <u>fasting</u>, pre-prandial, and <u>post-prandial</u> self-monitoring of blood glucose are recommended (ADA, 2016) to determine glycemic control throughout pregnancy (Shields and Tsay, 2015; ACOG, 2013)
 A nutritional anemia profile (hemoglobin/hematocrit, folate, B12, iron) and Vitamin D and other micronutrient screening, as needed help determine if the woman may benefit from additional counseling targeting specific nutrients (Shields and Tsay, 2015). For example, serum ferritin may be useful to identify pregnant women who would benefit from additional counseling about iron-rich foods and supplements (Kaiser and Campbell, 2014) or vitamin D screening may be considered for those who may be at risk of deficiency, such as lack of sun exposure, <u>vegan</u> or northern latitude (Kaiser and Campbell, 2014).
 Kidney function tests (creatinine clearance) (Shields and Tsay, 2015)

• Thyroid function (Shields and Tsay, 2015). Nutrition-Focused Physical Findings and Client History

Nutrition-focused physical findings and client history related to diabetes and pregnancy include: • Pertinent medical history (diseases, conditions, illnesses), previous obstetrical history • Age, number of fetuses, weeks of gestation, EDD

- Age, fullible of fetuses, weeks of gestation, lebb
 History of GDM duration of diabetes hypoglycemia, diabetes complications, family history (Shields and Tsay, 2015)
 GI discomforts, such as nausea, vomiting, etc. that may interfere with the ability to consume adequate nutrients
 Vital signs, such as <u>blood pressure</u> (Shields and Tsay, 2015) and general <u>health</u>
 Social history, living situation, <u>health literacy</u>, attitudes toward health including current diabetes knowledge (Shields and Tsay, 2015) and numeracy that may affect learning ability or needs and ability to implement dietary strategies or to make appropriate food choices
- Educational background and occupation, including financial and employment status (Shields and Tsay, 2015) may affect meal timing and schedule and healthy food purchasing ability.

• Recommendation Strength Rationale

Consensus: This topic was not included in the EAL systematic review. The recommendations are based on consensus publications.

Minority Opinions

None.

• Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

- <u>References</u>
 <u>References</u> not graded in Academy of Nutrition and Dietetics Evidence Analysis Process

 - Academy of Nutrition and Dietetics. Nutrition Terminology Reference Manual (eNCPT): Dietetics Language for Nutrition Care. 2016 edition. Accessed Nov 16, 2016: <u>http://ncpt.webauthor.com</u>.
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- <u>Gestational Diabetes</u>
 <u>Gestational Diabetes</u> (GDM) Guideline (2016)

Quick Links

Recommendations Summary

GDM: Medical Nutrition Therapy 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> <u>Evidence Section</u> below.

Recommendation(s)

GDM: Medical Nutrition Therapy (MNT)

The registered dietitian nutritionist (RDN) should provide medical nutrition therapy (MNT) that includes an individual nutrition prescription

and nutrition counseling for all women diagnosed with gestational diabetes mellitus (GDM). Research indicates that MNT provided by

an <u>RDN (or international equivalent)</u> as part of a comprehensive <u>nutrition intervention</u> that includes individualization of MNT is effective in

improving blood glucose control and neonatal and maternal outcomes in women with GDM. Improved outcomes included lower birth weight

and a reduction in the following: Incidence of macrosomia (LGA), need for insulin therapy, hypertensive disorders of pregnancy and

maternal hospitalizations, neonatal intensive care unit (NICU) admissions and neonatal deaths, premature births and rate of shoulder

dystocia, bone fracture and nerve palsy.

Rating: Strong Imperative

GDM: Frequency and Duration of MNT

The <u>RDN</u> should provide regular and frequent <u>MNT</u> visits to women with <u>GDM</u> to optimize outcomes. Visits should include an initial 60 to 90 minute <u>MNT</u> visit, followed by a second MNT visit (30 to 45 minutes) within one week, and a third MNT visit (15 to 45 minutes) within two to three weeks. Additional MNT visits should be scheduled every two to three weeks or as needed for the duration of the pregnancy. MNT assists the woman with GDM in meeting her blood glucose and weight gain targets, contribute to a well-balanced food intake and promote fetal and maternal well-being.

Rating: Consensus

Imperative

<u>Risks/Harms of Implementing This Recommendation</u>

There are no potential risks or harms associated with the application of these recommendations.

• Conditions of Application

For the recommendation GDM: Frequency and Duration of MNT, barriers to attendance may include financial constraints, scheduling conflicts, inability to take time off work or school, lack of child care and lack of transportation.

<u>Potential Costs Associated with Application</u>

Costs of MNT sessions and reimbursement vary. However, MNT sessions are essential for improved outcomes.

<u>Recommendation Narrative</u>

GDM: MNT

A total of five studies were included in the evidence supporting the recommendation:

- Two positive quality randomized controlled trials (RCTs) (Landon et al, 2009; Reader et al, 2006)
- One neutral quality <u>RCT</u> (Crowther et al, 2005)
- One neutral quality prospective <u>cohort study</u> (Maher et al, 2013)
- One neutral quality non-randomized controlled trial (Perichart-Perera et al, 2009).

Evidence Summary

- Five studies evaluated the effectiveness of <u>MNT</u> intervention, provided by an <u>RDN (or international equivalent)</u> (specifically, dietitian, registered dietitian or nutritionist) on <u>GDM</u>-related outcomes. Four studies (three RCTs, one non-randomized controlled trial) compared MNT intervention to standard or usual care in women with GDM. One prospective <u>cohort study</u> (Maher et al, 2013) evaluated early MNT during the subjects' first trimester (mean, 10.2 weeks gestation), as part of multi-disciplinary intervention in women with a history of insulin-requiring GDM. All studies found that the MNT intervention improved fetal/neonatal and maternal outcomes in women with GDM (Crowther et al, 2005; Landon et al 2009; Perichart-Perrera et al, 2009; Reader et al; 2006) or with women with a history of insulin-requiring GDM (Maher et al, 2013).
- The studies described MNT, provided by dietitians in a number of ways, including nutrition education or counseling (with nutrition assessment), diet therapy and dietary advice. All studies included individualization of MNT as part of a comprehensive intervention that included at least two of the following: education on diabetes, instructions in self-monitoring

of blood glucose (SMBG), regular follow up and monitoring with the physician, blood glucose (BG) monitoring and lifestyle (e.g., physical activity) counseling and advice. Insulin therapy was initiated, as required. Although the studies did not describe the actual number of MNT encounters during the intervention, all studies reported more than one MNT visit and one study (Reader et al, 2006) described a minimum of three MNT visits in the intervention. No studies described the frequency of MNT visits.

- MNT, as part of a comprehensive intervention improved blood glucose control (Perichart-Perrera et al, 2009; Reader et al, 2006) and improved the following adverse outcomes:
 - Maternal outcomes:
 - Fewer hypertensive disorders of pregnancy and pre-eclampsia (Landon et al, 2009; Perichart-Perrera et al, 2009)
 - Fewer maternal hospitalizations (Perichart-Perrera et al, 2009)
 - Fewer premature births (Perichart-Perrera et al, 2009)
 - Reduced need for insulin therapy (Reader et al, 2006).
 - Fewer caesarian deliveries (Landon et al, 2009)
 - Neonatal outcomes:
 - Fewer neonatal deaths (Crowther et al, 2005; Perichart-Perrera et al, 2009)
 - Fewer NICU admissions (Perichart-Perrera et al, 2009)
 - Lower birth weight (Crowther et al, 2005; Perichart-Perrera et al, 2009) and reduced neonatal fat mass (Landon et al, 2009)
 - Fewer LGA (Crowther et al, 2005; Landon et al, 2009) and lower prevalence of macrosomia (Crowther et al, 2005; Landon et al, 2009; Maher et al, 2013; Perichart-Perrera et al, 2009)
 - Reduced rate of shoulder dystocia (Landon et al, 2009; Crowther et al, 2005), bone fracture, and nerve

palsy (Crowther et al, 2005).

• Studies included: Crowther et al, 2005; Landon et al, 2009; Maher et al, 2013; Perichart-Perera et al, 2009; Reader et al,

2006.

GDM: Frequency and Duration of MNT

- No evidence was identified to evaluate the optimal frequency and duration of <u>MNT</u> visits by an <u>RDN (or international equivalent)</u> to improve fetal and maternal outcomes. However, the following guidance from Joslin Diabetes Center & Joslin Clinic (2011) provides support for the recommendation:
 - A minimum of three encounters with a Certified Diabetes Educator (CDE) (RDN, RN) for assessment and meal plan

modification (and <u>SMBG</u> instruction, if RDN is adequately trained) are recommended as follows.

- Visit One (60 to 90 minutes) individual or group visit
- Visit Two (30 to 45 minutes) one week after initial visit
- Visit Three (15 to 45 minutes) in one to three weeks.
- Additional visits every two to three weeks and as needed until delivery.

<u>Recommendation Strength Rationale</u>

- Conclusion statement supporting the recommendation *GDM: MNT* is Grade II
 Consensus: The recommendation *GDM: Frequency and Duration of MNT* is based on consensus publications. This topic was included in the EAL systematic review. However, no evidence was found to answer the research question.

Minority Opinions

None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

In women with GDM, what is the effectiveness of MNT intervention, provided by an RDN on fetal/neonatal and maternal outcomes?

<u>References</u>

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<u>Gestational Diabetes</u>
<u>Gestational Diabetes (GDM) Guideline (2016)</u>

Quick Links

Recommendations Summary

GDM: Calories 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> Evidence Section below.

<u>Recommendation(s)</u>

GDM: Calorie Prescription

For women with <u>gestational diabetes mellitus</u> (GDM), the <u>registered dietitian nutritionist</u> (RDN) should individualize the <u>calorie</u> prescription based on a thorough <u>nutrition assessment</u> with guidance from relevant references [Dietary Reference Intakes (DRI), Institute of Medicine (IOM)] and encourage adequate caloric intake to promote fetal/neonatal and maternal <u>health</u>, achieve glycemic goals, and promote appropriate <u>gestational weight gain</u> (GWG). No definitive research suggests there is a specific optimal calorie intake for women with <u>GDM</u> or if calorie needs are different than pregnant women without GDM. Limited research in women with GDM whose pre-pregnancy weights ranged from normal to <u>obese</u> showed no significant differences in most fetal/neonatal and maternal outcomes with various reported calorie intakes. intakes. In a study of obese women only, GWG slowed after women with GDM reportedly consumed 30% below their caloric requirements, without adverse effects.

Rating: Fair

Imperative

- Risks/Harms of Implementing This Recommendation
- There are no potential risks or harms associated with the application of this recommendation.
- Conditions of Application
 - Refer to the *GDM: Nutrition Assessment* and *GDM: Nutrition Monitoring & Evaluation* recommendations for factors to consider in determining and adjusting an individualized <u>calorie</u> prescription, such as pre-pregnancy weight and <u>BMI</u>, total and rate of <u>GWG</u> (IOM, 2009), single vs. multiple fetuses, <u>physical activity</u> level, etc.
 Individual caloric requirements during pregnancy vary among women and are dependent on several factors, including pre-pregnancy BMI and fat mass, and changes in physical activity (Ho et al, 2005).
- Potential Costs Associated with Application

Costs may include expenses related to medical nutrition therapy (MNT) visits from an RDN and higher food costs, if a

caloric increase is needed (e.g., types and amounts of food).

<u>Recommendation Narrative</u>

GDM: Calorie Prescription

A total of three studies were included in the evidence analysis supporting the recommendation:

- One positive quality prospective <u>cohort study</u> (Ho et al, 2005)
- One positive quality <u>randomized controlled trial</u> (RCT) (Rae et al, 2000)
 One neutral quality prospective cohort study (Romon et al, 2001).
- **Evidence Summary**
- One neutral quality prospective cohort study (Romon et al, 2001).
 ence Summary
 Three international studies evaluated the impact of calorie intake on fetal/neonatal and maternal outcomes (glycemic control, maternal weight gain, fetal growth/birth weight and adverse outcomes), in women with <u>GDM</u>.
 One positive quality prospective <u>cohort study</u> by *Ho et al*, 2005, evaluated a caloric prescription of 30kcal/kg body weight (BW) in 62 women with a <u>non-obese</u> pre-pregnancy weight (BMI range: 22.4±3.2 to 23.1±4.2kg/m²).
 Caloric intake of the women was categorized into three tertiles (calculated kcal/kg values): 1, 863kcals; 33kcal/kg BW (highest tertile), 1, 692kcals; 30.4 kcal/kg BW (middle tertile) and 1, 384kcals; 25 kcal/kg BW (lowest tertile), noting the women had a tendency to over-restrict their calorie intake.
 Women in the highest tertile had significantly higher post-dinner glucose concentration after controlling for pre-pregnancy weight and height. Total <u>GWG</u> was 20.2±7.9, 22±8.36, 22±9.5 pounds, respectively.
 There was no significant (NS) difference between caloric intake tertiles and either maternal GWG or neonatal outcomes [gestational age (GA), birth weight, crown heel length (CHL), <u>Apgar scores</u> at the first and fifth minute, incidence of <u>large-for-gestational-age</u> (LGA) or <u>small-for-gestational-age</u> (SGA) and placental weight].
 There was NS correlation between the incidence of <u>LGA</u> and <u>SGA</u> infants and caloric intake.
 One neutral quality prospective cohort study by *Romon et al*, 2001, evaluated a minimum caloric prescription of 1, 800kcals in 80 women who consumed an average of 1, 842±343kcals/day*.
 No relationship between calorie intake and infant birth weight was found.
 One positive quality <u>RCT</u> by *Rae et al*, 2000, evaluated the effect of a 30% reduction in <u>calorie</u> intake (1, 590-1, 776kcal/day) vs. no calorie restriction (2, 010-2, 200kcal/day) in 117 women with an <u>obese</u> pre-pregnancy

Australia) * [1, 560kcal intervention vs. 1, 630kcal control; <u>NS</u>], despite no prescriptive calorie restriction in

- Australia) * [1, 560kcal intervention vs. 1, 630kcal control; <u>NS</u>], despite no prescriptive calorie restriction in the control group.
 The mean rate of GWG slowed once dietary intervention started and 54.1% of the intervention vs. 40.7% of the control groups failed to gain or lost weight (NS). Women in both groups lost 1.68kg [SE 0.33, range 7.5-0.00 and SE 0.32, range 5.0-0.00 intervention vs. control, respectively]
 Total GWG was 25.4 pounds in the intervention and 21.3 pounds in the control group (NS).
 There were no differences between the groups in maternal outcomes (anemia, pre-existing <u>hypertension</u>, pre-eclampsia, premature rupture of membranes (PROM), threatened preterm labor, percent requiring insulin, ketonuria (34.5 vs. 38.5% nondetectable ketones), serum beta-hydroxybuterate, BG control, <u>HbA1C</u>, <u>GWG</u> or neonatal outcomes (rates of delivery mode, labor induction, fetal distress birth trauma, <u>GA</u> and incidence of <u>macrosomia</u>).
 Intervention group infants had greater average abdominal skinfold thickness, but mean total skinfold measurements were similar between the two groups.
 Control group infants had greater incidences of polycythemia and shoulder dystocia.

 More research is needed to elucidate the effect of caloric consumption (kcals/kg pre-pregnancy BW), independent of other factors, on fetal/neonatal and maternal outcomes.
 *The kcal intake per kg of body weight for the Romon et al, 2001, and Rae et al, 2000, studies could not be calculated for the groups.

<u>Recommendation Strength Rationale</u>

- Conclusion statement supporting GDM: Calorie Prescription is Grade III.
- Results of the studies were confounded by use of reported vs. actual caloric intakes (possible underreporting), tendency of
- the women to over-restrict caloric intake vs. prescribed, inconsistent stratification by pre-pregnancy BMI, and pre-pregnancy

weights not described, making comparison and synthesis of the research challenging.

Minority Opinions

None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

In women with GDM, what is the effect of caloric consumption on fetal/neonatal and maternal outcomes?

References

Ho L, Benzie IFF, Lao TT. Relationship between caloric intake and pregnancy outcome in diet-treated gestational diabetes mellitus. 2005: 7:15-20

Rae A, Bond D, Evans S, North F, Roberman B, Walters B. A randomised controlled trial of dietary energy restriction in the management of obese women with gestational diabetes. Aust N Z J Obstet Gynaecol 2000;40(4):416-422.

Romon M, Nuttens MC, Vambergue A, Verier-Mine O, Biausgue S, Lemaire C, Fontaine P, Salomez JL, Beuscart R. Higher sociated with decreased incidence of newborn macrosomia in women with destational diabetes.) Am Diet carbohydrate intake is associa Assoc 2001:101(8):897-902.

- References not graded in Academy of Nutrition and Dietetics Evidence Analysis Process
 - Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of Dietary Reference Intakes, and the Subcommittees on Opper Reference Levels of Nutrients and Interpretation and Oses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty acids, Cholesterol, Protein and Amino Acids. Food and Nutrition Board. Institute of Medicine. Washington DC, The National Academies Press; 2005. Accessed online February 03, 2016: http://books.nap.edu/openbook.php?record_id=10490.
 - Institute of Medicine (IOM) and National Research Council (NRC). 2009. Weight Gain During Pregnancy: Reexamining the

Guidelines. Washington, DC: The National Academies Press.

- <u>Gestational Diabetes</u>
 Gestational Diabetes (GDM) Guideline (2016)

Quick Links

Recommendations Summary

GDM: Macronutrients 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> Evidence Section below.

Recommendation(s)

GDM: Macronutrient Requirements

In women with <u>gestational diabetes mellitus</u> (GDM), the <u>registered dietitian nutritionist</u> (RDN) should provide adequate amounts of macronutrients to support pregnancy, based on nutrition assessment, with guidance from the Dietary Reference Intakes (DRI). The DRI for all pregnant women, including those with GDM, recommends a minimum of 175g carbohydrate (CHO), a minimum of 71g protein (or 1.1g per kg per day protein) and 28g fiber.

Rating: Consensus Imperative

GDM: Carbohydrate Prescription

The <u>RDN</u> should individualize both the amount and type of <u>CHO</u> for women with <u>GDM</u> based on <u>nutrition assessment</u>, treatment goals, blood glucose response and patient needs. Limited evidence does not confirm an ideal amount (grams or percent of total <u>calories</u>) of CHO for all women with GDM, but suggests an interaction between the amount and type of CHO. Several studies showed positive effects on glycemic control and neonatal/fetal and maternal outcomes in women with GDM, when evaluating varying amounts and types of CHO:

- Low <u>glycemic index</u> (GI) (less than 55) or medium GI (55 to 69) diets, containing a range of 36.7% to more than 60% CHO
 <u>Dietary Approaches to Stop Hypertension</u> (DASH) diets (greater than 65% CHO).
 However, when two studies evaluated the amount of CHO alone (without specifying the type of CHO) mixed results were found:
 A CHO prescription of 202g CHO per day was more effective at reducing post-prandial blood glucose (PPBG), compared to >270g

 - - CHO per day.
 A 23% incidence of <u>large-for-gestational-age</u> (LGA) infants was found with CHO intake of less than 211g per day day, but no <u>LGA</u> when greater than 211g per day.

Rating: Fair

Imperative

GDM: Carbohydrate and Post Prandial Breakfast Glycemia

The <u>RDN</u> should individualize both the amount and type of <u>CHO</u> at breakfast based on <u>nutrition assessment</u>, treatment goals, blood glucose response and patient needs. If the woman with GDM continues to experience elevated <u>PPBG</u> after breakfast, the RDN may further modify the amount or the type of CHO at breakfast to achieve blood glucose targets. Limited evidence examining the impact of CHO on PPBG after breakfast does not confirm an ideal amount (grams or percentage of total <u>calories</u>) or type of CHO for all women with GDM to achieve PPBG targets after breakfast, but suggests an interaction between the two.

- In women with GDM who followed low or medium <u>alycemic index</u> (GI) diets containing 42-60% total CHO (GI for breakfast meal <55; CHO range 15g to 60g or more) met PPBG targets after breakfast.
 One study evaluating a 45% CHO diet overall (without specifying the type of CHO), found improved PPBG after breakfast, compared to one that contained 60% CHO
- No studies evaluated the effect of only restricting individual foods (e.g., fruit or milk) at breakfast, although one study showed improved PPBG when fruit bread and milk were eaten in a low GI breakfast vs. a high GI breakfast with CHOs from other sources.

Rating: Fair Imperative

• Risks/Harms of Implementing This Recommendation

There were no potential risks or harms associated with the application of these recommendations.

• Conditions of Application

For the recommendation *GDM: Carbohydrate and Post Prandial Breakfast Glycemia*, the RDN should use clinical judgment in individualizing the breakfast meal. Although no evidence was found to support a specific or range of <u>carbohydrate</u> (CHO) distribution at meals or snacks, customary practice suggests limiting the amount and type of <u>CHO</u>s at breakfast (Joslin Diabetes Center & Joslin Clinic, 2013). The CHO intake is reassessed at subsequent visits for possible adjustment according to the blood glucose records (Shields & Tsay, 2015). See the recommendation *GDM: Distribution of Meals and Snacks*

Potential Costs Associated with Application

- Costs may include expenses associated with receiving care from an <u>RDN</u>.
 There may be extra time needed or increased food costs associated with improving the quality of the diet as recommended.

Recommendation Narrative

A total of 12 studies were included in the evidence analysis supporting these recommendations:

Six positive quality <u>randomized controlled trials</u> (RCTs) (Asem et al, 2014; Grant et al, 2011; Moreno-Castillo et al, 2013; Louie et al, 2011; Moses et al, 2009; Perichart-Perera et al, 2012) Two positive quality randomized crossover trial (Hernandez et al, 2014; Louie et al, 2013) Three neutral quality <u>RCTs</u> (Afaghi et al, 2013; Asemi et al, 2013 (a, b); Cypryk et al, 2007) One neutral quality prospective cohort (Romon et al, 2001). Impact of the amount of CHO consumed on fetal/neonatal and maternal outcomes [independent of dietary patterns based on the Dietary Approaches to Stop Hypertension (DASH) diet and Glycemic Index]

Conclusion: Limited evidence was found to demonstrate the impact of the amount of CHO consumption on neonatal or fetal and maternal outcomes in women with gestational diabetes mellitus (GDM). In one study, women prescribed a minimum of 1, 800kcal per day found reductions in post-prandial blood glucose (PPBG) levels at all three meals with 202g per day CHO, while those prescribed >270g CHO showed reductions in PPBG at two meals only. Another study of women with an average intake of 1, 852±343kcal per day found zero incidence of LGA when CHO intake was >211g per day, but a 23% incidence in women consuming less CHO. No other differences in fetal and maternal outcomes were found in these studies.

Overview

- Overview
 Three studies evaluated the impact of the amount of CHO consumed (independent of dietary patterns including DASH and glycemic index) on fetal or neonatal and maternal outcomes (glycemic control, maternal weight gain, fetal growth or birth weight, and adverse outcomes), in women with GDM.
 A neutral quality RCT (Cypryk et al, 2007) assigned 30 women with GDM to consume an 1, 800kcal diet with either low-CHO (LC) content [45% CHO (202g), 25% PRO, 30% FAT] or high-CHO (HC) content [>60% CHO (>270g), 25% PRO, 15% FAT] for two weeks. Actual intake was not reported. There was a significant reduction in PPBG concentrations for all meals in the LC group, while the HC group realized significant BG reductions after lunch and dinner only. No significant (NS) differences were observed between groups for ketonuria or obstetric outcomes.
 A positive quality RCT (Moreno-Castillo, 2013) assigned 150 women with GDM to either a LC diet (40% CHO) or a HC diet (55% CHO). There was one unexplained stillbirth to a woman in the LC group. There was included in the statistical analysis. There was one unexplained stillbirth to a woman in the LC group. There were no other significant differences between groups for either maternal or neonatal outcomes.
 A neutral quality prospective cohort study (Romon et al, 2001), evaluated actual intake in 80 women with an elevated pre-pregnancy BMI. Wome consumed an average of 1, 852±3434xcl per day [43.4% CHO (202±43g), 18.5% PRO, 37.9% FAT]. Mild ketonuria was present in 45% of the women during week 1, but decreased to 16%. No relationship between the reported calorie intake and infant birth weight was found. However, an inverse relationship between CHO intake and infant birth weight was found. However, and inverse relationship between CHO intake and infant birth weight was found. The 32 women who consumed >211g CHO per day and proportionately lower fat had no LGA infants, whereas in women consumig less CHO, 11 women (or 23%) had LGA infants.

Conclusion: Dietary patterns based on the <u>DASH</u> diet, (which contained higher amounts of CHO and dietary fiber, and less sucrose, total fat, dietary cholesterol and less sodium) when compared to a control diet, were effective in improving both fetal and maternal outcomes in women with GDM who did not require insulin at the time of diagnosis. Improvements were found in glucose tolerance,

glycosylated hemoglobin levels, insulin resistance, less need for insulin, lipid profile, systolic blood pressure and biomarkers of oxidative stress. There was also a lower incidence of Cesarean-section deliveries. Infant birthweights, head circumferences, ponderal indices and the incidence of macrosomia were lower in infants whose mothers consumed the DASH diet.

Overview

- Two RCTs by Asemi et al [2013 (a) and 2014] evaluated the impact of dietary patterns based on the DASH eating plan on fetal/neonatal and maternal outcomes (glycemic control, maternal weight gain, fetal growth/birth weight and adverse outcomes), in Iranian women with GDM who did not require insulin* at time of diagnosis. A third paper by Asemi et al [2013 (b)], reported additional outcomes for the same subjects in 2013 (a). The studies compared the DASH diet to a standard diet for a four-week period in women diagnosed with GDM at 24-28 weeks gestation. Both diets included the same prescribed macronutrient profile [range 40-55% CHO, 10-20% protein, 25-30% fat]. The DASH diet emphasized fruits, vegetables, whole grains and low-fat dairy products and lower amounts of saturated fats (SFA), dietary cholesterol, refined grains and sodium (Na). Based on weekly phone calls and food records, there was NS differences in total calorie and protein intakes between the groups. However, women in the DASH groups consumed less fat and more CHO than the prescribed amount. The DASH group also consumed higher amounts of dietary fiber (more fruits, vegetables, whole grains), less sucrose, less dietary cholesterol, and less sodium, compared to the control group. There were NS differences in maternal weight gain at the end of the intervention in the studies. Fetal and maternal outcomes were as follows: follows:
 - Asemi et al 2013 (a) (N=34) found significant improvements in SBP, glucose tolerance, HbAIc levels, total cholesterol, LDL cholesterol, total: HDL cholesterol ratio and triacylglycerol (TAG) levels in the DASH group. Women in the DASH group had significantly fewer c-section** deliveries and fewer women required insulin after delivery. Mean infant birth weights were lower in the DASH group compared to the control group. Additional outcomes for the subjects (N=32) were reported in Asemi et al 2013 (b). Significant improvements were found in fasting plasma glucose (FPG), serum insulin levels, HOMA-IR, total antioxidant capacity (TAC) and total glutathione levels in the DASH group compared to the control group. There were no differences in high-sensitivity CRP between groups.
 Asemi et al 2014 (N=52) found significantly fewer women in the DASH group required c-sections and insulin injections after the intervention compared to the control group. Significantly fewer infants were macrosomic in the DASH group and had significantly lower birth weights, head circumferences and ponderal indices compared to those born to the control mothers. The DASH diet outcomes remained significant even after controlling for pre-pregnancy body mass index (BMI < 30kg/m² and > 30kg/m²), baseline maternal FPG, and maternal age. NS differences were found between groups in Apgar scores, percentage of fetal/neonatal polyhydraminos or gestational
 - differences were found between groups in Apgar scores, percentage of fetal/neonatal polyhydraminos or gestational

age in weeks. * The authors noted that in previous studies conducted in Iran, insulin therapy was often recommended upon diagnosis of GDM, to reduce complications

* The authors noted c-section rates in Iran among women with GDM are very high (almost 90%).

Impact of dietary patterns based on the glycemic index on fetal/neonatal and maternal outcomes

Conclusion: A low (LGI) or medium GI (MGI) <u>dietary pattern</u> resulted in glycemic control and had similar neonatal or fetal and maternal outcomes in women with GDM in most studies. In a few studies, an LGI diet (36-47% CHO) was found to significantly reduce the need for insulin therapy and prevent excessive maternal weight gain. One study comparing an LGI-MGI diet (40% CHO, 45% fat) to an LGI-MGI diet (60% CHO, 25% fat) found that both diets achieved glycemia within target levels.

Overview

- Six studies evaluated the impact of dietary patterns based on the glycemic index (GI) on fetal or neonatal and maternal outcomes (glycemic control, maternal weight gain, fetal growth or birth weight, and adverse outcomes), in women with GDM

- Six studies evaluated the impact or olectary patterns based on the grycenic index (G1) on fetal or head and indertrain ducomes (glycemic control, maternal weight gain, fetal growth or birth weight, and adverse outcomes), in women with GDM.
 A low (LGI) or medium GI (MGI) dietary pattern resulted in glycemic control and had similar neonatal or fetal and maternal outcomes in women with GDM in most studies. In a few studies, an LGI diet (36-47% CHO) was found to significantly reduce the need for insulin therapy and prevent excessive maternal weight gain. One study comparing an LGI-MGI diet (40% CHO, 45% fat) to an LGI-MGI diet (40% CHO, 45% fat) to an LGI-MGI diet (60% CHO, 25% fat) found that both diets achieved glycemia within target levels.
 GI parameters for the purpose of study comparison are as follows: Low GI=0-55; Medium GI=56-69; and High GI=70 or greater (Augustin et al, 2013), compared an LGI diet X-126.9) to an all types of CHO diet (GI 48.648.4). A third study (Afaghi et al, 2013), compared an LGI GI GI 472±6.9) to an all types of CHO diet (GI 48.648.4). A third study (Afaghi et al, 2013), compared an LGI diet with added wheat fiber (GI ≤55) to an LGI diet without added wheat fiber (same composition). Two studies compared LGI diets to MGI diets. Grant et al, 2011 compared an LGI diet (GI 48.648.4). A third study (Afaghi et al, 2014) compared the LGI diet to MGI diets. Grant et al, 2011 compared an LGI diet (GI 56). The macronutrients as a percentage of total calories in these studies were similar between the comparison groups. One study (Hernandez et al, 2014) compared the glycemic control was achieved (Afaghi; Grant; Hernandez; Perichart-Perrera) and two of five studies showed the need for insulin therapy was significantly reduced (Afaghi, Moses), when following either an LGI or MGI diet. Afaghi et al, 2013 demonstrated improved glycemic control and reduced need for insulin in women who followed an LGI diet with added wheat fiber at each meal, compared to those fo
- - Low GI vs. Low GI Diets
- If vs. Low GI Diets
 Afaghi et al 2013 (N=31) found that women with GDM had significant reductions in fasting blood glucose (FBG) when consuming either an LGI diet (42% CHO; GI ≤55; GL 67-72) with 15g wheat fiber added to each of 3 meals per day or an LGI control diet (same composition, but no added wheat fiber). Further between group differences were found, with the LGI diet (+ wheat fiber) group experiencing significant improvements in two-hour PPBG and BG control, compared to controls. Fewer women in the LGI + wheat fiber group (38.9%; N=7) required insulin, compared to controls (76.9%; N=10).
 Louie et al, 2011 (N=91) found that excessive weight gain occurred less frequently and women tended to gain less weight when following an LGI (40-45% CHO; GI 47±1; GL 84±3), compared to those following a conventional HF (40-45% CHO; GI 53±1; GL105±4). Infant birth weight, birth weight percentile, head circumference and ponderal index were very similar and were within healthy norms in both groups (NS). There were no significant differences between groups for LGA, SGA, or macrosomic babies. Fewer women in the LGI group required insulin, but the difference was NS.
 Perichart-Perrera et al, 2012 (N=107; N=52 GDM; N=55 T2D) found that an LGI diet (46.6% ±9.1 CHO; GI 47.2 ± 6.9) was equally effective in improving glycemic control, as a diet including all types of CHO (45.8% ±8.3CHO; GI 48.6 ± 8.4), and there were no differences in glycemic control within groups between women with type 2 diabetes (T2D) and women with GDM. A lower proportion of LGI subjects exhibited excessive weight gain, but LGI women were more likely to have a premature birth. There was a trend toward lower birthweight in LGI infants, and one infant from the LGI group had a low head circumference. There were NS birthweight in LGI infants, and one infant from the LGI group had a low head circumference. There were NS differences in macrosomia or low birth weight between groups and NS differences in wasting or stunting

between groups. The risk of pre-eclampsia, intrauterine and neonatal death was the same for both groups. • Low GI vs. Medium GI Diets

- GI vs. Medium GI Diets
 Grant et al, 2011 (N=38) found NS differences in fasting serum glucose, mean post-prandial SMBG, HbA1C, fasting insulin, lipids or CRP between a group of women with GDM consuming an LGI diet (GI 49±0.8; GL 98.2±5.1) and a control group consuming a significantly higher GI (GI 58±0.5; GL125±8.8). The LGI diet group had significantly fewer fasting serum glucose measurements below target, and over twice as many on target, than the control group. Fewer PPBG measurements were above target in the LGI group. There was NS difference between groups in the number of women started on insulin, and insulin treatment was associated with significantly greater maternal weight gain. There were NS differences between groups in infant birth weight, LGA infants and SGA infants.
 Moses et al, 2009 (N=63) found that women with GDM who consumed a conventional HF diet (37.8±1% CHO; GI 56). Of women in the HF group who met criteria for insulin therapy, nearly half were able to avoid insulin use after switching to the LGI diet. There were NS differences were found between gloups for maternal weight gain, induction of delivery or type of delivery. No significant (NS) differences were found between groups for
- gain, induction of delivery or type of delivery. No significant (NS) differences were found between groups for fetal outcomes including gestational age at delivery, fetal or birth centile, or <u>ponderal index</u>.
 Low-Medium GI vs. Low-Medium GI Diets
- Low-Mealum GLVS. Low-Mealum GLDIets

 Hernandez et al, 2014 (N=16) found no between-diet differences for fasting or preprandial glucose in a group of women with GDM consuming either a low CHO/high fat diet (LC/CONV) (40% CHO, 45% fat; low to medium GI; breakfast GI 35.7) or a higher complex CHO/lower fat diet (CHOICE) diet (60% CHO, 25% fat; low to medium GI; breakfast 34.8). When considered as a mean across three meals, 1- and 2-hour PPBG and daytime mean glucose were modestly higher on the CHOICE diet. However, both diets produced results well within current treatment targets for daytime, nocturnal, post-prandial and mean BG levels. Free fatty acid (FFA) levels were significantly lower for the CHOICE diet.

 Impact of the type or amount of CHO consumed on post-prandial breakfast glycemia

Conclusion: Limited evidence was found to demonstrate the impact of the type or amount of <u>carbohydrate</u> (CHO) consumption on post-prandial breakfast glycemia in women with <u>gestational diabetes mellitus</u> (GDM). Three studies that evaluated <u>glycemic index</u> (GI) reported that lower <u>GI</u> diets containing 42-60% total CHO (GI for breakfast meal <55; CHO range 15g to 60g or more) improved glycemic control after breakfast. One study that did not consider the glycemic index showed that lower CHO (45% vs. 60% of kcals) improved post-prandial blood glucose after breakfast. No studies evaluated the effect of only restricting individual foods (e.g., fruit or milk) at breakfast although one study showed improved blood sugars when fruit bread and milk were eaten in a low GI breakfast over a high GI breakfast with carbohydrates from other sources.

Overview

- Five studies evaluated the impact of the type or amount of CHO on breakfast PPBG values in women with GDM. Three studies evaluated <u>dietary patterns</u> based on the GI with varying amounts of CHO (Grant et al, 2011; Hernandez et al, 2014; Perichart-Perrera et al, 2012) and one study (Louie et al, 2013) evaluated an LGI and HGI breakfast meal alone. One study evaluated the amount of CHO as a percentage of calories (Cypryk et al, 2007). GI parameters for the purpose of study comparison of the GI studies are as follows: Low GI=0-55; Medium GI=56-69; and High GI=70 or greater (Augustin et al, 2015). Three of these studies (Hernandez 2014, Perichart-Perrera 2012, and Louie 2013) specifically tested a controlled breakfast meal.
 A brief description of the comparison dists and ensuits outcomes and results for each study are as follows:
- A brief description of the comparison diets and specific glycemic outcomes and results for each study are as follows: *Cypryk et al, 2007* (N=30) compared a low-CHO diet (45% CHO, 30% fat) to a high-CHO diet (>60% CHO, 15% fat) and found a significant reduction in PPBG concentrations for all meals, including breakfast in women consuming a low-CHO diet (45% CHO, 30% fat) compared to women consuming a high-CHO diet (>60% CHO, 15% fat). he high-CHO group realized significant BG reductions only after lunch and dinner only. *Grant et al, 2011* (N=38) compared an LGI diet (% CHO NR; GI 49±0.8) to an MGI diet (% CHO NR; GI 58±0.5) and found a significant relationship between post-prandial SMBG after breakfast and pre-pregnancy BMI at baseline (P<0.001) in two study groups of women (control and low GI) diagnosed with gestational hyperglycemia. During the study, NS differences were observed between the changes in the low GI (fasting, -0.48±0.11 mmol/L; postprandial, -0.48±0.19 mmol/L) and control (fasting, -0.35±0.19 mmol/L; postprandial, -0.44±0.21 mmol/L) groups, although the fasting and (p=0.001) and mean postprandial (p < 0.001) fell significantly. Also, the control group demonstrated a strong positive relationship between pre-pregnancy BMI and SMBG after breakfast (R=0.75, P<0.001); although the low-GI group did not demonstrate this correlation, and the difference between groups was significant (P=0.021). However, post-intervention, the LGI group consumed significantly more dietary fiber than controls (30±1.6 and 23±1.0g, respectively; P=0.001) and had a significantly lower GL than control post-intervention (98.2±5.1 vs. 125±8.8; P=0.014). *Hernandez et al, 2014* (N=16) compared two low to medium GI (LGI-MGI) diets (40% CHO, 45% fat; GI NR; p=0.014).

 - Ine result was the LGI group had a significantly lower GL than control post-intervention (98.2±5.1 vs. 125±8.8; P=0.014).
 Hernandez et al, 2014 (N=16) compared two low to medium GI (LGI-MGI) diets (40% CHO, 45% fat; GI NR; breakfast GI 35.7) vs. (60% CHO, 25% fat; GI NR; breakfast 34.8) and found modestly higher 1- and 2-hour PPBG in women on a higher complex CHO/lower fat diet (60% CHO, 25% fat; low to medium GI; breakfast GI 35.7). However, PPBG after breakfast was within current treatment targets at one and two hours for both diets (1 hour, 115±2 vs. 107±3mg/dL, P≤0.01; 2 hours, 106±3 vs. 97±3mg/dL, P=0.001). The breakfast meal contained 25% of total kcals and reflected the overall macronutrient percentage for each diet.
 Louie et al, 2013 (N=10, crossover study design provided two groups of 10 subjects each), in a study focused on only a controlled breakfast (GI 82, GL 31). Louie et al found significantly lower peak BG levels (6.7±0.3mmol/L vs. 8.6±0.3mmol/L; P=0.001) in women consuming a low GI breakfast (GI 45; GL 21; 44.7g CHO*) compared with those consuming a high-GI breakfast (GI 82; GL 36; 42.7g CHO*). The area under the glucose curve (iAUCglucose) was significantly lower for the LGI group (21.2.7±22.9 vs. 340.8±23.4; P=0.001). There was large inter-subject variability in the timing of the peak BG level between the test meals, with peaks occurring at 45-75 minutes for the LGI meal.
 Perichart-Perrera et al, 2012 (N=107; N=52 GDM; N=55 T2D) compared an LGI diet (46.6±9.1% CHO; GI 47.2±6.9) to an all types of CHO diet (45.8±8.3% CHO; GI 48.6±8.4) and found that an LGI diet was equally effective in improving glycemic control, as a diet including all types of CHO. Breakfast was limited to 15-30g CHO in both diets. At the end of the study, there was a statistically significant increase in the number of women in the LGI group who met glycemic targets after lunch, pre-dinner and post-dinner (P<0.05); and in the all types of CHO diet (45.8±8.3% CHO; GI 48.6±8.4) and found th

*calculated value.

<u>Recommendation Strength Rationale</u>

- The recommendation GDM: Macronutrient Requirements is based on consensus publications. The topic was not included in
- The recommendation of the interview.
 Three conclusion statements supporting the recommendation *GDM: Carbohydrate Prescription* are grade III

 Interpretation of results for the topic on impact of <u>dietary patterns</u> based on the <u>alycemic index</u> on fetal or neonatal and maternal outcomes is limited due to inability to compare diets across studies and none of the studies included a comparison to the topic of the studies included and maternal outcomes is limited.
 - Interpretation of results for the topic on impact of dietary patterns based on the <u>DASH</u> diet on fetal or neonatal and maternal outcomes is limited due to subjects consuming relatively the same diet (despite differences in prescribed) diet), limited population.Interpretation of results for the topic on impact of the amount of CHO consumed (independent of dietary patterns)
 - DASH diet on fetal and maternal outcomes is limited because results of CHO were confounded by use of prescribed vs. reported intakes, variable sample sizes and different outcomes reported, making comparison and synthesis of the research challenging. In addition, studies used varying types and amounts of carbohydrates and outcomes measured varied widely among studies.
- Conclusion statement supporting the recommendation GDM: Carbohydrate and Post Prandial Breakfast Glycemia is grade III Interpretation of results for the topic on impact of the type or amount of CHO consumed on post-prandial breakfast

glycemia was challenging due to inability to compare diets across studies (varying amounts of CHO and GI), prescribed vs. reported intakes, or lack of description of the breakfast meal.

Minority Opinions

None.

• Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

In women with GDM, what impact does the amount or type of carbohydrate consumed have on post-prandial breakfast glycemia?

In women with GDM, what impact does the amount of carbohydrate consumed (independent of dietary patterns based on the DASH diet and alycemic index) have on fetal/neonatal and maternal outcomes?

In women with GDM, what impact do dietary patterns based on the DASH diet have on fetal/neonatal and maternal outcomes?

In women with GDM, what impact do dietary patterns based on the glycemic index have on fetal/neonatal and maternal outcomes?

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<u>Gestational Diabetes</u>
 <u>Gestational Diabetes (GDM) Guideline (2016)</u>

Recommendations Summary

GDM: Vitamins and Minerals 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> <u>Evidence Section</u> below.

- Recommendation(s)
- **GDM:** Dietary Vitamin and Mineral Intake

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The <u>registered dietitian nutritionist</u> (RDN) should encourage women with <u>gestational diabetes melliltus</u> (GDM) to make healthy food choices and consume a variety of foods to meet the micronutrient needs of pregnancy. The micronutrient needs of women with <u>GDM</u> are the same as for pregnant women without diabetes (emphasis on dietary intake of iron, folate, <u>calcium</u>, vitamin D, choline and iodine). The consumption of more food to meet caloric needs and the increased absorption and efficiency of nutrient utilization that occurs in pregnancy, are generally adequate to meet the needs for most nutrients, when good food choices are consistently made.

Rating: Consensus

Imperative

GDM: Vitamin and Mineral Supplementation

The <u>RDN</u> should consider recommending dietary supplementation within the <u>Dietary Reference Intakes</u> (DRI) for pregnancy with a prenatal multivitamin/mineral or specific vitamin or mineral supplement(s) to address inadequate dietary vitamin and mineral intake (e.g., iron, folate, <u>calcium</u>, vitamin D, choline and iodine) or documented micronutrient deficiency. <u>Dietary supplements</u> may be indicated in pregnant women at high risk for inadequate micronutrient intake, such as <u>food insecurity</u>; <u>alcohol</u>, tobacco or other substance dependency; anemia; strict <u>vegetarian</u> (vegan) diet; or poor eating habits.

Rating: Consensus

Imperative

- <u>Risks/Harms of Implementing This Recommendation</u>
 - Some individuals may not tolerate vitamin or mineral supplementation
 - In general, pregnant women should seek medical consultation before or while taking a non-prescribed over-the-counter (OTC) micronutrient supplement that exceeds the Tolerable Upper Limits (<u>UL</u>) for a particular vitamin or mineral (Kaiser & Campbell, 2014) or if taking herbal supplements.
- Conditions of Application
 - Consideration should be given to the total intake of micronutrients from all sources in the diet, such as fortified foods and beverages (e.g., calcium-fortified juice; grains enriched with iron, <u>folic acid</u> and other B-vitamins) and prescribed or non-prescribed vitamin and mineral supplements
 - The <u>RDN</u> should use professional judgment when assessing nutrition status and determining the need for vitamin and mineral supplementation for those at high risk of nutrient deficiencies, including history of malabsorptive disorders (bariatric surgery), multi-fetal pregnancy, omission of food groups and eating disorders (Kaiser and Campbell, 2014; Shields and Tsay, 2015)
- Potential Costs Associated with Application

There is an increased cost for vitamin and mineral supplements.

- <u>Recommendation Narrative</u>
 - The micronutrient needs of pregnant women with <u>GDM</u> are the same as for those without diabetes. Consuming sufficient <u>calories</u> to support recommended weight gain and eating a variety of foods to meet nutrient needs are beneficial for pregnant women (Marra and Boyar, 2009). As long as good food choices are made, the higher intake of calories, coupled with the increased absorption and efficiency of nutrient utilization that occurs in pregnancy are generally adequate to meet the needs for most nutrients (Kaiser and Campbell, 2014). However, vitamin and mineral supplementation may be warranted in pregnant women with multiple gestations, smoking and other substance dependency, poor quality diets, <u>food</u> insecurity, anemia or who are strict <u>vegetarians</u> (vegans) (Kaiser and Campbell, 2014; Shields & Tsay, 2015). For example, a <u>vegan</u> may need to supplement her diet with Vitamin D and Vitamin B12 (Shields and Tsay, 2015). While adequate intake of all micronutrients is important for the <u>health</u> of the mother and baby, special attention should be paid to the following micronutrients. food following micronutrients.
 - Iron

 - The overall prevalence of iron deficiency is nearly 18% in pregnant women in the United States, with anemia at 5% of pregnant women. Rates of iron deficiency increase across trimesters from 6.9% to 14.3% to 28.4% (Siu, 2015)
 The risk for pre-term labor, low body weight (LBW), and infant mortality increase if there is iron deficiency anemia during the first two trimesters of pregnancy. Iron supplementation is needed to meet the increased maternal and fetal demand for iron throughout pregnancy (Procter & Campbell, 2014)
 The <u>Recommended Dietary Allowance</u> (RDA) for iron is 27 mg/day [Institute of Medicine (IOM) 1997-2011]. Iron supplementation (30mg per day) is generally recommended starting at the first prenatal visit. However, while routine iron supplementation during pregnancy may improve maternal hematologic status and reduce the incidence of iron deficiency anemia (IDA) in the short term, no clear or consistent evidence was found that prenatal iron supplementation 30mg of iron. Women who have iron deficiency anemia during pregnancy should be prescribed 60mg to 120mg of elemental iron per day (Shields and Tsay, 2015).
 - Folic Acid
 - Folic acid is recognized for preventing <u>neural tube defects</u> and is important before (pre-conception) and during pregnancy (Procter and Campbell, 2014). Pregnant women should consume 600mcg of dietary folate equivalents (DFE) daily from all food sources (IOM, 1997-2011; Procter and Campbell, 2014). One DFE is equal to 1.0mcg food folate or 0.6mcg of folic acid from fortified food or as a supplement consumed with food (or 0.5mcg if supplement is taken on an empty stomach) (IOM, 1997-2011). Most prenatal multi-vitamin and mineral supplements contain 600mcg of folic acid cap acid to the woman in more folic acid cap acid to the woman is more than a supplement of the source of folic acid cap acid to the woman in more folic acid source of folic acid cap acid to the woman in more folic acid source of folic acid cap acid to the woman in more folic acid source of folic acid and cap acid to the woman in the previous of the woman is a supplement of the woman in the previous of the woman is a supplement to the previous of folic acid acid cap acid to the woman is more than the previous of the woman is a supplement of the previous of the woman is taken on an empty stomach (IOM, 1997-2011). Most previous of the 600mcg of folic acid and can assist the woman in meeting folic acid requirements of pregnancy (Shields and Tsay, 2015).
 - Women with a previous infant with <u>NTD</u> should consult their physician regarding a 4, 000mcg folic acid daily before and throughout the first trimester of pregnancy (Procter and Campbell, 2014).
 - Calcium
 - The <u>RDA</u> for <u>calcium</u> is 1, 000mg per day for women ages 19 to 50 years. The <u>DRI</u> for calcium in pregnancy is the same as for women of the same age who are not pregnant, due to increased efficiency in calcium absorption and maternal bone calcium mobilization during pregnancy (Procter and Campbell, 2014). Women with calcium intakes under 500mg per day may need supplementation (Procter and Campbell, 2014)
 - Vitamin D
 - · Vitamin D's function during pregnancy for both mother and fetus is not fully defined at this time and vitamin D supplementation during pregnancy remains controversial, althogh ongoing research suggests higher levels of supplementation appear to be safe and effective. The RDA for vitamin D is 600 IU (15mcg) per day (<u>IOM</u> 1997-2011) to meet the needs of most North American adults, including pregnant women (Procter and Campbell, 2014).
 - Choline
 - Because of its high rate of transport from mother to fetus, choline is considered an essential nutrient during pregnancy. A deficiency can interfere with normal fetal brain development (Procter and Campbell, 2014). The adequate intakes (AI) for choline is 450mg (IOM, 1997-2011). Most pregnant women do not consume the <u>AI</u> for choline, despite its presence in many foods (Procter and Campbell, 2014).
 - Iodine
 - Iodine is required for normal brain development and growth. Iodine requirements increase during pregnancy. Iodine
 deficiency is a growing concern and recent national surveys suggest a subset of pregnant women may have mild to moderately inadequate intake of iodine. The IOM recommends an iodine intake of 15mg per day before conception and 220mg per day for pregnant women (Procter and Campbell, 2014).

Recommendation Strength Rationale

- Consensus: This topic was not included in the EAL systematic review. The recommendations are based on consensus publications.
- Minority Opinions

None.

• Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

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<u>Gestational Diabetes</u>
 <u>Gestational Diabetes (GDM) Guideline (2016)</u>

Recommendations Summary

GDM: Meal and Snack Distribution 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> <u>Evidence Section</u> below.

<u>Recommendation(s)</u>

GDM: Meal and Snack Distribution

In women with <u>gestational diabetes mellitus</u> (GDM), the <u>registered dietitian nutritionist</u> (RDN) should distribute the total <u>calories</u> and <u>carbohydrate</u> (CHO) into smaller meals and multiple snacks per day. The distribution should be individualized, based on blood glucose levels, <u>physical activity</u> and medication, if any (e.g., insulin) and adjusted as needed. Three meals and two or more snacks helps to distribute <u>CHO</u> intake and reduce <u>post-prandial</u> blood glucose fluctuations.

Rating: Consensus Imperative

<u>Risks/Harms of Implementing This Recommendation</u>

There are no risks or harms associated with the application of this recommendation.

- Conditions of Application
 - The <u>RDN</u> should consider the following when individualizing the distribution of meals and snacks: Usual food intake, food preferences, pharmacotherapy, blood glucose levels (hypo- or hyperglycemia), activity level, sleep pattern, treatment goals, work schedule (e.g., shift work, night schedule), <u>food insecurity</u> and access, and cultural/religious beliefs and practices (e.g., <u>fasting</u>), etc.
 The RDN should encourage regular and timely consumption of meals and snacks and avoid fasting beyond 10 to 12 hours (e.g., skipping the evening snack at bedtime or skipping breakfast) to promote blood glucose control (Buchanan et al, 1990; Metger et al, 1982; Mills et al, 1998)

 - Pregnant women who opt to <u>fast</u> beyond 12 hours, due to cultural or religious reasons (e.g., Ramadan), should be medically evaluated prior to the fasting period for intensive management, self-management instruction, appropriate diet and insulin adjustment, if prescribed (Al-Arouj et al, 2010).

Potential Costs Associated with Application

Costs may include expenses related to medical nutrition therapy (MNT) visits from an <u>RDN</u>, blood glucose monitoring and associated medical follow-up.

Recommendation Narrative

No evidence was found to evaluate the impact of meal and snack distribution for women with <u>gestational diabetes mellitus</u> (GDM). However, the following provide support for the consensus recommendation:

- Six to eight small meals and snacks are suggested to decrease <u>nost-prandial</u> hyperglycemia in women with <u>GDM</u>. The distribution of <u>calories</u> should be individualized and based on usual intake, preferences and medication regimen [Joslin Diabetes Center & Joslin Clinic (Joslin), 2011]
 Three meals and two to three snacks is suggested to distribute glucose intake and reduce fluctuations in post-prandial glucose in women with GDM [American College of Obstetricians and Gynecologists (ACOG), 2013]
 Three meals and several snacks is recommended to prevent hypoglycemia, particularly for women with GDM who are taking glyburide or multiple insulin injections. The food distribution should be individualized to tolerance and preference (Shields and Tsay, 2015)
 In pregnancy, decreased insulin sensitivity occurs as hormonal production increases (Shields and Tsay, 2015). Although no evidence was found to support a specific or range of <u>CHO</u> distribution at meals or snacks, customary practice suggests limiting the amount and type of CHOs at breakfast (Joslin, 2011). The CHO intake is reassessed at subsequent visits for possible adjustment according to the blood glucose records (Shields and Tsay, 2015). See the recommendation **GDM**:

Macronutrients (GDM: Carbohydrate and Post Prandial Breakfast Glycemia).

Recommendation Strength Rationale

Consensus: This topic was included in the <u>EAL systematic review</u>. However, no evidence was found to answer the research question. The recommendation is based on consensus publications.

Minority Opinions

None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

- <u>References</u>
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<u>Gestational Diabetes</u>
Gestational Diabetes (GDM) Guideline (2016)

Recommendations Summary

GDM: High-Intensity Sweeteners 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> Evidence Section below.

Recommendation(s)

GDM: Use of High-Intensity Sweeteners

In pregnant women with <u>aestational diabetes mellitus</u> (GDM), who choose to consume <u>high-intensity sweeteners</u>, the <u>registered dietitian</u> <u>nutritionist</u> (RDN) should educate the woman to select only those approved or generally recognized as safe (GRAS) by the US Food and Drug Administration (FDA) and to limit her intake to the <u>acceptable daily intake</u> (ADI), established by the <u>FDA</u>. The FDA has concluded the safety of six high-intensity sweeteners [saccharin, aspartame, accesulfame potassium (Ace-K), sucralose, neotame and advantame] when consumed within the <u>ADI</u> by the general population, including pregnant women. Steviol glycosides and Luo Han Guo (monk fruit) extracts are also <u>GRAS</u> when consumed within the ADI.

Rating: Consensus

- Conditional
 - Risks/Harms of Implementing This Recommendation

In a 1985 review of saccharin, the American Medical Association suggested pregnant women should consider avoiding saccharin, due to limited epidemiological studies in pregnant women and children (Council on Scientific Affairs, 1985). To date, more than 30 human studies have found that saccharin is safe for human consumption (FDA, 2015). Saccharin is approved for use as a non-nutritive, high-intensity sweetener by the FDA (FDA, 2015).

- Conditions of Application

 - This recommendation applies to pregnant women with GDM who are considering use of <u>high-intensity sweeteners</u> as a replacement for higher <u>calorie</u> sweeteners (sucrose, fructose, honey, etc.)
 This recommendation applies only to high-intensity sweeteners within <u>ADI</u> levels (amount considered safe for consumption for each day over a person's lifetime) approved by the <u>FDA</u> and those that are <u>GRAS</u> in the United States
 Individuals with <u>phenylketonuria</u> (PKU), a rare hereditary disease, have difficulty metabolizing phenylalanine which is a component of aspartame. Those with <u>PKU</u> should control their intake of phenylalanine from all sources, including aspartame
 - (FDA, 2015).
 Individuals should not add high-intensity sweeteners to their diet with the intention of improving blood sugar levels. Consumption of high-intensity sweeteners has not been found to have a significant impact on glycemic control in non-pregnant <u>adults</u> with Type 1 and Type 2 diabetes (AND, 2015).
- Potential Costs Associated with Application

There are no obvious costs associated with the application of this recommendation.

- <u>Recommendation Narrative</u>
 - <u>High-intensity sweeteners</u> are commonly used as sugar substitutes or sugar alternatives because they are much sweeter than sugar, but contribute little to no <u>carbohydrates</u> or <u>calories</u>. High-intensity sweeteners are regulated by the <u>FDA</u> as a food additive, unless they are <u>GRAS</u>. Use of a GRAS substance does not require premarket approval by the FDA. For a substance to be determined GRAS there must be common knowledge within the expert scientific community regarding safety, and reasonable certainty that the substance is not harmful within intended use (Federal Register, 2016).
 Six high-intensity sweeteners are FDA-approved as food additives in the United States: Saccharin, aspartame, acesulfame potassium (Ace-K), sucralose, neotame and advantame. These high-intensity sweeteners met safety standards for consumption by the general population, including pregnant women under certain conditions of use, as identified by the FDA.
 - FDA (FDA, 2015)
 - An ADI level, which is the amount considered safe for consumption for each day over a person's lifetime, was set for each of

the high-intensity sweeteners. GRAS notices have been submitted to the FDA for steviol glycosides and Luo Han Guo extracts (FDA, 2015).

- The position of the Academy of Nutrition and Dietetics is that use of <u>nutritive sweeteners</u> is acceptable during pregnancy, but there is very little evidence to support the use of <u>nonnutritive sweeteners</u> in GDM. However, FDA-approved nonnutritive sweeteners are acceptable, with the exception of aspartame in women with <u>PKU</u> (Fitch & Keim, 2012; Kaiser and Campbell, 2014). Based on FDA guidance, the American Diabetes Association (ADA, 2007) and Sweet Success (Shields and Tsay, 2015) also state that use of high-intensity sweeteners within the ADI are considered safe for consumption in the pregnant population.
- Recommendation Strength Rationale

Consensus: This topic was not included in the EAL systematic review. The recommendation is based on consensus publications.

 Minority Opinions None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

- References
- References not graded in Academy of Nutrition and Dietetics Evidence Analysis Process

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 - .org/Portals/0/2015Guidelines/2015 CDAPPSweetSuccessGuidelinesforCare.pdf. 2016: http://www.cdappsweetsuccess
- <u>Gestational Diabetes</u>
 Gestational Diabetes (GDM) Guideline (2016)

Recommendations Summary

GDM: Alcohol 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> <u>Evidence Section</u> below.

<u>Recommendation(s)</u>

GDM: Alcohol Intake

The registered dietitian nutritionist (RDN) should reinforce abstinence from <u>alcohol</u> during pregnancy for women with <u>gestational diabetes</u> <u>mellitus</u> (GDM). The safest choice for all pregnant women is to abstain from alcohol to eliminate the risk for alcohol-related birth defects such as behavioral or neurological defects, growth deficiencies, facial abnormalities and impaired intellectual development.

Rating: Consensus Imperative

• Risks/Harms of Implementing This Recommendation

There are no potential risks or harms associated with the application of this recommendation.

- Conditions of Application

 - <u>Alcohol</u> use during pregnancy is typically addressed by their health care provider and other health professionals during the first obstetric visit and reinforced throughout pregnancy
 Women who are unwilling or unable to refrain from alcohol consumption during pregnancy (e.g., <u>heavy drinker</u>, alcohol dependency, binge drinker) should be referred for supportive services, such as counseling and possible treatment (O'Leary and Bower, 2012).
- Potential Costs Associated with Application

There are no obvious costs that may be associated with the application of this recommendation.

- <u>Recommendation Narrative</u>
 - <u>Alcohol</u> exposure during pregnancy has been linked to birth-related defects in the fetus including fetal alcohol spectrum disorders and low birth weight [Centers for Disease Control & Prevention (CDC), 2016] • Evidence-based scientific information is limited given the nature of any research involving the alcohol intake of pregnant

 - Evidence-based scientific information and institute given the ladie of any research involving the activity information interference of pregnant women. However, fetal alcohol spectrum disorders are the leading cause and the most commonly identifiable cause of preventable developmental delays and intellectual disabilities (CDC, 2016).
 While there is a lack of consensus among healthcare providers regarding the amount of alcohol that would be considered detrimental to the fetus, the Academy of Nutrition and Dietetics (The Academy) and several health organizations, including American Academy of Pediatrics (Williams et al, 2015), American College of Obstetricians and Gynecologists (2015), March of

- Dimes (2015), <u>CDC</u> (2016) have advised pregnant women to abstain from alcohol.
 The position of The Academy on alcohol use during pregnancy is as follows: "Alcohol should not be consumed by pregnant women or those who may become pregnant. Drinking alcohol during pregnancy, especially in early pregnancy, may result in behavioral or neurological defects in the offspring and affect a child's future intelligence. No safe level of alcohol consumption during pregnancy has been established (Procter & Campbell, 2014)."
- <u>Recommendation Strength Rationale</u>
- Consensus: This topic was not included in the EAL systematic review. The recommendation is based on consensus publications.

Minority Opinions

None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

- <u>References</u>
 References not graded in Academy of Nutrition and Dietetics Evidence Analysis Process

 - American College of Obstetricians and Gynecologists. Alcohol abuse and other substance use disorders: ethical issues in obstetric and gynecologic practice. Committee Opinion No. 633. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;125: 1, 529–1, 537.
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Gestational Diabetes Gestational Diabetes (GDM) Guideline (2016)

Recommendations Summary

GDM: Physical Activity 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> Evidence Section below.

<u>Recommendation(s)</u>

GDM: Physical Activity

Unless contraindicated, the <u>registered dietitian nutritionist</u> (RDN) should encourage women with <u>gestational diabetes mellitus</u> (GDM) to engage in a goal to achieve daily moderate exercise of 30 minutes or more per day. In addition to a healthy diet, exercise can help improve blood glucose control and achieve weight gain recommendations. Both aerobic exercise and non-weight-bearing exercise (e.g., stretching, swimming, yoga, etc.) have been shown to lower blood glucose levels in women with <u>GDM</u>. Lifestyle therapy for <u>GDM</u> results in lower birth weight and a lower incidence of <u>large-for-gestational-age</u> births and pre-eclampsia.

Rating: Strong Conditional

- Risks/Harms of Implementing This Recommendation
 - High-intensity or prolonged exercise in excess of 45 minutes can lead to hypoglycemia [American College of Obstetricians and Gynecologists (ACOG), 2015]

 - Pregnant women engaging in <u>physical activity</u> should be advised to ensure adequate caloric intake and to remain well hydrated (ACOG, 2015)
 Contact sports (ice hockey, boxing, soccer, basketball), activities with a high risk of falling (skiing surfing, off-road cycling, gymnastics, horseback riding), scuba diving, sky diving, and hot yoga or hot pilates should be avoided (ACOG, 2015).

• Conditions of Application

- Healthcare provider consultation is warranted or required prior to beginning any exercise program (ACOG, 2015)
 This recommendation applies to women with <u>GDM</u> for whom <u>physical activity</u> during pregnancy is not contraindicated.
 Absolute contraindications include, but are not limited to: Hemodynamically significant heart disease, restrictive lung disease, incompetent cervices or cerclage, multiple gestation at risk of premature labor, persistent second or third trimester bleeding, placenta previa after 26 weeks of gestation, premature labor during the current pregnancy windword purpose (HTN) and on one premise and means with the destation of the destation at risk of premature labor during the current pregnancy.
 - third trimester bleeding, placenta previa after 26 weeks of gestation, premature labor during the current pregnancy, ruptured membranes, preeclampsia or pregnancy induced <u>hypertension</u> (HTN) and severe anemia, and women with relative (ACOG, 2015) Relative contraindications include, but are not limited to: Anemia, unevaluated maternal cardiac arrhythmia, chronic bronchitis, poorly controlled type 1 diabetes, extreme morbid obesity, extreme underweight [<u>body mass index</u> (BMI) below 12kg/m²], history of extremely sedentary lifestyle, intrauterine growth restriction in current pregnancy, poorly controlled <u>HTN</u>, orthopedic limitations, poorly controlled seizure disorder, poorly controlled hyperthyroidism, heavy smoker (ACOG, 2015) Pregnant women with relative contraindications to physical activity may be able to incorporate physical activity with individualized recommendations provided by their health care provider (ACOG, 2015).
- Pregnant women who were sedentary or <u>obese</u> prior to their pregnancy should follow a gradual progression to physical activity goals (ACOG, 2015).
 <u>Overweight</u> or obese women should start with low-intensity, short periods of exercise and gradually increase as able (ACOG, 2015).
 Pregnant women who regularly engaged in physical activity before they were pregnant can continue to engage in <u>high</u> intensity aerobic activity in the absence of contraindications (ACOG, 2015)
 Safe activities within <u>moderate intensity</u> include: Walking, swimming, stationary cycling, low-impact aerobics, modified yoga, modified pilates, running or jogging, racquet sports or strength training (ACOG, 2015).

Potential Costs Associated with Application

There are no obvious costs that may be associated with the application of this recommendation.

<u>Recommendation Narrative</u>

The recommendation is based on The Endocrine Society's Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline (Blumer et al, 2013) as follows:

- Management of Elevated Blood Glucose

 "2.3b. We recommend that the initial treatment of gestational diabetes should consist of medical nutrition therapy and daily moderate exercise for 30 minutes or more. Rating: 1/+++ (Strong recommendation / Moderate quality

 evidence)

 - Summary of support for the recommendation:

 "Lifestyle therapy for <u>GDM</u> results in a lower incidence of reduced birth weight, <u>large-for-gestational-age</u> births, and preeclampsia. Both aerobic exercise and non-weight-bearing exercise have been shown to lower blood glucose levels in women with GDM."

Summary

Physical activity recommendations for pregnant women do not differ from recommendations for the general public (ACOG, 2015). Physical activity during pregnancy is considered safe and desirable for pregnant women in the absence of complications or contraindications (ACOG, 2015; Office of Disease Prevention & Health Promotion, 2008). After a thorough evaluation from the healthcare provider, initial treatment of GDM should include a working goal toward daily moderate exercise of 30 minutes or more (Blumer et al, 2013). Pregnant women should use perceived exertion as a method to monitor exercise intensity. Physical activity has been found to lower blood glucose levels and promote recommended weight status in women with GDM (ACOG, 2013, 2015: Blumer et al, 2013). 2015; Blumer et al, 2013).

Recommendation Strength Rationale

The Academy of Nutrition and Dietetics and the <u>GDM</u> Expert workgroup concur with The Endocrine Society's *Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline* recommendation rating for "Management of Elevated Blood Glucose."

- Minority Opinions
- None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

- References
- References not graded in Academy of Nutrition and Dietetics Evidence Analysis Process
 - Academy Quality Management Committee and Scope of Practice Subcommittee of Quality Management Committee. Academy of Nutrition and Dietetics: Scope of Practice for the Registered Dietitian. J Acad Nutr Diet. 2013 Jun;113(6 Suppl):517-28. doi: 10.1016/j.jand.2012.12.008. PMID: 23454020.
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- Gestational Diabetes Gestational Diabetes (GDM) Guideline (2016)

Recommendations Summary

GDM: Nutrition Monitoring and Evaluation 2016

<u>Click here</u> to see the explanation of recommendation ratings (Strong, Fair, Weak, Consensus, Insufficient Evidence) and labels (Imperative or Conditional). To see more detail on the evidence from which the following recommendations were drawn, use the hyperlinks in the <u>Supporting</u> Evidence Section below.

<u>Recommendation(s)</u>

GDM: Nutrition Monitoring and Evaluation

Following the nutrition intervention of women with <u>gestational diabetes mellitus</u> (GDM), to check progress, the <u>registered dietitian</u> <u>nutritionist</u> (RDN) should monitor and evaluate the following components at each visit and compare to desired individual outcomes relevant to the <u>nutrition diagnosis</u> and <u>nutrition intervention</u>. This may include, but is not limited to:

Food/Nutrition-Related History Outcomes

- Daily food intake in relation to post-meal glucose readings
 Food, beverage and nutrient intake including

 <u>Calorie</u> intake; types and amount of <u>carbohydrate</u> (including <u>fiber</u>) fat, <u>protein</u>; with special attention to high calorie, low-nutrient dense foods such as desserts, candy, <u>sugar-sweetened beverages</u>
 Serving sizes
 - Meal and snack patterns, including frequency and duration

 - Meal and shack patterns, including frequency and duration
 Recent changes to food choices and/or eating pattern
 Preferences, avoidance, intolerances, allergies including

 In relationship to gastrointestinal discomforts (e.g., nausea, vomiting, heartburn, constipation, ptyalism)
 Reaction to or changes in food tastes/smells related to pregnancy
 Cultural and religious considerations.

 Appetite and changes in appetite
 Frequency and intake of meals and snacks; meals eaten away from home
 Methods of food preparation; food safety
 Recommendation to add pharmacologic therapy (oral and/or insulin therapy) to maintain nutrient intake and achi

 - Recommendation to add pharmacologic therapy (oral and/or insulin therapy) to maintain nutrient intake and achieve glycemic targets
 Pharmacologic therapy – dose of diabetes medications: Oral glucose-lowering agent and insulin.

 - Changes in substance use: <u>alcohol</u>, tobacco, caffeine, recreational drugs
 Knowledge, beliefs or attitudes: Motivation, readiness to change, self-efficacy; willingness and ability to make lifestyle
- \odot 2017 Academy of Nutrition and Dietetics (A.N.D.), Evidence Analysis Library. Printed on: 03/30/17 from: http://www.andéal.org

changes; understanding of the treatment plan for GDM • <u>Physical activity</u> and function: Exercise patterns, functionality for activities of daily living, sleep patterns. **Anthropometric Measurement Outcomes** • Weight changes compared to previous obstetric visit or <u>medical nutrition therapy</u> (MNT) visit. **Biochemical Data, Medical Tests, and Procedure Outcomes:** • Self-monitoring blood glucose (SMBG) records, including meter downloads • Ketone testing records (if previously recommended because of weight loss or inadequate calorie intake) • Updated fetal and maternal testing or lab values. <u>Nutrition monitoring and evaluation</u> of these factors is needed to correctly/effectively diagnose nutrition problems that should be the focus of further nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes or initiation of or changes in pharmacologic therapy. pharmacologic therapy.

Rating: Consensus

Imperative

<u>Risks/Harms of Implementing This Recommendation</u>

There are no potential risks or harms associated with the application of this recommendation.

- Conditions of Application

 - If necessary data are not available, the <u>RDN</u> should use professional judgment to request or obtain addition data
 Women who have complicating conditions such as renal disease or eating disorders may require more indepth or specialized nutrition assessments [American Diabetes Association (ADA), 2016]
 RDNs should be alert to psychosocial stressors, such as family and household strain, verbal or physical abuse, exposure to discrimination, <u>food insecurity</u>, unemployment, low resources, major or catastrophic life events and anxiety about the current pregnancy. Such stressors may indicate need for further screening and referral to a mental health professional for early treatment to prevent adverse pregnancy outcomes (Kaiser and Cambell 2014) early treatment to prevent adverse pregnancy outcomes (Kaiser and Campbell, 2014).
- Potential Costs Associated with Application

Accessibility and costs of additional testing should be considered.

Recommendation Narrative

The purpose of <u>nutrition M&E</u> is to assess the effectiveness of <u>nutrition intervention</u> through monitoring, measuring, and evaluating changes in nutrition care indicators. The <u>RDN</u> determines the progress made for the nutrition intervention and whether the patient/client's nutrition related goals or desired outcomes are being achieved (eNCPT, 2016).

Outcomes are measured by data collection of appropriate nutrition outcome indicator(s).

Nutrition M&E in GDM is organized under three domains (categories): Food/Nutrition-Related History Outcomes; Anthropometric Measurement Outcomes; and Biochemical Data, Medical Tests, and Procedure Outcomes (eNCPT, 2016).

Food or Nutrition-Related History

Food and nutrition-related history pertinent to diabetes and pregnancy include:

- Dietary history includes a thorough review of usual food intake, pattern of intake (timing, meals and snacks) and previous history of diet adherence (ADA, 2013)

- Educational knowledge, such as nutrition and meal planning skills, barriers to dietary compliance, such as lack of family support, daily schedule or economic issues, etc. (ADA, 2013)
 <u>Macronutrient</u> (especially <u>CHO</u> and <u>fiber</u>) and micronutrient food intake (ADA, 2013)
 Vitamin and mineral supplement use (prenatal and non-prenatal) or use of natural remedies, such as herbs or alternative therapies (ADA, 2013)
 Ended allocations (Intel ADA, 2013) Food allergies/intolerances (ADA, 2013)
 Use of <u>alcohol</u>, tobacco, caffeine, or other substances [Joslin Diabetes Center & Joslin Clinic (Joslin), 2011]
 Medications: prescription (diabetes-related, non-diabetes-related); over the counter medications (ADA, 2013)
 <u>Exercise</u> pattern - type, frequency, duration [American College of Obstetricians and Gynecologists (ACOG, 2015; Joslin, 2011].

Anthropometric Measurements

- Anthropometric measurements pertinent to diabetes and pregnancy include:

 Weight should be tracked at each visit to determine if the <u>gestational weight gain</u> (GWG) is appropriate (within range), based on Institute of Medicine (IOM) revised guidelines for weight gain during pregnancy (IOM, 2009) (Shields and Tsay, 2015; Joslin, 2011; Kaiser and Campbell, 2014)
 Inappropriate weight gain (excess or inadequate weight gain) may require further assessment of food and calorie intake and adjustment in the nutrition prescription. (ADA, 2016).

 Biochemical Data, Medical Tests and Procedures

Clinical data related to medical tests pertinent to diabetes and pregnancy include: • Post-prandial <u>SMBG</u> is recommended (ADA, 2016) to determine glycemic control throughout pregnancy (Shields and Tsay, 2015; ACOG, 2013).

<u>Recommendation Strength Rationale</u>

Consensus: This topic was not included in the EAL systematic review. The recommendation is based on consensus publications.

Minority Opinions

None.

Supporting Evidence

The recommendations were created from the evidence analysis on the following questions. To see detail of the evidence analysis, click the blue hyperlinks below (recommendations rated consensus will not have supporting evidence linked).

- <u>References</u> References not graded in Academy of Nutrition and Dietetics Evidence Analysis Process
 - Academy of Nutrition and Dietetics. Nutrition Terminology Reference Manual (eNCPT): Dietetics Language for Nutrition Care.

 - Academy of Nutrition and Dietetics. Nutrition Terminology Reference Manual (eNCPT): Dietetics Language for Nutrition Care. 2016 edition. Accessed Nov 16, 2016: http://ncpt.webauthor.com.
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 ACOG. Physical activity and exercise during pregnancy and the postpartum period. Committee Opinion No. 650. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2015;126:e135-142.
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 Kaiser LL, Campbell CG; Academy Positions Committee Workgroup. Practice paper of the Academy of Nutrition and Dietetics abstract: nutrition and lifestyle for a healthy pregnancy outcome. *J Acad Nutr Diet*. 2014 Sep; 114 (9): 1, 447. PMID: 25699300.
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