Effective Health Care Program

Future Research Needs Paper
Number 6

Future Research Needs for Outcomes of Weight Gain in Pregnancy

Agency for Healthcare Research and Quality
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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting comparative effectiveness reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see http://effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

As part of a new effort in 2010, AHRQ has supported EPCs to work with various stakeholders, including patients, to further develop and prioritize the future research needed by decisionmakers. The Future Research Needs products are intended to inform and support researchers and those who fund research to ultimately enhance the body of comparative effectiveness evidence so that it is useful for decisionmakers.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative effectiveness reviews will be updated regularly.

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Executive Summary

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Background

This investigation of future research needs builds on work of the RTI–University of North Carolina at Chapel Hill Evidence-based Practice Center. Their team conducted the systematic evidence review on *Outcomes of Maternal Weight Gain* released in 2008. The rationale for the review cited specific trends in perinatal health with important public health implications as driving factors for conduct of the review:

- Since the 1990 Institute of Medicine (IOM) BMI guidelines on weight gain in pregnancy were published, data show that women in the United States are increasingly gaining more weight during pregnancy than recommended;[1] including excess weight gain among overweight and obese women.[2-4]
- Overweight and obesity among women of childbearing age are rising[5-8] as are levels among preschool children.[9]
- Adults tend to gain weight with age so that advancing maternal age contributes to higher prepregnancy body weight.
- Pregnancy complications associated with excess weight, such as gestational diabetes, large-for-gestational-age babies,[10] and cesarean birth,[11] are increasing in prevalence.

Parameters for the review were broad—findings were meant to be applicable to all pregnant women with singleton pregnancies. Notably, the typical dominant focus of systematic reviews on the effectiveness of interventions and comparisons of interventions was absent. This reflected the fact that the literature contained relatively few studies of interventions to support recommended weight gain that linked weight gain with outcomes. Rather, the review focused on whether evidence convincingly links weight gain or rate of gain to outcomes and evaluated whether the association was directly the result of weight gain and not indirectly the result of other factors closely related to weight gain, such as initial weight and nutritional content of the diet. The review team was interested in all outcomes, short- and long-term, and in all settings in which weight gain had been studied.

Key Questions Addressed by 2008 Systematic Review

The 2008 AHRQ systematic review addressed the following Key Questions (KQs):

Key Question 1. What is the evidence that either total weight gain or rate of weight gain during pregnancy is associated with (1) birth outcomes, (2) infant health outcomes, and (3) maternal health outcomes? Does any evidence suggest that either total weight gain or rate of weight gain is a causal factor in infant or maternal health outcomes?

Key Question 2. What are the confounders and effect modifiers for the association between maternal weight gain (overall and patterns) and birth outcomes? Based on the findings in KQ 1, do these confounders and effect modifiers themselves contribute to antepartum or postpartum complications or to longer-term maternal and fetal complications, including development of adult obesity?

Key Question 3. What is the evidence that weight gains above or below thresholds defined in the 1990 Institute of Medicine BMI Guidelines or weight loss in pregnancy contribute to antepartum or postpartum complications or longer-term maternal and fetal complications? How do these relationships vary by sociodemographic characteristics (i.e., race and age)?

Key Question 4. What are the harms or benefits of offering the same weight gain recommendations to all pregnant women, irrespective of age and body weight considerations (e.g., pregravid weight, actual body weight at a particular time point, or optimal body weight)?

Key Question 5. What are the anthropometric tools for determining adiposity and their appropriateness for the pregnancy state? What are the risks and benefits of measuring adiposity for (1) clinical management of weight gain during pregnancy and (2) evaluation of the relationship between weight gain and outcomes of pregnancy?

Examining these questions, the researchers concluded gestational weight gain is associated with some infant and maternal outcomes, including moderate evidence for an association of higher weight gain with increased risk of cesarean delivery, and for lower weight gain and increased risk of preterm birth, low birthweight, and small-for-gestational-age (SGA) infant. They noted strong evidence for high weight gain being associated with high birthweight, macrosomia, and large-for-gestational-age (LGA) infant. The studies reviewed provided strong evidence for the independent association of pregravid weight status amplifying the effect of gestational weight gain on outcomes. The systematic evidence review (SER) also concluded one weight gain recommendation for all women was not supported by the evidence. The report included a section on future research needs, which was the nidus of the list of research gaps identified and prioritized in this report.

Methods

This project had three phases: (1) update of the literature search from the 2008 report; (2) identification and ranking of future research needs stated as research questions; and (3) recommendations of optimal study design to address those research questions judged to be top priority.

Phase 1: Literature scan. We aimed to replicate the search executed in the 2008 report, from its end-date of October 2007 to January 2010. Our search included four databases: PubMed MEDLINE, EMBASE, the Cumulative Index to Nursing and Allied Health Literature

(CINAHL), and the Cochrane database. We also hand-searched reference lists of relevant articles to identify additional citations.

Once we identified articles we applied the inclusion criteria from the 2008 review. Two reviewers separately evaluated the abstracts. If one reviewer concluded the article was eligible we retained it. For the full article review two reviewers read each article and applied inclusion criteria. Critical information was abstracted to provide a snapshot of interim changes in the state of the literature. This included study design, country and setting of the research, specific interventions being evaluated, if interventions broadly defined as related to maternal weight or weight gain were included, and funding source.

Phase 2: Inquiry and concept building. Our protocol for obtaining stakeholder input on identification and prioritization of future research needs was loosely based on the principles of the Delphi process, modified to maximize electronic communication.[12-13]

To accommodate stakeholders and explore which approaches were preferred, we offered stakeholders three choices for participation in this phase: online, individual phone conversations, or group conference call. All participants selected to proceed by means of electronic communication (Web-based and e-mail). A total of 29 stakeholders representing academic research dietitians and epidemiologists, health care professional organizations, and national foundations and societies related to weight gain and/or maternal health participated in one or more of the stages of ranking and prioritization.

As a first step, we conducted an analysis of the 2008 review, the 2009 IOM BMI Guidelines, and other publications for stated future research needs and knowledge gaps. Our goal for this step was to clearly describe the content of the literature and provide a starting list from which to grow a "snowball" list of all questions believed to be important by stakeholders.

The nidus for the snowball was a list of 37 research questions grouped into five classes: General Evidence Gaps, Targets for Intervention, Standardization Issues, Policy, and Measurement. We invited the stakeholders to submit revisions and additions. At this phase, we intentionally did not ask the stakeholders to rank questions but rather to expand the list of items under consideration. This allowed unhindered entry of concepts onto the list.

The second step was an initial ranking of the 50 items resulting from snowballing. Stakeholders electronically ranked all items from 0 (low) to 10 (high) in four domains: overall importance, clinical utility, feasibility, and potential to advance science. At conclusion of this stage the lowest ranking responses were eliminated. An item was considered to be low ranking if fewer than 30 percent of stakeholders scored it as 9 or 10 across the four domains. We also included a separate set of items to prioritize among candidate measures and outcomes.

In the final step we provided the reduced list of future research questions to the stakeholders and asked them to again rank them across the four domains of overall importance, clinical utility, feasibility, and potential to advance science. Responses to this second survey were then used to create a final ranked list of research questions, measurement approaches, and outcomes.

Phase 3: Optimal research designs to address top priority questions. We held a concluding two and a half–hour conference call to consider what research approaches were most appropriate and feasible to address the identified questions and reflected back the summary to the group.

Results

Phase 1: Literature Scan

We identified 55 new relevant publications[14-68] representing 52 populations: three were randomized controlled trials (RCTs); three, systematic reviews and meta-analyses; and 46, observational studies. They were most frequently retrospective cohorts (n = 24) conducted in the United States (n = 27) with participants recruited most often from the community (n = 20). Funding for most of the current studies was from national sources, including various components of the National Institutes of Health in the United States and the Ministry of Health, Labor, and Welfare in Japan. The focus of all 52 studies was to determine the influence of prepregnancy weight or BMI. The measures of prepregnancy weight/BMI varied from measurements taken at the first prenatal visit to self-report of prepregnancy measurements. Risk of cesarean delivery was the focus for approximately one-fourth of all of the included studies, while nearly two-thirds reported infant and child health outcomes, including Apgar scores and birthweight. Three were small clinical trials of dietary counseling, two combined with physical activity.[16,35,56] Each found a higher portion of women advised about means to achieve target weight gain were more likely to do so that those in comparison groups. None of these studies were judged to definitively address one or more research gaps or to substantively change the framework or intended process for developing and prioritizing future research needs.

Phase 2: Inquiry and Concept Building

Step 1. During the snowballing process the stakeholders increased the list from 37 initial questions to 50. The 50 research questions captured both specific research methods that need to be used and knowledge gaps that must be filled to inform and ultimately improve clinical care. The research questions also encompassed a wide range of specific approaches to measurement of maternal weight, weight gain, and body habitus, as well as a range of specific outcomes.

Step 2. The full list of 50 items, 12 measurement approaches, and eight outcome categories was compiled and presented to the stakeholders for assigning priority scores as described in methods. Eliminating those items that were low scoring resulted in 27 remaining research questions. All questions related to issues of policy were eliminated at this stage. In addition, among the 12 measurement standards and eight outcomes, the lowest ranking one-third of each list was eliminated resulting in eight and five items respectively progressing into the next round.

Step 3. In the final stage of ranking to establish priorities, participants were asked to score the 27 research questions as well as the remaining eight candidate measures and five outcomes. We present the final priority ranking for measures and outcomes first since this ranking carries forward into the interpretation of the research questions prioritized.

"Total weight gain from prepregnancy to end of pregnancy" was considered the highest priority measure of maternal weight gain for future research followed by "prepregnancy baseline weight/BMI" and "change in body/body fat composition." The final prioritization of outcomes ranked "maternal postpartum" and "child health" outcomes as the most important outcomes for future research on maternal weight gain.

The full report presents the ranking scores and final prioritization of the research questions within the classes of items, including scores for each of the four domains (overall importance, clinical importance, feasibility of research, and potential to advance the science).

Based on scores only for the domain "overall importance" the top ranking items were:

1. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
2. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
4. What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?
5. What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?

Our process considered the final composite prioritization of all of the research questions for future research to be based on averaging the scores across all four domains. That approach to ranking resulted in the following list of the top five from highest priority to lower priority:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
4. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
5. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?

Phase 3: Optimal Research Designs To Address Top Priority Question

Stakeholders were reluctant to dictate a specific form of study design because many research areas are at a nascent stage that might benefit from a multiplicity of approaches. They indicated that it would be helpful to modify the causal framework to reflect that social, cultural, and environmental factors have an encompassing influence, not acting as the initial framework visually suggest primarily through influence on diet and energy expenditure. With that broad view in mind they expressed some dismay that the process did not ultimately provide top-ranking questions to be addressed by interventions, especially randomized trials, or by community-based research or hybrid approaches, such as fundamentally changing prenatal care and resources in communities.

Members noted that though it was possible to add items the process was unidirectional after the first step. They considered whether this resulted in inadvertently missing concepts that occurred to participants after the snowballing stage. When specifically queried about the two prioritization lists presented above, they did not feel the process had identified questions that were not of pressing concern or would not be among the crucial next questions to be answered in order to accomplish the goals of advancing the science and informing clinical care. On reflection, the group also noted that the emphasis on methodologic and analytic priorities is warranted, as doubts about the importance of maternal weight gain will persist until the science examining

causal contributions to outcomes is more highly developed. They expressed that once such associations are more definitively understood the field would be better prepared to direct interventions properly toward changing the desired outcomes.

Concepts presented as next steps included:

- Developing consensus about standards for methods of collecting prepregnancy weight and height as well as other body composition and anthropometric measures.
- Maximizing use of existing data collection infrastructure (new birth certificate formats, Behavioral Risk Factor Surveillance System [BRFSS], and the Pregnancy Risk Assessment Monitoring System [PRAMS]) to develop national surveillance studies with large sample size among representative populations.
- Using current Women, Infants, and Children (WIC) infrastructure to conduct postpartum followup to include weighing pregnant and nonpregnant women consistently to allow for accurate baseline data for any subsequent pregnancies.
- Conducting national surveys, with possible inclusion of questions on BRFSS instruments, in order to determine knowledge and attitudes among women about weight gain and their experiences in care.
- Conducting similar evaluations of the knowledge, attitudes, and perceived barriers of providers that inhibit addressing maternal weight and weight gain.
- Launching intervention studies that include efforts to change the physical environment, including community-based interventions (e.g., increasing access to gyms and community centers in neighborhoods where it is not safe to exercise outside by distributing coupons/incentives to facilities).
- Coupling community-based interventions with individual-level interventions such as behavioral counseling and nutrition education or innovative means of prenatal care delivery, such as Centering Pregnancy (group prenatal care).
- Designing randomized controlled trials of promising interventions with large enough scope to make the causal relationship between weight gains above guideline thresholds and poor outcomes (maternal and child) explicitly testable.
- Collecting longer-term outcomes, such as child health and development data and study of maternal weight trajectories between and after pregnancies with more rigorous measures than those available to date.
- Strategizing means to assure a focus on maternal weight gain measures in upcoming national studies including the National Children's Study.

Discussion and Conclusions

Our first phase examined progression of the literature. In the 27 month interval between October 2007 and January 2010, three randomized clinical trials, including a total of 386 women, were published.[16,35,56] In aggregate the results support prior findings that weight gain can be modified by dietary and lifestyle counseling interventions. None of the studies were large enough to adequately assess outcomes and did not contribute sufficient numbers to change aggregate knowledge about anticipated influence on outcomes among women who do or do not achieve target weight gains in pregnancy. No gap identified in the evidence review on maternal weight gain, the IOM proceedings, or the stakeholder discussions as part of this process was filled by a publication or changes in the body of evidence during the interim.

Across publications, stakeholder calls, and survey item development and responses, there was a strikingly consistent level of attention to the need (1) for greater uniformity in measures by means other than self-report, (2) for research that would open a vista on the biological mechanisms at work at a causal level, (3) for statistical analyses that explicitly address the joint contributions of multiple causal factors, and (4) for greater breadth and depth in outcomes assessed. Those engaged in this future research prioritization process indicated in both rankings and discussions that they favored operational definitions (such as research measurement of prepregnancy weight and height), approaches to data and analysis (encompassing baseline weight, caloric intake, nutrient content, physical activity, and weight gain patterns) and outcomes (such as child health and obesity and maternal life course weight trajectory) that can broadly be described as more rigorous than those that dominate the current literature.

In highly ranking both an explicit question about effect modification and another about confounding, this process reveals a level of scientific equipoise about causal influences that matches the large number of basic gaps identified in the literature and discussed in email and the call. Though we did not have a formal method for capturing impression about why this level of rigor was not yet commonly achieved, experts identified the need for greater funding resources and the challenges of long-term followup as barriers to accomplishing more definitive research.

Throughout the phases, the stakeholder group indicated a desire for more definitive understanding of how the many factors (such as those indicated in the causal pathway) work in concert to determine outcomes. They conveyed a level of concern that premature focus on interventions with a particular target, such as total weight gain, without attention to other factors, such as nutrient intake, could fail to improve the desired outcomes. Some participants reported frank doubts about whether the causal links are sufficiently formed to guide intervention solely for the sake of improving reproductive outcomes. However, a majority endorsed that in the United States cultural context of sedentary lifestyles, rising proportions of the population overweight or obese, and many with poor-quality diets, it is not inappropriate to simultaneously study interventions while studying causal factors. Intervention settings that attracted discussion ranged from conventional clinically anchored approaches to passionate advocacy for programs that seek to make more fundamental changes in how women think about weight and weight gain and how communities can be changed to promote healthy lifestyles.

This multiphase process for enumerating, multiplying, and prioritizing research questions to advance research in the area of maternal weight gain and pregnancy outcomes resulted in an actionable list of research topics to fill specific knowledge gaps that was endorsed by multidisciplinary experts. Inherent variation in how respondents valued items allowed selection of cut-offs to trim lists at each phase of prioritization. When the items were re-presented on shortened lists, constraining the scope, variation in prioritization persisted that made a final round of ranking desirable in solidifying recommendations for future research.

Stakeholders proposed ways to further extend the reach of the process to include greater scope in the candidate ideas via adding an early opportunity to create synergy in discussion and to actively encourage the “snowballing process.” However at conclusion, they were not dissatisfied with the prioritized topics. The core message of increased rigor as a necessity may be valuable for both endorsing streams of research considered descriptive, methodologic, and quantitatively focused—namely working out the nature of causal relationships—and for drawing the attention of investigators and funders to the importance of more demanding, larger, longer, prospective and intervention studies.

While the group was inspired to map the identified research priorities to study approaches, they were reluctant to specify a single, correct next step. They expressed confidence in the collective energy and creativity of the scientific community, suggesting that agencies and organizations seeking to advance research in this area solicit and amply fund investigator-initiated research rather than prespecifying study designs to answer high priority questions. Likewise there was confidence that robust expertise and appropriate study populations are available to realize answers to the prioritized questions quickly in order to bring practical tools and new knowledge to advancing the care of women and their children.

Background

2008 AHRQ Systematic Review of Outcomes of Maternal Weight Gain

This examination of future research needs builds on work of the RTI-University of North Carolina at Chapel Hill Evidence-based Practice Center. Their team conducted the systematic evidence review on *Outcomes of Maternal Weight Gain* released in 2008.[69] The rationale for the review cited specific trends in perinatal health with important public health implications as driving factors for conduct of the review:

- Since the 1990 IOM guidelines on weight gain in pregnancy, women in the United States are increasingly gaining more weight during pregnancy than recommended;[1] including excess weight gain among women who were overweight and obese before pregnancy.[2-4]
- Overweight and obesity among women of childbearing age are rising[5-8] as are the levels among preschool children.[9]
- Adults tend to gain weight with age so that advancing maternal age contributes to higher prepregnancy body weight.
- Pregnancy complications associated with excess weight such as gestational diabetes, large-for-gestational-age babies,[10] and cesarean birth[11] are increasing.

Ideal weight gain during pregnancy has long been debated. Gestational weight gain includes the products of conception, the fetus and placenta, as well as increases in maternal fat stores, plasma volume, and uterine and breast tissue. Because pregnancy is the only common clinical situation in which the care provider has at least two patients—the mother and the fetus(es)—balancing the amount of weight gain needed to optimize the growth of babies without jeopardizing the health of mothers in either the short or the long term is essential.

In the 1930s, the recommendation to all pregnant women, irrespective of pregravid weight status, was 6.8 kg (about 15 pounds). This recommendation to restrict weight gain to decrease risk of pregnancy complications continued until 1970. It stemmed largely from the observation that increased maternal weight gain was related to higher birthweights.[70] In 1970, however, the IOM determined that restriction of weight gain was likely to be harmful with respect to restricting birthweight; subsequently, formal weight gain recommendations were eased from less than 20 pounds throughout pregnancy to a range of 20 to 27 pounds.[71]

Over the next two decades, accumulating research suggested that one guideline was unlikely to suit all women and their fetuses. This recognition led an IOM committee to issue guidance to providers and to the public that was based on a woman's pregravid weight.[1] The 1990 IOM recommendations (Table 1) were weight gains of (1) 28 to 40 pounds for women with low body mass index (BMI), defined as < 19.8; (2) 25 to 35 pounds for women with normal BMI (19.8-26); and (3) 15 to 25 pounds for women with high BMI (> 26.0-29.0). Further, the recommendations included a weight gain of at least 15 pounds for obese women (BMI > 29), weight gain in the upper end of the recommended range for adolescents and black women, and weight gain in the lower end of the recommended range for women of shorter stature (< 157 centimeters [cm] or 62 inches). These recommendations were the first to account for pregravid weight status and to encourage obese women to gain weight during pregnancy, citing the nutritional needs of the fetus.

Table 1. IOM 1990 recommendations for weight gain during pregnancy by prepregnancy BMI

Prepregnancy BMI	BMI (kg/m^2)	Total Weight Gain Range (lbs)	Rates of Weight Gain 2nd and 3rd Trimester (Mean Range in lbs/wk)
Underweight	<19.8	28-40	1 (1-1.3)
Normal weight	19.8-26	25-35	1 (0.8-1)
Overweight	>26-29	15-25	0.6 (0.5-0.7)
Obese (all classes)	>29.0	15	0.5 (0.4-0.6)

The IOM also addressed patterns of weight gain by providing guidance on the ideal amount to be gained in the first trimester and rates of weight gain in the second and third trimesters. These recommendations tended to focus on the prevention of low birth-weight deliveries rather than the impact on maternal obesity and related health outcomes.

In 1996, an expert panel assembled by the Maternal and Child Health Bureau of the US Health Resources and Services Administration reexamined these recommendations. At the time, the panel decided that revisions were unnecessary. They found, however, that the evidence to date suggested that the recommendations for higher weight gains by black women and adolescents and lower weight gains for women of shorter stature were not well supported; they concluded that these subpopulations should be advised to stay within the IOM's recommended weight range specific for their pregravid BMI.[72]

Since the 1990 IOM recommendations, several studies documented the low proportion of women meeting the guidelines. In a 1998 study of more than 120,000 women, 34 percent gained weight within the recommended ranges.[73] The proportion of women gaining more than the recommended range increased over the time span 1990 to 1996 from 42 percent to 44 percent.[73] The proportion of women gaining less than recommended remained relatively stable (23 percent to 22 percent). Other studies reporting on various subpopulations since the 1990 report also found that 30 to 40 percent of women gained weight within the recommended ranges.[4,74-83] Although the IOM recommendations had been in place for almost two decades, between 35 percent and 60 percent of pregnant women reported receiving no advice from their providers about appropriate pregnancy weight gain.[84-85] Pregnant women who reported being advised about the appropriate amount of weight to gain during pregnancy were more likely to gain within the recommended range than women who did not receive such advice.[86-87] This link rests on a handful of studies, most conducted before or soon after the 1990 IOM guidelines.[84,86-87]

Persistent non-adherence to weight gain guidelines and wide variability in the amount of weight gained during pregnancy has served as the impetus for much research on predictors of gestational weight gain. This body of work suggests a multifactorial model is required.[85,88-89] The bulk of research notes the importance of pregravid weight status, parity, height, race or ethnicity, age, age at menarche, physical activity, and psychosocial stress in influencing weight gain.[85,88-91] Although such investigations are important, even more basic is an understanding of the short- and long-term benefits and risks of gestational weight gain for the mother, the fetus, and the child. The 2008 AHRQ SER was undertaken to fully explore what had been learned about the impact of gestational weight gain since the 1990 IOM recommendations. The parameters for the review were broad—the target population of interest for whom the findings were meant to be applicable was all pregnant women with singleton gestations. Notably, the common dominant focus of systematic reviews on the effectiveness of interventions and comparisons of interventions was absent. This reflected the fact that the literature contained relatively few

studies focused on interventions to support recommended weight gain. The review took a more fundamental approach to determining whether there was evidence to convincingly link weight gain or rate of gain to outcomes and to assure that the association was direct and not indirectly the result of other factors that are closely related to weight gain like initial weight and nutritional content of the diet. The review team was interested in all outcomes, short- and long-term, and in all settings in which weight gain had been studied.

Key Questions Addressed by 2008 AHRQ Review

Key Questions (KQs) addressed by the 2008 AHRQ systematic review were:

Key Question 1. What is the evidence that either total weight gain or rate of weight gain during pregnancy is associated with (1) birth outcomes, (2) infant health outcomes, and (3) maternal health outcomes? Does any evidence suggest that either total weight gain or rate of weight gain is a causal factor in infant or maternal health outcomes?

Key Question 2. What are the confounders and effect modifiers for the association between maternal weight gain (overall and patterns) and birth outcomes? Based on the findings in KQ 1, do these confounders and effect modifiers themselves contribute to antepartum or postpartum complications or to longer-term maternal and fetal complications, including development of adult obesity?

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Key Question 4. What are the harms or benefits of offering the same weight gain recommendations to all pregnant women, irrespective of age and body weight considerations (e.g., pregravid weight, actual body weight at a particular time point, or optimal body weight)?

Key Question 5. What are the anthropometric tools for determining adiposity and their appropriateness for the pregnancy state? What are the risks and benefits of measuring adiposity for (1) clinical management of weight gain during pregnancy and (2) evaluation of the relationship between weight gain and outcomes of pregnancy?

Examining these questions, the authors concluded gestational weight gain is associated with some infant and maternal outcomes, including moderate evidence for an association of higher weight gain and with increased risk of cesarean delivery, and for lower weight gain and increased risk of preterm birth, low birthweight, and small-for-gestational-age (SGA). They noted strong evidence for high weight gain being associated with high birthweight, macrosomia, and large-for-gestational-age (LGA). The studies reviewed provided strong evidence for the independent association of pregravid weight status amplifying the effect of gestational weight gain on outcomes. The SER also concluded one weight gain recommendation for all women was not supported by the evidence.

Change in National Guidelines for Maternal Weight Gain

During the timeframe of the AHRQ report, the IOM convened the Committee to Reexamine the IOM Pregnancy Weight Guidelines. In 2009 they published *Weight Gain During*

Pregnancy: Reexamining the Guidelines.[1] This report outlined the need to reexamine the 1990 guidelines given the changing population of American women giving birth (older, more diverse, more likely to be overweight/obese). The Committee focused primarily on the importance of the woman's weight at the start of pregnancy and the increased risk of chronic disease with overweight status and obesity. The new guidelines are based on the measure of body mass index and the categories developed by the World Health Organization (WHO) and implemented by National Heart, Lung, and Blood Institute (NHLBI). The IOM highlights that the new recommendations (Table 2) differ from the previous ones in that they are based in the WHO BMI categories and include a more restrictive range of weight gain for obese women. In contrast to the earlier guidance, women of shorter stature and racial and ethnic groups are advised to follow guidelines set for the whole population depending on their BMI category.

Table 2. IOM 2009 recommendations for weight gain during pregnancy by prepregnancy BMI

Prepregnancy BMI	BMI (kg/m^2)	Total Weight Gain Range (lbs)	Rates of Weight Gain 2nd and 3rd Trimester (Mean Range in lbs/wk)
Underweight	<18.5	28-40	1 (1-1.3)
Normal weight	18.5-24.9	25-35	1 (0.8-1)
Overweight	25.0-29.9	15-25	0.6 (0.5-0.7)
Obese (all classes)	≥30.0	11-20	0.5 (0.4-0.6)

The 2009 IOM recommendations differed from the 1990 IOM recommendations by adjusting the BMI ranges to match the WHO definitions, by allowing for as little as 11 pounds weight gain in women with obese prepregnant weight, and by eliminating special considerations other than prepregnant BMI. The IOM process also recognized that the 2008 AHRQ systematic review served as a stimulus for identifying current gaps in knowledge and critical future research.

Research Gaps Identified in Prior Work

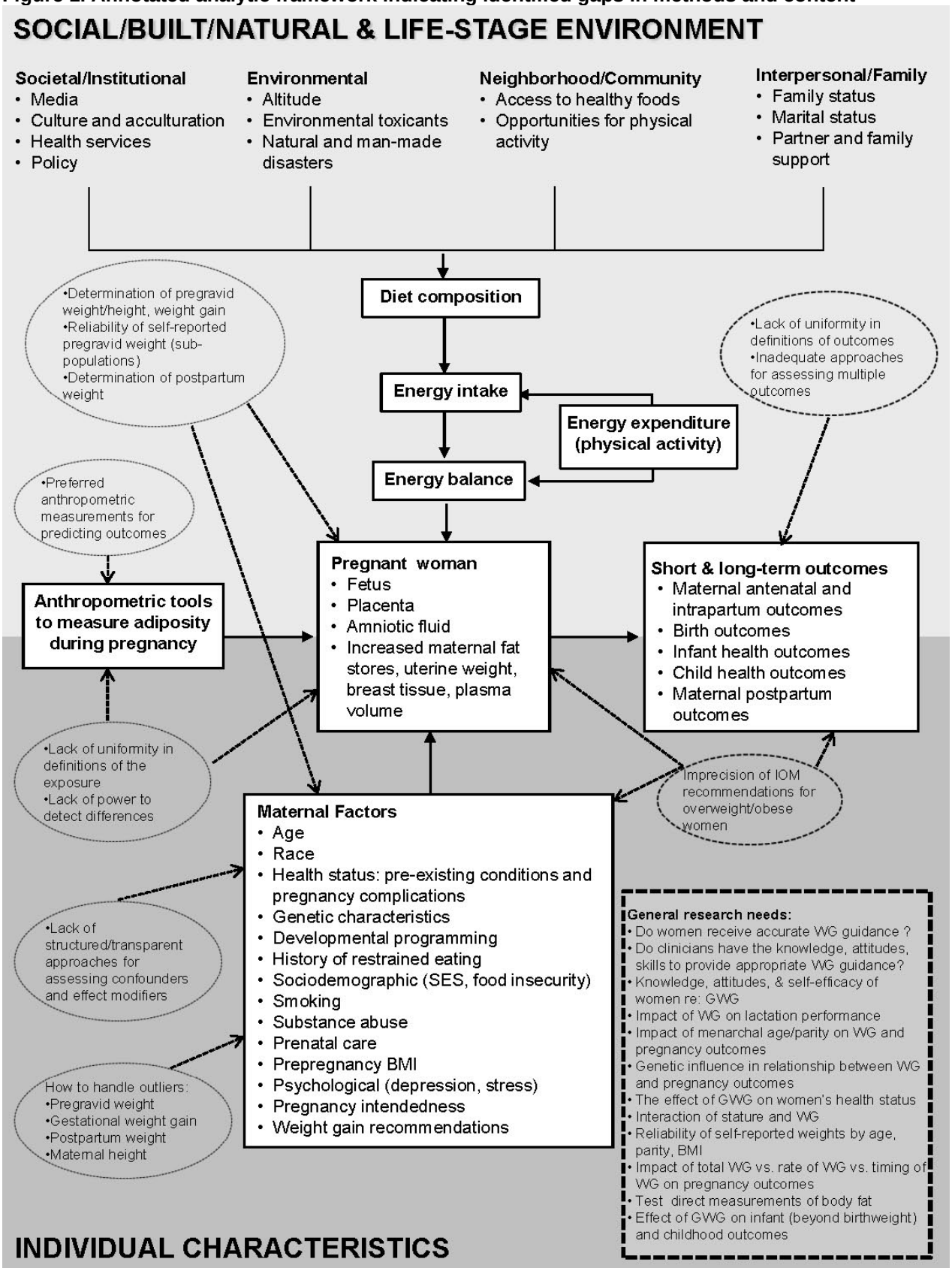
The AHRQ 2008 review included attention to defining critical topics for future research. The review team identified the limitations of the evidence and research gaps in two broad areas: (1) overall need for studies and (2) methodologic challenges to existing studies that limited the EPC's ability to draw conclusions. For example, to understand fully the impact of gestational weight gain on short- and long-term outcomes for women and their offspring would require that researchers use consistent definitions of weight gain during pregnancy, improve standardization of methods and timing of weight measures, better address confounders in their analyses, improve study designs and statistical models, and conduct studies with longer followup. As a matter of course, the SER was not able to address the newest 2009 IOM recommendations (Table 2), which raise additional questions.

The analytic framework for the 2008 report, adopted from the 1990 IOM report, has been modified here to illustrate research gaps that remained and were identified in the report and our review of literature published since 2008 (Figure 1). This analytic framework indicates gaps identified during the 2008 review and our horizon scan of the literature through the use of dashed circles and squares. The dashed circles represent gaps linked to specific stages in the framework. However, there were several general research needs that could not be linked to particular components of the pathway as they likely have broad influence on both weight gain and

outcomes. They are included in the dashed square in the bottom right of the diagram. The primary linkages are indicated in the boxes along the center line where individual maternal factors and society meet. In this annotated framework, key questions are not indicated. Each of the domains listed among individual and social/built/natural and life-stage environment, such as media, environmental toxicants, access to healthy foods, and family status, has been shown to influence diet composition, energy intake, energy expenditure, and energy balance.

Methodological concerns related to measurement included the source of information on weight gain and the timing of measurement of weight gain. Studies that rely solely on self-reported pregravid and final pregnancy weights suffer from well-documented issues of recall bias. In addition, individuals tend to misreport their weight and at times height, and this bias varies by weight status[92] and ethnicity.[93] The timing of weight measurement (for pregravid weight and final weight) vary depending on the design of the study; when unreported, the total weight gain during pregnancy cannot be assumed to be collected at similar time points for all women within the study, resulting in further bias. Additional concerns include need for use of tools that are *de rigeur* in non-pregnancy weight and body habitus studies such as: standardization of weight measures including calibration of scales and stadiometers and introduction of use of anthropomorphic and other measures to assess body weight composition, distribution of body fat and patterns of weight gain.

Figure 1. Annotated analytic framework indicating identified gaps in methods and content



Consideration of Feasible Study Types for Addressing Gaps

Authors reflecting on research gaps in this area, as well as the experts who provided input for this report, note that the gold standard for establishing causation is to conduct randomized controlled trials at varied "exposures" to the causal agent under study. In this case to directly assess links between maternal weight gain and outcomes would require women be randomized to a particular weight gain target (and achieve the target). This has not been considered a feasible means to determine the influence of different levels of weight gain by women of varying pregravid weights on outcomes. If that is so, well-conducted observational studies continue to be necessary as one path to understanding associations and refining weight gain goals.

Observational studies bring with them a high bar for quality of measurement and rigor in statistical analysis in order correctly identify association with outcomes while accounting for confounding and modifying factors. Well-documented associations then have potential to serve as guides for the anticipated benefits and safety of trials that attempt behavioral, nutritional, or educational interventions to achieve desired target. Although the 2008 review included several studies that took advantage of large databases and longitudinal data that allowed investigation of the influence of weight gain on short- and long-term outcomes, it yielded little in the way of consistent findings because the body of research was assessed to lack methodological rigor, precision, concordance in findings and analytic sophistication.

Summary

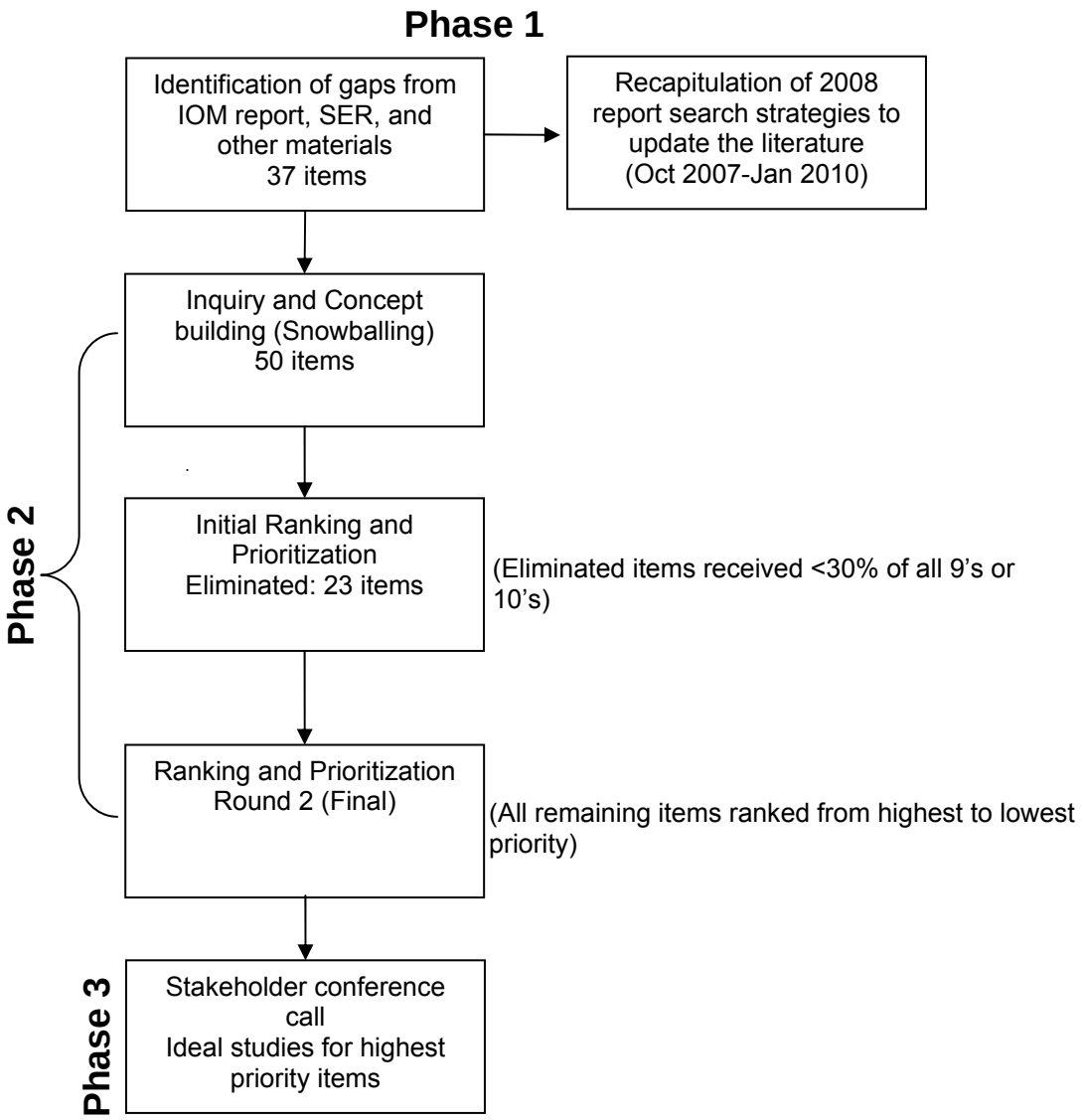
In summary the desire for evidence-based guidance about optimal maternal weight gain is important to women, their care providers, researchers, policy makers, and those who fund research and healthcare. It has special urgency given cultural trends in rising prevalence of overweight and obesity and given the public health repercussions of a population at increasing risk of chronic disease, earlier onset of those conditions, and resulting decreases in quality of life. There is a lack of definitive evidence about what factors in pregnancy exert most influence on outcomes, for example baseline weight or BMI, weight gain or patterns of weight gain, caloric or nutrient intake. This lack of evidence hinders ability to appropriately design and test interventions designed to modify the most critical components in order to improve fetal, neonatal, maternal, and childhood outcomes.

The future research needs project described in this report was undertaken to provide an overview of any fundamental changes in the state of the evidence since completion of the 2008 evidence review and to expand on identification of future research needs by engaging a group of experts from the range of disciplines that contribute to understand outcomes of maternal weight gain. These include nutritionists, reproductive epidemiologists, registered dietitians, multiple disciplines of prenatal care providers, researchers focused specifically on causal associations with maternal weight and weight gain, and others who study interventions to modify weight or nutritional intake. In the coming sections we describe our approach (1) to assessing whether there had been fundamental advances in the literature; (2) to compiling previously identified research gaps and soliciting identification of additional gaps; (3) to prioritizing among the many research needs identified; and (4) to discussing future research agendas and study designs that could be brought to bear on filling the gaps.

Methods

The three phases of this project, including the update of the literature search from the 2008 report and the identification and prioritization of future research needs, are summarized in Figure 2. While we began the first two phases of the project at the same time, they were undertaken separately.

Figure 2. Identification and prioritization process diagram



Phase 1: Identifying Recently Completed and Ongoing Studies

Databases. We aimed to replicate the search executed in the 2008 report, from its end-date of October 2007 to January 2010. Our search included examination of results in four databases: PubMed MEDLINE, EMBASE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Cochrane database (Tables 3-6). We also hand-searched the reference lists of relevant articles to identify additional citations for review.

Search terms. Controlled vocabulary terms served as the foundation of our search in each resource, complemented by additional keyword terms and phrases selected to represent each of the key concepts in the search. We also employed indexing terms when possible to exclude undesired publication types (e.g., reviews, case reports, letters, etc.) and articles published in languages other than English.

Table 3. PubMed search strategies

Search #	Terms
#1	Weight gain[mh]
#2	Pregnancy[mh]
#3	#1 AND #2
#4	Gestational weight gain
#5	#3 OR #4
#6	(#3 OR #4) AND eng[la] AND humans[mh]
#7	("Outcome Assessment (Health Care)"[MeSH] OR "Outcome and Process Assessment (Health Care)"[MeSH] OR "Pregnancy Outcome"[MeSH] OR "Reproductive History"[MeSH] OR "birth outcomes" OR "infant health outcomes" OR "maternal health outcomes") AND eng[la] AND humans[mh]
#8	#6 AND #7 AND eng[la] AND humans[mh]
#9	"counseling"[mh] OR "directive counseling"[mh]
#10	#6 AND #8
#11	"body weights and measures"[mh]
#12	#6 AND #10
#13	Anthropometry[mh]
#14	#11 AND #12
#15	#7 OR #9 OR #13
#16	limit #14 to items added to PubMed from 10/03/2007 to present

Table 4. EMBASE search strategies

Search #	Terms
#1	exp weight gain/
#2	exp pregnancy/
#3	#1 AND #2
#4	exp pregnancy outcome/
#5	exp pregnancy complication/
#6	#4 OR #5
#7	#3 AND #6
#8	limit #7 to human and English language
#9	morphometrics/ or anthropometry/
#10	#3 AND #9
#11	limit #10 to human and English language
#12	#8 OR #11
#13	limit #12 to yr="2007-Current"

Table 5. CINAHL search strategies

Search #	Terms
#1	MH “Weight gain+” OR “weight gain”
#2	MH "pregnancy+" OR pregnancy OR pregnant OR maternal
#3	#1 AND #2
#4	MH "pregnancy outcomes+" OR MH "pregnancy complications+" OR MH "infant, large for gestational age" OR MH "infant, low birthweight+" OR MH "infant, premature"
#5	limit #3 AND #4 to English language, peer-reviewed journals and excluding MEDLINE records
#6	MH "counseling+" OR counseling OR advice OR advise OR guidance
#7	limit #3 AND #6 to English language, peer-reviewed journals and excluding MEDLINE records
#8	MH “Body Weights and Measures+”
#9	limit #3 AND #8 to English language, peer-reviewed journals and excluding MEDLINE records
#10	#5 OR #7 OR #9
#11	limit #10 to items published from 2007 to present

Table 6. Cochrane search strategies

Search #	Terms
#1	(maternal weight gain OR gestational weight gain OR weight gain during pregnancy).mp.

Article selection process. In order to properly update the search from the 2008 report we used the same inclusion and exclusion criteria, with a modification of publication date (Table 7). Once we identified articles through the electronic database searches and bibliographies we examined the abstracts of articles to determine the inclusion criteria set by the 2008 review. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an updated Abstract Review Form (Appendix C). If one reviewer concluded that the article was eligible based on the abstract, we retained it. For the full article review two reviewers read each article and decided whether it met the inclusion criteria, using the Full Text Inclusion/Exclusion Form (Appendix C).

Table 7. Inclusion/exclusion criteria for gestational weight gain

Category	Criteria
Study population	Women of any age with singleton pregnancies
Study settings and geography	KQ 1, KQ 2, KQ 4: Developed nations: United States, Canada, Western Europe, Japan, Australia, New Zealand KQ 3: United States KQ 5: All countries
Time period	October 2007 to January 2010
Publication languages	English only

Category	Criteria
Admissible evidence (study design and other criteria)	Admissible designs: • Controlled trials (n ≥ 40), nonrandomized controlled trials (n ≥ 40), systematic reviews, meta-analyses, prospective trials with historical controls (n ≥ 40), prospective or retrospective observational cohort studies (n ≥ 40), and medium to large case series (n ≥ 100) Other criteria • Original research studies must provide sufficient detail regarding methods and results to enable use and adjustment of the data and results. • Relevant outcomes must be abstractable from data presented in the papers. • Sample sizes must be appropriate for the study question addressed in the paper; single case reports or small case series (n < 100) are excluded. • For KQ 1, 2, 3, and 4: prepregnancy body mass index (BMI) or weight must be accounted for in the relationship between maternal weight gain and outcome. • Studies limited to women with preexisting health conditions only are excluded.

Engaging Stakeholders, Researchers, Funders

The Vanderbilt Evidence-based Practice Center worked with the Scientific Resource Center to develop a group of stakeholder individuals and organizations with expertise and vested interest in the topic. We asked for the organizations to nominate potential stakeholders in four areas: advocacy, clinical practice, research, and research funding priorities. The initial list of potential organizations, developed by the Vanderbilt Evidence-based Practice Center, from which stakeholder nominations was solicited is in Table 8. We aimed for balanced representation across provider specialties, interest of advocacy organizations, those involved in making guidelines and recommendations, and in prioritizing use of research funds.

Table 8. Weight gain in pregnancy stakeholder sample organizations

Maternal Weight Gain Stakeholder Organizations/Affiliations
American Academy of Family Physicians
American Academy of Nurse Practitioners
American Academy of Pediatrics (Perinatology Section)
American Association for Diabetes Educators
American College of Nurse Practitioners
American College of Nurse-Midwives
American Congress of Obstetricians and Gynecologists
American Diabetes Association
American Dietetic Association
American Nurses Association
American Public Health Association
American Society for Nutrition
Association of Women's Health, Obstetric and Neonatal Nurses
Centers for Disease Control and Prevention-Nutrition Branch
Childbirth Connection
Health Resources and Services Administration
International Food Information Council Foundation
March of Dimes
Midwives Alliance of North America
National Association of Nurse Practitioners in Women's Health
National Eating Disorders Association
National Institute of Child Health and Human Development-Perinatology Research Branch

Maternal Weight Gain Stakeholder Organizations/Affiliations
Our Bodies, Ourselves
The American Pregnancy Association
The Obesity Society
Trust for America's Health
World Health Organization

Prioritizing Future Research

Phase 2: Prioritizing research. Our protocol for obtaining stakeholder input on research question prioritization was loosely based on the principles of the Delphi process, modified to maximize electronic communication and to streamline discussion. In short, we began by identifying a list of candidate research topics and initiating an iterative electronic process to refine and then rank the topic list. We then concluded the process with a teleconference that allowed personal interaction between the participants and discussion of the research priorities.

Initially, we conducted a detailed analysis (two readers and electronic key word searches within documents) of the 2008 review, and the IOM Guidelines searching for stated future research needs or identification of specific gaps. Our goal for this step was to clearly describe the state of the literature and form the starting point for the "snowball" list of all possible domains.

Review of the pilot protocol to gather stakeholder input was reviewed and approved by the Vanderbilt Institutional Review Board. Potential stakeholders were contacted by email, with a personal phone call followup as needed, to participate in the process. To maximize ability to engage stakeholders and to explore which approaches they preferred, we offered stakeholders three choices for participation in the very first phase of Inquiry and Concept Building (snowballing of ideas): online submission of information, individual phone conversations, or group conference call. The general consensus was to proceed with the "snowballing" process by means of electronic communication.

Step 1: Snowballing. Drawing on the 2008 report, the 2009 IOM report and other publications, we developed a list of 37 research questions for electronic review by the stakeholder panel. This initial list of candidate research questions was divided into five classes by the Vanderbilt Evidence-based Practice Center team: General Evidence Gaps, Interventions, Standardization Issues, Policy, and Measurement, which were used to seed the snowballing process with stakeholders. We invited the panel to submit comments regarding the initial list, including better ways to express research topics, ways to make the list broader and more comprehensive and to suggest topics we may have omitted. We intentionally did not ask the stakeholders to rank questions or to suggest ways to reduce the number of items at this "snowballing" point in the process, as we wanted to be as inclusive as possible, to ensure that the review panel would have a complete and relatively unbiased list of research topics from which to begin the prioritization process.

Step 2: Initial ranking. After "snowballing" the list of items we had a total of 50 research questions related to evidence gaps. We asked stakeholders to electronically rank these items from 0-10 in four domains: overall importance, clinical utility, feasibility, and potential to advance science. In this stage the lowest ranking responses were eliminated. They were considered to be low ranking if fewer than 30 percent of stakeholders scored the item as a 9 or 10 across the four domains.

After ranking research questions, stakeholders were also asked to prioritize candidate measures and outcomes arising from the research questions. Because questions included both a measure of exposure—in this case multiple candidate approaches to measuring maternal weight or weight gain—and an outcome, the number of combinations of exposures and outcomes would have resulted in a total number of questions that were impractical for ranking if all possible permutations were added to the list. Therefore we also sought to gain a sense of the perceived importance of focusing future research on specific measures of maternal weight gain; assigning "1" as the most important and "12" as the least important. The ranking scores were added together across respondents so that the measure with the highest score was identified as the least important. A similar process was used to rank the five broad categories of outcomes that encompassed all the outcomes proposed in the full list of items. They included: maternal antepartum outcomes, development of gestational diabetes, fetal outcomes, intrapartum outcomes, neonatal outcomes, maternal postpartum outcomes, infant health outcomes, and child health outcomes.

Step 3: Final ranking of reduced list of items. We then sent the reduced list of future research questions to the stakeholders and asked them to again rank them across the four domains of overall importance, clinical utility, feasibility, and potential to advance science. Responses to this second survey were then used to create a ranked list of the topics for discussion during a teleconference call. For this step in ranking research questions, the ranking scores were multiplied by the number of responses and these scores were added together so that the measure with the highest score was the most important. For example, if out of 5 participants 3 ranked the question as 5 out of 10 in importance and 2 ranked the question as 10 out of 10, that question would receive a score of (5*3) + (2*10) =35. These scores were then compared across questions and a final listing of top priority items prepared for review with the stakeholders.

Determining Appropriate and Feasible Study Design

Phase 3. Optimal research designs to address top priority questions. In the final phase of this project, the stakeholder panel held a two and a half hour teleconference on the final ranking of priorities for future research in order to inform recommendations about the ideal study design(s) to address the highest priority items. A face-to-face meeting was initially planned but proved to be unworkable within the project timeline.

In advance of the meeting, participants were provided with the final overall rankings which included the five questions that ranked as highest priority by each domain as well as the summary results for the prioritization of the measures of maternal weight and weigh gain and categories of outcomes. All prior results, including rankings within classes of research questions (General Evidence Gaps, Interventions, Standardization Issues, and Measurement) and by overall importance, clinical utility, feasibility, and potential to advance science, were available to participants during the call.

The group discussed the utility and clarity of the causal framework, their impression of the final list and its comprehensiveness and discussed remaining gaps which they felt were overlooked in the process. However the primary agenda for the meeting was to recommend the most appropriate and feasible research designs to address the top priority items.

Handling Conflicts of Interest

We obtained the standard AHRQ Conflict of Interest forms from all participants including our EPC faculty and staff. None of the identified stakeholders or EPC team members had a conflict judged to preclude participation in the process. Stated conflicts included the following:

- Funded research from agencies and foundations such as the NICHD, NHLBI, and the American Diabetes Association
- Employment with a professional organization
- Involvement with the adoption of 2009 IOM recommendations by the government (Canada)
- Membership on the board of a foundation related to obesity and maternal and child health research

During the snowballing and ranking process the participant stakeholders had no information about the identities of the other participants. Until the conclusion of each step they did not have access to scores and then only to the aggregate. Beginning the process with recruitment of additional items was intended to allow the scope of topics for future research to expand and to assure that a large number and range of potentially important topics were considered. Since the group elected to do their work electronically, individual persuasiveness or dominance of the conversation by particular topics did not have potential to sway the group opinion or the overall process.

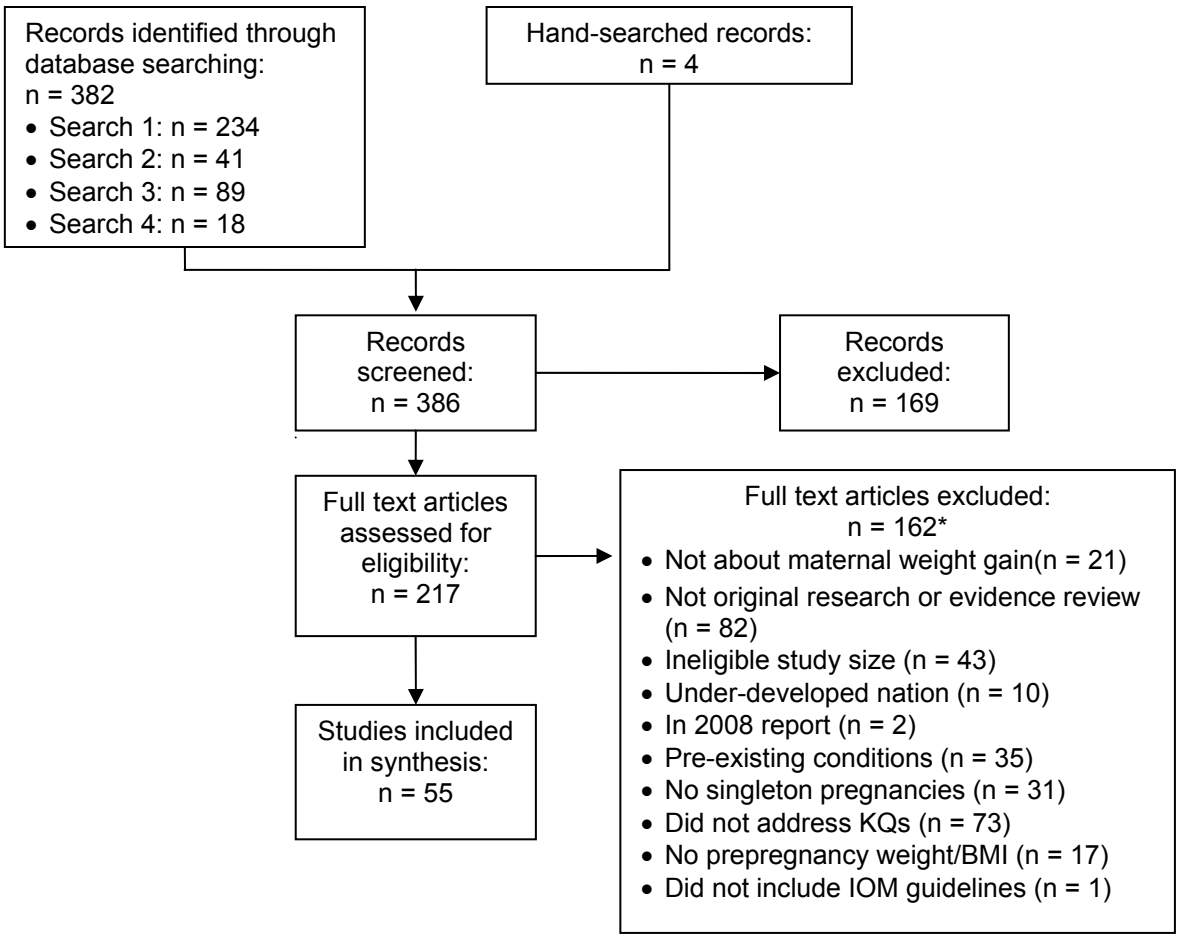
At conclusion of the project, the preliminary draft of this report was also posted for public comment. We specifically solicited feedback about [what elements]. Public commentary was [characterize] and emphasized [what exactly]. The input has been incorporated in this final version of the report.

Results

Phase 1: Updating the 2008 SER Literature Review

Our search updating the 2008 evidence review was executed in January 2010. From PubMed, we identified 234 items for further review; EMBASE yielded 41 items; CINAHL yielded 89 items; and the Cochrane database yielded 18 citations. After eliminating duplicates, 386 citations comprised our pool of publications to screen of which 55 publications, representing 52 populations, were ultimately relevant to describing research completed since the 2008 report. Fifty articles pertained to KQ 1, 19 to KQ 2, 18 to KQ 3, seven to KQ 4, and one to KQ 5.

Figure 3. Disposition of articles for updating status of maternal weight gain literature



*Exceeds total number of articles excluded because some articles fit multiple exclusion categories.

Table 9 provides an overview of these 55 publications,[14-68] representing 52 populations. They were most frequently retrospective cohorts (n = 24) conducted in the United States (n = 27) with participants recruited most often from the community (n = 20). Funding for most of the current studies was from national sources, including various components of the National

Institutes of Health in the United States and the Ministry of Health, Labor, and Welfare in Japan. The focus of all 52 studies was to determine the influence of prepregnancy weight or BMI. The measures of prepregnancy weight/BMI varied from measurements taken at the first prenatal booking to self-report of prepregnancy measurements. Risk of cesarean delivery was the focus for approximately one-fourth of all of the included studies, while nearly two-thirds reported infant and child health outcomes, including APGAR scores and birthweight.

Table 9. Summary of new publications in the maternal weight gain literature since 2008 review

Characteristic	Populations Studied				
	US (n = 27)	Europe (n = 18)	Asia (n = 2)	Other (n = 5)	Total (n = 52)
Study type					
Case series	1	1	0	0	2
Retrospective cohort	13	8	1	2	24
Prospective cohort	10	8	1	1	20
Randomized controlled trials	1	1	0	1	3
SER/meta-analyses	2	0	0	1	3
Focus of research					
Influence of prepregnancy BMI/weight	27	18	2	5	52
Weight gain and cesarean risk	5	5	0	2	12
Infant/child health outcomes	15	11	2	5	33
Participant source					
Academic single site	4	3	1	2	10
Academic multisite	3	1	1	0	5
Community	8	12	0	0	20
Database	11	4	0	2	17
Funding source					
National (NIH, MRC, etc.)	18	5	1	3	27
Foundation/other	6	9	0	2	17
Not reported	3	4	1	0	8

Only two studies of direct comparisons met our inclusion/exclusion criteria. They include a study of dietary consultations by a trained dietitian (ten 1-hour sessions) vs. usual care (no dietary consultations)[56] and another of dietary and lifestyle counseling vs. usual prenatal care.[16]

Phase 2: Steps of the Modified Delphi Process

Step 1. Building on the nidus of 37 questions from prior work. During the snowballing process the stakeholders increased the initial panel of items from 37 to a total of 50 candidate research questions that would advance the state of the science and fill important knowledge gaps. The research questions captured both methodologic needs for advancement of the science and knowledge gaps that must be filled to inform and ultimately guide clinical care. The research questions also encompassed a wide range of specific methods for measurement of maternal weight, weight gain, and body habitus, as well as a range of specific outcomes that could be broadly grouped into maternal, fetal, neonatal, and childhood outcomes.

Table 10. Initial list of future research needs

General Evidence Gaps
Is total weight gain or rate of weight gain during pregnancy associated with (1) birth outcomes, (2) infant health outcomes, and (3) maternal health outcomes?
What factors confound the relationship between gestational weight gain (overall and patterns) and birth outcomes?
What factors modify the relationship between gestational weight gain (overall and patterns) and birth outcomes?
What is the impact of age on the relationship of weight gain and pregnancy outcomes?
Does age at menarche modify the relationship of weight gain and pregnancy outcomes?
Does weight gain above thresholds defined in the 2009 IOM body mass index (BMI) guidelines contribute to the following: (a) antepartum complications (b) postpartum complications (c) longer-term maternal and infant complications
Does weight gain below thresholds defined in the 2009 IOM body mass index (BMI) guidelines contribute to the following: (a) antepartum complications (b) postpartum complications (c) longer-term maternal and infant complications
Do weight loss thresholds defined in the 2009 IOM body mass index (BMI) guidelines contribute to the following: (a) antepartum complications (b) postpartum complications (c) longer-term maternal and infant complications
How do these relationships vary by sociodemographic characteristics (i.e., race and age)?
What are the harms or benefits of offering the same weight gain recommendations to all pregnant women, irrespective of age and body weight considerations (e.g., pregravid weight, actual body weight at a particular time point, or optimal body weight)? (AHRQ 2008)
Which anthropometric tools are most appropriate for determining adiposity and are appropriate during pregnancy?
What are the risks and benefits of measuring adiposity for (1) clinical management of weight gain during pregnancy and (2) evaluation of the relationship between weight gain and outcomes of pregnancy?
What are the level of knowledge, attitudes, and self-efficacy of women regarding gestational weight gain? (AHRQ 2008)
Does weight gain influence lactation initiation and maintenance?
Does parity modify the relationship of weight gain and pregnancy outcomes?
Do genetic factors influence the relationship between weight gain and pregnancy outcomes?
Is there an interaction of stature and weight gain? (AHRQ 2008)
What is the impact of total weight gain vs. rate of weight gain vs. timing of weight gain on pregnancy outcomes? (AHRQ 2008)
What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes? (AHRQ 2008)
What are the optimal weight gains for obese women? (AHRQ 2008)
What research and databases describe the distribution of maternal weight (prior to, during, and after pregnancy) among different populations of women in the United States? (NRC-IOM 2007)
What research and databases inform understanding of the effects of different weight patterns (including underweight and overweight) during pregnancy on maternal and child health outcomes? (NRC-IOM 2007)

Table 10. Initial list of future research needs (continued)

Interventions
Do women receive accurate weight gain guidance by their prenatal clinicians; whether clinicians have the knowledge, attitudes, and skills necessary to provide appropriate weight gain guidance? (AHRQ 2008)
What research has been conducted to describe the individual, community, and health care system factors that impede or foster compliance with recommended GWG guidelines? (NRC-IOM 2007)
What intervention(s) are effective for achieving recommended maternal weight gain?
What methods are effective for helping women understand goals for weight gain in pregnancy?
What role does physical activity play in achieving recommended maternal weight gain?
What role does nutrition play in achieving recommended maternal weight gain?
Standardization Issues
How should outliers in pregravid weight, gestational weight gain, postpartum weight, and maternal height be handled in analyses?
What is the need for standardization of research measures to advance the field?
Policy
How accurate is self-reported compared to measured weight (prepregnancy, in pregnancy, and post-partum) in all populations and among women of varying pregravid weights and gestational ages?
What are the tests of the reliability of self-reported weights in pregnancy by age, parity, and BMI? (AHRQ 2008)
What opportunities exist for Title V maternal and child health programs to build on this knowledge to help childbearing women achieve and maintain recommended weight? (NRC-IOM 2007)
What future research and data collection efforts could improve the efforts of Title V programs to support women from different racial and ethnic backgrounds in their efforts to comply with recommended weight guidelines and to improve their maternal health? (NRC-IOM 2007)
Measurement
Is rate of weight gain, adequacy of rate of weight gain, or total weight gain superior for predicting adverse outcomes?
What are the preferred anthropometric measurements for predicting outcomes of interest? (AHRQ 2008)
Does direct measurement of body fat (prepregnancy, in pregnancy, post-partum) contribute to the understanding of outcomes?

Step 2. Initial scoring and item reduction. The full list of 50 items, 12 measurement approaches, and eight outcome categories were compiled and presented to the stakeholders for assigning priority scores as described in methods.

Eliminating those items that were low scoring resulted in a total of 27 remaining research questions. All questions related to issues of policy were eliminated at this stage. In addition, among the 12 measurement standards and eight outcomes, the lowest ranking one-third of each list was eliminated resulting in eight and five items respectively progressing into the next round. The complete results of the first round of scoring in order to rank items by priority are included in Appendix C.

Step 3. Final ranking of reduced list of items. In the next stage of ranking, respondents re-ranked the candidate 27 research questions. They also ranked the remaining eight measures and five outcomes of maternal weight gain as those with the greatest value for use in future research.

Prioritization of measures. Respondents were asked to rank the measures, with "1" (or "first place") as the highest ranking and "8" as the lowest. The result of this ranking was selection of "total weight gain from prepregnancy to end of pregnancy" as the highest priority measure of maternal weight gain, followed by "prepregnancy baseline weight/BMI" and "change body/body fat composition" (Table 11).

Table 11. Prioritization of measures of maternal weight gain for use in future research

Measure	Total points	Rank
Total weight gain from prepregnancy to end of pregnancy	47	1st
Prepregnancy baseline weight/BMI	63	2nd
Change in body/body fat composition	65	3rd
Pattern of weight gain across pregnancy as a statistical trend line or function	79	4th
Total weight gain from first trimester to end of pregnancy	82	5th
Pattern of weight gain across trimesters	82	6th
Rate of weight gain	84	7th
Change in BMI from prepregnancy to end of pregnancy	88	8th

Prioritization of outcomes. Participants were asked to rank the five remaining outcomes. The final prioritization ranked "maternal postpartum" and "child health" outcomes as the most important outcomes related to maternal weight gain.

Table 12. Prioritization of specific outcomes to study in relation to maternal weight gain

Type of outcome	Total points	Rank
Maternal postpartum outcomes	43	1st
Child health outcomes	46	2nd
Infant health outcomes	47	3rd
Development of gestational diabetes	52	4th
Fetal outcomes	52	5th

In the next sections we summarize the prioritization of research questions within the classes that were used initially to group them. Then we present the highest priority items across all the classes—in other words the highest ranking items from the entire panel of research questions.

General evidence gaps. The original list of general evidence gaps contained 22 questions. After the snowballing phase 29 questions were included in this class. At the conclusion of the first stage of ranking 12 questions were eliminated – leaving 17 to be ranked in the second phase. The table below shows the resulting score totals from the second phase, across the four domains: overall importance, clinical utility, feasibility, and potential to advance science. The table is arranged by highest overall importance score. In terms of clinical utility, "Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?" scored highest among general evidence gaps. For feasibility, "What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?" scored highest among general evidence gaps. Finally, for potential to advance the science "What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?" scored highest among general evidence gaps.

Table 13. Prioritization of general evidence gaps by overall importance score

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?	124	112	100	122
Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?	123	117	109	115
Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?	119	112	114	117
What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?	117	106	101	107
What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?	116	102	96	113
Does physical activity [metabolic expenditure] confound the relationship between [weight gain in pregnancy] and [outcomes]?	114	108	107	112
What are the optimal gestational weight gains for women with varying degrees of prepregnancy obesity?	114	114	97	112
Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?	113	117	110	112
Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?	110	117	110	112
What are the harms and benefits of offering standardized weight gain recommendations to all pregnant women?	110	111	85	105
Does pregravid health status confound the relationship between [weight gain in pregnancy] and [outcomes]?	109	101	83	107
What is the relative impact of total weight gain vs. rate of weight gain vs. timing of weight gain (by trimester) on pregnancy outcomes?	108	109	99	106
What is the general health literacy (i.e., the level of knowledge, attitudes and self-efficacy) of women regarding gestational weight gain?	106	103	109	101
Which anthropometric tools are most appropriate for determining adiposity in pregnant women?	104	99	99	105
Does use of insulin or other diabetes medications modify the relationship between [weight gain in pregnancy] and [outcomes]?	102	110	110	109
What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?	102	93	117	96
What research studies and databases are available to inform our understanding of the effects of different weight patterns (including underweight and overweight) during pregnancy on maternal and child health outcomes?	92	87	108	95

For addressing general evidence gaps as listed above, the three research questions with the highest priority scores for overall importance were:

1. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?

2. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?

Averaging across all four domains, the three research questions with the highest priority scores for addressing general evidence gaps were:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?

Targets for interventions. Research gaps identified in prior reports or during snowballing that reflected targets for intervention, such as knowledge and attitudes, or intent to assess interventions for modifying weight gain were grouped together as a class of survey items. The original list of gaps related to interventions contained six questions. After the snowballing phase, seven questions were included in this class. At the conclusion of the first stage of ranking one question was eliminated—leaving six to be ranked in the second phase. The table below shows the score totals across the four domains: overall importance, clinical utility, feasibility, and potential to advance science. The highest scoring questions were "Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?" scored highest for both clinical utility and feasibility, while "What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?" scored highest for the potential to advance science.

Table 14. Prioritization of intervention gaps by overall importance ranking

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
How does physical activity affect maternal weight gain?	111	110	97	102
What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?	108	107	101	104
Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?	104	113	104	95
How does total caloric intake and dietary composition of caloric intake affect maternal weight gain?	99	96	78	98
What methods are effective for helping women acquire knowledge and understanding of the goals for weight gain, and skills for controlling weight gain?	93	95	86	82
What research has been conducted to describe the individual, community, and health care system factors that impede or foster adherence to recommended gestational weight gain guidelines?	89	88	97	85

For addressing intervention gaps as listed above, the three research questions with the highest priority scores for overall importance were:

1. How does physical activity affect maternal weight gain?
2. What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?
3. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

Averaging across all for domains, the three research questions with the highest priority scores for addressing intervention gaps were:

1. How does physical activity affect maternal weight gain?
2. What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?
3. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

Standardization issues. Research gaps identified in prior reports or during snowballing that reflected targets for standardization related to measures and the overall lack of standardization related to maternal weight gain were included in this class of items. The original list of gaps related to standardization issues contained two questions. After the snowballing phase, six questions were included in this class. At the conclusion of the first stage of ranking four questions were eliminated—leaving two to be ranked in the second phase. The table below shows the score totals across the four domains: overall importance, clinical utility, feasibility, and potential to advance science. "What is the need for standardization of research measures to advance the field of research related to weight gain in pregnancy?" ranked highest across all of the domains.

Table 15. Prioritization of standardization issues by overall importance ranking

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
What is the need for standardization of research measures to advance the field of research related to weight gain in pregnancy?	90	76	95	84
Is there a lack of standardization in current research in terms of maternal weight gain measures?	70	62	82	72

Policy. The original list of research questions and the snowballing phase resulted in four questions related to policy issues. After the initial ranking phase all four questions were eliminated from the ranking because none of the questions received the required number of 9s or 10s to remain on the list.

Measurement. Research gaps identified in prior reports or during snowballing that reflected targets for measurement issues were included in this class of items. The original list of gaps related to measurement issues contained three questions. After the snowballing phase, four questions were included in this class. At the conclusion of the first stage of ranking two questions were eliminated—leaving two to be ranked in the second phase. The table below shows the score totals across the four domains: overall importance, clinical utility, feasibility, and potential to advance science. "What are the preferred anthropometric measurements for

predicting birth, maternal, and infant outcomes?" ranked highest across all of the domains, except for clinical utility.

Table 16. Prioritization of measurement research questions

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
What are the preferred anthropometric measurements for predicting birth, maternal, and infant outcomes?	90	86	78	91
Is rate of weight gain, change in BMI, adequacy of rate of weight gain, or total weight gain superior for predicting adverse birth, maternal, and infant outcomes?	86	87	76	84

Across all of the classes, the highest priority questions by overall importance were:

1. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
2. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
4. What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?
5. What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?

The questions with the most clinical utility were:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
3. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
4. What are the optimal gestational weight gains for women with varying degrees of prepregnancy obesity?
5. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

The questions rated as highest priority based on feasibility were:

1. What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?

3. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
4. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
5. Does use of insulin or other diabetes medications modify the relationship between [weight gain in pregnancy] and [outcomes]?

The future research questions rated as highest priority for advancing the science relating maternal weight gain and outcomes were (the final four items received the same score):

1. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
4. What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?
5. Does physical activity [metabolic expenditure] confound the relationship between [weight gain in pregnancy] and [outcomes]?
5. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
5. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
5. What are the optimal gestational weight gains for women with varying degrees of prepregnancy obesity?

Highest Priority Research Questions

The top 5 questions by highest average score across all four domains were:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
4. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
5. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?

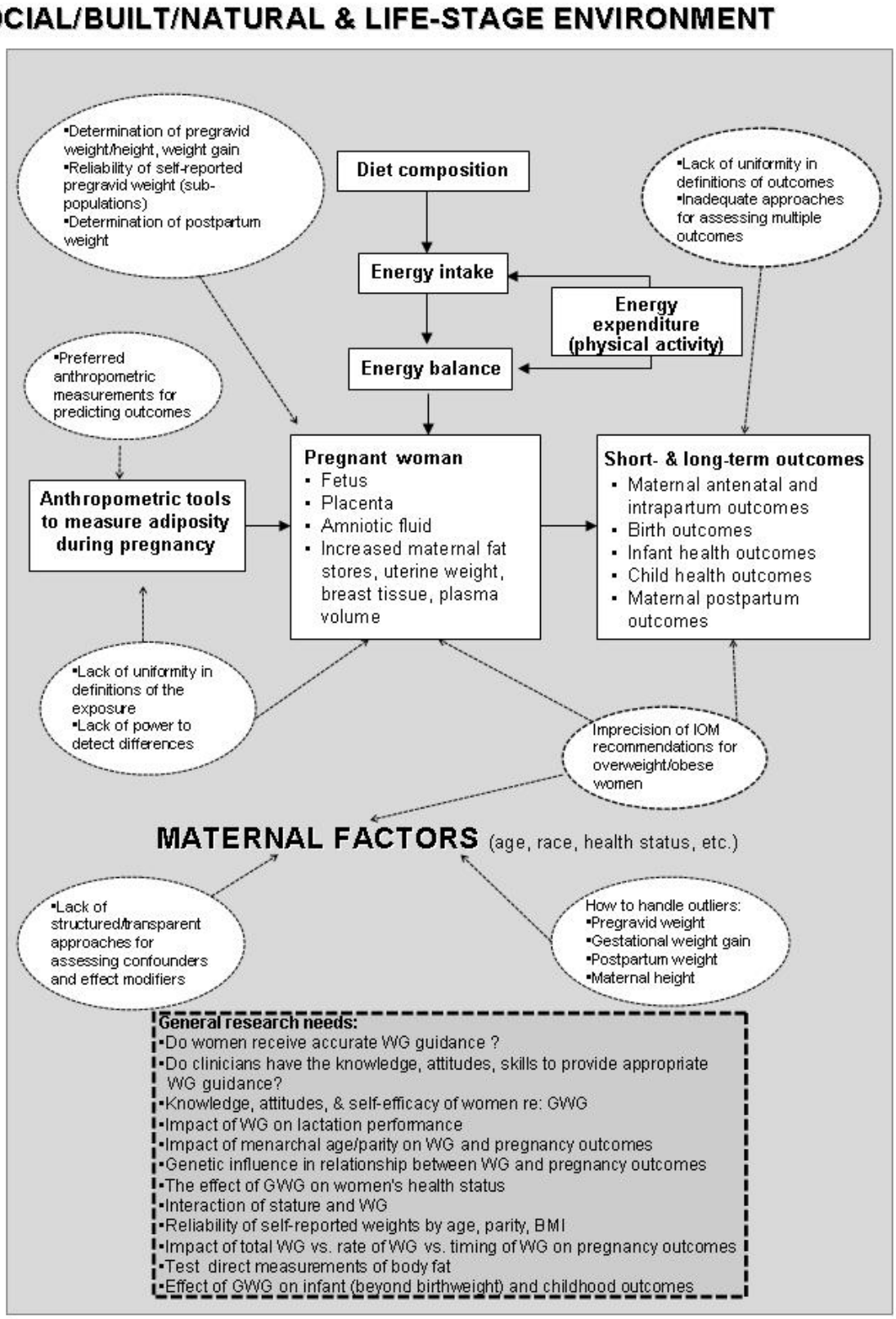
Phase 3: Optimal Research Designs To Address Top Priority Questions

After the list of research needs and knowledge gaps had been prioritized, we engaged stakeholders in a conference call in order to discuss with them the study designs that would be the most successful in answering the research questions needed to fill the related gaps in knowledge. During the call, stakeholders provided feedback on the revised analytic framework (Figure 3). These revisions reflect the complex interaction between the "Social/Built/Natural & Life-Stage Environment" and "Maternal Factors."

In addition stakeholders suggested next steps and general study designs that they felt would be essential to moving the science related to the outcomes of weight gain in pregnancy forward. These suggestions included:

- Developing consensus about standards for methods of collecting prepregnancy weight and height as well as other body composition and anthropometric measures.
- Maximizing use of existing data collection infrastructure (new birth certificate formats, Behavioral Risk Factor Surveillance System [BRFSS], and Pregnancy Risk Assessment Monitoring System [PRAMS]) to develop national surveillance studies with large sample size among representative populations.
- Using current WIC (Women, Infants, and Children) infrastructure to conduct postpartum followup to include weighing pregnant and non-pregnant women consistently to allow for accurate baseline data for any subsequent pregnancies.
- Conducting national surveys, with possible inclusion of questions on BRFSS instruments, in order to determine knowledge and attitudes among women about weight gain and their experiences in care.
- Conducting similar evaluations of the knowledge, attitudes, and perceived barriers of providers that inhibit addressing maternal weight and weight gain.
- Launching intervention studies that include efforts to change the built environment, including community-based interventions (e.g., increasing access to gyms and community centers in neighborhoods where it is not safe to exercise outside by distributing coupons/incentives to facilities)
- Coupling community-based interventions with individual-level interventions such as behavioral counseling and nutrition education or innovative means of prenatal care delivery such as centering (group prenatal care).
- Designing randomized controlled trials of promising interventions with large enough scope to make the causal relationship between weight gains above guideline thresholds and poor outcomes (maternal and child) explicitly testable.
- Collecting longer-term outcomes, such as child health and development data and study of maternal weight trajectories between and after pregnancies with more rigorous measures than those available to date.
- Strategizing means to assure a focus on maternal weight gain measures in upcoming national surveys including the National Children's Study.

Figure 4. Final modified analytic framework for future research



Social/Built/Natural and Life-stage Environment includes the following domains and sub-domains:

- Societal/Institutional
    - Media
    - Culture and acculturation
    - Health services
    - Policy
- Environmental
    - Altitude
    - Environmental toxicants
    - Natural and man-made disasters
- Neighborhood/Community
    - Access to healthy foods
    - Opportunities for physical activity
- Interpersonal/Family
    - Family status
    - Marital status
    - Partner and family support

Maternal factors include, but are not limited to the following:

- Age
- Race
- Health status: pre-existing conditions and pregnancy complications
- Genetic characteristics
- Developmental programming
- History of restrained eating
- Sociodemographic (SES, food insecurity)
- Smoking
- Substance abuse
- Prenatal care
- Prepregnancy BMI
- Psychological (depression, stress)
- Pregnancy intendedness
- Weight gain recommendations

Discussion and Conclusions

Our first phase examined progression of the literature in the time from the 2008 evidence review. In the 27 month interval, three randomized clinical trials, including a total of 386 women, were published.[16,35,56] Each aimed to assist women in achieving target weight gains appropriate for their self-reported baseline BMI. Each included a component of individualized dietary counseling with advice about caloric intake and dietary composition. Two added targets for physical activity.[16,35] All found that intervention helped some women stay within targets for weight gain. The largest study, in Australia, included women across the spectrum from underweight to obese. They found that underweight and overweight women benefited from the intervention while normal weight and obese women in the intervention arm were no more likely to be in the target than those in the comparison group. In aggregate the findings support prior findings that weight gain can be modified by dietary and lifestyle counseling interventions. None of the studies were large enough to adequately assess fetal, neonatal, or maternal outcomes and do not contribute sufficient numbers to change aggregate knowledge about anticipated influence on outcomes among women who do or do not achieve target weight gains in pregnancy.

Many of the new studies identified rely on administrative or survey samples that do not acquire physical measurement of weight or weight change, such as surveys of post-partum women and birth certificate analyses. No literature in the intervening period makes substantive, novel contributions to achieving targets of measured changes in maternal weight or assessment of large prospectively collected data that allows disentanglement of the many causal factors that may confound or modify effects of weight gain on outcomes.

No gap identified in the evidence review on maternal weight gain, the IOM proceedings, or the stakeholder discussions as part of this process to prioritize questions for future research was filled by changes in the body of evidence during the interim. This suggests that existing evidence reviews may serve as a profitable starting point for identifying a nidus of future research questions to jump start considerations of expert panels charged with prioritizing future research needs.

Across publications, stakeholder calls, and survey item development and responses, there was a strikingly consistent level of attention to the need for: (1) greater uniformity in measures, (2) research that would open a vista on the biological mechanisms at work at a causal level, (3) statistical analyses that explicitly address the joint contributions of multiple causal factors, and (4) greater breadth and depth in outcomes assessed. Those engaged in this future research prioritization process indicated in both rankings and discussions that they favored operational definitions (such as research measurement of prepregnancy weight and height), approaches to data and analysis (encompassing baseline weight, caloric intake, nutrient content, physical activity, and weight gain patterns) and outcomes (such as child health and obesity and maternal lifecourse weight trajectory) that can broadly be described as more rigorous than those which dominate the current literature.

The first two research questions in the final priority ranking of the five top research questions reflect this inclination to employ the “gold standard” of prepregnancy BMI or weight in analyses that address whether baseline characteristics or weight gained during pregnancy operate jointly or independently to influence outcomes:

- Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?

- Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
- In highly ranking both an explicit question about effect modification and another about confounding, this process reveals a level of scientific equipoise about causal influences that matches the large number of basic gaps discussed in calls. Though we did not have a formal method for capturing stakeholder impression about why this level of rigor was not yet commonly achieved, discussion often identified the need for greater funding resources and challenges of long-term followup as barriers to accomplishing more definitive research.

Because there were an exceptionally large number of permutations of proposed measures of weight and weight gain and specific outcomes, we engaged the stakeholders in prioritizing measures of weight and weight gain and outcomes separately. The reduced list of priority measures from higher to lower ranking was:

1. Total weight gain from prepregnancy to end of pregnancy
2. Prepregnancy baseline weight/BMI
3. Change in body/body fat composition
4. Pattern of weight gain across pregnancy as a statistical trend line or function
5. Total weight gain from first trimester to end of pregnancy
6. Pattern of weight gain across pregnancy
7. Rate of weight gain
8. Change in BMI from prepregnancy to end of pregnancy

The reduced list of prioritized outcomes was:

1. Maternal postpartum outcomes
2. Child health outcomes
3. Infant health outcomes
4. Development of gestational diabetes
5. Fetal outcomes

If there was complete internal consistency within ranking the top priority research question would link the top measure and the top outcome. In other words, "How does total weight gain from prepregnancy to end of pregnancy influence maternal postpartum outcomes?" would have surfaced among the final prioritized questions. However it did not explicitly appear in this form. After the first two items about effect modification and confounding, the third highest priority research question was based on weight gain and focused on infant and child health outcomes, not maternal outcomes:

"What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?"

Maternal outcomes were subsumed in the last two of the final five items that received the highest priority rankings which included interest in multiple outcome categories:

- Does gestational weight gain above targets defined in 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum, and longer-term maternal and infant complications)?

- Does gestational weight gain below targets defined in 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum, and longer-term maternal and infant complications)?

Across the four major domains queried (overall importance, clinical utility, feasibility of the research, and potential to advance the science), there was a high level of consistency in the type of questions that ranked among those with high priority.

In discussion throughout the phases, the stakeholder group indicated a desire for more definitive understanding of how the many factors (such as those indicated in the causal pathway) work in concert to determine outcomes. They conveyed a level of concern that premature focus on intervening with a particular target like total weight gain without attention to other factors such as nutrient intake could fail to improve the desired outcomes. Some participants reported frank doubts about whether the causal links are sufficiently formed to guide intervention solely for the sake of improving reproductive outcomes. However, a majority seemed to endorse that in the U.S. cultural context of sedentary lifestyles, rising proportions of the population overweight or obese, and many with poor quality diets, it was not inappropriate to simultaneously study interventions while studying causal factors. Intervention settings that attracted discussion ranged from conventional clinically anchored approaches to passionate advocacy for programs that seek to make more fundamental changes whether it is in how women think about weight and weight gain in pregnancy and well-being or how communities can be changed to promote healthy lifestyles. Likewise there was interest in understanding more about the knowledge and attitudes of care providers and in means to disseminate recommendations.

Stakeholders noted they hoped that the funneling process used to reduce the priorities list did not have the unintended effect of suggesting that qualitative studies, investigations heavily using biomarkers, studies of genetic influences, intervention trials, and community-based research be dismissed. Rather they emphasized the importance of timely and coordinated answers to the core gaps in measurement and causal links as having exceptionally high value for informing all future research.

In general stakeholders reported the future research prioritization process was worthwhile. However, there was an impression both within the EPC team and the SER group that the process could have benefitted from:

- In-person discussion or at minimum teleconferencing both early and later in the process
- Means to avoid a “one-way street” in which items could be added only at the beginning and were trimmed without opportunity to introduce late-breaking ideas or concepts
- Decreasing the number of questions and options given during the ranking and prioritization portions of the process
- Less emphasis on selection of a specific study design to accomplish answers to priority items (believing that investigators will bring many valid approaches to addressing the questions)

When specifically queried if they believed the process concluded with research questions prioritized that are *not* of central importance across the domains, there was no concern expressed that items were included that should not be. Among the participants available for the wrap-up call, there was agreement that answer to the proposed priority research questions would make pivotal contributions towards understanding the results of maternal weight gain, caring for

pregnant women, and honing new investigative tools. They would urge funders and policy makers to support enhanced funding and opportunities to focus on these gaps in knowledge.

Conclusions

This multiphase process for enumerating, multiplying, and prioritizing research questions to advance research in the area of outcomes of maternal weight gain in pregnancy resulted in an actionable list of research topics to fill specific knowledge gaps. The results of prioritization, including these top five items, were endorsed by multidisciplinary experts:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
4. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?
5. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer-term maternal and infant complications)?

Inherent variation in how respondents valued items did allow selection of cut-offs to trim lists at each phase of prioritization. When the items were re-presented on shortened lists, constraining the scope, variation in prioritization persisted that made a final round of ranking desirable in solidifying recommendations for future research.

The expert stakeholders proposed ways to further extend the reach of the process to include greater scope in the candidate ideas by adding an early teleconference to create synergy in discussion and to actively encourage input in the “snowballing process”. However at conclusion, they were not dissatisfied with the prioritized topics. The core message of increased rigor as a necessity is valuable for both endorsing streams of research considered descriptive, methodologic, and quantitatively focused—namely working out the nature of causal relationships—and for drawing the attention of investigators and funders to the importance of more demanding, larger, and longer prospective and intervention studies.

While the group was inspired to map the identified research priorities to specific study approaches, they were reluctant to specify a single, correct next step. Confidence in the collective energy and creativity of the scientific endeavor, suggested that agencies and organizations seeking to advance research in this area would do best to solicit and amply fund research concepts that are responsive to the needs and to select those ideas that come forward as the most innovative and sophisticated means to support next steps. Likewise there was confidence that robust expertise and appropriate study populations are available to realize answers to the prioritized answer in a rapid timescale in order to bring practical tools and new knowledge to advancing the care of women and their infants.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
BMI	Body mass index
BRFSS	Behavioral Risk Factor Surveillance System
CER	Comparative Effectiveness Reviews
CMTP	Center for Medical Technology Policy
EHC	Effective Health Care
EPC	Evidence-based Practice Center
GWG	Gestational weight gain
IOM	Institute of Medicine
kg	Kilogram(s)
KQ	Key question
LGA	Large-for-gestational age
PICO	Population, Intervention, Comparator, Outcome
PRAMS	Pregnancy Risk Assessment Monitoring System
SER	Systematic evidence review
SGA	Small-for-gestational age
SR	Systematic review
WG	Weight gain
WIC	Women, Infants, and Children

Appendixes

Appendix A. Search Strategy for Ongoing Studies
Appendix B. List of Ongoing Studies
Appendix C. Prioritization Tools and Results
Appendix D. Excluded Studies

Appendix A. Search Strategy for Ongoing Studies

www.clinicaltrials.gov:
maternal weight gain [=47 studies]
gestational weight gain [=33 studies]
(maternal OR gestational OR pregnancy OR pregnant) AND (weight gain OR overweight OR obesity) [=147 studies]
 # Citations: 20 selected for database

NIH RePORTER:
maternal weight gain [=84 studies]
gestational weight gain [=49 studies]
 # Citations: X in table above

www.controlled-trials.com: (includes coverage of UK / European trials information)
(maternal OR pregnancy OR pregnant OR gestational) AND weight [=40 studies]
(maternal OR pregnancy OR pregnant OR gestational) AND (weight OR overweight OR obese OR obesity) [=40 studies]

 # Citations: none appear relevant to topic

Appendix B. List of Ongoing Studies

Title (project number)	Description	Comments	Principal Investigator	Organization
Limiting weight gain in overweight pregnant women: effects on mother and child (5R01HL094235-03)	Maternal obesity entering pregnancy and excessive gestational weight gain produce substantial morbidity, and both have been rising in prevalence in the past 2 decades. Researchers at the University of Adelaide, Australia, are now funded to begin the largest-by a factor of 10-RCT to limit gestational weight gain among overweight and obese women. The trial will involve state-of-the-art diet and physical activity intervention components to limit weight gain during pregnancy to 0 to 5 kg among a diverse population of 2500 pregnant women. The trial is powered to detect important maternal and infant morbid outcomes based on routinely collected clinical data. Unfortunately, the funding for this trial is not sufficient to collect data on body composition and cardio-metabolic outcomes for mother and child. Yet these biomarker data would be invaluable in elucidating physiologic pathways by which the intervention has its effects, in determining the intervention effect on intermediate maternal outcomes, and perhaps most importantly for the long-term, investigating effects on body composition and cardio-metabolic outcomes among the offspring. The overall goal of this proposal is to assess the effects of an intervention to limit excessive gestational weight gain among overweight and obese pregnant women on markers of adiposity and cardio-metabolic risk in mother, fetus, and newborn. Outcome measures will include Mother: At 28 weeks' gestation, estimated insulin resistance, glucose tolerance, and levels of triglycerides, leptin, adiponectin, and C-reactive protein. Fetus: Change in estimated fetal weight from 18-28 and 28-36 weeks. Newborn: Body fat by air displacement plethysmography and skinfold thicknesses, and cord blood levels of leptin and adiponectin. This proposal reflects a new interdisciplinary collaboration between researchers at Harvard Medical School and the University of Adelaide, with combined expertise in RCTs involving behavior change and in pregnancy, numerous studies of pregnant women and their offspring, and measurement and interpretation of body composition, physiologic, and cardio-metabolic data in mother and child. By obtaining the data from this ancillary study, the trial will be set up not only to provide answers to the proposed aims, but also-with additional funding for followup and to take advantage of the stored biosamples-to address numerous questions on long-term health of the mother and the growing child. Limiting excess weight gain during pregnancy among overweight and obese women could help prevent serious health	National Heart, Lung, and Blood Institute (NHLBI) Funding: $309,415 For more details, see http://projectreporter.nih.gov/project_info_description.cfm?aid=7885660&icde=5088205	Gillman, Matthew W	Harvard Pilgrim Health Care, Inc.

Title (project number)	Description	Comments	Principal Investigator	Organization
	consequences in the mother and child, and a large 4-year randomized controlled trial will begin in mid- 2008 to test this theory. As an ancillary study to the parent trial, the proposed project will add crucial information about the physiology of the mother, the growth of the fetus, and the body composition of the newborn baby. This study will repay its investment many times over by examining how and how well the parent trial works, and by setting up a biological resource that scientists could use to address additional key questions about long-term health of the mothers and children.			
GWA mapping: maternal metabolism-birth weight interactions (3U01HG004415-02S1)	Low and high birth weights are a major cause of neonatal morbidity and mortality, and epidemiological data have established an association between birth weight and later risk of adult metabolic disease. Fetal growth is determined by complex interactions between fetal genes and the maternal uterine environment. Subtle or overt variation in maternal glucose tolerance which is, in part, genetically determined, is related to fetal size at birth. New emerging data suggest that genetic variation in the fetus can impact maternal metabolism. Given the above, we are hypothesizing that during pregnancy, gene-environment interactions in the context of the maternal-fetal unit impact fetal size at birth and maternal metabolism. To address this hypothesis, we are proposing to perform genome wide association (GWA) mapping on a subset of ~37,000 DNA samples that were collected from mothers and their offspring as part of the NIH-funded Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study. HAPO is a multicenter, international study in which high quality phenotypic data related to fetal growth and maternal glucose metabolism has been collected from 25,000 pregnant women of varied racial and sociodemographic backgrounds using standardized protocols that were uniform across centers. We are proposing to genotype 1,500 infants and their mothers of European descent to accomplish the following specific aims: (1) To apply analytic approaches for conducting GWA mapping studies on quantitative phenotypes related to offspring size at birth (birth weight, ponderal index, head circumference and adiposity) allowing for other known influences such as gestational age, parity, and maternal weight gain. (2) To apply the above approaches to identify genetic variation that impacts maternal glucose tolerance at ~28 weeks of gestation (fasting glucose, glucose during an oral glucose tolerance test, and insulin sensitivity expressed as quantitative traits) allowing for other known influences such as maternal weight gain, parity and age. (3) To examine the interaction between maternal genes, the intrauterine environment, and fetal genes to identify interactions that modulate genetic regulation of size at birth and fetal genetic variation	National Human Genome Research Institute Funding: $65,044 For more details, see http://projectreporter.nih.gov/project_info_description.cfm?aid=7923473&icde=5088205	Lowe, William L	Northwestern University

Title (project number)	Description	Comments	Principal Investigator	Organization
	that impacts on maternal glucose tolerance. A replication study will be performed in additional infants and mothers of European descent with followup studies also planned in Afro-Caribbeans, Hispanics of Mexican descent and Thais.			
Maternal overweight: consequences for insulin signaling in the offspring (5R01DK084225-02)	The major reasons underlying the remarkable global rise in obesity remain unclear. While, diet composition and life-style factors such as physical activity undoubtedly have important roles in determining body composition, maternal overweight (OW) status (BMI > 25) at conception may be a critical synergizing factor. In clinical studies, we found that maternal OW status significantly increased risk of OW (i.e. the % above the 95th percentile) at 6 months of age, in infants born with normal body weights. Our overall objective is to investigate interactions in the offspring, between an obesegenic environment (consumption of a high-fat diet, HFD) and prior exposure to maternal OW during gestation. To this end, we have developed a rat model in which metabolic and endocrine abnormalities akin to obesity in human subjects were reproduced prior to conception. Exposure to maternal OW did not influence birth weight/size of offspring. However, offspring from OW dams when fed a HFD became obese to much greater extent compared to offspring from lean dams on the same diet, without changes in caloric intake. Offspring of OW rats also developed hyperinsulinemia, adipose tissue hypertrophy and showed lipogenic gene expression. Based on our preliminary studies, we hypothesize that increased glucose flux into adipose tissue and accelerated lipogenesis causes obesity in the offspring of OW dams when fed a HFD. The proposed studies are aimed at understanding the underlying differences in energy balance and insulin signaling prior to the development of obesity in the offspring. In Specific Aim 1, indirect calorimetry will be utilized to examine if gestational OW decreases energy expenditure in the offspring. In Specific Aim 2, we will test the hypothesis that maternal OW leads to skeletal muscle insulin resistance in the offspring, consequently increasing glucose partitioning into adipose tissue, lipogenesis and fat mass accretion. This will be addressed via hyperinsulinemic-euglycemic clamp experiments using labeled tracers, and will reveal the status of insulin sensitivity in the individual tissues (skeletal muscle, adipose and liver) and whole-body glucose flux. Studies examining responsiveness of adipose tissue to insulin signaling via IR-PI3K-Akt to increase lipogenic gene expression and de novo lipid synthesis and will be performed in Specific Aim 3. Finally, Specific Aim 4 will employ physical activity prior to conception as an intervention and will test the hypothesis that increased physical activity (treadmill running) in the OW dams prior to conception will improve offspring insulin sensitivity	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Funding: $349,272 For more details, see http://projectreporter.nih.gov/project_info_description.cfm?aid=7880140&icde=5088205	Shanar, Kartik	Arkansas Children's Hospital Research Institute

Title (project number)	Description	Comments	Principal Investigator	Organization
	and mitigate increased adipose tissue anabolism. Overall, these studies will elucidate important metabolic mechanisms in the offspring altered by maternal OW and high-fat diets, which may contribute to increased susceptibility to obesity. PUBLIC HEALTH RELEVANCE: Maternal overweight (OW) during pregnancy significantly increases the risk of OW in the offspring. While, the underlying reasons remain unclear, using a new model of maternal OW in the rat, we have identified that, post-natal high-fat diets significantly exacerbate development of obesity in offspring of OW rats. We will examine changes in glucose flux and the synthesis of fat in the adipose tissues of OW offspring. These mechanisms may underlie the predisposition of the offspring to gain more fat relative to muscle mass, leading to obesity. These studies will elucidate mechanisms that are altered in the offspring due to maternal OW and provide novel opportunities for intervention and prevention of obesity.			
Limiting the phenotypic effect of pregnancy related weight gain (5K23NR010748-02)	This program of research focuses on obesity in women, with an emphasis on the genetic effects on weight gain, especially in the vulnerable time of pregnancy and interventions to prevent and/or limit excessive pregnancy weight gain. The intermediate goals of this career development plan focus on education and research. The educational goal is to acquire skills central to test gene-environment interactions and the implementation of intervention studies in the context of an interdisciplinary team in preparation for a full scale R01. The research goal is to develop expertise as an independent investigator by implementing two projects to develop expertise as an independent involving (a) clarification of the gene-environment interaction of the GNB3 gene and (b) focus groups to elicit the attitudes and beliefs of African-American women about physical activity during pregnancy. The findings will provide a framework for the establishing a foundation for genetic-based behavioral intervention research. These goals are the direct result of the candidate's experiences as a women's health nurse practitioner coupled with training at the NINR summer genetics institute in 2006. Practice as a clinician providing health care to underserved and uninsured women since 1994 has extensively influenced my research goals. This proposed career development plan pulls together discrete areas of research that require very different skill sets. Therefore, an interdisciplinary team of mentors and consultants, with distinct areas of expertise, have been included in this career development team. Environment: The University of Rochester, School of Nursing, a part of the University of Rochester Medical Center, has a long history of nursing research. In 2006 the University of Rochester received a $40 million NIH award to establish a Clinical and Translational Science	National Institute of Nursing Research FY total funding: $130,130 For more details, see http://projectreporter.nih.gov/project_info_description.cfm?aid=7942760&icde=5092019	Groth, Susan W	University of Rochester

Title (project number)	Description	Comments	Principal Investigator	Organization
	Institute (CTSI), which has increased support to researchers across the medical center and created an atmosphere conducive to collaborative and interdisciplinary teams for translational research from T1-T4. The candidate received funding from the CTSI for a KL2 scholar award in July 2008, which provides bridging funding for 1-2 years until individual funding can be attained. Given the supportive environment, the early stages of this career development plan recently began under the guidance of this team of experienced NIH funded, nationally recognized mentors, who provide an essential combination of expertise for the identified areas of development: expertise in research design including RCTs and focus groups, cultural competency and recruiting of vulnerable populations, genetics, and exercise in pregnancy. Research: Recent figures indicate three-quarters of all African-American women are overweight or obese. Obesity in African-American women is due, in part, to excessive pregnancy weight gain. Genetic susceptibility and individual behaviors likely interact and contribute to pregnancy weight gain, which then contributes to long- term obesity. Thus, prevention of excessive gestational weight gain would decrease morbidity and mortality in US African-American women. Little is known about gene-environment interactions that contribute to pregnancy weight gain. Seventy percent of the world-wide African-American population carries the GNB3 825T allele, which appears to be associated with increased gestational weight gain, postpartum weight retention, and low birth weight. It is postulated that African-American women who gain and retain excessive pregnancy weight and deliver smaller infants are carriers of the 825T allele—an effect that may be attenuated by physical activity. The overarching goal of this proposal is to establish the foundation to develop, test, and implement a physical activity intervention in high-risk African American women using the essential amount of physical activity, based on genotype, required to limit excessive weight gain/retention in pregnancy. To this end, the research plan has 3 aims: (a) examine the GNB3 825T allele gene-environment interaction during pregnancy; (b) determine the critical levels of physical activity essential to prevent excessive weight gain for women who carry the 825T allele; and (c) identify women's beliefs regarding physical activity during pregnancy and what physical activities African-American women would participate in while pregnant. To accomplish these goals two projects will be conducted: (1) Phase I study—a prospective candidate gene-association study examining the GNB3 825T allele and how it interacts with physical activity during pregnancy and (2) Phase II study—a qualitative, descriptive study that utilizes focus groups to elicit the attitudes and			

Title (project number)	Description	Comments	Principal Investigator	Organization
	beliefs of African-American women regarding physical activity during pregnancy. The Phase I study, utilizing established interviews and questionnaires for dietary and physical activity measurement, pedometers, weight/height measurement, resting energy expenditure measures, and deoxyribonucleic acid (DNA) was approved by the University of Rochester Research Subjects Review Board. The protocol and procedures are in place and active recruitment has recently commenced. PUBLIC HEALTH RELEVANCE: Obesity in US women, especially African-American women is due, in part, to excessive pregnancy weight gain. Genetic susceptibility and individual behaviors likely interact and contribute to pregnancy weight gain, which then contributes to obesity. Prevention of excessive gestational weight gain would decrease morbidity and mortality in US African-American women.			
Maternal overnutrition and offspring fat mass, metabolic and vascular function (5R01DK077659-04)	We propose to study the effects of maternal obesity, weight gain and diet during pregnancy on offspring fat mass, fat distribution, vascular and metabolic function. Specifically we will: 1. Determine the magnitudes of the associations of maternal BMI, weight gain and diet during pregnancy with offspring adiposity (DXA assessed fat mass and fat distribution), vascular function (blood pressure, pulse pressure and endothelial function) and metabolic function (fasting glucose, insulin and lipids). 2. Determine whether any association between maternal factors and offspring outcomes represent a specific intrauterine effect by comparing the maternal-offspring associations to equivalent paternal-offspring associations. 3. Examine the role of intrauterine growth, offspring nutrition and physical activity in explaining the associations of maternal obesity, weight gain and diet during pregnancy with offspring obesity, metabolic and vascular function. These aims and objectives will be achieved using data from a large, population-based cohort of children recruited before birth and followed up to the present day. The study - the Avon Longitudinal Study of Parents and Children (ALSPAC) - recruited 14,541 pregnant women in 1991-92. Of these 13,617 women delivered a live singleton child who was still alive at one year after birth. Of these singleton births we have measurements of offspring outcomes: fat mass and fat distribution determined by Dual Emission X-Ray Absorptiometry (DXA), blood pressure, endothelial function determined by high-resolution ultrasound imaging and metabolic function determined by fasting glucose, insulin and lipids up to age 15 years on over 7,000. Further, DNA has been extracted on both mothers and their offspring. A large amount of data has been collected on both parents, including their weight and height and diet in pregnancy. This work will make an important contribution to our	NIDDK FY total funding: $237,097 For more details, see http://projectreporter.nih.gov/project_info_description.cfm?aid=7686755&icde=5092019	Lawlor, Debbie Anne	University of Bristol

Title (project number)	Description	Comments	Principal Investigator	Organization
	understanding of the developmental origins of obesity and its associated vascular and metabolic abnormalities. It will provide the necessary evidence for the development of randomised controlled trials concerned with examining the effectiveness of brief interventions during the intrauterine period (a key developmental period for obesity) in the prevention of future obesity.			
Weight management for improved pregnancy outcomes (3R01HD058061-01A1S1)	Historically, under nutrition has been a major health concern. Recently however, over nutrition has also become a serious public health problem in the United States and other industrialized countries. With the new obesity epidemic we see increasing morbidity, mortality, and public health burden, particularly among reproductive-aged women. Whereas morbid obesity was once rare among pregnant women, a rapidly increasing proportion of obstetrics patients now have levels of obesity which dramatically increase their risk of serious pregnancy complications. These complications include increased risk of miscarriage, stillbirth, having a fetus that is too large leading to cesarean section or birth injuries for mom and baby from vaginal delivery, and death of the infant in the newborn period. More than 1/3 of women in the U.S. are now starting their pregnancies with a body mass index or 30 or greater, a condition that was unusual to rare 50 years ago. Given the serious consequences of added weight gain during pregnancy for obese women, such as gestational diabetes, preeclampsia, or cesarean delivery, the best strategy during their pregnancy may be to maintain a steady weight rather than gaining 15 pounds or more. Unfortunately, there is little research on the efficacy and feasibility of minimizing weight gain during pregnancy. This study is designed to address that problem. Two hundred women with BMIs of 30 or greater at the start of their pregnancy will be recruited for this feasibility test. All participants will be members of a non-profit managed care organization that provides high-quality obstetrics care. Patients who volunteer to participate will be randomly assigned to either a weight maintenance intervention or to usual care. Participants assigned to the intervention will participate in a weight maintenance program designed to help them eat a nutritionally balanced diet and to also control energy intake to minimize weight gain during their pregnancy. Participants (and their babies) in both groups will participate in followup assessments at 2 weeks postpartum, 6 months postpartum and one year postpartum. The primary outcome measures will be mothers' weight gain during pregnancy, the amount of weight retained after delivery, and the proportion of large for gestational age infants. Secondary outcomes will include multiple safety measures of the mothers and their babies. In addition to measures of safety, our secondary analyses will	Eunice Kennedy Shriver National Institute of Child Health & Human Development Funding: $26,825 For more details, see http://projectreporter.nih.gov/project_info_description.cfm?aid=8007523&icde=5092019	Stevens, Victor J	Kaiser Foundation Research Institute

Title (project number)	Description	Comments	Principal Investigator	Organization
	address the feasibility and acceptability of a weight management intervention among obese pregnant women.			

Appendix C. Prioritization Tools and Results

1. Abstract and Full-Text Review Forms
2. Snowballing Tool
3. Initial Ranking Tool
4. Final Ranking Tool
5. Initial and Final Ranking Results

Maternal Weight Gain
Abstract/Title Review Form

First Author, Year: _____

Reference #_____ Abstractor Initials: ___ ___ ___

Primary Inclusion/Exclusion Criteria			
1. Related to topics of maternal weight gain or the measurement of body fat in women with singleton pregnancies	Yes	No	Cannot Determine
2. Original research (exclude editorials, commentaries, letters, etc)	Yes	No	Cannot Determine
3. Time Period: January 1990 to present	Yes	No	Cannot Determine
4. Study published in English	Yes	No	Cannot Determine
5. Eligible study size: Cohort studies (trials, observational cohorts, meta-analyses, reviews, etc.): n ≥ 40 Case-series: n ≥ 100	Yes	No	Cannot Determine
6. Includes participants with no pre-existing conditions	Yes	No	Cannot Determine
7. Conducted in a developed nation	Yes	No	Cannot Determine

Comments:

Outcomes of Maternal Weight Gain
Full-text Review Form

First Author, Year: _____ Ref ID #: _____ Abstractor Initials: _ _ _

Primary Inclusion/Exclusion Criteria		
1. Is the publication concerned with topics relevant to maternal weight gain or the measurement of body fat in pregnant women?	Yes	No
2. Original research or an evidence review (exclude commentaries, editorials, etc.)?	Yes	No
3. Eligible study size (N>40 for cohort studies or N>100 for case series)?	Yes	No
4. Published in English?	Yes	No
5. Published after 1990?	Yes	No
6. Published in a developed nation?	Yes	No
7. Does the study include any participants without pre-existing conditions?	Yes	No
8. Does the study include any participants with singleton pregnancies?	Yes	No
9. Does study answer one or more of the following key questions? (place an X next to the question(s) the publication applies to)	Yes	No
___ KQ1. What is the evidence that either total weight gain or rate of weight gain during pregnancy is associated with: (1) birth outcomes, (2) infant health outcomes, and (3) maternal health outcomes? ___ KQ 2. What are the confounders and effect modifiers in examining the association between maternal weight gain (overall and patterns) and birth outcomes? ___ KQ 3. What is the evidence that weight gain above or below thresholds defined in the 1990 Institute of Medicine BMI Guidelines or weight loss in pregnancy contributes to ante-partum complications, or longer-term maternal and fetal complications? ___ KQ 4. What are the harms or benefits of offering the same weight gain recommendations to all pregnant women, irrespective of age and body weight considerations (e.g. pregravid weight, actual body weight at a particular time point, or optimal body weight)? ___ KQ5. What are the anthropometric tools for determining adiposity and their appropriateness for the pregnancy state?		
10. IF KQ1 - 4 SELECTED: Is pre-pregnancy weight or BMI included in study?	Yes/NA	No
11. IF KQ3 SELECTED: Does the study include IOM guidelines?	Yes/NA	No
If you answered YES to all, hand search references and record relevant reference numbers here:		

EXCLUDE IF AN ITEM IN A GRAY BOX IS SELECTED

If EXCLUDED, retain for:

_____BACKGROUND/DISCUSSION _____REVIEW OF REFERENCES _____OTHER_____

COMMENTS:

MWG Full Text Review Form

Exploring Future Research Related to The Outcomes of Maternal Weight Gain - Survey

Thank you for your participation in the *Future Research Priorities for Understanding Weight Gain in Pregnancy in the Context of Maternal, Fetal, and Infant Health* project.

Our project team has compiled initial research questions. The purpose of this part of our work is to generate an exhaustive list of potential research questions. We would like your input in the following areas:

- The addition of new research questions
- Specific edits and/or refinements to the proposed research questions
- The exclusion of questions for which ongoing research is likely to provide appropriate answers to fill current evidence gaps
- Any additional general feedback on the research questions

We ask that you provide your edits/comments on the initial list of research questions as well as any new research questions by 05/27/2010.

There are several categories of future research questions in this survey. We ask that you view the survey in its entirety and answer accordingly. In particular, the categories are:

- General Evidence Gaps - 11 Questions
- General Evidence Gaps (Continued) - 11 Questions
- Interventions - 6 Questions
- Statistical Issues - 2 Questions
- Policy - 4 Questions
- Measurement - 3 Questions
- Additional Questions Relevant to Weight Gain during Pregnancy
- Additional Comments/Questions

If you have any questions or concerns regarding this survey or this project, please do not hesitate to contact Nikki McKoy at jnikki.mckoy@Vanderbilt.edu.

A. General Evidence Gaps - Please review and edit the following research questions related to the outcomes of Maternal Weight Gain.

1. Is total weight gain or rate of weight gain during pregnancy associated with (1) birth outcomes, (2) infant health outcomes, and (3) maternal health outcomes?

   ➢

2. What factors confound the relationship between gestational weight gain (overall and patterns) and birth outcomes?

   ➢

3. What factors modify the relationship between gestational weight gain (overall and patterns) and birth outcomes?

   ➢

4. What is the impact of age on the relationship of weight gain and pregnancy outcomes?

   ➢

5. Does age at menarche modify the relationship of weight gain and pregnancy outcomes?

   ➢

6. Does weight gain above thresholds defined in the 2009 IOM body mass index (BMI) guidelines contribute to the following:
   (a) antepartum complications
   (b) postpartum complications
   (c) longer term maternal and infant complications

   ➢

7. Does weight gain below thresholds defined in the 2009 IOM body mass index (BMI) guidelines contribute to the following:
   (a) antepartum complications
   (b) postpartum complications
   (c) longer term maternal and infant complications

   ➢

8. Does weight loss thresholds defined in the 2009 IOM body mass index (BMI) guidelines contribute to the following:
(a) antepartum complications
(b) postpartum complications
(c) longer term maternal and infant complications

➢

9. How do these relationships vary by sociodemographic characteristics (i.e., race and age)?

➢

10. What are the harms or benefits of offering the same weight gain recommendations to all pregnant women, irrespective of age and body weight considerations (e.g., pregravid weight, actual body weight at a particular time point, or optimal body weight)? (AHRQ 2008)

➢

A. General Evidence Gaps (Continued) - Please review and edit the following research questions related to the outcomes of Maternal Weight Gain.

11. Which anthropometric tools are most appropriate for determining adiposity and are appropriate during pregnancy?

➢

12. What are the risks and benefits of measuring adiposity for (1) clinical management of weight gain during pregnancy and (2) evaluation of the relationship between weight gain and outcomes of pregnancy?

➢

13. What are the level of knowledge, attitudes, and self-efficacy of women regarding gestational weight gain? (AHRQ 2008)

➢

14. Does weight gain influence lactation initiation and maintenance?

➢

15. Does parity modify the relationship of weight gain and pregnancy outcomes?

➢

16. Do genetic factors influence the relationship between weight gain and pregnancy outcomes?

➢

17. Is there an interaction of stature and weight gain? (AHRQ 2008)

➢

18. What is the impact of total weight gain vs. rate of weight gain vs. timing of weight gain on pregnancy outcomes? (AHRQ 2008)

➢

19. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes? (AHRQ 2008)

- ➢

20. What are the optimal weight gains for obese women? (AHRQ 2008)

- ➢

21. What research and databases describe the distribution of maternal weight (prior to, during, and after pregnancy) among different populations of women in the United States? (NRC-IOM 2007)

- ➢

22. What research and databases inform understanding of the effects of different weight patterns (including underweight and overweight) during pregnancy on maternal and child health outcomes? (NRC-IOM 2007)

- ➢

B. Interventions - Please review and edit the following research questions related to the outcomes of Maternal Weight Gain.

1. Do women receive accurate weight gain guidance by their prenatal clinicians; whether clinicians have the knowledge, attitudes, and skills necessary to provide appropriate weight gain guidance? (AHRQ 2008)

   ➢

2. What research has been conducted to describe the individual, community, and health care system factors that impede or foster compliance with recommended GWG guidelines? (NRC-IOM 2007)

   ➢

3. What intervention(s) are effective for achieving recommended maternal weight gain?

   ➢

4. What methods are effective for helping women understand goals for weight gain in pregnancy?

   ➢

5. What role does physical activity play in achieving recommended maternal weight gain?

   ➢

6. What role does nutrition play in achieving recommended maternal weight gain?

   ➢

C. Statistical Issues - Please review and edit the following research questions related to the outcomes of Maternal Weight Gain.

1. How should outliers in pregravid weight, gestational weight gain, postpartum weight, and maternal height be handled in analyses?

   ➢

2. What is the need for standardization of research measures to advance the field?

   ➢

D. Policy - Please review and edit the following research questions related to the outcomes of Maternal Weight Gain.

1. How accurate is self-reported compared to measured weight (prepregnancy, in pregnancy, and post-partum) in all populations and among women of varying pregravid weights and gestational ages?

   ➢

2. What are the tests of the reliability of self-reported weights in pregnancy by age, parity, and BMI? (AHRQ 2008)

   ➢

3. What opportunities exist for Title V maternal and child health programs to build on this knowledge to help childbearing women achieve and maintain recommended weight? (NRC-IOM 2007)

   ➢

4. What future research and data collection efforts could improve the efforts of Title V programs to support women from different racial and ethnic backgrounds in their efforts to comply with recommended weight guidelines and to improve their maternal health? (NRC-IOM 2007)

   ➢

E. Measurement - Please review and edit the following research questions related to the outcomes of Maternal Weight Gain.

1. Is rate of weight gain, adequacy of rate of weight gain, or total weight gain superior for predicting adverse outcomes?

   ➢

2. What are the preferred anthropometric measurements for predicting outcomes of interest? (AHRQ 2008)

   ➢

3. Does direct measurement of body fat (prepregnancy, in pregnancy, post-partum) contribute to the understanding of outcomes?

   ➢

F. Additional Questions Relevant to Maternal Weight Gain in Pregnancy

Please use this section to add any additional research questions you find to be imperative when addressing knowledge gaps and research needs in the context of maternal weight gain in pregnancy.

➢

G. Additional Comments/Questions

➢

Research Gaps in Maternal Weight Gain Ranking Survey

Ranking Measures of Weight Gain in Pregnancy

All of the proposed research questions to address gaps in knowledge rely on some specification of a measurement of weight or body composition.

Please rank the measure you think is most important to address research gaps related to weight gain in pregnancy as #1 and the least important as #12.

* 1. Candidate measure of maternal weight status (at baseline or as measures of change)

	1	2	3	4	5	6	7	8	9	10	11	12
Early pregnancy baseline weight/BMI	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Pre-pregnancy baseline weight/BMI	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Total weight gain from first trimester to end of pregnancy	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Total weight gain from pre-pregnancy to end of pregnancy	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Pattern of weight gain across trimesters (e.g., low-low-high vs. low-high-high, etc.)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Pattern of weight gain across pregnancy as a statistical trend line or function	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Rate of weight gain (e.g., kilograms per week)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Change in BMI from first trimester to end of pregnancy	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Change in BMI from pre-pregnancy to end of pregnancy	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Body/body fat composition by caliper, impedence, "BodPod" or other measure	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Change in body/body fat composition	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Anthropomorphic groupings (e.g., waist-to-hip ratio)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

Research Gaps in Maternal Weight Gain Ranking Survey

Ranking Outcomes of Weight Gain in Pregnancy

All of the proposed research questions to address gaps in knowledge rely on some specification of an outcome or outcomes of interest.

Please rank the outcome you think is most important to address research gaps related to weight gain in pregnancy as #1 and the least important as #8.

* 2. Candidate outcomes of interest related to maternal weight status (at baseline or as measures of change)

	1	2	3	4	5	6	7	8
Maternal antepartum outcomes	◯	◯	◯	◯	◯	◯	◯	◯
Development of gestational diabetes	◯	◯	◯	◯	◯	◯	◯	◯
Fetal outcomes (e.g. stillbirth, fetal distress in labor)	◯	◯	◯	◯	◯	◯	◯	◯
Intrapartum outcomes (e.g. shoulder dystocia, cesarean birth)	◯	◯	◯	◯	◯	◯	◯	◯
Neonatal outcomes (e.g. preterm birth, NICU admission, birth injury)	◯	◯	◯	◯	◯	◯	◯	◯
Maternal postpartum outcomes (e.g. postpartum weight loss, initiation of lactation, duration of lactation)	◯	◯	◯	◯	◯	◯	◯	◯
Infant health outcomes (e.g. growth in first year of life, developmental milestones)	◯	◯	◯	◯	◯	◯	◯	◯
Child health outcomes (e.g. overweight and obesity)	◯	◯	◯	◯	◯	◯	◯	◯

Research Gaps in Maternal Weight Gain Ranking Survey

General Evidence Gaps

For the balance of the survey items we have simplified the questions to indicate "[weight gain in pregnancy]" and "[outcomes]" as generic stand-ins for specific targets. The ranking of the above items will be used later by the group to help merge the prioritization of specific measure of weight gain/outcomes with proposed research questions. This will multiply the number of items for final rankings in a future round.

A number of the research questions and suggestions for new items and edits emphasized the need to understand the inter-relationship of causal factors, for instance calorie expenditure, nutritional content of meals, and maternal weight gain. The intent of these questions is to more clearly understand the independent contribution of specific factors of two types: 1) confounders and 2) effect modifiers. The research questions themselves are not required to be accessible to a lay audience, rather to provide information to guide prioritization of topics to fill gaps in knowledge at the scientific level. *Don't worry about word-smithing to make the research questions transparent for the public.*

We have grouped the research questions here by focus on confounding versus effect modification. The level of granularity of the items differs from broad to specific.

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

Confounding

Questions about confounding are aimed at assuring that an influence on outcome(s) is not incorrectly attributed to one factor (e.g. weight gain) if actually being driven by another confounding factor (e.g. nutritional composition of the diet). Confounders are associated with both the exposure of interest (i.e. some specific measure of weight gain in pregnancy) and the outcome under study (i.e. some specific maternal, fetal, or infant outcome) and mask or inflate the estimated effects of the exposure of interest.

3. What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

4. Does nutrient content of the diet confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

5. Does physical activity [metabolic expenditure] confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

6. Does socioeconomic status confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

7. Does pregravid health status confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

8. Does pre-pregnancy BMI or pre-pregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

General Evidence Gaps (continued)

Effect Modifiers

Questions about effect modification, also termed interaction, are aimed at understanding whether the relationship between the exposure of interest and the outcome is fundamentally different based on status of another characteristic. For instance: Does Type II diabetes modify the relationship between total maternal weight gain and risk of macrosomia?

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

9. What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

10. Does maternal age modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

11. Does pre-pregnancy BMI or pre-pregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

12. Does weight at menarche modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

13. Does use of insulin or other diabetes medications modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

General Evidence Gaps (continued)

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

14. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

15. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

16. Does race modify the relationship between gestational weight gain above (or below) thresholds defined in the 2009 IOM weight gain and complications?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

17. Does maternal age modify the relationship between gestational weight gain above (or below) thresholds defined in the 2009 IOM weight gain and complications?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

18. What are the harms and benefits of offering standardized weight gain recommendations to all pregnant women?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

General Evidence Gaps (Continued)

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

19. Which anthropometric tools are most appropriate for determining adiposity in pregnant women?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

20. What are the strengths and weaknesses of measuring adiposity for the clinical management of weight gain during pregnancy?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

21. What are the strengths and weaknesses of measuring adiposity for the evaluation of the relationship between weight gain and outcomes of pregnancy?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

22. What is the general health literacy (i.e., the level of knowledge, attitudes and self-efficacy) of women regarding gestational weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

23. Does weight gain during pregnancy influence lactation initiation and maintenance?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

24. Does parity influence the relationship of weight gain and pregnancy outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

25. Do the mother's or father's genetic factors influence the relationship between weight gain and pregnancy outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

26. Is there an interaction between mother's stature and weight gain during pregnancy that affects the outcomes of the pregnancy?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

27. What is the relative impact of total weight gain vs. rate of weight gain vs. timing of weight gain (by trimester) on pregnancy outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

28. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

29. What are the optimal gestational weight gains for women with varying degrees of pre-pregnancy obesity?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

30. What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

31. What research studies and databases are available to inform our understanding of the effects of different weight patterns (including underweight and overweight) during pregnancy on maternal and child health outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

Interventions

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

32. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

33. Do women receive weight gain guidance from their prenatal clinicians? If so, is the guidance consistent with the 2009 IOM/NRC Gestational Weight Gain publication?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

34. What methods are effective for helping women acquire knowledge and understanding of the goals for weight gain, and skills for controlling weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

35. What research has been conducted to describe the individual, community, and health care system factors that impede or foster adherence to recommended gestational weight gain guidelines?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

36. What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

37. How does physical activity affect maternal weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

38. How does total caloric intake, and dietary composition of caloric intake affect maternal weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

Statistical Issues

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

39. In conducting analyses on weight gain in pregnancy, how should one define outliers in pregravid weight, gestational weight gain, postpartum weight, and maternal height?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

40. How should outliers in pregravid weight, gestational weight gain, postpartum weight, and maternal height be handled analytically?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

41. What is the need for standardization of research measures to advance the field of research related to weight gain in pregnancy?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

42. How much variability is there in measurement of factors associated with maternal weight gain and pregnancy outcomes such as definition of diet composition, measurement of maternal and neonatal body composition and agreement on ideal neonatal weight and body composition?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

43. Is there a lack of standardization in current research in terms of maternal weight gain measures?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

44. Is there a lack of standardization in current research in terms of birth, maternal, and infant outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

Policy Issues

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

45. How accurate is self-reported compared to measured weight (prepregnancy, in pregnancy, and postpartum) in all populations and among women of varying pregravid weights and gestational ages?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

46. How reliable is self-reported prepregnancy weight in pregnancy by age, parity, and BMI?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

47. What opportunities exist for Title V maternal and child health programs to assist childbearing women in achieving and maintaining recommended weight?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

48. What future research and data collection efforts could improve the efforts of Title V programs to support women from different racial and ethnic backgrounds in their efforts to meet recommended weight guidelines and to improve their maternal health?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey

Measurement Issues

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

49. Is rate of weight gain, change in BMI, adequacy of rate of weight gain, or total weight gain superior for predicting adverse birth, maternal, and infant outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

50. What are the preferred anthropometric measurements for predicting birth, maternal, and infant outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

51. Does direct measurement of body fat (prepregnancy, in pregnancy, postpartum) and other body composition factors and biomarkers (for example, blood lipids) contribute to the understanding of birth, maternal, and infant outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

52. Would a direct measure of body fat prior to pregnancy be more closely related to pregnancy outcomes such as infant birth weight than pre-pregnancy BMI?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

Ranking Measures of Weight Gain in Pregnancy

All of the proposed research questions to address gaps in knowledge rely on some specification of a measurement of weight or body composition.

Please rank the measure you think is most important to address research gaps related to weight gain in pregnancy as #1 and the least important as #8.

* 1. Candidate measure of maternal weight status (at baseline or as measures of change)

	1	2	3	4	5	6	7	8
Pattern of weight gain across trimesters (e.g., low-low-high vs. low-high-high, etc.)	◯	◯	◯	◯	◯	◯	◯	◯
Total weight gain from pre-pregnancy to end of pregnancy	◯	◯	◯	◯	◯	◯	◯	◯
Pre-pregnancy baseline weight/BMI	◯	◯	◯	◯	◯	◯	◯	◯
Total weight gain from first trimester to end of pregnancy	◯	◯	◯	◯	◯	◯	◯	◯
Pattern of weight gain across pregnancy as a statistical trend line or function	◯	◯	◯	◯	◯	◯	◯	◯
Rate of weight gain (e.g., kilograms per week)	◯	◯	◯	◯	◯	◯	◯	◯
Change in body/body fat composition	◯	◯	◯	◯	◯	◯	◯	◯
Change in BMI from pre-pregnancy to end of pregnancy	◯	◯	◯	◯	◯	◯	◯	◯

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

Ranking Outcomes of Weight Gain in Pregnancy--Round 2

All of the proposed research questions to address gaps in knowledge rely on some specification of an outcome or outcomes of interest.

Please rank the outcome you think is most important to address research gaps related to weight gain in pregnancy as #1 and the least important as #5.

*** 2. Candidate outcomes of interest related to maternal weight status (at baseline or as measures of change)**

	1	2	3	4	5
Infant health outcomes (e.g. growth in first year of life, developmental milestones)	◯	◯	◯	◯	◯
Fetal outcomes (e.g. stillbirth, fetal distress in labor)	◯	◯	◯	◯	◯
Maternal postpartum outcomes (e.g. postpartum weight loss, initiation of lactation, duration of lactation)	◯	◯	◯	◯	◯
Child health outcomes (e.g. overweight and obesity)	◯	◯	◯	◯	◯
Development of gestational diabetes	◯	◯	◯	◯	◯

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

General Evidence Gaps

For the balance of the survey items we have simplified the questions to indicate "[weight gain in pregnancy]" and "[outcomes]" as generic stand-ins for specific targets. The ranking of the above items will be used later by the group to help merge the prioritization of specific measure of weight gain/outcomes with proposed research questions. This will multiply the number of items for final rankings in a future round.

A number of the research questions and suggestions for new items and edits emphasized the need to understand the inter-relationship of causal factors, for instance calorie expenditure, nutritional content of meals, and maternal weight gain. The intent of these questions is to more clearly understand the independent contribution of specific factors of two types: 1) confounders and 2) effect modifiers. The research questions themselves are not required to be accessible to a lay audience, rather to provide information to guide prioritization of topics to fill gaps in knowledge at the scientific level. *Don't worry about word-smithing to make the research questions transparent for the public.*

We have grouped the research questions here by focus on confounding versus effect modification. The level of granularity of the items differs from broad to specific.

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

Confounding

Questions about confounding are aimed at assuring that an influence on outcome(s) is not incorrectly attributed to one factor (e.g. weight gain) if actually being driven by another confounding factor (e.g. nutritional composition of the diet). Confounders are associated with both the exposure of interest (i.e. some specific measure of weight gain in pregnancy) and the outcome under study (i.e. some specific maternal, fetal, or infant outcome) and mask or inflate the estimated effects of the exposure of interest.

3. What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

4. Does physical activity [metabolic expenditure] confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

5. Does pregravid health status confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

6. Does pre-pregnancy BMI or pre-pregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

General Evidence Gaps (continued)

Effect Modifiers

Questions about effect modification, also termed interaction, are aimed at understanding whether the relationship between the exposure of interest and the outcome is fundamentally different based on status of another characteristic. For instance: Does Type II diabetes modify the relationship between total maternal weight gain and risk of macrosomia?

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

7. What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

8. Does pre-pregnancy BMI or pre-pregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

9. Does use of insulin or other diabetes medications modify the relationship between [weight gain in pregnancy] and [outcomes]?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

General Evidence Gaps (continued)

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

10. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

11. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

12. Does maternal age modify the relationship between gestational weight gain above (or below) thresholds defined in the 2009 IOM weight gain and complications?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

13. What are the harms and benefits of offering standardized weight gain recommendations to all pregnant women?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

General Evidence Gaps (Continued)

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

14. Which anthropometric tools are most appropriate for determining adiposity in pregnant women?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

15. What is the general health literacy (i.e., the level of knowledge, attitudes and self-efficacy) of women regarding gestational weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

16. What is the relative impact of total weight gain vs. rate of weight gain vs. timing of weight gain (by trimester) on pregnancy outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

17. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

18. What are the optimal gestational weight gains for women with varying degrees of pre-pregnancy obesity?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

19. What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

20. What research studies and databases are available to inform our understanding of the effects of different weight patterns (including underweight and overweight) during pregnancy on maternal and child health outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

Interventions

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

21. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

22. What methods are effective for helping women acquire knowledge and understanding of the goals for weight gain, and skills for controlling weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

23. What research has been conducted to describe the individual, community, and health care system factors that impede or foster adherence to recommended gestational weight gain guidelines?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

24. What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

25. How does physical activity affect maternal weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

26. How does total caloric intake, and dietary composition of caloric intake affect maternal weight gain?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

Statistical Issues

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

27. What is the need for standardization of research measures to advance the field of research related to weight gain in pregnancy?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

28. Is there a lack of standardization in current research in terms of maternal weight gain measures?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Research Gaps in Maternal Weight Gain Ranking Survey--Round 2

Measurement Issues

Please score all items, from 0 (low) to 10 (high), for the following domains: overall interest, clinical utility, feasibility of the research, and potential to advance the science.

29. Is rate of weight gain, change in BMI, adequacy of rate of weight gain, or total weight gain superior for predicting adverse birth, maternal, and infant outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

30. What are the preferred anthropometric measurements for predicting birth, maternal, and infant outcomes?

	Ranking Choices
Overall importance	
Clinical utility	
Feasibility of the research	
Potential to advance the science	

Maternal Weight Gain Ranking Survey Results

Participants were asked to rank the measures with 1 being the most important and 12 as the least important. The ranking scores were added together so that the measure with the highest score was the least important. Our goal was to eliminate at least one-third (4) of the measures so the highlighted measures will not be used for the next ranking.

Measures of maternal weight gain

Measure	Total Score
Total weight gain from prepregnancy to end of pregnancy	73
Total weight gain from first trimester to end of pregnancy	89
Prepregnancy baseline weight/BMI	93
Pattern of weight gain across pregnancy as a statistical trend line or function	93
Pattern of weight gain across trimesters	94
Rate of weight gain	101
Change in BMI from prepregnancy to end of pregnancy	106
Change in body/body fat composition	107
Early pregnancy baseline weight/BMI	110
Change in BMI from first trimester to end of pregnancy	116
Body/body fat composition by caliper, impedence, “BodPod” or other measure	118
Anthropomorphic groupings	149

Participants were asked to rank the outcomes with 1 being the most important and 8 as the least important. The ranking scores were added together so that the outcome with the highest score was the least important. Our goal was to eliminate at least one-third (3) of the outcomes so the highlighted outcomes will not be used for the next ranking.

Outcomes of interest related to maternal weight gain

Outcomes	Total Score
Development of gestational diabetes	46
Child health outcomes	56
Fetal outcomes	67
Infant health outcomes	70
Maternal postpartum outcomes	75
Intrapartum outcomes	79
Neonatal outcomes	79
Maternal antepartum outcomes	84

We used a two-step process to identify questions for elimination. The proportion of 9 or 10 votes cast for each domain was first calculated. Next, the proportion of 9-10 votes assigned for clinical utility, feasibility of the research, and potential to advance the science were averaged. This left two measures: the proportion of 9-10 votes assigned for overall importance for each question and the average proportion of 9-10 votes for the additional three domains combined. Questions highlighted in red below received fewer than 30 percent of 9-10 level votes by each measure.

General evidence gaps

Question	Overall Importance	Clinical Utility	Feasibility	Advance science	Overall Average	Average (3 items)
What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?	46.7%	20.0%	20.0%	26.7%	28.3%	22.2%
Does nutrient content of the diet confound the relationship between [weight gain in pregnancy] and [outcomes]?	27%	13.3%	13.3%	33.3%	21.7%	20.0%
Does physical activity [metabolic expenditure] confound the relationship between [weight gain in pregnancy] and [outcomes]?	50%	35.7%	42.9%	50.0%	44.6%	42.9%
Does socioeconomic status confound the relationship between [weight gain in pregnancy] and [outcomes]?	20%	13.3%	20.0%	6.7%	15.0%	13.3%
Does pregravid health status confound the relationship between [weight gain in pregnancy] and [outcomes]?	33%	33.3%	6.7%	13.3%	21.7%	17.8%
Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?	53%	26.7%	46.7%	33.3%	40.0%	35.6%
What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?	40%	33.3%	13.3%	26.7%	28.3%	24.4%
Does maternal age modify the relationship between [weight gain in pregnancy] and [outcomes]?	20%	13.3%	26.7%	13.3%	18.3%	17.8%
Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?	47%	46.7%	40.0%	40.0%	43.3%	42.2%
Does weight at menarche modify the relationship between [weight gain in pregnancy] and [outcomes]?	0%	0.0%	6.7%	0.0%	1.7%	2.2%
Does use of insulin or other diabetes medications modify the relationship between [weight gain in pregnancy] and [outcomes]?	20%	40.0%	26.7%	33.3%	30.0%	33.3%
Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?	40%	46.7%	40.0%	40.0%	41.7%	42.2%
Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?	40%	46.7%	40.0%	40.0%	41.7%	42.2%
Does race modify the relationship between gestational weight gain above (or below) thresholds defined in the 2009 IOM weight gain and complications?	20%	20.0%	33.3%	20.0%	23.3%	24.4%

Question	Overall Importance	Clinical Utility	Feasibility	Advance science	Overall Average	Average (3 items)
Does maternal age modify the relationship between gestational weight gain above (or below) thresholds defined in the 2009 IOM weight gain and complications?	13%	26.7%	40.0%	20.0%	25.0%	28.9%
What are the harms and benefits of offering standardized weight gain recommendations to all pregnant women?	60%	66.7%	26.7%	53.3%	51.7%	48.9%
Which anthropometric tools are most appropriate for determining adiposity in pregnant women?	47%	33.3%	33.3%	33.3%	36.7%	33.3%
What are the strengths and weaknesses of measuring adiposity for the clinical management of weight gain during pregnancy?	27%	20.0%	6.7%	26.7%	20.0%	17.8%
What are the strengths and weaknesses of measuring adiposity for the evaluation of the relationship between weight gain and outcomes of pregnancy?	27%	26.7%	20.0%	33.3%	26.7%	26.7%
What is the general health literacy (i.e., the level of knowledge, attitudes and self-efficacy) of women regarding gestational weight gain?	33%	13.3%	33.3%	13.3%	23.3%	20.0%
Does weight gain during pregnancy influence lactation initiation and maintenance?	20%	20.0%	6.7%	13.3%	15.0%	13.3%
Does parity influence the relationship of weight gain and pregnancy outcomes?	13%	13.3%	20.0%	13.3%	15.0%	15.6%
Do the mother's or father's genetic factors influence the relationship between weight gain and pregnancy outcomes?	27%	6.7%	6.7%	26.7%	16.7%	13.3%
Is there an interaction between mother's stature and weight gain during pregnancy that affects the outcomes of the pregnancy?	20%	13.3%	13.3%	13.3%	15.0%	13.3%
What is the relative impact of total weight gain vs. rate of weight gain vs. timing of weight gain (by trimester) on pregnancy outcomes?	53%	40.0%	33.3%	46.7%	43.3%	40.0%
What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?	80%	46.7%	33.3%	73.3%	58.3%	51.1%
What are the optimal gestational weight gains for women with varying degrees of prepregnancy obesity?	60%	53.3%	26.7%	40.0%	45.0%	40.0%
What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?	40%	13.3%	26.7%	20.0%	25.0%	20.0%
What research studies and databases are available to inform our understanding of the effects of different weight patterns (including underweight and overweight) during pregnancy on maternal and child health outcomes?	33%	6.7%	20.0%	20.0%	20.0%	15.6%

Interventions

Question	Overall Importance	Clinical Utility	Feasibility	Advance science	Overall Average	Average (3 items)
Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?	40%	60.0%	46.7%	13.3%	40.0%	40.0%
Do women receive weight gain guidance from their prenatal clinicians? If so, is the guidance consistent with the 2009 IOM/NRC Gestational Weight Gain publication?	27%	40.0%	40.0%	6.7%	28.3%	28.9%
What methods are effective for helping women acquire knowledge and understanding of the goals for weight gain, and skills for controlling weight gain?	53%	60.0%	33.3%	20.0%	41.7%	37.8%
What research has been conducted to describe the individual, community, and health care system factors that impede or foster adherence to recommended gestational weight gain guidelines?	33%	46.7%	46.7%	33.3%	40.0%	42.2%
What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?	73%	73.3%	26.7%	60.0%	58.3%	53.3%
How does physical activity affect maternal weight gain?	47%	33.3%	33.3%	33.3%	36.7%	33.3%
How does total caloric intake, and dietary composition of caloric intake affect maternal weight gain?	40%	26.7%	20.0%	40.0%	31.7%	28.9%

Statistical issues

Question	Overall Importance	Clinical Utility	Feasibility	Advance science	Overall Average	Average (3 items)
In conducting analyses on weight gain in pregnancy, how should one define outliers in pregravid weight, gestational weight gain, postpartum weight, and maternal height?	27%	20.0%	13.3%	13.3%	18.3%	15.6%
How should outliers in pregravid weight, gestational weight gain, postpartum weight, and maternal height be handled analytically?	27%	0.0%	20.0%	6.7%	13.3%	8.9%
What is the need for standardization of research measures to advance the field of research related to weight gain in pregnancy?	40%	33.3%	33.3%	33.3%	35.0%	33.3%
How much variability is there in measurement of factors associated with maternal weight gain and pregnancy outcomes such as definition of diet composition, measurement of maternal and neonatal body composition and agreement on ideal neonatal weight and body composition?	20%	0.0%	13.3%	13.3%	11.7%	8.9%

Question	Overall Importance	Clinical Utility	Feasibility	Advance science	Overall Average	Average (3 items)
Is there a lack of standardization in current research in terms of maternal weight gain measures?	40%	20.0%	33.3%	26.7%	30.0%	26.7%
Is there a lack of standardization in current research in terms of birth, maternal, and infant outcomes?	20%	13.3%	26.7%	26.7%	21.7%	22.2%

Policy

Question	Overall Importance	Clinical Utility	Feasibility	Advance science	Average	Average (3 items)
How accurate is self-reported compared to measured weight (prepregnancy, in pregnancy, and postpartum) in all populations and among women of varying pregravid weights and gestational ages?	7%	6.7%	46.7%	20.0%	20.0%	24.4%
How reliable is self-reported prepregnancy weight in pregnancy by age, parity, and BMI?	20%	13.3%	26.7%	20.0%	20.0%	20.0%
What opportunities exist for Title V maternal and child health programs to assist childbearing women in achieving and maintaining recommended weight?	13%	13.3%	13.3%	6.7%	11.7%	11.1%
What future research and data collection efforts could improve the efforts of Title V programs to support women from different racial and ethnic backgrounds in their efforts to meet recommended weight guidelines and to improve their maternal health?	13%	6.7%	13.3%	6.7%	10.0%	8.9%

Measurement

Question	Overall Importance	Clinical Utility	Feasibility	Advance science	Overall Average	Average (3 items)
Is rate of weight gain, change in BMI, adequacy of rate of weight gain, or total weight gain superior for predicting adverse birth, maternal, and infant outcomes?	40%	40.0%	20.0%	33.3%	33.3%	31.1%
What are the preferred anthropometric measurements for predicting birth, maternal, and infant outcomes?	33%	33.3%	13.3%	33.3%	28.3%	26.7%
Does direct measurement of body fat (prepregnancy, in pregnancy, postpartum) and other body composition factors and biomarkers (for example, blood lipids) contribute to the understanding of birth, maternal, and infant outcomes?	27%	33.3%	13.3%	26.7%	25.0%	24.4%
Would a direct measure of body fat prior to pregnancy be more closely related to pregnancy outcomes such as infant birthweight than prepregnancy BMI?	27%	26.7%	20.0%	26.7%	25.0%	24.4%

Maternal Weight Gain Ranking Survey Results—Round 2

In the first round of ranking (see results above) we were able to eliminate the lowest ranking responses. In the second round of ranking participants were asked to rank the remaining eight measures with 1 being the most important and 8 as the least important. The ranking scores were added together so that the measure with the highest score was the least important.

Measures of maternal weight gain

Measure	Total
Total weight gain from prepregnancy to end of pregnancy	**47**
Prepregnancy baseline weight/BMI	63
Change in body/body fat composition	65
Pattern of weight gain across pregnancy as a statistical trend line or function	79
Total weight gain from first trimester to end of pregnancy	82
Pattern of weight gain across trimesters	82
Rate of weight gain	84
Change in BMI from prepregnancy to end of pregnancy	88

Total weight gain from prepregnancy to end of pregnancy was the most important measure of maternal weight gain, followed by prepregnancy baseline weight/BMI and change body/body fat composition.

Participants were asked to rank the five remaining outcomes with 1 being the most important and 5 as the least important.

Outcomes of interest related to maternal weight gain

Outcomes	Total
Maternal postpartum outcomes	**43**
Child health outcomes	46
Infant health outcomes	47
Development of gestational diabetes	52
Fetal outcomes	52

Participants ranked maternal postpartum and child health outcomes as the most important outcomes related to maternal weight gain.

In the first round of ranking we used the percentage of 9's or 10's as our elimination standard. However, for the second round of ranking the ranking scores were multiplied by the number of responses and these scores were added together so that the measure with the highest score was the most important. For example, if out of 5 participants 3 ranked the question as 5 out of 10 in importance and 2 ranked the question as 10 out of 10, that question would receive a score of (5*3) + (2*10) =35. These scores were then compared across questions.

General Evidence Gaps

The table below is the score totals across the four domains, overall importance, clinical utility, feasibility, and potential to advance science.

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?	117	106	101	107

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
Does physical activity [metabolic expenditure] confound the relationship between [weight gain in pregnancy] and [outcomes]?	114	108	107	112
Does pregravid health status confound the relationship between [weight gain in pregnancy] and [outcomes]?	109	101	83	107
Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?	119	112	114	117
What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?	116	102	96	11
Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?	123	117	109	115
Does use of insulin or other diabetes medications modify the relationship between [weight gain in pregnancy] and [outcomes]?	102	110	110	109
Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?	113	117	110	112
Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?	110	117	110	112
What are the harms and benefits of offering standardized weight gain recommendations to all pregnant women?	110	111	85	105
Which anthropometric tools are most appropriate for determining adiposity in pregnant women?	104	99	99	105
What is the general health literacy (i.e., the level of knowledge, attitudes and self-efficacy) of women regarding gestational weight gain?	106	103	109	101
What is the relative impact of total weight gain vs. rate of weight gain vs. timing of weight gain (by trimester) on pregnancy outcomes?	108	109	99	106
What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?	124	112	100	122
What are the optimal gestational weight gains for women with varying degrees of prepregnancy obesity?	114	114	97	112
What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?	102	93	117	96
What research studies and databases are available to inform our understanding of the effects of different weight patterns (including underweight and overweight) during pregnancy on maternal and child health outcomes?	92	87	108	95

In overall importance the top three questions were:

1. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
2. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?

The top three questions by averaging all four scores were:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?

Interventions

The table below is the score totals across the four domains, overall importance, clinical utility, feasibility, and potential to advance science.

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?	104	113	104	95
What methods are effective for helping women acquire knowledge and understanding of the goals for weight gain, and skills for controlling weight gain?	93	95	86	82
What research has been conducted to describe the individual, community, and health care system factors that impede or foster adherence to recommended gestational weight gain guidelines?	89	88	97	85
What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?	108	107	101	104
How does physical activity affect maternal weight gain?	111	110	97	102
How does total caloric intake, and dietary composition of caloric intake affect maternal weight gain?	99	96	78	98

In overall importance the top three questions were:

1. How does physical activity affect maternal weight gain?
2. What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?
3. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

The top three questions by averaging all four scores were:

1. How does physical activity affect maternal weight gain?
2. What interventions are effective for the outcome of maternal weight gain within the recommended range(s)?
3. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

Statistical issues

The table below is the score totals across the four domains, overall importance, clinical utility, feasibility, and potential to advance science.

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
What is the need for standardization of research measures to advance the field of research related to weight gain in pregnancy?	90	76	95	84
Is there a lack of standardization in current research in terms of maternal weight gain measures?	70	62	82	72

"What is the need for standardization of research measures to advance the field of research related to weight gain in pregnancy?" was the question that was the most important overall by overall importance score and also by averaging all four scores.

Measurement

The table below is the score totals across the four domains, overall importance, clinical utility, feasibility, and potential to advance science.

Question	Overall Importance	Clinical Utility	Feasibility	Advance Science
Is rate of weight gain, change in BMI, adequacy of rate of weight gain, or total weight gain superior for predicting adverse birth, maternal, and infant outcomes?	86	87	76	84
What are the preferred anthropometric measurements for predicting birth, maternal, and infant outcomes?	90	86	78	91

"What are the preferred anthropometric measurements for predicting birth, maternal, and infant outcomes?" was the question that was most important overall by overall importance score and also by averaging all four scores.

Across all of the categories the most important questions by overall importance were:

1. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
2. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
4. What factors confound the relationship between [weight gain in pregnancy] and [outcomes]?
5. What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?

The questions with the most clinical utility were:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?
3. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?
4. What are the optimal gestational weight gains for women with varying degrees of prepregnancy obesity?
5. Do prenatal care providers have the necessary knowledge, attitudes, and skills to provide appropriate weight gain guidance to women?

The questions that were scored as the most feasible were:

1. What research studies and databases are available to describe the distribution of maternal weight gain (prior to, during and after pregnancy) among different populations of women in the US?

2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?
4. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?
5. Does use of insulin or other diabetes medications modify the relationship between [weight gain in pregnancy] and [outcomes]?

The questions that had the greatest potential to advance science were:

1. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
4. What physiologic or clinical factors modify the relationship between [weight gain in pregnancy] and [outcomes]?
5. Does physical activity [metabolic expenditure] confound the relationship between [weight gain in pregnancy] and [outcomes]?
5. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?
5. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?
5. What are the optimal gestational weight gains for women with varying degrees of prepregnancy obesity?

The top five questions by highest average score across all four domains were:

1. Does prepregnancy BMI or prepregnancy weight modify the relationship between [weight gain in pregnancy] and [outcomes]?
2. Does prepregnancy BMI or prepregnancy weight confound the relationship between [weight gain in pregnancy] and [outcomes]?
3. What is the effect of gestational weight gain on infant (beyond birthweight) and childhood outcomes?
4. Does gestational weight gain above targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?
5. Does gestational weight gain below targets defined in the 2009 IOM weight gain guidelines contribute to complications (including antepartum, postpartum longer term maternal and infant complications)?

Appendix D. Excluded Studies

1. Abstracts. Obstetrics & Gynecology 2007;109(1):197-200. X-2
2. Gestational weight gain and child adiposity. ACOG Clinical Review 2007;12(5):13-13. X-2
3. Gestational weight gain and neonatal outcome. ACOG Clinical Review 2007;12(3):5-5. X-2
4. Hot papers in the literature. Journal of Women's Health (15409996) 2007;16(7):1076-1084. X-1
5. Interpregnancy weight gain and adverse outcome. ACOG Clinical Review 2007;12(4):4-5. X-2
6. Literature review. Women's Health. Nurse Practitioner. 2007;32(6):19-19. X-2
7. New in review. Periodicals. Journal of the American Dietetic Association 2007;107(3):512-517. X-2
8. Obese mums given healthy lifestyle advice. Practising Midwife 2007;10(9):13-13. X-2
9. Research round-up. RCM Midwives 2007;10(6):265-265. X-2
10. 2008 SNRS abstracts—A. Southern Online Journal of Nursing Research 2008;8(4):1-1. X-2
11. 2008 SNRS abstracts—F–G. Southern Online Journal of Nursing Research 2008;8(4):5-5. X-2
12. 2008 SNRS abstracts—H. Southern Online Journal of Nursing Research 2008;8(4):6-6. X-2
13. 2008 SNRS abstracts—I–K. Southern Online Journal of Nursing Research 2008;8(4):7-7. X-2
14. 2008 SNRS abstracts—T–V. Southern Online Journal of Nursing Research 2008;8(4):13-13. X-2
15. Abstracts. American Journal of Health Promotion 2008;23(2):152-153. X-2
16. Abstracts. Obstetrics & Gynecology 2008;112(4):939-942. X-1
17. Abstracts. Annals of Epidemiology 2008;18(9):708-741. X-2
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20. Gestational weight gain and normal body mass index. ACOG Clinical Review 2008;13(3):3-3. X-2
21. Gestational weight gain and obese women. ACOG Clinical Review 2008;13(3):3-4. X-2
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26. Obesity, multiple gestations may be factors in stillbirths. Contemporary OB/GYN 2008;53(1):20-20. X-2, X-9
27. Online. The latest web-only papers. Midwives 2008;11(6):26-26. X-2
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30. Bulletin board. Journal of Women's Health (15409996) 2009;18(7):919-922. X-2
31. Do fast food restaurants contribute to obesity? Natl Bur Econ Res Bull Aging Health 2009;(1):2-3. X-2, X-3, X-7, X-8, X-9
32. Excessive weight gain and fetal macrosomia. ACOG Clinical Review 2009;14(3):4-4. X-2
33. High BMI. Midwifery Matters 2009;(120):25-27. X-2
34. International news. Midwifery 2009;25(5):469-472. X-2
35. News breaks. Nutrition Today 2009 Jan-Feb;44(1):4-5. X-2
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37. Share with women. Women of size and pregnancy. Journal of Midwifery & Women's Health 2009;54(2):153-154. X-2
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