

# CAPQuaM HROB Measures #1-4 Appendix

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## ***Appendix A***

*All References (Literature Cited)*

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## ***Appendix B***

### *Literature Review*



# CAPQuaM

## High Risk Obstetrical Services

Literature Review

November 5, 2012



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## Executive Summary

The management of services rendered to high risk obstetrical patients presents challenges to both clinicians and non-clinicians alike. The objective of services rendered is to insure optimal maternal and fetal outcomes. To achieve those outcomes, care must be effective, evidence-based, and appropriately coordinated.

Three research questions have been proposed that will inform the development of a measure construct designed to address evidence-based, effective interventions related to the provision of services to high-risk obstetrical patients.

The first research question defines the specific high-risk obstetric populations of interest and is designed to identify the interventions, services, policies and practices that are effective in reducing morbidity and mortality in mothers and infants. The focus is on interventions, services, policies, and practices that are applied at the population/systems level (effectiveness rather than efficacy). Those specific high-risk populations are patients with either:

- Diabetes/obesity
- Cardiac disease
- Preeclampsia/Eclampsia
- Hypertension
- Psychiatric/mental health disorders
- Hemorrhage

### Diabetes/Obesity

Diabetes and obesity are associated primarily with adverse outcomes such as large-for-gestational-age neonates, elevated fetal insulin levels, and complications during delivery, including emergent cesarean section and shoulder dystocia. Further, about 50% of women who develop gestational diabetes will become diabetic later in life.

The interventions supported most strongly that lead to improved maternal-fetal outcomes include individual nutritional counseling and reduction of weight gain during pregnancy. Other interventions assessed which were also effective in improving outcomes among obese patients included self monitoring of glucose levels, weight loss or limited weight gain, and use of a balanced nutritional regimen with recording and daily diaries.

Outcomes assessed in trials included maternal weight gain, results of glucose tolerance testing, reported cesarean section, shoulder dystocia, rectal lesions during birth, labor induction, and the incidence of preeclampsia and gestational hypertension.

Accurate identification of diabetic pregnant women is essential in recommending interventions that can assist in reducing maternal fetal morbidity and mortality. Three interventions examined and found to have a positive effect on outcomes were creating an individual diabetes management plan, patient education, and tight glycemic control with insulin or oral hypoglycemic agents. When diet and insulin therapy were combined, rather than diet



adjustments alone, maternal morbidity was reduced, and the use of insulin, glyburide, lispro, and other anti-glycemics have also reduced fetal complications.

### **Cardiac Disease**

Whether occurring prior to conception or concomitant with pregnancy, maternal cardiac disease of any type has the potential for significant morbidity and mortality during the prenatal, postpartum, or labor and delivery phases. Available literature on this topic was limited due to ethical implications of research among pregnant women. Although there were no randomized control trials (RCTs), other types of literature were available for review. While few of these limited publications offer definitive positive interventions, many are suggestive of directions for management and future research regarding cardiac arrest, management of intercurrent cardiac disorders, cardiac surgery prior to conception, and anesthetic management.

#### Cardiac Arrest during Pregnancy

Perimortem C-section (PMCS) was the topic of two reviews, with findings that although infrequently performed within the recommended 5 minutes of cardiac arrest, it was effective in enabling survival of two of 12 mothers and five of 12 neonates. Optimal resuscitation techniques, including tilting prior to chest compressions, have yet to be defined and require more research.

#### Management of Cardiac Disorders during Pregnancy

In the reviews of both valvular heart disease and exposure to cardiopulmonary by-pass, it was noted that management by a multidisciplinary team was an essential component of care. Early identification of women at risk and careful monitoring during pregnancy were additional management strategies identified. There was review of different anticoagulation regimes for patients with mechanical heart valves, concluding that whichever medication regime was used, close monitoring was required. Finally it was noted that any contemplated surgery should only occur after medical therapy has failed.

#### Management of Pregnant Patients Who Had Cardiac Surgery Prior to Conception

There are 2 publications addressing care for pregnant patients who had cardiac surgery prior to conception. Although diagnoses were different in each group, each had open surgical intervention. It was concluded that coordinated care between a heart disease specialist and a high-risk obstetrician should occur for patients with prior open heart surgery, that neuraxial analgesia and anesthesia can be safely administered to patients, and that excellent labor analgesia and attentive surgical anesthesia can lead to successful outcomes for the majority of patients.

#### Anesthetic Management

There were 2 small studies examining anesthetic management of women with long QT syndrome and aortic stenosis, concluding that a multidisciplinary approach is required and that anesthesia modalities should be determined on the basis of multidisciplinary team input.

### **Preeclampsia/Eclampsia**

Preeclampsia is usually diagnosed when the systolic blood pressure exceeds 140 mm Hg or more and diastolic pressure exceeds 90 mm Hg., which can occur as early as 20 weeks gestation. Unfortunately, about 5 women in every 10,000 develop a serious condition, eclampsia, either before giving birth or within 48 hours after. Eclampsia is defined as seizures or coma in a patient with other indications of pregnancy-induced hypertension.

Maternal/fetal morbidity outcomes assessed included incidence of intra uterine growth retardation (IUGR), fetal complications, small for gestational age (SGA), low birth weight (LBW), spontaneous preterm birth, premature birth, placenta abruption, perinatal death, neonatal death (stillbirth), maternal bleeding and post partum hemorrhage. Five interventions were examined in this literature review; use of low dose aspirin, calcium supplementation, magnesium sulphate use, L-arginine dietary supplementation, and administration of Vitamins C and E.

#### Low-Dose Aspirin

Several large trials of anti-platelet agent (aspirin or dipyridole) administration vs. placebo have verified that these agents are effective for prevention of preeclampsia, particularly when used in groups of women at high risk for development of the disorder. Another study of 341 patients found a positive correlation with an increase in birth weight and gestational age upon delivery, when aspirin was given eight hours after awakening or before bedtime.

#### Calcium Supplementation

Mixed results have been noted in clinical trials that have examined calcium supplementation for the prevention of preeclampsia. While some trials have noted effectiveness in populations at high risk or with low calcium intake, there was no difference in outcomes noted in other trials.

#### Magnesium Sulfate

In several trials of magnesium sulfate use it was found that the incidence of eclampsia was halved, placental abruption and emergency deliveries were reduced and there was a reduction in maternal mortality.

#### L-arginine and Vitamins C and E

Large trials reviewing the benefits of vitamins C and E could not demonstrate improved outcomes; however, a trial with foods containing both L-arginine and anti-oxidant vitamins reduced the incidence of preeclampsia in high risk populations.

### **Hypertension**

Hypertension is the first stage of what is often a progression of hypertensive disorder through stages of severe hypertension, preeclampsia, and eclampsia, and can lead to significant maternal and neonatal morbidity and mortality. There are 4 types of interventions assessed in this literature review, which are dietary calcium or vitamin supplementation, anti-hypertensive medication administration, elective late-term delivery, and bed rest.

#### Elective Late-Term Delivery

Several large-scale trials have demonstrated that elective delivery at more than 37 weeks' gestation offers the optimal opportunity for termination of hypertension and the most beneficial maternal and neonatal outcomes. Review of evidence for the remaining three interventions is less clear than the imperative for elective delivery at 38-39 weeks gestation.

#### Anti-Hypertensive Medications

A Cochrane Review and several RCTs with adequate numbers of participants have failed to identify the most effective anti-hypertensive medication. Many other limited publications also failed to demonstrate any effectiveness of anti-hypertensive drug therapy. There was one study of oral beta-blockers, concluding that there was no benefit to their use, although there was a decrease in the risk of severe hypertension.

### Vitamin Supplementation

There were low levels of evidence for a positive effect on birthweight with the administration of vitamin B6. Vitamins C and E supplementation have shown a higher rate of the development of gestational hypertension, but another trial has noted no difference among Vitamins C and E treatment and placebo groups.

### Bed Rest

Small RCTs comparing bed rest at home, hospital admission, or day care have shown moderate quality evidence that some hospital rest was effective in reducing pre-term births.

## **Psychiatric/Mental Health**

Mental illness during pregnancy presents a number of challenges for treatment. Decisions about appropriate treatment modalities must be carefully considered with respect to the impact on the health of the mother and the outcomes of the pregnancy, in addition to fetal development and neonatal health. Although limited due to ethical considerations of conducting research on pregnant women, the available literature addressed interventions related to depression/prevention of post partum depression, electroconvulsive therapy, substance abuse, psychosis, and bi-polar disorder.

### Depression/Prevention of Postpartum Depression

Two studies assessed prevention of postpartum depression. One cited the importance of identifying pregnant women experiencing symptoms of depression. This study concluded that individual interventions that included Interpersonal Therapy, Cognitive Behavioral Therapy and a psychosocial approach that was delivered during pregnancy can be effective in preventing postnatal depression. The second study noted short term success with similar interventions but long term success was lacking.

The use of antidepressants during pregnancy was addressed as follows:

- One review conducted to determine the safety of selective serotonin reuptake inhibitors (SSRIs) and other anti-depressants used in pregnancy demonstrated a statistical association between paroxetine use and major malformation in the newborn.
- Another study demonstrated that infants exposed to either depression or SSRIs continuously across gestation were more likely to be born preterm than infants with partial or no exposure to either.
- A third study noted that there was consensus that pregnant mothers exposed to antidepressants are more likely to have spontaneous abortions, stillbirths, and preterm deliveries.

In general the findings demonstrated the need to exercise caution with SSRI use during pregnancy and that more research is needed.

### Electroconvulsive Therapy (ECT)

In a review of articles published from 1942-2007, there were 11 reports of fetal/neonatal abnormalities. 18 cases demonstrated adverse maternal effects believed to be related to ECT. Due to the range of adverse effects on the fetus related to medication therapy, ECT is viewed as an alternate therapy for treating major mental illness during pregnancy.

### Substance Abuse

Substance abuse during pregnancy is not uncommon and illicit drug use is not insignificant. It is noted that pregnant women with substance abuse problems face a number of barriers to

receiving optimal prenatal care, and substance abuse contributes to poor maternal and fetal outcomes. The major emphasis on interventions included substance abuse screening of all pregnant women, brief interventions, harm reduction, and priority access to withdrawal treatment and addiction management.

### Treating Psychosis

A challenge of treating the pregnant woman with psychosis is that medication therapy cannot be discontinued. A review of first and second generation antipsychotics (FGAs & SGAs) demonstrated that SGAs show significant improvement with respect to the occurrence of side effects compared to the FGAs, and therefore SGAs are usually considered first-line options for drug therapy.

### Treating Bi-Polar Disorder

As noted above with psychosis, the pregnant woman with bi-polar disorder cannot discontinue medication. Two reviews were conducted of pharmacological interventions. One review determined that all mood stabilizers reviewed demonstrated increased risk of fetal malformation. The second review studied cardiovascular, gastrointestinal, neurological, orofacial, and urogenital teratogenic effects. Adverse effects were reported in all of these areas for the drugs valproate, lamotrigine, and carbamazepine. Authors of both reviews agreed that further research is needed.

## **Hemorrhage**

Obstetric hemorrhage is a common cause of maternal death and is a major cause of maternal morbidity. The review of the literature identified evidence-based interventions that are effective in improving outcomes. The types of interventions that are implemented are dependent on a multitude of factors, and decisions for intervention should be made carefully. Effective interventions that have been identified included: Uterotonics in the third stage of labor (including oxytocin, syntometrine, and carbetocin) as a first-line treatment of hemorrhage; compressive devices (balloon tamponade) or sutures, medication administration (recombinant factor VII and tranexamic acid) as second-line approaches; hysterectomy as a last resort.

The second research question is designed to elicit the findings and recommendations from review of the literature related to the previous six specific high-risk conditions that have been used as evidence-based guidelines or quality measures.

## **Diabetes/Obesity**

Guidelines were identified by the following organizations:

- The Society of Obstetricians and Gynaecologists of Canada (SOGC)
- American College of Obstetrics and Gynecologists (ACOG)
- Australian Diabetes in Pregnancy Society (ADIPS)
- French-Speaking Diabetes Society

The principal recommendations focused on:

- Daily exercise, nutritional counseling and dietary management
- Weight control
- Maternal glucose control

- Consideration of cesarean delivery to prevent traumatic birth injury
- Multidisciplinary management of diabetes during pregnancy

### **Cardiac Disease**

Guidelines were identified by the following organizations:

- European Society of Cardiology
- Japanese Circulation Society

The principal recommendations focused on:

- Pre-pregnancy counseling and testing
- Specialized care rendered by a multidisciplinary team
- Caution with medication management and surgical interventions
  - angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers are contraindicated in the second and third trimester of pregnancy
- close maternal-fetal monitoring
- evaluation of maternal-fetal risks for decision making regarding timing of delivery.

### **Preeclampsia/Eclampsia**

One guideline identified from the American College of Obstetrics and Gynecologists (ACOG) with principal recommendations focused on:

- The use of Magnesium Sulfate
- Regional or neuraxial anesthesia
- Low-dose aspirin
- Calcium supplementation
- Management of severe preeclampsia

### **Hypertension**

Guidelines were identified by the following organizations:

- American College of Obstetrics and Gynecologists (ACOG)
- European Society of Cardiology (ESC)

The principal recommendations focused on:

- Angiotensin-converting enzyme inhibitors (ACEI) are contraindicated during pregnancy
- Antihypertensive medications are required in women with severe hypertension and acute blood pressure elevation.
- Labetolol suggested as first line treatment option for chronic hypertension in pregnancy

### **Psychiatric/Mental Health**

Guidelines were identified by the following organizations:

- American College of Obstetrics and Gynecologists (ACOG)
- The Society of Obstetricians and Gynaecologists of Canada (SOGC)

The principal recommendations focused on:

- Screening of all pregnant women for substance abuse
- Brief interventions
- Harm reduction

- Multidisciplinary management involving the patient's obstetrician, mental health clinician, primary health care provider, and pediatrician
- Pharmacological therapy should be individualized with consideration of risks vs. benefits
- Careful monitoring of the mother and infant development throughout the pregnancy.

### **Hemorrhage**

Guidelines were identified from the following organizations:

- American College of Obstetrics and Gynecologists (ACOG)
- The Society of Obstetricians and Gynaecologists of Canada (SOGC)

The principal recommendations focused on:

- Active management of hemorrhage
- Multidisciplinary approach
- Medication management with uterotonic agents
- Surgical interventions with hemorrhage unresponsive to medical therapy

The final research question defines specific obstetric services – availability of 24 hour obstetric and anesthesia services, and access to maternal/fetal medicine specialists, subspecialty care and multidisciplinary care - that have been addressed in the professional literature, and the impact of varying availability and accessibility on fetal and maternal morbidity and mortality.

#### **24 Hour Obstetrical Care Availability**

Very little evidence was found in this literature review relating to availability of 24 hour obstetrical care. One very large (n=1,039,560) review of neonatal deaths in Scotland, and another smaller study both suggested that lack of specialty providers during the off-hours contributed to intra partum anoxia and increased numbers of neonatal deaths.

#### **24 Hour Anesthesia Availability**

The Guidelines for Perinatal Care 6<sup>th</sup> Ed. (2007) define educational requirements for anesthesia practitioners in facilities with level I, II, and III nurseries, but describe availability as “per hospital policy”. Effect of 24 hour availability on the anesthesia workforce was assessed in a 2010 study but no conclusions were drawn. In another study it was noted that the demand for 24 hour anesthesia services has led to a reduction in vaginal birth after cesarean section (VBAC) deliveries in smaller hospitals. The same study noted that institutions caring for high risk obstetrical patients should investigate training of new providers via simulation, but further research is needed.

This literature review did not identify specific recommendations addressing the issue of provider availability.

#### **Access to a Maternal-Fetal Medicine Specialist**

The Guidelines for Perinatal Care 6<sup>th</sup> Ed (2007) strongly recommend that all high risk obstetrical patients have access to a maternal-fetal medicine specialist and that facilities caring for high risk patients must have a full-time, board-certified maternal-fetal medicine specialist acting as

director of maternal-fetal medicine and providing subspecialty care. There are additional staffing requirements for newborn intensive care units and consultative services.

Studies have focused on rural areas and distribution of specialty services. Findings were:

- Correlation between lack of insurance and an increase in neonatal mortality rates
- A parallel relationship between the availability of specialty care and an increase in adverse outcomes of the neonate
- Maternal and fetal outcomes are improved when more specialty care is available and provided (Nguyen, et al., 1991)
- 27% of rural Minnesota providers had a restriction on their care practices, limiting obstetrical services due largely to Medicaid reimbursement provisions. However, 12 communities without provider availability had perinatal outcomes equal to other adequately-staffed communities.

### **Access to Subspecialty Care**

The literature has limited discussion regarding the availability or accessibility of evidence-based services or interventions for the six identified conditions. However, two common approaches emerged, irrespective of the underlying condition or type of subspecialty needed:

1. Early screening and assessment of high risk patients is essential
2. Multidisciplinary care and epidural/neuraxial anesthesia are essential to ensure optimal outcomes

Additional interventions found to be effective were management by skilled multidisciplinary team members on the obstetrical unit rather than care in a single subspecialty unit, particularly for psychiatric patients and hypertensive patients, and formation of a rapid response team for management of major hemorrhage in obstetric patients.

### **Access to Multidisciplinary Care Providers**

Communication and coordination of care is the most common theme addressed when assessing access to, or functioning of, multidisciplinary care teams. "High Reliability" perinatal units, wherein all providers facilitate team communication and early assessment, was cited as the most effective approach to improving outcomes and reducing adverse events. Further, a study of tertiary multidisciplinary care clinics vs. public health obstetric clinics found improved outcomes in the public health group. Finally, there was a 2004 study of the workloads of neonatal intensivists demonstrating that by adding midwives to the staff caring for healthier obstetric patients, the workload of the intensivists was reduced, expected to result in improved outcomes for the high risk patients that the intensivists care for.

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## I. Search Methodology

### Methodology:

The work began with a review of the three proposed High Risk Obstetrical research questions, with a focus on the following six conditions:

1. Diabetes/Obesity
2. Cardiac Disease
3. Preeclampsia/Eclampsia
4. Hypertension
5. Psychiatric/Mental Health
6. Hemorrhage

The search was conducted on August 5, 2012, through September 22, 2012. **3,663** literature abstracts and titles were retrieved and approximately **515** sources were analyzed and **310** were used in the literature review.

### Part II (Research Question 1)

The Mount Sinai Scientific Team and Clinical Experts refined the original search methodology, and yielded **1,736** results.

The database searched by Mount Sinai Scientific Team was OvidSP.

The database searched was OvidSP; each of the 6 conditions was searched independently:

- Diabetes/Obesity yielded **386** sources and **40** sources were used.
  - Cardiac disease yielded **186** sources and **11** sources were used.
  - Preeclampsia/Eclampsia yielded **355** sources and **31** sources were used.
  - Hypertension yielded **126** sources and **13** sources were used.
  - Psychiatric/Mental Health yielded **366** sources and **23** sources were used.
  - Hemorrhage yielded **317** sources and **34** sources were used.
- **1** article was included in the Hemorrhage literature review as *de novo* literature that was deemed by the CAPQuaM High Risk Obstetric Clinical Experts to be seminal during the full-text literature review.

Abstracts and titles were evaluated for content. This produced **274** full-text sources examined where in **151** were used in the literature review.

For the detailed search methodology and terms used by the Mount Sinai Scientific Team refer to Appendix A.

### Part III (Research Question 2)

The Mount Sinai Scientific Team conducted a search:

- Yielded a total of **802** sources that were compiled into an endnote library for review.
- The Medline/OvidSP database was searched and yielded **744** sources.
- **58** articles were included as *de novo* literature that was deemed by the CAPQuaM High Risk Obstetric Clinical Experts to be seminal during the original search.

Abstracts and titles were evaluated for content. This produced **75** full-text sources examined where in **54** were used in the literature review.

For the detailed search methodology and terms used by the Mount Sinai Scientific Team refer to Appendix B.

#### **Part IV (Research Question 3)**

The Mount Sinai Scientific Team conducted the search:

- Yielded a total of **763** sources that were compiled into an endnote library for review.
- The following databases were searched and yielded **748** results:
  - Medline/OvidSP database yielded **563** results.
  - Embase (OvidSP) database yielded **68** results.
  - Cochrane Database of Systematic Reviews-Cochrane Library/OvidSP database yielded **4** results.
  - Central-Cochrane Library/OvidSp yielded **51** results.
  - DARE-Cochrane Library/OvidSP yielded **8** results.
  - CINAHL/EbscoHost database yielded **54** results.
- **15** articles were included as *de novo* literature that was deemed by the CAPQuaM High Risk Obstetric Clinical Experts to be seminal during the original search.
- **5** articles were included as *de novo* literature that was deemed by the CAPQuaM High Risk Obstetric Clinical Experts to be seminal during the full-text literature review.

Abstracts and titles were evaluated for content. This produced **139** full-text sources examined where in **61** were used in the literature review.

For the detailed search methodology and terms used by the Mount Sinai Scientific Team refer to Appendix C.

#### **Part V (Grey Literature Search)**

The following strategies were used by Mount Scientific Team and yielded **362** sources:

Searched:

State Health Department websites for:

High risk pregnancy outcomes

High risk obstetrics  
Pregnancy outcomes

New York City Health Department website for:  
High risk pregnancy outcomes  
High risk obstetrics  
Pregnancy outcomes

National Guideline Clearinghouse for:  
High risk pregnancy outcomes.

**469** results were yielded, **63** guidelines were chosen.

New York Academy of Medicine for:  
High risk pregnancy

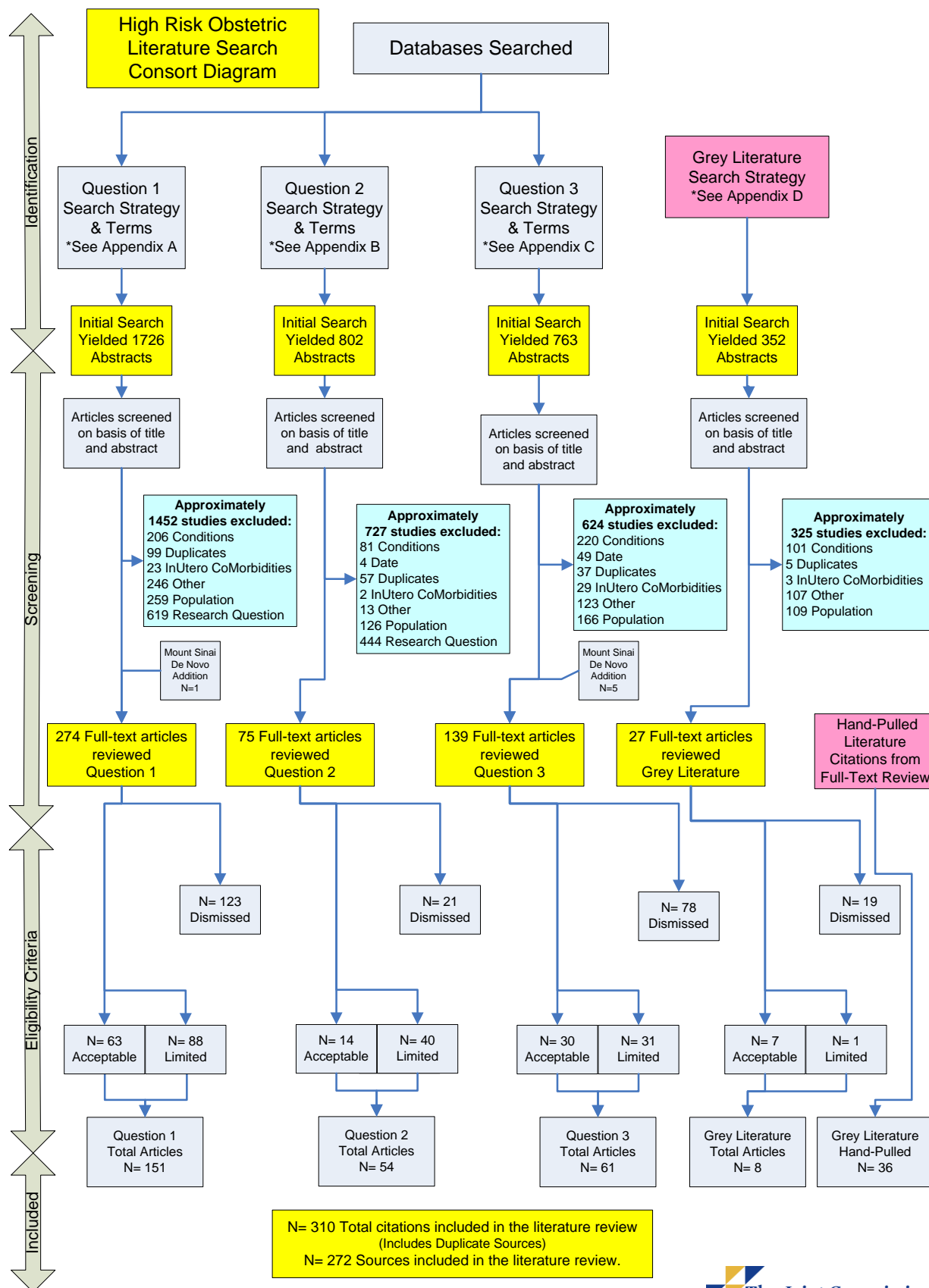
State Health Department websites also led to other searchable organizations for occasional reports.

Abstracts and titles were evaluated for content. This produced **27** full-text sources examined where in **8** were used in the literature review.

As the full-text analysis progressed, **36** sources were hand-pulled based on content and relevance to the subject matter, however these sources were not reviewed as they were not part of the original search results. The 36 sources are cited in Part V of this literature review document.

## Search Considerations

- Pregnant mothers of all ages with at least one of six existing conditions.
- Categories used to exclude abstracts and titles:
  - Conditions that were not related to one of the six identified.
  - Dates earlier than 1980.
  - References that were duplicated.
  - In utero co-morbidity.
  - Population not related to maternal-fetal.
  - Research study was not related to research question.
- Resources used included those related to interventions, services, procedures or practices that were shown to be effective or ineffective in reducing maternal or infant morbidity and mortality, with a focus on diabetes and obesity, cardiac disease, preeclampsia and eclampsia, hypertension, psychiatric and mental health, and hemorrhage.



## II. Research Question 1

**What high risk interventions, services, policies, and practices related to the high risk co-morbid conditions have been demonstrated to be effective in reducing morbidity and mortality in mothers and infants?**

### Summary

Three research questions have been proposed that will inform the development of a measure construct designed to address evidence-based, effective interventions related to the provision of services to high-risk obstetrical patients.

The first research question defines the specific high-risk obstetric populations of interest and is designed to identify the interventions, services, policies and practices that are effective in reducing morbidity and mortality in mothers and infants. The focus is on interventions, services, etc. that are applied at the population/systems level (effectiveness rather than efficacy). Those specific high-risk populations are patients with either:

- Diabetes/obesity
- Cardiac Disease
- Preeclampsia/Eclampsia
- Hypertension
- Psychiatric/mental health disorders
- Hemorrhage

Specific review of each of the six enumerated conditions follows.

### Diabetes/Obesity

The occurrence of either obesity or diabetes during pregnancy presents a significant challenge to managing clinicians and their patients; both disorders are associated primarily with large-for-gestational-age neonates, elevated fetal insulin levels, and complications during delivery, such as emergent cesarean section and shoulder dystocia. There are several mechanisms by which diabetes occurs in pregnancy. Either:

- A woman who is obese prior to conception develops (gestational) diabetes during the pregnancy, or
- A woman who is diabetic prior to conception becomes pregnant, escalating caloric needs and altering carbohydrate metabolism, or
- Less commonly, a woman who is neither obese nor diabetic prior to conception becomes both obese and diabetic during the pregnancy.

There are also implications for those women who develop gestational diabetes, since about 50% of women who develop gestational diabetes will become diabetic later in life. The occurrence of obesity either prior to or during pregnancy usually leads to development of gestational diabetes, and it is difficult to review obesity issues in pregnancy without also addressing diabetes.

The literature review for diabetes and obesity found relevant information regarding evidence-based interventions that can reduce the incidence of maternal/fetal morbidity and mortality.

Outcomes assessed in trials included maternal weight gain, results of glucose tolerance testing, reported cesarean section, shoulder dystocia, rectal lesions during birth, labor induction, and the incidence of preeclampsia and gestational hypertension.

## **Obesity**

The interventions to reduce maternal/fetal morbidity and mortality among obese patients included weight control, weight loss, and personal review with individual dietary advice by qualified dietitians, instructions regarding self monitoring of glucose levels, nutritional counseling, and use of a balanced nutritional regimen with recording in daily diaries.

### Weight Management

Reduction in weight, weight control and limit-setting for weight gain during pregnancy to increase positive perinatal outcomes (Beucher et al., 2010) was noted in many evidence-based guidelines. Intensive treatment of moderate gestational diabetes mellitus was also examined and found to be very advantageous in reducing morbidity. Promotion of weight control or weight loss was also found to improve neonatal outcomes (Birdsall et al., (2009).

### Nutritional Counseling

Crowther et al., (2005) in the Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) study found that individual counseling, including a personal review with a qualified dietician with individual dietary advice, and instructions regarding the self monitoring of glucose (QID, then tapered depending on results) significantly lowered the rate of perinatal complications and thus decreased incidence of morbidity and mortality. Interventions regarding individual counseling with frequent prenatal visits were examined by Royall (2006) as well in the review of European guidelines. The author found that nutritional counseling was rated as a GRADE A recommendation for improvement of maternal-fetal outcomes. This recommendation was again echoed in the American Diabetes Association 2006 position statement regarding nutrition recommendations. Both Tanentsapf et al., (2011) and Thagaratinam et al., (2012) supported the use of multiple differing dietary interventions to reduce weight gain during pregnancy. Thornton et al. (2009) further defined the interventions to include a balanced nutritional regimen with maternal record of all daily food intake to reduce weight gain and improve perinatal outcomes.

These studies confirmed that if appropriate interventions were not implemented respecting obesity, an increase in morbidities of both mother and infant, such as macrosomia, would be expected. The ACHOIS study determined that patient obesity education was the strongest intervention to improve outcomes; their study supported that if interventions are not done, fetal outcomes are affected.

## **Diabetes**

Accurate identification of diabetic pregnant women is essential in recommending interventions that can assist in reducing maternal fetal morbidity and mortality. Coustan et al., (2010) enrolled >25,000 patients in 9 countries into a trial using the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) criteria, which are 3 - 75-g, 2-hour oral glucose tolerance test thresholds are met or exceeded: fasting 92 mg/dL, 1-hour 180 mg/dL, or 2 hours 153 mg/dL.. The authors concluded that by using this criteria, populations of patients can be assessed and when diagnosed with gestational diabetes, interventions can be initiated that decrease morbidity and

mortality. Outcomes related to maternal and fetal morbidity were assessed by analyzing this group's incidence of fetal macrosomia, neonatal fat mass, shoulder dystocia, preeclampsia and cesarean section.

Three additional interventions were examined and found to have a positive effect on maternal fetal morbidity and mortality in the diabetic patient. These interventions include creating an individual plan through individual telephonic nurse management, patient education, and tight glycemic control with insulin or oral hypoglycemic agents.

### Individual Management

Individual telephone nurse management was evaluated by Ferrara, et al., (2012), to measure successful management and improved outcomes in patients with gestational diabetes. This review found that individual telephonic nurse management was associated with a lower risk of macrosomia. Gonzales-Quintero et al. (2007) found that in addition to an individualized plan, as described above, the link between patient education was more indicative of determining improvements in maternal and fetal outcomes.

### Medication Management

Murphy et al., (2008), Correa et al., (2012) and the literature reviewed in the Metformin in Gestational Diabetes (MIGs) Trial by Rowan, and Rowan et al., (2007, 2008, and 2010), found that tight glycemic control was the most effective method to reduce incidence of risk for macrosomia or large for gestational age (LGA) neonates.

These interventions (telephonic nurse management, patient education, and tight glycemic control) were well-received in the community, but primary fetal outcomes continue to be affected by uncontrolled maternal hyperglycemia. This review further investigated diet and insulin combinations that supported maternal fetal outcomes based on those populations with uncontrolled hyperglycemia, despite the above interventions.

Guiffrida et al., (2003) conducted a systematic review that determined a greater reduction of morbidity when diet and insulin therapy were combined, rather than diet adjustments alone. The use of insulin has effectively reduced the incidence of macrosomia and the incidence of large for gestational age (LGA) neonates (Bertini et al., 2007, DiCianni et al., 2007 and Gindlesberger et al., 2007). The literature supports similar findings when mothers are treated with glyburide, lispro, acarbose and metformin. All studies concluded some positive results in prevention of macrosomia, or large for gestational age neonate, but no consistency was found in the magnitude of this benefit. It is also notable that incidental findings included an increase in maternal cesarean sections or fluctuation in Apgar scores; differences in maternal preference with regard to route of medication were also noted.

Some trials such as those by Ijas et al., (2011) and Bertini et al., (2005) had a small number of participants, limiting generalizability. The MIGs Trial had a good number of participants, but no difference in maternal/fetal outcomes was found in the use of metformin compared with insulin.

### **Summary**

Prevention of obesity prior to conception is a common theme; however, studies reviewed populations where obesity and/or gestational diabetes was present prior to entry to the study. Obesity prior to conception commonly results in the outcome of gestational diabetes once the

woman conceives, however it is the management of this disease that this literature focused on. Efforts revolving around the development of an individual plan of care, as well as diet control, have resulted in good outcomes for the obese pregnant patient,. Tight glycemic control, regardless of medication methodology, was found to decrease maternal/ fetal morbidity and mortality in those patients who have consistently remained hyperglycemic despite best efforts.

### **Cardiac Disease**

Whether occurring prior to conception or concomitant with pregnancy, maternal cardiac disease of any type has the potential for significant maternal and neonatal morbidity and mortality, and can be challenging for clinicians to manage during the prenatal, postpartum, or labor and delivery phases.

Available literature, summarized below, related to effective interventions to improve maternal and neonatal outcomes in the presence of maternal cardiac disease is limited. There are no RCTs addressing the topic, due to ethical limitations of research among pregnant women; published literature consists of either small-n retrospective case series reports, adverse event reports, safety warnings, expert or consensus statements, and the like, or large-scale population-based studies of incidence, lacking sufficient detail or lacking adjustment for confounding factors. Within these limitations, however, available publications address a variety of cardiac compromise, with the most reliable literature focusing on management of cardiac arrest, management of cardiac disorders during pregnancy, management of patients undergoing cardiac surgery prior to conception, and anesthetic management of patients during labor and delivery who have cardiac disease. Although few of these limited publications offer definitive positive interventions, many are suggestive of directions for management and future research.

#### **Cardiac Arrest During Pregnancy**

Dijkman et al., (2012) published a 15 year study of 55 women who suffered cardiac arrest during pregnancy; 12 underwent perimortem C-Section (PMCS). In theory, PMCS is expected to yield a lower fatality rate in mothers and infants when applied in the correct manner and within the appropriate time frame. The study confirmed the hypothesis that PMCS is potentially beneficial in maternal resuscitation in that eight of the 12 women regained cardiac output after the procedure. Of the 12, there were two maternal survivors and five neonatal survivors. In the prior year, Jeejeebhoy et al., (2011) published the results of a systematic literature review, noting among other findings that maternal and neonatal survival had been documented with PMCS, but it also noted that the procedure is rarely performed within the recommended 5 minutes of cardiac arrest. Other findings in this review noted that optimal resuscitation techniques, including tilting prior to chest compressions, have yet to be defined and require more research.

#### **Management of Cardiac Disorders During Pregnancy**

The beneficial and adverse effects of different medical or interventional treatment modalities for valvular heart disease in pregnancy was assessed by Henriquez et al., (2011) in a systematic literature (Cochrane) review (68 studies, n=1289). There were no trials comparing medical vs. interventional management of valvular heart disease. Outcomes reported were for patients treated with either percutaneous balloon valvulotomy or surgical interventions for the treatment of mitral stenosis in pregnancy. Six maternal deaths were reported and 63 fetal and neonatal deaths were reported. Thirty-nine adverse events were reported, including cardiac arrhythmias,



thromboembolism, cardiac tamponade, fistula at, and bleeding from, the puncture sites, and endocarditis. Major complications included severe mitral regurgitation and cardiac failure. The authors concluded that evidence was insufficient to identify the most effective interventional treatment of valvular heart disease in pregnancy to improve maternal and neonatal outcomes. Management of women with acute pulmonary edema during pregnancy was the topic of a literature review by Dennis and Solnordal (2012). Goals of treatment are to: 1) reduce left ventricular preload 2) reduce left ventricular afterload, 3) reduce/prevent myocardial ischemia, and 4) maintain adequate oxygenation and ventilation with clearance of pulmonary edema. Management strategies should include identification of pregnant women at risk and engagement of a skilled multidisciplinary team. Short term management should focus on monitoring of vital signs, (respiration, cardiac, hematologic and renal functions), fetal well being, avoidance of precipitants (fluid balance and restriction), and blood pressure control. Long term follow-up is necessary.

In McClintock et al., (2009) published a retrospective study of 31 New Zealand women (47 pregnancies) to review maternal/fetal outcomes in women with mechanical heart valves managed with enoxaparin during pregnancy. Deliveries occurred between January 1997 and July 2008. Of the 35 pregnancies surviving more than 20 weeks, thromboembolic complications associated with enoxaparin therapy occurred in 7 pregnancies and there were 8 pregnancies with hemorrhagic complications. Overall the data suggested that administration of therapeutic-dose enoxaparin in combination with low-dose aspirin can be used for prevention of valvular thrombosis in pregnant women with mechanical heart valves, but close clinical follow-up by a multidisciplinary team is crucial if enoxaparin is the chosen anticoagulant. In a smaller study of pregnant women with mechanical heart valves, Yinon et al., (2009) reviewed 17 women (23 pregnancies) who were treated with low molecular weight heparin (LMWH) during pregnancy. Measured outcomes were one maternal thromboembolic event resulting in maternal and fetal death, five women with other adverse maternal cardiac events, nine pregnancies with fetal or neonatal adverse events and postpartum hemorrhage in three pregnancies. Although this study concluded that carefully monitored LMWH may be a suitable anticoagulation strategy in pregnant women with mechanical heart valves, this group of women remains at risk for maternal cardiac and fetal complications.

John et al., (2011) reviewed 21 pregnant women who had cardiothoracic surgery performed between 1976 and 2009 to determine maternal/neonatal outcomes of cardio-pulmonary bypass during surgery. All patients demonstrated improvement to New York Heart Association functional class I or II. There was one maternal death 2 days after emergent mechanical aortic valve thrombectomy and 3 late maternal deaths that occurred 2, 10, and 19 years postoperatively. Three fetal deaths were reported in mothers with additional medical co-morbidities. Patients with congenital heart disease had higher rates of preterm deliveries and required emergent surgery more frequently. Fetal losses occurred when the urgent surgeries were performed at an early gestational age. Although it was concluded that cardiothoracic surgery can be performed with relative safety during pregnancy, there are factors that should be taken into account:

- Surgery should be considered only after medical therapy has failed,
- Normothermia,
- High flow cardio-pulmonary bypass and avoidance of surgery at an early gestational age,
- Elective delivery prior to surgery should also be considered,
- Patients should be managed by a multidisciplinary team including cardiologists, surgeons, maternal fetal medicine specialists, anesthesiologists, and neonatologists.

## **Management of Patients Undergoing Cardiac Surgery Prior to Conception**

There are 2 publications addressing care for pregnant patients who had cardiac surgery prior to conception. Although diagnoses were different in each group, each had open surgical intervention.

Tobler et al., (2010) reviewed 74 women with transposition of the great arteries (TGA) who had undergone an arterial switch operation (ASO). Retrospective chart review identified 9 women who had 17 pregnancies from 2000 - 2009. Four of the pregnancies resulted in miscarriage. Six women had clinically important valve and ventricular lesions before the index pregnancy. Two women developed cardiac complications during pregnancy. There were no maternal deaths. Larger studies are necessary to determine predictors of adverse pregnancy outcome for these women. In the mean time, coordinated care between a congenital heart disease specialist and a high-risk obstetrician should be implemented.

In Arendt et al., (2011) reviewed 27 deliveries in 20 patients over a 14 year time frame (1994-2008), focusing on intrapartum and post partum anesthetic management of pregnancies after surgery prior to conception to repair tetralogy of Fallot (TOF). All patients received neuraxial anesthesia. Three of the 21 patients received invasive arterial blood pressure monitoring; 5 received continuous telemetry; 3 experienced congestive heart failure that required diuresis; 4 had obstetric or neonatal complications; and 3 had anesthesia complications. Cesarean delivery was required in 4 patients. There was 1 neonatal death. Six patients had an elective cesarean delivery; no anesthetic or immediate obstetric complications occurred. This study concluded that patients with surgically repaired TOF can experience peripartum complications. Neuraxial analgesia and anesthesia can be safely administered to patients and that excellent labor analgesia, and attentive surgical anesthesia can lead to successful outcomes for the majority of patients.

## **Anesthetic Management**

A literature review was undertaken by Drake et al., (2007) to define appropriate anesthetic management of pregnant women with long QT syndrome (LQTS). Anesthetic management is focused on prevention of prolonged QTc in addition to being prepared to immediately treat any episode of torsades de pointes, a potentially lethal form of ventricular fibrillation. Effects of anesthetic agents are not entirely clear and recommendations are often based on isolated cases or studies in patients who do not have LQTS. A multidisciplinary approach is recommended for management and care of these patients throughout pregnancy.

A report reviewing peripartum anesthetic management of patients with moderate and severe aortic stenosis (AS), in context with a systematic review of previously reported cases was published by Loscovich et al., (2009, n=12). Of 12 patients, six had moderate and six had severe AS. All patients had non-invasive monitoring of B/P and EKG. One patient had an arterial line to measure B/P. None of the patients experienced significant morbidity or died. Mode of delivery should be determined on the basis of obstetrical indications and with team input from the obstetrician, cardiologist, anesthesiologist and neonatologist. Carefully titrated regional analgesia is usually tolerated in patients undergoing vaginal delivery. It is possible to use neuraxial anesthesia with sufficient time to titrate the desired effect. General anesthesia may be necessary in patients with critical AS or uncompensated failure.

## Summary

Cardiac disorders present a management challenge to all practitioners caring for pregnant patients with any history of, or active presentation involving cardiac compromise; retrospective review of small numbers of cases are predominant, and RCTs to guide treatment do not exist. While there are no definitive recommendations for treatment approaches to specific disorders, there is consensus that pregnant patients with any cardiac disorder are best managed by a multidisciplinary team of specialists, and close monitoring of maternal and fetal well-being is required.

### Preeclampsia/Eclampsia

Pregnancy induced hypertension can manifest as preeclampsia when the pregnant woman experiences protein excretion in the urine greater than or equal to 300 mg in a 24 hour urine collection, or a urine dipstick of protein greater than 2 (Trivedi et al., 2011) occurs. Causes of preeclampsia are thought to arise from a lack of prostacyclin, or excessive production of thromboxane (Duley et al., 2007). The causative mechanism is unclear, however as it is thought that this chemical imbalance causes abnormal placental implantation due to inflammatory mediators in the placenta, or a maternal response from the placenta preventing normal implantation. Preeclampsia is usually diagnosed when the systolic pressure exceeds 140 mm Hg or more and diastolic pressure exceeds 90 mm Hg., which can occur as early as 20 weeks gestation (Trivedi et al., 2011). Unfortunately, about 5 women in every 10,000 develop a serious condition, eclampsia, either before giving birth or within 48 hours after. Eclampsia is defined as seizures or coma in a patient with other indications of pregnancy-induced hypertension. Pregnant woman with high blood pressure who have a seizure that can't be attributed to some other cause can be diagnosed with eclampsia, either preceded by preeclampsia or by hypertension alone.

Maternal/fetal morbidity outcomes in the preeclampsia/eclampsia population that were examined in this literature review include incidence of intra uterine growth retardation(IUGR), fetal complications, small for gestational age (SGA), low birth weight (LBW), spontaneous preterm birth, premature birth, placenta abruption, perinatal death, neonatal death (stillbirth), maternal bleeding and post partum hemorrhage.

Five interventions have been examined in this literature review. They are use of low dose aspirin, calcium supplementation, magnesium sulphate use, L-arginine dietary supplementation, and administration of Vitamins C and E.

### Low-Dose Aspirin

Use of low dose aspirin and dipyramirole (both antiplatelet agents) has been under consideration for reducing the risk for development of preeclampsia, due to the hypothesis that antiplatelet agents might prevent or delay the excessive production of thromboxane. Coomarasay et al., (2003) found a reduction in perinatal death, reduced incidence of preeclampsia, and reduced rates of spontaneous preterm birth when they evaluated the effectiveness of aspirin and dipyridamole with variable dosages.

Askie et al., (2007, 31 randomized trials, n=32,217) , and Duley et al., (2007, 59 trials, n=37,560) found a benefit in the prevention of preeclampsia when antiplatelet agents were administered. Trivedi et al., (2011, 19 RCTs, n=28,237) stratified risk of preeclampsia into groups and found a reduced rate of preeclampsia by 27% in the high risk group in their meta

analysis of studies of women given low dose aspirin vs. placebo for prevention of preeclampsia; there was no effect on the low-risk group. Morbidity, such as premature birth and the incidence of prenatal death and postpartum hemorrhage, was lowered as well as reducing the risk of preeclampsia.

Hermida et al., (2003) examined the development of preeclampsia in relation to varying rest and activity cycles in high risk pregnant patients (n=341) receiving low dose aspirin 100mg. per day at varying times of day vs. placebo.. They found a positive correlation with an increase in birth weight and gestational age upon delivery, when aspirin was given eight hours after awakening or before bedtime.

### **Calcium Supplementation**

The use of calcium supplementation to prevent pregnancy induced hypertension from progressing into preeclampsia was also reviewed. Epidemiological studies have supported the hypothesis that those women with greater calcium intake had less incidence of preeclampsia. Hofmeyr et al., (2006) found no relationship between calcium supplementation and reduction of preeclampsia. However, when Hofmeyr et al., (2007) searched 12 randomized control trials (RCTs), all using at least one gram of calcium daily during pregnancy, they determined a benefit in the populations who were already at risk for developing preeclampsia, or for those who had a baseline deficit of calcium intake. Four of these trials noted a reduction in morbidity; however, there was no difference in the other outcomes measured, such as risk of premature birth, stillbirth, or death. Other authors examined this as well, but found limited data to support improved outcomes with this intervention.

### **Magnesium sulfate**

In the sixteen trials reviewed by Duley et al., (2005), it was found that treatment with magnesium sulfate does not reduce risk of developing preeclampsia, but does reduce the incidence of progression to eclampsia by more than half. When magnesium sulfate is used, it blocks calcium, which prevents vasodilatation in the pregnant mother. Cerebral ischemia caused by neuronal damage associated with ischemia is blocked when magnesium prevents calcium influxes to the brain. Placental abruption and emergency cesarean sections were also reduced in cases where magnesium sulfate was used. Interestingly, Duley et al., (2010) noted in a later study a reduction in maternal mortality with the use of magnesium sulfate, however neonatal mortality was not reduced.

### **L-arginine and Vitamins C and E**

It has been postulated that food containing both L-arginine and antioxidant vitamins would reduce the incidence of free amino acids, which may be critical to reducing the mechanisms of vasoconstrictors in preeclampsia (Vadillo-Ortega et al., 2011). When L-arginine is introduced in the diet, it facilitates nitric oxide synthesis that promotes vasodilation. The Vadillo-Ortega RCT (n=450) tested participants who received either placebo, Vitamins C and E, or L-arginine plus antioxidant vitamins. The study concluded that food containing both L-arginine and antioxidant vitamins reduced the incidence of preeclampsia in populations at high risk for this condition. However, smaller trials reviewed the same concepts with the use of antioxidants alone, and reported opposing findings.

## Summary

Large trials reviewing the benefit of supplementation with Vitamins C and E could not demonstrate a reduction in maternal/fetal morbidity or mortality. It was found that some studies noted an increased incidence and risk of placental abruption. No reduction in preeclampsia or maternal fetal morbidity or mortality was noted with Vitamins C and E administration. This review of literature examined the theories associated with the pathological process relating to the manifestation of preeclampsia and found a variety of studies that reported a decrease in maternal fetal morbidity and mortality. Use of low dose aspirin or other antiplatelet medications was found effective in delaying excessive production of thromboxane thus lowering maternal/fetal morbidity and mortality. Magnesium sulfate use was found to halve the progression of preeclampsia to eclampsia, and to reduce placental abruption, emergency cesarean section rates, and maternal mortality. Calcium supplements prevent the stimulation of the parathyroid and attendant rennin release, which affected smooth muscle cell vasoconstriction; some reviews found that calcium supplementation was effective in lowering the risk of preeclampsia in high risk populations. Introduction of L-arginine and antioxidants into the diet was examined and shown to lower the risk of preeclampsia in high-risk populations.

## Hypertension

Hypertension is one of the clinical conditions accounting for a significant number of patients with adverse pregnancy outcomes. It is the first stage of what is often a progression of hypertensive disorder through stages of severe hypertension, preeclampsia, and eclampsia, and can lead to significant maternal and neonatal morbidity and mortality. Hypertension may pre-date pregnancy or may occur during the pregnancy (gestational hypertensive disorder); in the latter case, when the pregnancy ends, the hypertensive disorder also ends.

Review of the literature identified four types of interventions that have been assessed for reducing morbidity and mortality associated with hypertension in pregnancy; those intervention types are dietary calcium or vitamin supplementation, anti-hypertensive medication administration, elective late-term delivery, and bed rest.

### Elective Late-term Delivery

Elective late-term delivery, as an effective intervention, has been reported most consistently to offer a viable approach to reducing maternal and neonatal morbidity. An RCT (Koopman et al., 2009) conducted over a two and a half-year period in 38 hospitals assessed 756 women with singleton pregnancies at 36-41 weeks gestation, complicated by gestational hypertension or mild preeclampsia; subjects were assigned to induction of labor or monitoring. Significantly fewer (31% vs. 44%) of the induction group experienced maternal complications. Authors concluded that elective delivery is associated with lower maternal morbidity and should be offered to women with mild hypertensive disease beyond 37 weeks gestation. Further, in a 2010 publication of a 20 year USA population-based cohort study of more than 150,000 pregnant women with pre-existing hypertension (Hofmyer et al., 2010), neonatal outcomes were measured via assessment of the week-specific risks of stillbirth between 36-41 weeks of gestation and contrasted those risks with the week-specific risk of neonatal mortality and serious neonatal morbidity among births following induction of labor. The author concluded that elective delivery at 38-39 weeks of gestation provides the optimal time window for delivery for women with pre-existing hypertension and otherwise-uncomplicated pregnancies. Finally, in a 2011 database review of 1856 high-risk women with stable mild gestational hypertension and a

singleton pregnancy, it was found that elective delivery at 34-36 weeks gestation yielded increased neonatal complications and lengths of stay compared with those delivered at 37 or more weeks (Barton et al., 2011). Thus, both maternal and neonatal outcomes have been assessed for women with both gestational and pre-existing hypertension, with all evidence demonstrating agreement respecting the advantages of elective delivery beyond 37 weeks gestation.

Review of evidence for the remaining three interventions is less clear than the imperative for elective delivery at 38-39 weeks gestation.

### **Anti-hypertensive Medications**

Several studies of anti-hypertensive medications vs. placebo or other anti-hypertensive medications have been reported in the literature, but there is little homogeneity among studies in terms of medications or doses compared and outcomes measured. The most effective anti-hypertensive medication remains unidentified, with some question about the effectiveness of medications compared with placebo. One of the more definitive publications is a systematic literature review (Duley, 2011) in which 69 RCTs and observational studies were identified, conducted from 1966 through 2010, with GRADE level evidence, comparing any anti-hypertensive vs. placebo or another anti-hypertensive to answer several research questions related to effectiveness of interventions for hypertension, preeclampsia and eclampsia for women with mild to moderate hypertension in pregnancy. Effective interventions identified were:

- Moderate quality evidence that beta blockers reduced the percentage of babies born small for gestational age than when no beta blockers were given (13 RCTs, n=854).
- Very low quality evidence that anti-hypertensive drugs may be more effective at reducing the risk of severe hypertension, but not preeclampsia, when compared with placebo or no drug.
- Compared with methyldopa, beta blockers were more effective at reducing the risk of severe hypertension (moderate quality evidence, (8 RCTs, n=493)).

This publication followed another, earlier Cochrane review by the same author (Duley et al., 2006) that although limited by somewhat small n numbers in some RCTs, identified 4 RCTs (n=200) demonstrating that hydralazine “may be” more effective than ketanserin in lowering blood pressure, but concluding that 12 RCTs (n=2949) contained insufficient evidence to show which of several drugs is most effective.

Many other publications are limited by virtue of low numbers of study participants, mixed results, or unclear findings. In Abalos et al., (2007) identified in a Cochrane review, 46 RCTs comparing one or more medications vs. other medications or placebo, concluding that effectiveness of anti-hypertensive drug therapy was not clear. In a 2010 continuing medical education (CME) article, Nij Bivarik et al., (2010) identified 5 small studies (total n=147) assessing the effects of nifedipine on pre-existing or gestational hypertension; 87% of subjects had a reduction in blood pressure – 70% within 23 minutes of drug administration. Finally, in a 2012 update of a Cochrane review originally published in 2003 (Magee and Duley, 2003), effectiveness of oral beta blockers to control mild to moderate gestational hypertension vs. placebo, no intervention, or other anti-hypertensives was assessed. The conclusion was that there was no benefit to beta blockers, although 11 trials (n=1128) decreased the risk of severe hypertension.

## **Vitamin Supplementation**

Supplementation with B, C, and E, vitamins, either alone or in some combination has been assessed in several trials, but either no effect was identified or evidence levels for positive effects were low. In the most comprehensive systematic review and meta-analysis of vitamin supplementation during pregnancy with GRADE level evidence (Dror and Allen, 2012), 11 studies (n=2500) of Vitamin B6 supplementation identified low to very low levels of evidence for findings of a significant positive effect on birth weight and possible reduction in maternal nausea and vomiting, congenital malformations, and anemia. Interestingly, development of gestational hypertension was noted to occur at a higher rate among those receiving supplementation with C and E (13 trials, n=>150,000). This finding may be slightly different than the earlier work of Rumbold et al., (2006), who, in a study of 1877 nulliparous Australian women undergoing supplementation with Vitamin C and Vitamin E, noted no difference in treatment and placebo groups in the development of preeclampsia and prenatal complications. The Vitamin C and E trials may be concordant in that the Rumbold trial did not assess hypertension, but assessed for preeclampsia.

## **Bed Rest**

Bed rest, as an intervention for hypertension, has been infrequently assessed. Duley in 2011 identified 4 RCTs with a total of 449 subjects in which bed rest, hospital admission, or day care were evaluated; 1 RCT, n=218 yielded low quality evidence of the effectiveness of either intervention in reducing severe hypertension, and 1 RCT, n=218 yielded moderate quality evidence that some rest in the hospital was effective in reducing the incidence of preterm birth (vs. normal activity at home).

## **Summary**

In summary, there is clear testing and evidence of the effectiveness of elective late-term delivery at 38-39 weeks in lowering maternal and neonatal mortality, but evidence and imperative for therapeutic interventions incorporating supplementation with calcium or vitamins, anti-hypertensive medication, or bed rest remain unclear.

## **Psychiatric/Mental Health**

Mental illness during pregnancy presents a number of challenges for treatment. Decisions about appropriate treatment modalities must be carefully considered with respect to the impact on the health of the mother and the outcomes of the pregnancy, in addition to fetal development and neonatal health.

Due to the ethical considerations of conducting research on pregnant women, review of available literature yielded a limited number of randomized control trials (RCTs). The published literature summarized below consists primarily of literature reviews involving electronic data base searches, case study reports with a small n, and systematic literature reviews. The publications included here address the following conditions related to interventions for improving outcomes for the pregnant woman suffering from mental illness:

- Depression/prevention of post partum depression
- Electroconvulsive therapy
- Substance abuse
- Psychosis
- Bi-polar disorder

## Depression/Prevention of Post Partum Depression

A literature review by Clatworthy (2012) was conducted to assess the effectiveness of antenatal interventions designed to prevent postnatal depression in high-risk women. The author reviewed 11 studies (1995-2010) that reported on interventions delivered during pregnancy that included Interpersonal Therapy, Cognitive Behavioral Therapy and a psychosocial approach. The studies demonstrated large variation in the degree of depression during pregnancy ranging from no/low depression, to moderate to severe depression. It was concluded that individual interventions are more effective than group interventions and that evidence suggests that interventions delivered in pregnancy can be effective in preventing postnatal depression. Additionally it is important to identify pregnant women experiencing symptoms of depression and to deliver evidence based psychological interventions.

With respect to prevention of post partum depression (PPD), Boath et al., (2005) conducted a systematic review in which 21 RCTs were identified that dealt with prevention of PPD. Interventions reviewed included: psychological and social support, interpersonal therapy, postnatal stress debriefing, information and discussion, reconfiguring midwifery, individual home based care, antidepressant prevention, and hormonal prevention. Although results demonstrated short term success, long term success was lacking and the authors concluded that further trials were needed.

In consideration of the use of anti-depressant medications for treating depression during pregnancy, the following reviews are noted:

Tuccori et al., (2009) conducted a review of observational studies and meta-analyses to determine the safety of selective serotonin reuptake inhibitors (SSRIs) and other anti-depressants used in pregnancy. Findings demonstrated: a statistical association between paroxetine use and major malformation in the newborn; pregnancy loss did not differ significantly; evidence supports an association between third trimester use of SSRIs and symptoms of neonatal behavioral syndrome; studies did not identify an increased risk of persistent pulmonary hypertension among anti-depressant users vs. normal controls. Wisner et al., (2009) conducted a study on the impact of major depression and antidepressant treatment on pregnancy and neonatal outcomes. Outcomes showed that neither SSRIs nor depression had any effect on the occurrence of minor physical anomalies or reduced maternal weight gain, but infants exposed to either depression or SSRIs continuously across gestation were more likely to be born preterm than infants with partial or no exposure to either. Other findings noted the need to exercise caution with SSRI use during pregnancy and that more research is needed.

In a systematic review of literature published between 2000 and August 2011, Oyeboode et al., (2012) noted that there was consensus that pregnant mothers exposed to antidepressants are more likely to have spontaneous abortions, stillbirths, and preterm deliveries (9 studies, n=unstated). There is considerable evidence that 1) fetuses exposed to anti-depressants are delivered small for gestational age (4 studies), and 2) fetuses exposed to anti-depressants in the third trimester are associated with lower 5-minute Apgar scores, respiratory distress syndrome, convulsions, jaundice and other disorders (8 studies). However, the risk of major malformations does not appear to be elevated (7 studies). There is inconclusive evidence of the effect of exposure on subsequent infant and childhood mental development, with most studies reporting no noticeable effect (6 studies).



## **Electroconvulsive Therapy (ECT)**

Anderson and Reti, (2009) conducted a review of articles published from 1942-2007. In 68 of 339 cases providing efficacy data, 11 fetal/neonatal abnormalities were reported: 8 transient fetal arrhythmias, 1 fetal death secondary to status epilepticus, 1 miscarriage in the first trimester, and 1 case of multiple cortical and deep white matter infarctions. Eighteen cases demonstrated adverse maternal effects believed to be related to ECT: status epilepticus, hematuria, uterine contractions and/or pre-term labor, vaginal bleeding, abdominal pain, and placental abruption. Due to the range of adverse effects on the fetus related to medication therapy, ECT has been viewed as an alternate therapy for treating mental illness during pregnancy. The authors concluded that the use of ECT seemed to be effective for treatment of major mental illness during pregnancy.

## **Substance Abuse during Pregnancy**

Substance abuse during pregnancy is not uncommon and illicit drug use is not insignificant. It is noted that pregnant women with substance abuse problems face a number of barriers to receiving optimal prenatal care. The use of alcohol and/or drugs contributes to poor maternal and fetal outcomes.

The search for this project yielded the Clinical Consensus Guidelines on Alcohol Use and Pregnancy, Carson et al., (2010), approved by the Society of Obstetricians and Gynecologists of Canada. The guidelines note the importance of screening to improve maternal and child health outcomes through early identification and reduction of maternal alcohol consumption and early identification of infants at potentially high risk for fetal alcohol spectrum disorder (FASD). Key recommendations of the guidelines include:

- Brief interventions consisting of 4 components: assessment and feedback, goal setting, positive reinforcement, and education.
- Harm reduction - Reducing the harms associated with alcohol use by promoting a reduction in consumption in working toward abstinence.
- Priority access to withdrawal management and treatment should be given to pregnant women.

The range of evidence for the recommendations noted here is II-2B to III-A.

The Society of Obstetricians and Gynecologists of Canada also has approved guidelines addressing substance use in pregnancy, Wong et al. (2011). The guideline recommendations include:

- Screening of all pregnant women for alcohol, tobacco, and prescription and illicit drug use.
- Employment of a flexible approach to the care of women who have substance use problems, and encouragement of the use of all available community resources.
- Harm reduction through counseling about the risks of drug use and smoking cessation counseling which should be considered a first-line intervention for pregnant smokers.
- Opiate substitution therapy through methadone maintenance treatment, or consideration of other slow-release opioid preparations if methadone is not available.

The range of evidence for the recommendations noted in this summary is I-A to III-B.

With respect to dealing with opioid dependency during pregnancy, Jones et al., (2010) conducted an RCT to review the following primary outcomes of treatment with buprenorphine vs. methadone: number of neonates requiring treatment for neonatal abstinence syndrome

(NAS); peak NAS score; total amount of morphine needed to treat NAS; length of the hospital stay for neonates; neonatal head circumference. Additional evaluated outcomes included: number of medication treatment days for NAS; weight and length at birth; preterm birth (defined as birth at <37 weeks of gestation); gestational age at delivery; 1 and 5-minute Apgar scores. 131 mothers completed the study through the end of pregnancy. Overall the results demonstrated positive outcomes for the group treated with buprenorphine for the following primary outcomes: significantly less morphine required (mean dose, 1.1 mg vs. 10.4 mg) and shorter hospital stay (4.1 days vs. 9.9 days). The results were not significantly different for the remaining primary outcomes. A significant difference was demonstrated only in one of the secondary outcomes, a shorter duration of treatment for NAS (4.1 days vs. 9.9 days). The authors concluded that the demonstrated benefits of buprenorphine treatment suggest that it should be considered a first-line treatment option for mothers with opioid dependency during pregnancy.

### **Treating Psychosis during Pregnancy**

One of the challenges of treating pregnant women with psychosis during pregnancy is that most women with a serious psychiatric illness cannot discontinue their medication. Unfortunately there is a scarcity of information and a lack of RCTs on this topic. Boskovic (2009) conducted a literature search of studies published from 1966 – 2008. This review included first and second generation antipsychotics (FGAs & SGAs). The FGAs included: phenothiazines, butyrophenones, thioxanthenes, dibenzoxazepines, and dihydroindolones. The SGAs were: clozapine, risperidone, olanzapine, quetiapine, ziprasidone, and aripiprazole. The review demonstrated that SGAs show significant improvement with respect to the occurrence of side effects of the FGAs, i.e., extrapyramidal symptoms, tardive dyskinesia, and hyperprolactinemia. It is noted that this article's focus was only on the risk of major physical malformations. Based upon the available evidence-based information at the time, it appeared that SGAs were not found to increase the risk for birth defects or other adverse effects above rates in the general population. SGAs are usually considered first-line options for drug therapy.

### **Treating Bi-Polar Disorder during Pregnancy**

There is a demonstrated need for the use of medication therapy during pregnancy and the post partum period for women with bi-polar disorders. Again however, there is a lack of evidence-based research on the use of pharmacological interventions. Galbally et al., (2010) conducted a systematic review to study the effects of exposure to mood stabilizers, i.e., lithium carbonate and the anti-epileptic drugs (AEDs) sodium valproate, carbamazepine, and lamotrigine during pregnancy. All mood stabilizers reviewed demonstrated increased risk of fetal malformation. The malformations were predominantly structural, particularly among the AEDs, demonstrating neural tube defects but also cardiac and craniofacial defects. Lithium exposure increased the risk of cardiovascular defects. Nguyen et al. (2009) conducted a review to assess the teratogenic effects of valproate, lamotrigine, carbamazepine, lithium, and antipsychotics. The teratogenic effects that were reviewed included: CV=cardiovascular; GIT=gastrointestinal; Neuro=neurological; OF=orofacial; UG=urogenital. Adverse effects were reported in all areas for valproate, lamotrigine, and carbamazepine. With the exception of CV effects, there was insufficient data for Lithium and antipsychotics for the other noted categories. Both reviews were consistent in that the authors agreed that further research is needed.

## Summary

Mental illness during pregnancy presents a number of challenges. There are several barriers that may impact the mother's ability to obtain appropriate prenatal care. There are a variety of treatment modalities to consider, including but not limited to: individual and group psychotherapy, pharmacological therapy, ECT, and substance abuse withdrawal management. The challenge for treatment however is further complicated by limited research conclusions. Despite the cited need for further research there appeared to be consensus in the literature with respect to the following:

- Comprehensive care models with management by a multidisciplinary team
- The importance of assessment, counseling, and intervention
- For pharmacological interventions:
  - Avoidance of polypharmacotherapy
  - Utilization of lowest possible doses
  - Careful monitoring of the pregnancy and of infant development

Decisions about appropriate treatment modalities must be carefully considered with respect to the impact on the health of the mother and the outcomes of the pregnancy, in addition to the impact on fetal development and neonatal health.

## Hemorrhage

Obstetric hemorrhage is a common cause of maternal death and is a major cause of maternal morbidity. The review of this literature has identified evidence-based interventions that are effective in improving outcomes of maternal mortality and morbidity. The basic care plan for postpartum hemorrhage consists of active management of the third stage of labor and treatment. The first line of care is preventative therapies, such as oxytocin or syntometrine, that aid in reducing the incidence of obstetric hemorrhage, as well as reducing blood loss during hemorrhage. A second line of therapies focuses on managing and treating the existing hemorrhage, including surgical interventions, and/or radiological or new medical treatments such as recombinant activated factor VII (rFVIIa). The final end intervention is a hysterectomy, which is indicated when a massive hemorrhage has not responded to previous interventions and there is no other intervention or procedure to control the bleeding and avoid maternal death.

### First-line Management

Active management of the third stage of labor has been proven to be successful in reducing the risks of postpartum hemorrhage. The literature search yielded information on uterotonics, such as oxytocin, syntometrine, carbetocin and misoprostol. The uterotonic agent oxytocin is recognized by many studies to be the most widely used agent and is effective in reducing postpartum hemorrhage and mean blood loss (Sloan et al., 2010; Chemlow, 2010). Syntometrine, a combination of oxytocin and ergometrine, is associated with a reduction in blood loss of 500 ml or greater when compared to oxytocin. However, there was not a significant difference in the reduction of severe (1000 ml or more) blood loss compared to oxytocin. Syntometrine is also associated with more maternal side effects, such as increased blood pressure, vomiting and nausea (McDonald et al., 2004).

Nirmala et al., (2009) conducted a randomized controlled study (n=120) which assessed carbetocin, a synthetic analogue of oxytocin, in comparison to syntometrine for prevention of postpartum hemorrhage during vaginal deliveries. The results demonstrated that a single carbetocin 100 µg intramuscular injection in high risk women significantly lowered the estimated

mean blood loss (99mL less) when compared to an intramuscular injection of syntometrine, and was much less likely to produce side effects such as nausea and vomiting. Su et al., (2012) also compared carbetocin and syntometrine in a study which indicated that women who received carbetocin had less blood loss in comparison to syntometrine, and had less adverse effects. In cesarean sections, Borruto et al., (2009) found results that the mean blood loss after the intravenous administration of carbetocin was 30 ml less than after a continuous 2-hour oxytocin infusion. The longer action of carbetocin is due to its long half-life, therefore less uterotonic agents and less need for uterine massage are required compared to oxytocin, which requires repeated injections. Su et al, (2012) also concluded similarly that for cesarean deliveries, carbetocin resulted in a significant reduction in the need for uterotonics, however the data indicated that there was no difference in blood loss.

Boucher et al., (2004) concluded that women who have a vaginal delivery and had at least one risk factor for postpartum hemorrhage, and were given a 100 µg IM carbetocin injection, were less likely to require uterotonic intervention, than those administered a continuous 2-hour infusion of oxytocin. Therefore, IM carbetocin injection is more likely to prevent postpartum hemorrhage in women at risk when compared to a continuous oxytocin infusion.

The use of misoprostol, when evaluated and compared with no uterotonic prophylaxis, was associated with a reduction in postpartum hemorrhage and severe postpartum hemorrhage, as well as a lower mean blood loss (Sloan et al., 2010). Findings revealed that misoprostol is effective in reducing severe hemorrhage and the need for blood transfusions; however, it is not more effective than oxytocin and is accompanied by more side effects. The authors concluded that oxytocin is the uterotonic of choice (10 international units) administered intravenously or intramuscularly. Misoprostol is thought to be effective in low resource settings where there is low access to facilities and skilled healthcare workers (Tuncalp et al., 2012).

## **Second-line Management**

When medical management is unsuccessful at preventing or reducing blood loss in obstetric hemorrhage, a second line of therapies can be considered. These include uterine compression sutures, uterine balloon tamponade, arterial ligation, pelvic artery ligation, interventional radiology, tranexamic acid, rFVIIa, and hysterectomy.

Doumouchtsis et al., (2007) performed a systematic review of 46 observational studies that assessed the success rates for various treatments of major postpartum hemorrhage. Success rates for arresting postpartum hemorrhage were calculated and the results were: 84.0% for balloon tamponade, 90.7% for arterial embolization, 91.7% for compression sutures, and 84.6% for pelvic devascularization. These interventions may require specialists; for example, arterial embolization requires the skills of an interventional radiologist. The authors were unable to conclude that one intervention was better than another. It was also suggested to use balloon tamponade as the first line of intervention due to the non-invasiveness of the procedure. As for a hysterectomy, the procedure should be performed before catastrophe derived from massive blood loss, hemodynamic instability, and significant coagulopathy, which is inevitable. Kayem et al., (2011) also focused on measuring the rates of success and effectiveness of uterine compression sutures, pelvic vessel ligation, interventional radiology and rFVIIa. Overall, uterine compression sutures and interventional radiology procedures had a higher success rate, 75% and 86% respectively, than rFVIIa and pelvic vessel ligation, 31% and 36% respectively. The rates of success did not differ significantly when used after uterotonic agents alone, or after uterotonic agents and intrauterine tamponade combined.

Uterine compression sutures have been used to stop postpartum hemorrhage, and have been suggested as a first-line intervention for preventing hysterectomies in patients with uterine atony who respond to bimanual compression. Uterine compression sutures require less skill and have fewer complications. These include the B-Lynch sutures, multiple square sutures, and Hayman sutures. A retrospective study, Ouahba et al., (2007) assessed the effectiveness of uterine compression suturing technique in reducing postpartum hemorrhage in women with uterine atony and postpartum bleeding that did not react to usual medical management. In 95% of the women, the uterine compression sutures immediately stopped the bleeding. There were no documented complications related to the suturing. Alouini et al., (2011) assessed the efficiency and morbidity related to use of multiple square sutures in severe postpartum hemorrhage. Multiple square sutures were found to stop postpartum hemorrhage in 28 of the 30 patients. Another suturing technique is the Hayman suture, a technique that has been described as being simple, fast, and an easily applied intervention. In a cohort study (n=11), by Ghezzi et al., (2007) the Hayman suture was effective in treatment of postpartum hemorrhage and preventing any further interventions in 10 of the 11 women. The search did not yield articles that met our inclusion criteria regarding the B-Lynch technique specifically. But it is noteworthy that Nelson and O'Brien (2007), addressed the technique of combining the B-Lynch compression suture and an intrauterine Bakri balloon. The results indicated that the combination of the B-Lynch compression suture and intrauterine Bakri balloon was a successful technique to avoid the need for a hysterectomy and reduction of further blood loss in the five patients tested.

Recombinant activated factor VII (rFVIIa) has been studied in women with massive postpartum hemorrhage (Leduc et al., 2009). Two studies assessed in our review suggested the use of rFVIIa for postpartum hemorrhage, with early administration appearing to be an optimal intervention to achieve control of bleeding. Franchini et al., (2008) reviewed the literature and reported that rFVIIa was effective in stopping or reducing bleeding in nearly 90% of the reported cases. Baudo et al., (2006) also identified 11 articles that included 39 patients that were administered rFVIIa, 38 of the 39 patients had reduced bleeding. The data available indicates that rFVIIa has the ability to decrease postpartum hemorrhage; however, further evidence is needed to assess the dosage, effectiveness and safety of rFVIIa (Franchini et al., 2008).

An additional intervention is the use of tranexamic acid, an antifibrinolytic agent. It has been shown to be safe and effective in the prevention and management of bleeding during pregnancy, and this agent reduces the amount of blood loss after delivery, including during both cesarean sections and vaginal deliveries (Peitsidis and Kadir, 2011; Ferrer et al., 2009). Tranexamic acid has been suggested as a possible useful tool for hemorrhage due to placental abruption, as it suppresses fibrinolysis and thus can suppress hemorrhage during pregnancy. With this limited information, it is clear that further studies and investigations are needed to validate the use of tranexamic acid.

## Summary

This review examined interventions that have demonstrated the ability to prevent, reduce, or treat postpartum hemorrhage, which ultimately improve outcomes related to maternal morbidity and mortality. However, the types of interventions that are implemented are dependent on a multitude of factors, and decisions for intervention should be made carefully by healthcare providers and patients. Effective interventions that have been identified, in varying clinical circumstances, are:

- Uterotonics in the third stage of labor (including oxytocin, syntometrine, and carbetocin) as first-line treatment of hemorrhage

- Compressive devices (balloon tamponade) or sutures and medication administration (recombinant factor VII and tranexamic acid) as second-line approaches
- Hysterectomy as a last resort

## Bibliography

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Abalos, E., Duley, L., Steyn, D. W., & Henderson-Smart, D. J. (2007). Antihypertensive drug therapy for mild to moderate hypertension during pregnancy. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(1), CD002252.

Impact Factor: 5.72

Quality of Evidence: Acceptable

Condition: Hypertension

n= Not specified

Cochrane Study; 46 RCT's

Reviewed different hypertensive medications and effectiveness with mild to moderate hypertension. Reviewed included populations from the Cochrane Pregnancy and Childbirth Group Trials register. The study reviewed 46 RCT's comparing one or more medications. Trials compared both medication vs. placebo or medication comparisons. In the trials reviewed, there was no clear difference that indicated alternative drugs were more effective in decreasing the risk or development of proteinuria or preeclampsia. The review concludes that the effectiveness of the antihypertensive drug therapy was not clear.

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Alexander, J. M., Sarode, R., McIntire, D. D., Burner, J. D., & Leveno, K. J. (2009). Whole blood in the management of hypovolemia due to obstetric hemorrhage. [Comparative Study]. *Obstetrics & Gynecology*, 113(6), 1320-1326.

Impact Factor: 4.36

Quality of Evidence: Limited

Condition: Hemorrhage

n=66,369

Population-Based, Observational Study (between March 2002 and June 2006)

This study assessed the use of blood products for management of obstetric hemorrhage requiring transfusion. Women in the study were separated into three groups: those receiving only packed red blood cells, only whole blood, or a combination of whole blood and packed red blood cells, fresh frozen plasma, platelets, or cryoprecipitate. The group that received the combination therapy received on average of more units of blood in comparison to the other groups, suggesting this group experienced more serious obstetric hemorrhages. The packed red blood cells and whole blood groups experienced significantly different rates of organ morbidities, for example, the packed red blood cell group often developed acute tubular necrosis which was possibly due to the fact that the women did not have adequate replacement of circulatory blood volume; the whole blood group often experienced pulmonary edema, which was thought to be due to an over-replacement of blood volume. There were three maternal deaths reported, one occurred in the packed red blood cell group and two deaths occurred in the combination group. The authors referred to reports from the war in Iraq that observed the benefit of fresh warm whole blood, over component therapy in the management of acquired

coagulopathy. This report, another cited article, and the study's results provide reasons to believe that transfusion of whole blood should be reconsidered in the management of serious obstetric hemorrhage.

Allen, V. M., Armson, B. A., Wilson, R. D., Blight, C., Gagnon, A., Johnson, J.-A., . . . Gynecologists of, C. (2007). Teratogenicity associated with pre-existing and gestational diabetes. [Practice Guideline]. *Journal of Obstetrics & Gynaecology Canada: JOGC*, 29(11), 927-944.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= Not Specified

Guideline (1990-2005)

Reviewed by the Genetics and Maternal Fetal Medicine Committees of the Society of Obstetricians and Gynecologists of Canada (SOGC)

Insulin does not cross the placenta barrier, but high blood sugar does. The only way to protect the infant from high blood sugar, is to contain the sugar with insulin in the mother. Newer sulfonylurea's (such as glyburide) controls sugar, but does not cross the placenta. These medications have not been associated with congenital abnormalities. The use of biguanides may cause a risk for adverse perinatal outcomes. The risk of congenital abnormalities is increased in the offspring of obese women with diabetes.

Alouini, S., Coly, S., Megier, P., Lemaire, B., Mesnard, L., & Desroches, A. (2011). Multiple square sutures for postpartum hemorrhage: results and hysteroscopic assessment. *American Journal of Obstetrics & Gynecology*, 205(4), 335.e331-336.

Impact Factor: 3.28  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

n=30 cases

Retrospective Study

This retrospective study assessed the efficiency and morbidity related to use of multiple square sutures in severe postpartum hemorrhage. One of the main outcomes assessed was the ability of the multiple square sutures to stop the hemorrhage. Multiple square sutures stopped postpartum hemorrhage in 28 of the 30 cases. Upon hysteroscopy, the most frequent findings were a normal uterine cavity, or minimal intrauterine adhesions, which were removed. Thus, multiple square sutures were deemed safe and effective for the control of postpartum hemorrhage.

Altman, D., Carroli, G., Duley, L., Farrell, B., Moodley, J., Neilson, J., . . . Magpie Trial Collaboration, G. (2002). Do women with pre-eclampsia, and their babies, benefit from magnesium sulphate? The Magpie Trial: a randomized placebo-controlled trial. [Clinical Trial, Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *Lancet*, 359(9321), 1877-1890.

Impact Factor: 23.46  
 Quality of Evidence: Acceptable  
 Condition: Preeclampsia/Eclampsia

n=10,141 patients

RCT

Reviewed use of magnesium sulfate vs. placebo for management of pre-eclampsia. Women in intervention group had 58% lower risk of eclampsia, than those with placebo. Maternal mortality was lowered among intervention group as well, no clear risk of fetal mortality, no notable difference in maternal or neonatal morbidity for placental abruption. Implications regarding minimum dosages and long term consequences need further investigation.

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Alwan, N., Tuffnell, D. J., & West, J. (2009). Treatments for gestational diabetes. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(3), CD003395.

Impact Factor: 5.72  
 Quality of Evidence: Acceptable:  
 Condition: Diabetes/Obesity

n= 1418

Cochrane Review, 8 RCT's

Specific treatment, including dietary advice and insulin reduced maternal and perinatal morbidity. There is an associated risk with labor induction with this group. No conclusion of specific medications.

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Anderson, E. L., & Reti, I. M. (2009). ECT in pregnancy: a review of the literature from 1941 to 2007. [Review]. *Psychosomatic Medicine*, 71(2), 235-242.

Impact Factor: 3.97  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n = 339

Literature Review

Literature search yielding 57 articles published between 1942 - 2007. Articles included were those that provided case report data on electroconvulsive therapy (ECT) being used as an exclusive treatment, in combination with medications, or in conjunction with other somatic therapies. 68 of the 339 cases provided efficacy data. Upon exclusion of complications not related to ECT, 11 fetal/neonatal abnormalities were reported: 8 transient fetal arrhythmias, 1 fetal death secondary to status epilepticus, 1 miscarriage in the first trimester, and 1 case of multiple cortical and deep white matter infarctions. With respect to maternal adverse effects, 18 cases were believed to be possibly due to ECT. The complications included: status epilepticus, hematuria, uterine contractions and/or pre-term labor, vaginal bleeding, abdominal pain, and placental abruption. ECT has been viewed as an alternate therapy for treating mental illness during pregnancy, due to the range of adverse effects on the fetus related to medication therapy. The authors concluded that the use of ECT seemed to be effective for treatment of major mental illness during pregnancy with a low risk for adverse events.

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Angel P, L., C., Murthy, Y., and Cino, P. (2009). Key issues and barriers to obstetrical anesthesia care in Ontario community hospitals with fewer than 2,000 deliveries annually. *Canadian Journal of Anesthesia* 56, 667-677.

Impact Factor: 2.35  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= Not Specified

Cochrane Review (1995-2010)

Secondary analysis of qualitative data from 18 anesthesiologists and family practitioners who had participated in a large provincial study. Physicians identified barriers encountered including lack of time, need for CME's, need for hospital infrastructure, need for development of "best practice protocols", and need for mentorship supports. The study reconfirmed the shortage in obstetrical services was related to the lack of Family Practitioners /General Practitioner anesthetists in the rural communities.

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Arendt, K. W., Fernandes, S. M., Khairy, P., Warnes, C. A., Rose, C. H., Landzberg, M. J., . . . Hebl, J. R. (2011). A case series of the anesthetic management of parturients with surgically repaired tetralogy of Fallot. [Research Support, Non-U.S. Gov't]. *Anesthesia & Analgesia*, 113(2), 307-317.

Impact Factor: 3.29  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n=20 patients (27 deliveries)

Study conducted at Mayo Clinic and the Brigham and Women's Hospital over a 14 year time frame (1994-2008). The study involved a query of the medical records data base for each institution and focused on intrapartum and post partum anesthetic management of pregnancies after surgery to repair Tetralogy of Fallot (TOF). 21 deliveries involved a trial of labor. All of these patients received neuraxial anesthesia. Three of the 21 patients received invasive arterial blood pressure monitoring; 5 received continuous telemetry; 3 experienced congestive heart failure that required diuresis; 4 had obstetric or neonatal complications; and 3 had anesthesia complications. Cesarean delivery was required in 4 patients. There was 1 neonatal death due to cardiovascular, obstetric, and anesthetic complications. Six patients had an elective cesarean delivery; 4 received epidural and 2 received spinal anesthesia; no anesthetic or immediate obstetric complications occurred. Among all patients, 5 reported symptoms of congestive heart failure at the time of delivery. This study concluded that patients with surgically repaired TOF can experience peripartum complications. Neuraxial analgesia and anesthesia can be safely administered to patients and that excellent labor analgesia and attentive surgical anesthesia can lead to successful outcomes for the majority of patients.

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Askie, L. M., Duley, L., Henderson-Smart, D. J., Stewart, L. A., & Group, P. C. (2007). Antiplatelet agents for prevention of pre-eclampsia: a meta-analysis of individual patient data. [Meta-Analysis, Research Support, Non-U.S. Gov't, Review]. *Lancet*, 369(9575), 1791-1798.

Impact Factor: 23.46

Quality of Evidence: Limited  
Condition: Preeclampsia/Eclampsia

n=32,217

Meta-analysis, 31 RCT

This meta analysis included patient data for 32, 217 women from 31 RCTs examining preeclampsia and primary prevention. Relative risk of developing preeclampsia when medicated with antiplatelet agents was reduced to 0.9 % from the baseline. Antiplatelet medications used were not listed in this meta analysis. Premature delivery or serious adverse outcome of pregnancy were reduced as well. This review did not note individual reduction data on those outcomes noted above. Antiplatelet had no reduction on the outcome of fetal death, small for gestational age infants, or bleeding events. This review did not note individual reduction data on those outcomes noted above.

Atallah, A. N., Hofmeyr, G. J., & Duley, L. (2002). Calcium supplementation during pregnancy for preventing hypertensive disorders and related problems. [Review]. *Cochrane Database of Systematic Reviews*(1), CD001059.

Impact Factor: 5.72

Quality of Evidence: Acceptable

Condition: Hypertension

n = Not Specified

Cochrane study reviewing the use of dietary calcium supplementation during pregnancy to prevent hypertensive disorders. Populations from the Cochrane Pregnancy and Child Birth Group Trials register were reviewed; eleven RCT's were identified comparing one gram of calcium during pregnancy with placebo. The outcome was measurement of relative risk for developing hypertension. Those at the highest risk were found to have the greatest benefit from calcium supplementation; which reduced the risk of developing preeclampsia. Findings were similar to those with low baseline calcium intake. There were no detrimental effects, such as still birth, low birth weight (less than 2500g) among women with high risk of hypertension. One study did find a reduction in childhood systolic blood pressure above the 95th percentile.

Barton, J. R., Barton, L. A., Istwan, N. B., Desch, C. N., Rhea, D. J., Stanziano, G. J., & Sibai, B. M. (2011). Elective delivery at 340(/)7 to 366(/)7 weeks' gestation and its impact on neonatal outcomes in women with stable mild gestational hypertension. *American Journal of Obstetrics & Gynecology*, 204(1), 44.e41-45.

Impact Factor: 3.28

Quality of Evidence: Limited

Condition: Hypertension

n= 1858

Database review

Review of database entries to determine rate of late term elective delivery among high-risk women with stable mild gestational hypertension and a singleton pregnancy. Among 1251 delivered electively, 25.5% were late pre-term (34-36 weeks) deliveries. There were increased neonatal lengths of stay and increased neonatal complications in this group of neonates

compared with those delivered at 37 or more weeks, including higher rates of newborn intensive care unit (NICU) admission, jaundice, respiratory distress syndrome, and assisted ventilation. It is unknown if adverse pregnancy outcomes would have otherwise occurred, apart from the late pre-term delivery. Database review reflected that RCT is needed.

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Basaran, A., Basaran, M., & Topatan, B. (2010). Combined vitamin C and E supplementation for the prevention of preeclampsia: a systematic review and meta-analysis. [Meta-Analysis, Review]. *Obstetrical & Gynecological Survey*, 65(10), 653-667.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n=19,675

Systematic Review and Meta-analysis, 9 RCTs

Systematic review and meta analysis of supplementation with Vitamins C and E for prevention of preeclampsia. Nine RCT studies were reviewed, consisting of 19,675 patients. The authors concluded that there was insufficient evidence to support combined Vitamin C and E supplementation as a prevention to decrease the risk of preeclampsia. The authors concluded that there might be an increased risk of gestational hypertension and the risk of placental abruption.

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Baskett, T. F. (2007). Uterine compression sutures for postpartum hemorrhage: efficacy, morbidity, and subsequent pregnancy. *Obstetrics & Gynecology*, 110(1), 68-71.

Impact Factor: 4.36

Quality of Evidence: Limited

Condition: Hemorrhage

n=28

Prospective Review

The study assessed the efficacy of uterine compression sutures in severe postpartum hemorrhage, occurring in patients over a 7 year period in one hospital. The next step after compression sutures in the process of management of post partum hemorrhage (PPH) is a hysterectomy; however 23 of the 28 (82%) women avoided a hysterectomy. The study concluded that uterine compression sutures may provide the opportunity to avoid a hysterectomy.

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Baudo, F., Caimi, T. M., Mostarda, G., de Cataldo, F., & Morra, E. (2006). Critical bleeding in pregnancy: a novel therapeutic approach to bleeding. [Review]. *Minerva Anestesiologica*, 72(6), 389-393.

Impact Factor: 2.66

Quality of Evidence: Limited

Condition: Hemorrhage

n=39

Literature Review

The article reviewed studies, published between 2001 and 2005, that focused on the use of activated recombinant factor VII (rFVIIa) in postpartum hemorrhage in 39 patients. 38 of the 39 patients had controlled or reduced bleeding reported. This intervention is also suggested to be used as early as possible, with a recommended dose of 90 mg/kg every 2 hours, but this dose should be adjusted according to the severity of bleeding and degree of hemostasis.

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Beazley, D., Ahokas, R., Livingston, J., Griggs, M., & Sibai, B. M. (2005). Vitamin C and E supplementation in women at high risk for preeclampsia: a double-blind, placebo-controlled trial. [Clinical Trial, Randomized Controlled Trial]. *American Journal of Obstetrics & Gynecology*, 192(2), 520-521.

Impact Factor: 1.04

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n=109

Randomized Control Trial

This study was a RCT to review women at risk, by history for preeclampsia. Women were assigned to a vitamin group, which consisted of Vitamin C and Vitamin E, or placebo group. Funding was terminated after 109 participants, prior to all delivery. There was no difference in women who received vitamins versus the placebo group in reducing the risk of preeclampsia. The potential benefit has not been determined.

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Begum, M. R., Begum, A., & Quadir, E. (2002). Loading dose versus standard regime of magnesium sulfate in the management of eclampsia: a randomized trial. [Clinical Trial, Comparative Study, Randomized Controlled Trial]. *Journal of Obstetrics & Gynaecology Research*, 28(3), 154-159.

Impact Factor: 0.94

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n= 401 Loading dose with magnesium sulfate (N= 202) Standard (N=199)

Randomized Control Trial

RCT of differing doses of magnesium sulfate and its effectiveness in controlling convulsions in eclampsia. This study compared continuous IV infusion with combined IM and IV doses. There was little documented difference in success rates in reducing the rate of recurrent convulsions. No statistical difference between groups was found

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Belfort, M. A., Anthony, J., Saade, G. R., Allen, J. C., Jr., & Nimodipine Study, G. (2003). A comparison of magnesium sulfate and nimodipine for the prevention of eclampsia. [Clinical Trial, Comparative Study, Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't, Research Support, U.S. Gov't, P.H.S.]. *New England Journal of Medicine*, 348(4), 304-311.

Impact Factor: 53.30

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n= 1650

Randomized Control Trial

RCT comparing nimodipine (60mg orally q4hr) with IV Magnesium Sulfate (per protocol) for 24 hours. Development of eclampsia was defined as witnessed tonic-clonic seizures. The ante partum seizure group did not differ in seizure response with medication, however, post partum women seized more (1.1% total women who seized post partum) on nimodipine. Magnesium sulfate was more effective in protecting post partum women from seizures. Measured fetal outcomes were higher birth weight in the nimodipine group and APGAR scores greater than 7. An incidental finding was that those women who required hydralazine to control blood pressure were more likely to seize post partum when they received nimodipine.

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Bertini, A. M., Silva, J. C., Taborda, W., Becker, F., Lemos Beber, F. R., Zucco Viesi, J. M., . . . Engel Ribeiro, T. (2005). Perinatal outcomes and the use of oral hypoglycemic agents. [Comparative Study, Randomized Controlled Trial]. *Journal of Perinatal Medicine*, 33(6), 519-523.

Impact Factor: 1.7

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=147

Randomized Control Trial

Comparison of insulin, glyburide and acarbose. No statistical difference was found in outcomes measured: fasting and post prandial glucose level or average newborn weight. Fetuses were still larger than normal, but no difference between each tested group. Glyburide was found to be most effective for glucose control. Newborn Capillary glucose was tested.

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Beucher, G., Viaris de Lesegno, B., & Dreyfus, M. (2010). Maternal outcome of gestational diabetes mellitus. [Review]. *Diabetes & Metabolism*, 36(6 Pt 2), 522-537.

Impact Factor: 2.43

Quality of Evidence: Acceptable

Condition: Diabetes/Obesity

n= Not Specified

Cochrane Review (1995-2010)

This article is a review of literature to estimate the outcome of treated gestational diabetes. Recommendations from learned societies such as Haute Authority de Sante (HAS), National Institute for Health and Clinical Excellence (NICE), Royal College of Obstetricians and Gynecologist (RCOG), American College of Obstetricians and Gynecologists (ACOG), Society of Obstetricians and Gynecologists of Canada (SOGC), as well as the Royal Australian and New Zealand College of Obstetricians and Gynecologist (RANZCOG) were reviewed. Outcomes analyzed were Caesarean section, shoulder dystocia, rectal lesions, labor induction, preeclampsia, and gestational hypertension. They recommend that intensive treatment of moderate Gestational Diabetes Mellitus helps to reduce the risk of adverse events, such as preeclampsia, and excessive weight gain, compared to absence of therapy. No change in risk of caesarean section, operative vaginal delivery and post partum hemorrhage was found.

Reducing and limiting weight gain in obese women is associated with a reduction in the risk of preeclampsia.

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Birdsall, K. M., Vyas, S., Khazaezadeh, N., & Oteng-Ntim, E. (2009). Maternal obesity: a review of interventions. [Review]. *International Journal of Clinical Practice*, 63(3), 494-507.

Impact Factor: 2.41

Quality of Evidence: Acceptable

Condition: Diabetes/Obesity

n= Not Specified

Comprehensive Review

This study reviewed the interventions to promote weight control, or weight loss in women at the time of pregnancy. The study finds a deficiency in interventions for maternal obesity. The following interventions were found advantageous in the management of obese pregnant women:

individual nutritional counseling

integrated program of exercise

local radio broadcast

pamphlets advising health eating and exercise in pregnancy,

supermarket tours,

cooking demonstration

group walking sessions.

No significant outcome was found to support programs increased health outcomes

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Bismuth, E., Bouche, C., Caliman, C., Lepercq, J., Lubin, V., Rouge, D., . . . French-Speaking Diabetes, S. (2012). Management of pregnancy in women with type 1 diabetes mellitus: guidelines of the French-Speaking Diabetes Society (Societe francophone du diabete [SFD]). *Diabetes & Metabolism*, 38(3), 205-216.

Impact Factor: 2.43

Quality of Evidence: Acceptable

Condition: Diabetes/Obesity

n= Not Specified

Guideline Review

Guidelines of the French-Speaking Diabetes Society were reviewed.

Interventions included were:

- Avoidance of ACE inhibitors for antihypertensive agents.
- Avoidance of Diuretics
- Preferable to use Calcium Inhibitors as first line therapy
- Preferred use of Labatolol
- No statin use during pregnancy
- Low dose ASA limited
- Dietary Management
- Insulin therapy
- Glycemic control and monitor of HbA1C.
- Fasting BS 60-90- post AC <140 mg/dL, <120 mg/dL 2 hr post AC.

- Insulin lispro is recommended
- Insulin aspart is recommended
- Insulin glulisine not recommended
- Insulin glargine not recommended
- Insulin determine r reviewed
- insulin pumps reviewed on case by case

Blomberg, M. (2011). Maternal obesity and risk of postpartum hemorrhage. [Research Support, Non-U.S. Gov't]. *Obstetrics & Gynecology*, 118(3), 561-568.

Impact Factor: 4.73

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=1,114,071 1997-2008

Population based cohort study

Population based cohort study of risk for post partum hemorrhage. There was a two fold increase in risk of hemorrhage (1000ml EBL) for women (8%-13%) with a BMI of 40 or higher after normal delivery, compared with normal-weight women. Post partum hemorrhage was more profound with instrumental delivery.

Boath, E., Bradley, E., & Henshaw, C. (2005). The prevention of postnatal depression: a narrative systematic review. [Comparative Study, Meta-Analysis]. *Journal of Psychosomatic Obstetrics & Gynecology*, 26(3), 185-192.

Impact Factor: 1.39

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=Not Specified

Systematic Review

Search yielded 109 articles, with 21 randomized control trials (RCTs) identified that dealt with prevention of postnatal depression (PND). Interventions addressed included: psychological and social support, interpersonal therapy, postnatal stress debriefing, information and discussion, reconfiguring midwifery, individual home based care, antidepressant prevention, and hormonal prevention. Other services included two studies that looked at dietary calcium and thyroxine. Results demonstrated some short term success in seven of the psychological/supportive interventions, one antidepressant, and a study of calcium. Long term success was lacking. Methodological flaws were noted, with future trials needed.

Borruto, F., Treisser, A., & Comparetto, C. (2009). Utilization of carbetocin for prevention of postpartum hemorrhage after cesarean section: a randomized clinical trial. [Comparative Study, Randomized Controlled Trial]. *Archives of Gynecology & Obstetrics*, 280(5), 707-712.

Impact Factor: 0.91

Quality of Evidence: Acceptable

Condition: Hemorrhage

n=104

Randomized Controlled Clinical Trial

This trial, between September 2007 and January 2008, assessed the effectiveness of a single intravenous injection of carbetocin with that of a standard 2-hour oxytocin intravenous infusion after a cesarean section among patients with at least one risk factor for postpartum hemorrhage. Outcomes measured were maintenance of uterine tonicity and limitation of blood losses in the pre- and post-operative period of a cesarean delivery. It was found that a single 100 µg intravenous injection of carbetocin results in outcomes similar to those of a continuous 2-hour infusion of oxytocin.

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Boucher, M., Nimrod, C. A., Tawagi, G. F., Meeker, T. A., Rennicks White, R. E., & Varin, J. (2004). Comparison of carbetocin and oxytocin for the prevention of postpartum hemorrhage following vaginal delivery: a double-blind randomized trial. [Clinical Trial, Comparative Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *Journal of Obstetrics & Gynaecology Canada: JOGC*, 26(5), 481-488.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Hemorrhage

n=160

Randomized Double-Blind Placebo-Controlled Study

The study compared the effectiveness of intramuscular carebetocin injection to a 2-hour oxytocin intravenous infusion in reducing postpartum hemorrhage in women that were at risk. The results concluded that women who were give 100 ug IM carbetocin injection were less likely to require utertonic intervention, than those administered a continuous 2-hour infusion of oxytocin. However 43.4% of women in the carbetocin group required one uterine massage intervention, in comparison to the 62.3% of women that needed uterine massage in the oxytocin group. There was no difference in the requirement for additional utertonic medication or estimated blood loss after vaginal delivery. In conclusion, there was no significant benefit of carbetocin over oxytocin in the prevention of postpartum hemorrhage.

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Buchbinder, A., Miodovnik, M., Khoury, J., & Sibai, B. M. (2002). Is the use of insulin lispro safe in pregnancy? [Review]. *Journal of Maternal-Fetal & Neonatal Medicine*, 11(4), 232-237.

Impact Factor: 1.50

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n= Not Specified

Systematic Literature Review

Data on Lispro insulin does not have adverse maternal or fetal effects during pregnancy. RCT is needed. Reviewed the work done by Kitzmiller et al, Bhattacharyya and Vice Buchbinder et al, with Garg et al. to analyze maternal retinopathy.

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Carson, G., Cox, L. V., Crane, J., Croteau, P., Graves, L., Kluka, S., . . . Gynaecologists of, C. (2010). Alcohol use and pregnancy consensus clinical guidelines. [Practice Guideline, Research Support, Non-U.S. Gov't]. *Journal of Obstetrics & Gynaecology Canada: JOGC*, 32(8 Suppl 3), S1-31.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Psychiatric/Mental Health

n=Not Applicable

#### Clinical Consensus Guidelines on Alcohol Use and Pregnancy

This document provides clinical guidelines on alcohol use and pregnancy with a focus on providing a basis for assessment, counseling, and intervention for women who are pregnant and consume alcohol. The guidelines note the importance of screening to improve maternal and child health outcomes through early identification and reduction of maternal alcohol consumption, and early identification of infants at potentially high risk for fetal alcohol spectrum disorder (FASD). Research supports the effectiveness of brief interventions and the guidelines recommend they be provided. Brief interventions consist of 4 components: assessment and feedback, goal setting, positive reinforcement, and education. Harm reduction is another guideline recommendation. This involves reducing the harms associated with alcohol use, by promoting a reduction in consumption in working toward abstinence. Noting that women who are alcohol dependent experience difficulty to stop drinking during pregnancy, it is recognized that they require intense and specialized counseling and support. Medical support is essential during the process of withdrawal. Therefore, the guidelines also recommend that priority access to withdrawal management and treatment should be given to pregnant women. The range of evidence for the recommendations noted in this summary is II-2B to III-A

Chelmow, D. (2011). Postpartum haemorrhage: prevention. *Clinical Evidence*.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

n=Not Specified

#### Systematic Review

A review of 40 systematic reviews, randomized controlled trials, or observational studies. The study also included a GRADE evaluation of the quality of evidence for interventions. The aim was to answer the question: "What are the effects of non-drug interventions and of drug interventions to prevent primary postpartum hemorrhage?"

Some of the key relevant findings are:

- active management during the third stage of labor with controlled cord traction, early cord clamping plus drainage, and prophylactic oxytocic agents reduces the risk of postpartum hemorrhage and its complications
- oxytocin effectively reduces the risk of postpartum hemorrhage
- oxytocin plus ergometrine seem more effective than oxytocin alone, however there are more adverse effects with the addition of ergometrine
- ergot alkaloids seem as effective as oxytocin, but they are associated with adverse effects

- prostaglandin treatments vary in effectiveness and all are associated with adverse effects
- misoprostol (a prostaglandin), when administered sublingually, may be more effective in preventing postpartum hemorrhage when compared to a placebo., It also has similar effects as injected agents and has more adverse effects
- oxytocin, ergometrine or combination are preferred to misoprostol

Chiaffarino, F., Parazzini, F., Paladini, D., Acaia, B., Ossola, W., Marozio, L., . . . Del Giudice, A. (2004). A small randomised trial of low-dose aspirin in women at high risk of pre-eclampsia. [Clinical Trial, Comparative Study, Randomized Controlled Trial]. *European Journal of Obstetrics, Gynecology, & Reproductive Biology*, 112(2), 142-144.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n= 35

Randomized Control Trial

This RCT measured mean birth weight and found it to be higher in the low dose aspirin treated group, than in the no treatment group, but the difference was not statistically significant. This data is limited for a potential favorable effect in using ASA in pregnant women at risk for preeclampsia, Pregnancy Induced Hypertension (PIH) and Intra Uterine Growth Retardation (IUGR).

Clatworthy, J. (2012). The effectiveness of antenatal interventions to prevent postnatal depression in high-risk women. [Research Support, Non-U.S. Gov't, Review]. *Journal of Affective Disorders*, 137(1-3), 25-34.

Impact Factor: 3.76

Quality of Evidence: Acceptable

Condition: Psychiatric/Mental Health

n = 800 Papers

Literature Review

This literature review was conducted to assess the effectiveness of antenatal interventions designed to prevent postnatal depression in high-risk women. An electronic data base and reference list search yielded eleven studies published 1995 - 2010 that met inclusion criteria. The papers selected for review were those reporting a randomized controlled trial of an intervention delivered during pregnancy, with the aim of reducing postnatal depression in high risk women. The studies demonstrated large variation in the degree of depression. The women experienced depression ranging from no/low depression, to moderate to severe. It appeared that interventions to prevent postnatal depression were more successful when delivered to women experiencing symptoms of depression in pregnancy. The interventions included interpersonal therapy, cognitive behavioral therapy and a psychosocial approach. Interventions provided to individuals were found to be effective where group interventions demonstrated mixed results. The authors concluded that evidence suggests that interventions delivered in pregnancy can be effective in preventing postnatal depression. Effective interventions are those that are based on psychological therapies and provided to women experiencing antenatal depression. The authors noted that the interventions

might be better conceptualized as early treatment, rather than preventive interventions. On a clinical level, there is a need to identify pregnant women experiencing symptoms of depression and to deliver evidence based psychological interventions.

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Conde-Agudelo, A., Romero, R., Kusanovic, J. P., & Hassan, S. S. (2011). Supplementation with vitamins C and E during pregnancy for the prevention of preeclampsia and other adverse maternal and perinatal outcomes: a systematic review and metaanalysis. [Meta-Analysis, Research Support, N.I.H., Intramural, Review]. *American Journal of Obstetrics & Gynecology*, 204(6), 503.e501-512.

Impact Factor: 1.04

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n=19,810

Systematic Review and meta-analysis, 9 RCTs

This article was a systematic review and meta-analysis of supplementation with Vitamins C and E during pregnancy for prevention of preeclampsia and other outcomes. There was no difference between the vitamin and placebo groups in the risk of preeclampsia. Women with low/moderate risk for preeclampsia were at risk for developing gestational hypertension and premature rupture of membranes and decreased risk of placenta abruption. The authors conclude that supplementation with Vitamins C and E during pregnancy does not prevent preeclampsia.

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Coomarasamy, A., Honest, H., Papaioannou, S., Gee, H., & Khan, K. S. (2003). Aspirin for prevention of preeclampsia in women with historical risk factors: a systematic review. [Meta-Analysis, Research Support, Non-U.S. Gov't, Review]. *Obstetrics & Gynecology*, 101(6), 1319-1332.

Impact Factor: 4.73

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n=12,416

Systematic Review of Literature, 14 RCTs

14 RCTs, including 12,416 pregnant women with a historical risk factor. They evaluated the effectiveness of aspirin, and dipryridamole with variable dosages (50-150mg ASPRIN (ASA) or 225-300mg dipryridamole) at an unknown frequency, and compared this with placebo or no treatment. Trial results supported reduction of perinatal death, reduced incidence of preeclampsia, and lower rates of spontaneous preterm birth with the use of ASA. ASA use was also associated with a mean increase in neonatal birth weight. No changes were found in the incidence of placental abruption with ASA administration.

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Correa, A., Gilboa, S. M., Botto, L. D., Moore, C. A., Hobbs, C. A., Cleves, M. A., . . . National Birth Defects Prevention, S. (2012). Lack of periconceptional vitamins or supplements that contain folic acid and diabetes mellitus-associated birth defects. [Controlled Clinical Trial, Multicenter Study, Research Support, U.S. Gov't, P.H.S.]. *American Journal of Obstetrics & Gynecology*, 206(3), 218.e211-213.

Impact Factor: 3.28  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= 14,721

National Birth Defects Prevention Study (1997-2004)

This article reviewed the concept associated with a lack of folic acid in prenatal vitamins. It was determined that this may be associated with a 2-4 fold risk of birth defect in patients with pre pregnancy diabetes mellitus. Observational data concludes that good glycemic control improves outcomes, decreasing birth defects. However, this data adds merit to the health concerns for needed prevention of birth defects. Work done by Yoon et al (2001) and Cogswell et al (2009) support this data.

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Coustan, D. R., Lowe, L. P., Metzger, B. E., Dyer, A. R., International Association of, D., & Pregnancy Study, G. (2010). The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study: paving the way for new diagnostic criteria for gestational diabetes mellitus. [Practice Guideline, Research Support, N.I.H., Extramural, Research Support, Non-U.S. Gov't]. *American Journal of Obstetrics & Gynecology*, 202(6), 654.e651-656.

Impact Factor: 3.28  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= Not Specified

Article describing meta-analysis of 5 RCT's

Hyperglycemia and Adverse Pregnancy Outcome (HAPO) criteria. Three values were determined to be accurate in the 75g, 2 hour oral glucose tolerance test for identifying those at risk. The authors conclude that identification of these patients by the HAPO criteria is an important intervention to decrease morbidity and mortality. Morbidity analyzed included reduction in macrosomia, neonatal fat mass, shoulder dystocia, preeclampsia and cesarean section.

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Crowther, C. A., Hiller, J. E., Moss, J. R., McPhee, A. J., Jeffries, W. S., Robinson, J. S., & Australian Carbohydrate Intolerance Study in Pregnant Women Trial, G. (2005). Effect of treatment of gestational diabetes mellitus on pregnancy outcomes. [Clinical Trial, Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *New England Journal of Medicine*, 352(24), 2477-2486.

Impact Factor: 47.05  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= 490

Randomized Clinical Trial

Pregnant women in intervention group

Rate of perinatal complications was measured and found to be significantly lower in the intervention group (1% vs. 4%). The intervention was: Personal review with a qualified dietician, individualized dietary advice, instructions on self monitoring of glucose levels; (QID, then

tapered depending on results). Control group received universal screening and routine clinical care. Patients were not aware of their glucose intolerance. If other testing caused concern for diabetes, further assessment needed was determined. Hospital records were reviewed. The conclusion supported that if interventions are not done, fetal outcomes were affected.

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de Barros, M. C., Lopes, M. A. B., Francisco, R. P. V., Sapienza, A. D., & Zugaib, M. (2010). Resistance exercise and glycemic control in women with gestational diabetes mellitus. [Comparative Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *American Journal of Obstetrics & Gynecology*, 203(6), 556.e551-556.

Impact Factor:3.28

Quality of Evidence:Limited

Condition: Diabetes/Obesity

n=64

Randomized Control Trial (Exercise group vs. Control group)

Exercise combined with glycemic control via insulin on Gestational Diabetes Mellitus patients. Physiological discussion regarding muscle activity and glucose control. Intervention was to exercise with a rubber band stretching 90 minutes post meal, and the measurement of accurate glucose was checked. If elevated, 100-250 then stretching prior to exercise was advised. 15 repetitions of each exercise station was defined, with 30 second resting periods. This was increased with a schedule during the weeks 1-3 of their participation in the trial. The exercise group spent more time in the target blood glucose range during their testing time. Blood glucose levels were unchanged. Amount of insulin was unchanged. Newborn birthweight was greater than 400g in only one exercise case.

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Dennis, A. T., & Solnordal, C. B. (2012). Acute pulmonary oedema in pregnant women. [Meta-Analysis, Review]. *Anaesthesia*, 67(6), 646-659. doi: <http://dx.doi.org/10.1111/j.1365-2044.2012.07055.x>

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Cardiac Disease

n=Not Specified

Literature Reviewed

Reviewed articles addressing pulmonary edema in pregnant women with discussion of immediate management for risk reduction and preventive strategies. Literature reviewed included: any systematic review, randomized control trial, observational study, case report or expert or consensus statement pertaining to pregnant women and their cardiovascular physiology, cardiovascular pathophysiology, acute pulmonary edema, and management and interventions in pregnant women with acute pulmonary edema. The goals of treatment are: 1) Reduce left ventricular preload, 2) Reduce left ventricular afterload, 3) Reduce/prevent myocardial ischemia, and 4) Maintain adequate oxygenation and ventilation with clearance of pulmonary edema. Management strategies should include identification of pregnant women at risk and engagement of a skilled multidisciplinary team. Short term management should focus on monitoring of vital signs, (respiration, cardiac, hematologic and renal functions), fetal well being, avoidance of precipitants (fluid balance and restriction), and blood pressure control. Long term follow-up is necessary.

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Dhulkotia, J. S., Ola, B., Fraser, R., & Farrell, T. (2010). Oral hypoglycemic agents vs insulin in management of gestational diabetes: a systematic review and metaanalysis. [Comparative Study, Meta-Analysis, Review]. *American Journal of Obstetrics & Gynecology*, 203(5), 457.e451-459.

Impact Factor:3.28

Quality of Evidence:Limited

Condition: Diabetes/Obesity

n= 1388

Randomized Control Trials

Review comparing oral hypoglycemic agents with insulin to achieve glycemc control and evaluate perinatal outcomes. No difference in outcomes was found.

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Di Cianni, G., Volpe, L., Ghio, A., Lencioni, C., Cuccuru, I., Benzi, L., & Del Prato, S. (2007). Maternal metabolic control and perinatal outcome in women with gestational diabetes mellitus treated with lispro or aspart insulin: comparison with regular insulin. [Letter, Randomized Controlled Trial]. *Diabetes Care*, 30(4), e11.

Impact Factor:8.09

Quality of Evidence:Limited

Condition: Diabetes/Obesity

n=96

Randomized Control Trials

Short acting insulin like Lispro and Aspart are more likely to mimic normal human insulin patterns. Aspart was found to decrease incidence of macrosomia.

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Diemert, A., Ortmeyer, G., Hollwitz, B., Lotz, M., Somville, T., Glosemeyer, P., . . . Hecher, K. (2012). The combination of intrauterine balloon tamponade and the B-Lynch procedure for the treatment of severe postpartum hemorrhage. *American Journal of Obstetrics & Gynecology*, 206(1), 65.e61-64.

Impact Factor:3.28

Quality of Evidence:Limited

Condition: Hemorrhage

n=24

Retrospective Analysis

This study assessed 24 cases of severe postpartum hemorrhage between January 2005 and July 2010 at their center, and focused on the combination of intrauterine balloon tamponade and the B-Lynch procedure for the treatment of severe postpartum hemorrhage. The outcome measured was the prevention of a hysterectomy. Sixty percent of the cases were treated successfully with the balloon tamponade, while 30% were successfully treated with the balloon and the B-Lynch suture. The results demonstrated that the tamponade balloon with or without the B-Lynch sutures is an effective intervention for the treatment of severe postpartum hemorrhage.

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Dijkman, A., Huisman, C. M. A., Smit, M., Schutte, J. M., Zwart, J. J., van Roosmalen, J. J., & Oepkes, D. (2010). Cardiac arrest in pregnancy: increasing use of perimortem caesarean section due to emergency skills training? [Multicenter Study]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 117(3), 282-287.

Impact Factor:3.41

Quality of Evidence:Limited

Condition: Cardiac Disease

n=55

Retrospective Cohort Study

Of 55 pregnant women who had cardiac arrest; 12 underwent perimortem caesarean section (PMCS). Study presented an overview of 15 years of the use of PMCS. In theory, PMCS is expected to yield a lower fatality rate in mothers and infants when applied in the correct manner and within the appropriate time frame. The study confirmed the hypothesis that PMCS is potentially beneficial in maternal resuscitation in that eight of the 12 women regained cardiac output after the procedure. Of the 12 there were two maternal survivors and five neonatal survivors.

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Doumouchsis, S. K., Papageorghiou, A. T., & Arulkumaran, S. (2007). Systematic review of conservative management of postpartum hemorrhage: what to do when medical treatment fails. [Review]. *Obstetrical & Gynecological Survey*, 62(8), 540-547.

Impact Factor:2.51

Quality of Evidence:Acceptable

Condition:Hemorrhage

n=Not Specified

Systematic Review

This review analyzed 46 observational studies that assessed the success rates for various treatments of major postpartum hemorrhage. Success rates for arresting postpartum hemorrhage were calculated and the results were: 84.0% for balloon tamponade, 90.7% for arterial embolization, 91.7% for compression sutures, and 84.6% for pelvic devascularization. These interventions may require specialists; for example, arterial embolization requires the skills of an interventional radiologist. From the review, the authors were unable to conclude that one intervention was better than another. It is also suggested to use balloon tamponade as the first line of intervention, due to the non-invasiveness of the procedure.

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Drake, E., Preston, R., & Douglas, J. (2007). Brief review: anesthetic implications of long QT syndrome in pregnancy. [Review]. *Canadian Journal of Anaesthesia*, 54(7), 561-572.

Impact Factor: 2.35

Quality of Evidence: Limited

Condition: Cardiac Disease

n=Not Specified

Literature Review

This source was a review of articles from a MEDLINE and PubMed search to review the effects of long QT syndrome (LQTS) in pregnant women and current anesthetic management. Due to the challenge of managing LQTS in pregnant women, a multidisciplinary approach is recommended for management and care of these patients throughout pregnancy. Anesthetic management is focused on prevention of prolonged QTS in addition to being prepared to immediately treat any episode of torsade. (Torsade de pointes is an uncommon and distinctive form of polymorphic ventricular tachycardia). The effects of anesthetic agents are not entirely clear and recommendations are limited, being based upon isolated cases or studies in patients who do not have LQTS.

Dror, D. K., & Allen, L. H. (2012). Interventions with vitamins B6, B12 and C in pregnancy. *Paediatric and Perinatal Epidemiology*, 26 Suppl 1, 55-74. doi: <http://dx.doi.org/10.1111/j.1365-3016.2012.01277.x>

Impact Factor: 1.80  
 Quality of Evidence: Acceptable  
 Condition: Hypertension

n= Variable by intervention

Systematic review and meta-analyses

This is a comprehensive review of the effects of Vitamins B6, B12, or C given during pregnancy With GRADE level of evidence assigned.

Vitamin B6: 11 studies done 1960-2009, n=>2500, variable Vitamin B6 dosing, low to very low levels of evidence for findings of a significant positive effect on birth weight and possible reduction in maternal nausea and vomiting, congenital malformations, and anemia.

Vitamin B12: No studies have been done in supplementing with B12 exclusively.

Vitamin C: Most interventions have included both Vitamins C and E in combination, rather than C alone (2 trials with C alone, 13 trials with C and E). n=>150,000. Dosing varied. There was no significant effect on any maternal or neonatal outcome when compared with placebo except for one effect: more women in the treatment group than in the control group developed gestational hypertension. Most studies rated as a high or moderate level of evidence, one study rated a low level of evidence.

Duley, L. (2005). Evidence and practice: the magnesium sulphate story. [Review]. *Best Practice & Research in Clinical Obstetrics & Gynaecology*, 19(1), 57-74.

Impact Factor: 1.87  
 Quality of Evidence: Acceptable  
 Condition: Preeclampsia/Eclampsia

n=11,444

Systematic Review of Literature, RCT=16

This article reviewed six trials with (11,444) women, comparing magnesium sulfate with placebo or no anticonvulsant. Treatment of magnesium sulfate decreased eclampsia by more than half. No difference was found overall in rate of still birth, or neonatal death (results contingent upon gestational age). Maternal outcome was a reduced placental abruption with magnesium sulphate, as well as a decrease in caesarean section. No effect was found on the risk of induction of labor, post partum hemorrhage or manual removal of placenta.



Duley, L. (2011). Pre-eclampsia, eclampsia, and hypertension. *Clinical Evidence*.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n= Variable (30,000+)

Systematic literature review 69 RCT's and observational studies from US and UK  
Systematic review of trials and studies from 1966 through 2010, with GRADE levels of evidence assigned to answer several research questions related to effectiveness of interventions for hypertension, preeclampsia and eclampsia. For women with mild to moderate hypertension in pregnancy:

Anti-hypertensives: overall there were 46 RCTs (n=4282) comparing any anti-hypertensive vs. placebo or another anti-hypertensive. There was very low quality evidence that anti-hypertensive drugs reduced fetal or neonatal death (26 RCTs, n=3081). There was moderate quality evidence that beta blockers reduced the percentage of babies born small for gestational age than when no beta blockers were given (13 RCTs, n=854). There was very low quality evidence that anti-hypertensive drugs may be more effective at reducing the risk of severe hypertension, but not pre-eclampsia, when compared with placebo or no drug (19 RCTs, n=2409, 22 RCTs, n=2702, and 11 RCTs, n=1128). Compared with methyldopa, beta blockers were more effective at reducing the risk of severe hypertension (moderate quality evidence, 8 RCTs, n=493). 13 small RCTs found that ACE inhibitors used in the second or third trimester led to fetal renal failure, another study found that ACE inhibitors used in the first trimester led to increased congenital malformations (n unknown)

Bed rest/hospital admission vs. no hospital admission: A total of 4 RCTs, n=449 were found. 1 RCT, n=218 yielded low quality evidence of the effectiveness of either intervention in reducing severe hypertension; 1 RCT, n=218 yielded moderate quality evidence that some rest in the hospital was effective in reducing the incidence of preterm birth (vs. normal activity at home). 1 RCT (n=395) comparing antenatal day care with inpatient care yielded high-quality evidence that daycare was no more effective than inpatient care in lowering maternal blood pressure.

Duley, L., Henderson-Smart, D. J., & Meher, S. (2006). Drugs for treatment of very high blood pressure during pregnancy. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(3), CD001449.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Hypertension

This is a review of the Cochrane Pregnancy and Childbirth Group Trials Register, searches performed in 2006 and 2012, to determine the effectiveness of various anti-hypertensive drugs during pregnancy. RCTs compared one anti-hypertensive drug with another. Results were: Calcium channel blockers vs. hydralazine (5 RCTs, n=263) – women on calcium channel blockers less likely to have persistent high blood pressure (6% vs. 18%). Ketanserin vs. hydralazine (4 RCTs, n=200) – Ketanserin was associated with more persistent high blood pressure (27% vs. 6%), but fewer side effects (3 RCTs, n=120, results percentages

unstated) and a lower risk of hemolysis, elevated liver enzymes, and lowered platelets (HELLP) syndrome (1 RCT, n=44).

Labetalol - was associated with a lower risk of hypotension (1 RCT, n=90) and caesarean section than diazoxide (percentages unstated).

Nimodipine vs. magnesium sulphate – risk of persistent high blood pressure was lower for nimodipine (2 RCTs, n=1683, 47% vs. 65%), lower risk of respiratory difficulties, fewer side effects, and less postpartum hemorrhage (percentages unstated). However, nimodipine administration yielded a higher risk of eclampsia (percentages unstated).

Authors conclude that there is insufficient evidence to show which drug is most effective, but some evidence shows that ketanserin may not be as effective as hydralazine, and diazoxide may lower blood pressure too quickly.

Duley, L., Henderson-Smart, D. J., Meher, S., & King, J. F. (2007). Antiplatelet agents for preventing pre-eclampsia and its complications. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(2), CD004659.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n=37,560

Cochrane Review of Literature, 59 RCTs

Cochrane Pregnancy and Childbirth Group Trial Register. Review of Literature regarding RCT's (37,560 patients with 59 trials) with Antiplatelet agents for women at risk for developing preeclampsia. Authors concluded that moderate benefits are found when Antiplatelets are used for prevention of preeclampsia. Trials reduced the risk of developing preeclampsia by a sixth (17%) with similar lowering of the mortality of the baby (14%), and lowering the risk of premature birth as well by 8%.

Duley, L., Henderson-Smart, D. J., Walker, G. J., & Chou, D. (2010). Magnesium sulphate versus diazepam for eclampsia. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(12), CD000127.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n=1396

Cochrane Review of Literature, 3 RCTs,

The Cochrane Pregnancy and Childbirth Group Trials Register was searched to review the use of magnesium sulphate versus diazepam for eclampsia. Maternal risk of death was reduced with the use of magnesium sulphate, but maternal morbidity and perinatal mortality were not affected. Meta trials had better outcomes of APGAR scores.

Einarson, A., & Boskovic, R. (2009). Use and safety of antipsychotic drugs during pregnancy. [Comparative Study, Research Support, Non-U.S. Gov't, Review]. *Journal of Psychiatric Practice*, 15(3), 183-192.

Impact Factor: 2.16  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n= Not Specified  
 Literature Search

Database search included studies published in English from 1966 to 2008. Discussion of the importance of evaluating the safety of antipsychotic drugs in pregnancy, as most women with a serious psychiatric illness cannot discontinue their medication. The authors recognized the scarcity of information on this topic related to ethical considerations and the lack of RCTs on this topic. This review included first generation antipsychotics (FGAs): which includes the phenothiazines, butyrophenones, thioxanthenes, dibenzoxazepines, and dihydroindolones. The review also included Second Generation Antipsychotics (SGAs) which includes: Clozapine, Risperidone, Olanzapine, Quetiapine, Ziprasidone, and Aripiprazole. The SGAs have demonstrated significant improvement with respect to the side effects of the FGAs, i.e., extrapyramidal symptoms (EPS), tardive dyskinesia (TD), and hyperprolactinemia. SGAs are usually considered first line options for drug therapy. It is noted that this article's focus was only on risk of major physical malformations. Based upon the available evidence-based information at the time, it appeared that these drugs were not found to increase the risk for birth defects or other adverse effects above rates in the general population. Mental illness can present serious challenges to the pregnant woman. The use of antipsychotics during pregnancy should be carefully considered and evaluated by the treating physician.

Farrar, D., Tuffnell, D. J., & West, J. (2007). Continuous subcutaneous insulin infusion versus multiple daily injections of insulin for pregnant women with diabetes. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(3), CD005542.

Impact Factor: 5.72  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n= 153

Cochrane Review of 5 Randomized Control Trials.

Review of use of continuous subcutaneous insulin versus multiple daily injections of insulin. Outcomes measured in five key studies, where neonatal birth weight, infant glucose, maternal glycemic control and maternal weight gain were measured and compared. There is little evidence to support the recommended use of either type, over the other type.

Fassett, M. J., Dhillon, S. H. K., & Williams, T. R. (2007). Effects on perinatal outcome of treating women with 1 elevated glucose tolerance test value. *American Journal of Obstetrics & Gynecology*, 196(6), 597.e591-594; discussion 597.e594.

Impact Factor: 3.28  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=126

Retrospective Case Study

Medical nutrition therapy and home glucose monitoring evaluated to reduce complications. Treatment group received routine medical nutrition therapy (meal plans) and self blood glucose monitoring, weekly contact with perinatal nurse coordinator under supervision of Maternal Fetal Medicine specialist and one dietitian follow up visit. The treated group had higher birthweight babies. Treatment did NOT reduce the incidence of perinatal complications

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Ferrara, A., Hedderson, M. M., Ching, J., Kim, C., Peng, T., & Crites, Y. M. (2012). Referral to telephonic nurse management improves outcomes in women with gestational diabetes. [Evaluation Studies, Research Support, N.I.H., Extramural, Research Support, U.S. Gov't, P.H.S.]. *American Journal of Obstetrics & Gynecology*, 206(6), 491.e491-495.

Impact Factor: 5.72  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n=11,435

Cochrane Review

Telephone nurse management for assistance with Gestational Diabetes Mellitus was associated with a lower risk of macrosomia. Intervention at 12 Kaiser Medical Centers and compared to national data. Those centers with an average amount of referrals to telephone nurses had smaller babies, <30%referral= (5.3%), 30-70% referrals (4.6%), <70% referral (5.5%) had less than 2500g birthweight.

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Ferrer, P., Roberts, I., Sydenham, E., Blackhall, K., & Shakur, H. (2009). Anti-fibrinolytic agents in post partum haemorrhage: a systematic review. [Review]. *BMC Pregnancy & Childbirth*, 9, 29.

Impact Factor: 1.72  
 Quality of Evidence: Limited  
 Condition: Hemorrhage

n=461

Systematic Review and Meta-Analysis, RCTs=3

Review of anti-fibrinolytic agents, particularly tranexamic acid, given during post partum bleeding. The primary outcome measured was maternal mortality. One study reported zero deaths while the other two studies did not report on mortality data. The three trials provide some evidence that a single dose of 1 gram of tranexamic acid given intravenously reduces mean blood loss within two hours of delivery. However, due to the poor quality of the trials and the lack of data on mortality, this review concluded that there is not enough evidence to support the use of tranexamic acid in postpartum bleeding.

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Field, T., Diego, M. A., Hernandez-Reif, M., Schanberg, S., & Kuhn, C. (2004). Massage therapy effects on depressed pregnant women. [Clinical Trial, Randomized Controlled Trial, Research Support, Non-U.S. Gov't, Research Support, U.S. Gov't, P.H.S.]. *Journal of Psychosomatic Obstetrics & Gynecology*, 25(2), 115-122.

Impact Factor: 1.39  
 Quality of Evidence :Limited

Condition: Psychiatric/Mental Health

n=84

Study conducted to determine if massage therapy may be an effective intervention for prenatal depression in women. Depressed pregnant women were recruited during the second trimester and randomly assigned to a massage therapy group, a progressive muscle relaxation group, or a control group that only received standard prenatal care. Following massage therapy on the first and last days of a 16-week period, the women reported lower levels of anxiety and depression and decreased leg and back pain. At the end of the study it was noted that the massage group had higher dopamine and serotonin levels and lower levels of cortisol and norepinephrine. Better neonatal outcomes were noted for the massage group, i.e., decreased incidence of prematurity and low birthweight, as well as better performance on the Brazelton Neonatal Behavior Assessment. The data suggest that massage therapy provides potential benefit for depressed pregnant women and their offspring.

Franchini, M., Franchi, M., Bergamini, V., Salvagno, G. L., Montagnana, M., & Lippi, G. (2008). A critical review on the use of recombinant factor VIIa in life-threatening obstetric postpartum hemorrhage. [Review]. *Seminars in Thrombosis & Hemostasis*, 34(1), 104-112.

Impact Factor: 4.52

Quality of Evidence: Limited

Condition: Hemorrhage

n=118

Systematic review

This systematic review was performed to evaluate and summarize the use of recombinant activated factor VII (rFVIIa) for management of major postpartum hemorrhage. There were 118 cases of massive postpartum hemorrhage treated with rFVIIa. This review recommends a bolus dose of 60 to 90 Ug/kg, which may be needed to be repeated within 30 minutes, if there is no clinical improvement. It was also suggested that this agent is not used as a last resort, it should be considered and used as an early intervention. It was concluded that more randomized controlled trials are needed to provide more information on the effectiveness and safety of rFVIIa.

Galbally, M., Roberts, M., Buist, A., & Perinatal Psychotropic Review, G. (2010). Mood stabilizers in pregnancy: a systematic review. [Review]. *Australian & New Zealand Journal of Psychiatry*, 44(11), 967-977.

Impact Factor: 2.93

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

Electronic database search from 1950 - 2009. Focus of this review: effects of exposure to mood stabilizers i.e., lithium carbonate and the anti-epileptic drugs (AEDs) sodium valproate, carbamazepine, and lamotrigine during pregnancy. All mood stabilizers reviewed demonstrated increased risk of malformation in pregnancy. The malformations were predominantly structural, particularly with the AEDs, demonstrating neural tube defects, but also cardiac and craniofacial

defects. Lithium exposure increased the risk of cardiovascular defects. Fetal growth and length of gestation may be impacted by all four mood stabilizers.

Given the identified risks the following is recommended:

- Fetal growth surveillance
- Serum glucose and liver function tests for those exposed to sodium valproate
- All exposed infants be observed for sedation, withdrawal, and toxicity
- Cord blood lithium levels, neonatal thyroid function tests and urea and electrolytes for infants exposed to lithium

The risks for exposure to mood stabilizers in pregnancy must be balanced with the risks of untreated or under-treated major mental illness in pregnancy. With respect to the risks involved, collaborative discussion of treatment regimens with women before pregnancy would seem prudent. The authors noted the importance of a comprehensive management plan to include clear communication with all involved clinicians: general practice, obstetrics, pediatrics, maternal and child health, and mental health.

Gallos, G., Redai, I., & Smiley, R. M. (2009). The role of the anesthesiologist in management of obstetric hemorrhage. *Semin Perinatol*, 33(2), 116-123. doi: 10.1053/j.semperi.2008.12.005

Impact Factor: 2.33

Quality of Evidence: Limited

Condition: Hemorrhage

n=Not Specified

Informational

Assessed the role of the anesthesiologist in the management of obstetric hemorrhage. Pregnant women that are at high risk for hemorrhage should receive anesthesia consultation before the delivery date.

Gentile, S. (2006). Prophylactic treatment of bipolar disorder in pregnancy and breastfeeding: focus on emerging mood stabilizers. [Review]. *Bipolar Disorders*, 8(3), 207-220.

Impact Factor:5.5

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=Not Specified

Literature Review of published articles from 1980 - 2006

Due to the high incidence of bipolar disorders, a need is demonstrated for the use of pharmacological therapy during pregnancy and the postpartum period. This review was conducted to compare information on the safety of newer agents: lamotrigine, oxcarbazepine, risperidone, olanzapine, and quetiapine to the safety data on classic mood stabilizers during pregnancy and the postpartum period. At the time of the review it was noted that the emerging mood stabilizers demonstrate uncertain safety parameters. There is limited information on lamotrigine and oxcarbazepine and does not suggest a clear increase in teratogenicity, while olanzapine appears to be associated with a higher risk of metabolic complications in pregnant women. Data about risperidone and quetiapine are still inconclusive. It is acknowledged that

prophylactic treatment of women with bipolar disorders may be indicated when the benefits of mood stabilization therapy outweigh the risks of unwanted effects for the fetus or breastfeeding infant. Some precautions that should be taken: avoidance of polypharmacotherapy, utilizing the lowest possible dose, careful monitoring of the progression of pregnancy and infant development. The author concluded that literature on the safety of these compounds in breastfeeding was anecdotal.

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Gentile, S. (2010). Antipsychotic therapy during early and late pregnancy. A systematic review. [Comparative Study, Review]. *Schizophrenia Bulletin*, 36(3), 518-544.

Impact Factor: 8.8

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n > than 2000 articles

Systematic Review

Review of published articles from 1950 - 2008. Review objective was to systematically analyze the safety of First and Second Generation Antipsychotics (FGAs & SGAs) during pregnancy and to potentially identify less harmful treatment options for the mother and infant. FGAs reviewed: Butyrophenone, Diphenylbutylpiperidine, and Thioxathene Derivates, Penfluridol and Pimozide, and Phenothiazines. SGAs reviewed: Amisulpride, Aripiprazole, Clozapine, Olanzapine, Quetiapine, Risperidone, Sertindole, and Ziprasidone. Review of the literature does suggest that both classes of drugs appear to be associated with an increased risk of neonatal complications, i.e., fetal malformations, perinatal complications, postnatal behavioral sequelae, and gestational complications. It also appeared that the use of SGAs seemed to increase the risk of gestational metabolic complications and babies large for gestational age. However, due to the lack of randomized control trials and limitations of the reviewed information, it is not possible to draw definitive conclusions on structural teratogenicity of FGAs and SGAs. The following treatment guidelines were noted in this review:

- Due to the risks of untreated mental illness, antipsychotic therapy must be provided to women with persistent psychiatric disorders even during pregnancy.
- Maintain the choice of previous or existing effective drug therapy during pregnancy.
- In drug naïve patients, select the drug with the lowest reported number of fetal anomalies (e.g., chlorpromazine).
- Provide strict gynecological surveillance for the patient being treated with FGAs and SGAs.
- Consider the possibility of decreasing drug dosages during the last trimester in order to reduce the risk of neonatal extrapyramidal reactions and seizures.
  - This to be taken into consideration of avoiding risk of relapse of psychotic symptoms.
- Provide multidisciplinary care between all practitioners in order to promote optimal maternal antenatal care and management of potential complications.
- Provide regular follow-up of children exposed in utero to either FGAs and SGAs, in order to diagnose and manage possible signs of neurodevelopmental delay.

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Geoghegan, J., Daniels, J. P., Moore, P. A. S., Thompson, P. J., Khan, K. S., & Gulmezoglu, A. M. (2009). Cell salvage at caesarean section: the need for an evidence-based approach. [Review]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 116(6), 743-747.

Impact Factor: 3.41  
 Quality of Evidence: Limited  
 Condition: Hemorrhage

n=Not Specified

Comprehensive Literature Search

Intraoperative Cell Salvage (IOCS) has been proposed as a technique that may reduce allogenic blood transfusion in cases of cesarean section hemorrhage. This literature review found one small randomized controlled trial. The study did report a reduction in the number of patients requiring transfusion in those that were given IOCS. Another study, a multicentre cohort study, reported 11 out 186 women who received IOCS avoided blood transfusions. All patients receiving IOCS were considered high risk patients. However, this particular study did not provide the data to support their conclusion. The article lastly mentions the need for a large multicentered collaboration to address intra-operative blood loss.

Ghezzi, F., Cromi, A., Uccella, S., Raio, L., Bolis, P., & Surbek, D. (2007). The Hayman technique: a simple method to treat postpartum haemorrhage. [Multicenter Study]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 114(3), 362-365.

Impact Factor: 3.41  
 Quality of Evidence: Limited  
 Condition: Hemorrhage

n=11

Cohort Study

The study reported on the use of the Hayman suture technique for massive postpartum hemorrhage, between January 2004 and April 2006. The Hayman technique has been described as being simpler and easier technique than the B-Lynch technique. In 10 of the 11 women with the Hayman sutures good compression of the uterus and hemostasis was achieved; no further interventions were required. The results of this study demonstrate that the Hayman sutures are a safe and effective intervention for treatment of postpartum hemorrhage.

Gindlesberger, D., Schrage, S., Johnson, S., & Neher, J. O. (2007). Clinical inquiries. What's the best treatment for gestational diabetes? [Review]. *Journal of Family Practice*, 56(9), 757-758.

Impact Factor: 0.61  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n= Not Specified

6 RCT's

The article reveals historical evidence that treatment of Gestational Diabetes Mellitus reduced mortality. There is no conclusion regarding what the best treatment plan is with Glyburide vs. Insulin reviewed. Glyburide had tighter glycemc control, with no change in outcome of birth. Diet vs. insulin was also reviewed, with insulin yielding a decrease in macrosomia.



Giuffrida, F. M. A., Castro, A. A., Atallah, A. N., & Dib, S. A. (2003). Diet plus insulin compared to diet alone in the treatment of gestational diabetes mellitus: a systematic review. [Comparative Study, Meta-Analysis, Research Support, Non-U.S. Gov't, Review]. *Brazilian Journal of Medical & Biological Research*, 36(10), 1297-1300.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n=1281

#### Systematic Review

Diet plus insulin compared to diet alone. 6 RCTs were reviewed. Primary outcome assessed was fetal macrosomia, secondary was birth weight, hypoglycemia, hypocalcemia, hypobilirubinemia, respiratory distress and congenital malformations. The article summarized that the need for individual treatment for each diabetic case prevents a standardized approach from being developed.

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Goler, N. C., Armstrong, M. A., Taillac, C. J., & Osejo, V. M. (2008). Substance abuse treatment linked with prenatal visits improves perinatal outcomes: a new standard.[Erratum appears in J Perinatol. 2009 Feb;29(2):181]. [Evaluation Studies, Research Support, Non-U.S. Gov't]. *Journal of Perinatology*, 28(9), 597-603.

Impact Factor:1.8  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

N=49,985

#### Retrospective Cohort Study

Study conducted to evaluate the impact of Early Start, an obstetric clinic-based prenatal substance abuse treatment program, on perinatal outcomes. The study included women who completed Substance Abuse Screening Questionnaires at obstetric clinics between January 1999 and June 2003, had urine toxicology screening tests and either live births or intrauterine fetal demises (IUFDs). The study involved comparison of 4 groups:

1. Women screened/assessed positive and treated by Early Start (n=2073)
2. Women screened/assessed positive without treatment (n=1203)
3. Women screened positive only (n=156)
4. Controls who screened negative (n=46,553)

There are 3 key components of the Early Start Program: (1) Placing a licensed substance abuse expert in the OB/GYN department and coordinating appointments for assessment and treatment with the patients' prenatal care appointments, (2) Universal screening of all women for drugs and alcohol and, testing urine toxicology (3) Education of all care providers and patients about the effects of drug and alcohol use during pregnancy.

The following ten maternal/neonatal outcomes were evaluated:

1. Neonatal-assisted ventilation
2. Low birth weight <2500 gms
3. Preterm delivery <37 weeks
4. Neonatal intensive care unit admission
5. Infant rehospitalization

6. Infant emergency department visit
7. Placental abruption
8. Preterm labor
9. Cesarean section
10. Intrauterine fetal demise

The results of the study demonstrated that the SAT women had either similar or slightly higher rates than the control group on most outcomes. The SAT group had significantly lower rates than the S women. The SA women had intermediate rates to the SAT and S women. In multivariate analysis, the S group had significantly worse outcomes than the SAT group in the following areas: preterm delivery, placental abruption, and intrauterine fetal demise. The study concluded that the coordination of care between mental health and obstetric professionals enhances the care delivery model for addressing substance abuse in pregnancy. Substance abuse treatment integrated with prenatal visits was associated with a positive effect on maternal and newborn health.

Gonzalez-Quintero, V. H., Istwan, N. B., Rhea, D. J., Rodriguez, L. I., Cotter, A., Carter, J., . . . Stanziano, G. J. (2007). The impact of glycemic control on neonatal outcome in singleton pregnancies complicated by gestational diabetes. *Diabetes Care*, 30(3), 467-470.

Impact Factor:8.09  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n=3218

Retrospective Review

Review of population in large prenatal database containing deidentified information. Women received outpatient service for surveillance and management of Gestational Diabetes Mellitus through Matria Healthcare from Jan 2001 to 2005. All women were educated on diet, exercise and blood sugar monitoring. Data was then divided into those who had blood glucose not controlled, defined as elevated 1 hour and 2 hour post prandial glucose results, (n= 1188) and compared with those who had controlled blood glucose (n=2030). Cited Crowther (2005), and stated their study supports the increase in macrosomia with uncontrolled blood sugar n= 15.7 % vs. n=9.3% respectively.

Henriquez, D. D., Roos-Hesselink, J. W., Schlij, M. J., Klautz, R. J., Helmerhorst, F. M., & de Groot, C. J. (2011). Treatment of valvular heart disease during pregnancy for improving maternal and neonatal outcome. [Meta-Analysis,Review]. *Cochrane Database of Systematic Reviews*(5), CD008128.

Impact Factor: 5.72  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n=1289

Cochrane Review

Review objective: to assess beneficial and adverse effects of different treatment modalities of

valvular heart disease in pregnancy to improve maternal and neonatal outcomes. The intent of the review was to include clinical trials for purposes of comparing medical therapy with percutaneous or surgical intervention for the treatment of valvular heart disease in pregnancy. The search identified no randomized controlled trials, quasi-randomized controlled trials, or cluster-randomized trials. Of 100 publications reviewed, 28 were excluded, and most reported treatment for mitral stenosis during pregnancy. Four publications were not retrievable for review. A search of the Pregnancy and Childbirth Group Trials Register identified one report that was excluded due to a comparison of medical therapy to placebo and not an intervention. The outcomes reported were for patients treated with either percutaneous balloon valvulotomy or surgical interventions for the treatment of mitral stenosis in pregnancy. Six maternal deaths were reported and 63 fetal and neonatal deaths were reported. Thirty-nine adverse events were reported and they included: cardiac arrhythmias, thromboembolisms, cardiac tamponade, fistula at and bleeding from the puncture sites and endocarditis. Major complications included: severe mitral regurgitation and cardiac failure. The authors concluded that the evidence was insufficient to identify the most effective treatment of valvular heart disease in pregnancy to improve maternal and neonatal outcomes.

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Hermida, R. C., Ayala, D. E., & Iglesias, M. (2003). Administration time-dependent influence of aspirin on blood pressure in pregnant women. [Clinical Trial, Randomized Controlled Trial]. *Hypertension*, 41(3 Pt 2), 651-656.

Impact Factor: 6.21

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n= 341

RCT

A prospective study was done to investigate the potential influence of low dose aspirin (ASA) on the development of preeclampsia in varying rest/activity cycles. Groups were randomized for time of day ASA was administered; placebo was given to control groups. Time of day of the most effective use of ASA was 8 hours after awakening. This administration time reduced blood pressure by 9.7/6.6 mm Hg in a 24 hour mean for systolic/diastolic blood pressure at the time of delivery. ASA given in the am, on awakening, had the same effect on blood pressure as placebo. ASA given at bedtime produced more complications. ASA given 8 hours after awakening or before bedtime produced an increase in birth weight and increased gestational age. There were no differences in the incidence of maternal bleeding, placental abruption, or fetal complication in either administration or placebo groups.

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Hofmeyr, G. J., Atallah, A. N., & Duley, L. (2006). Calcium supplementation during pregnancy for preventing hypertensive disorders and related problems. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(3), CD001059.

Impact Factor: 5.72

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n=6894

Cochrane Review of Literature 11 RCTs,

Eleven studies of supplementation with at least one gram of Calcium per day during pregnancy were reviewed, demonstrating a reduced incidence of preeclampsia . The studies found no overall effect on the risk of preterm delivery, but there was reduced risk of developing hypertension. There was no effect on the risk of stillbirth or death.

Hofmeyr, G. J., Duley, L., & Atallah, A. (2007). Dietary calcium supplementation for prevention of pre-eclampsia and related problems: a systematic review and commentary. [Review]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 114(8), 933-943.

Impact Factor: 3.97

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n=15,528

12 RCTs searched from the Cochrane Pregnancy and Childbirth Group Trials Register and the Cochrane Central Register of Controlled Trials (2006)

This is a systematic review of literature regarding dietary calcium supplementation for prevention of preeclampsia. All RCTs used at least 1 gram of calcium daily during pregnancy versus placebo. These studies found that the effects were greater for those women who were at high risk of developing high blood pressure, and for those who had a low baseline of calcium intake. There was a composite reduction in serious morbidity in four trials. There was no difference in the risk of preterm birth, stillbirth, or death before discharge from the hospital.

Hofmeyr, G. J., Gulmezoglu, A. M., Novikova, N., Linder, V., Ferreira, S., & Piaggio, G. (2009). Misoprostol to prevent and treat postpartum haemorrhage: a systematic review and meta-analysis of maternal deaths and dose-related effects. [Research Support, U.S. Gov't, Non-P.H.S., Review]. *Bulletin of the World Health Organization*, 87(9), 666-677.

Impact Factor: 5.3

Quality of Evidence: Acceptable

Condition: Hemorrhage

n=>40,000

Systematic Review, RCTs=46

The review analyzed the connection between maternal deaths and severe morbidity with the use of misoprostol for prevention and treatment of postpartum hemorrhage. There were 11 deaths reported in five trials and 8 occurred in women administered misoprostol; 6 of the 8 were associated with postpartum hemorrhage. When misoprostol was compared to other uterotonics there were similar numbers of adverse events for both the prevention and treatment trials. However, when misoprostol was compared to a placebo there was an increase in adverse events in the misoprostol group for both the prevention and treatment trials. Analysis also demonstrated that there was less blood loss experienced with 600 µg or 400 µg of misoprostol than the placebo. The study concluded that more research is needed to assess the beneficial and harmful effects of misoprostol. It was recommended that 400 µg of misoprostol was deemed safer than ≥ 600 µg.

Hofmeyr, G. J., Lawrie, T. A., Atallah, A. N., & Duley, L. (2010). Calcium supplementation during pregnancy for preventing hypertensive disorders and related problems. [Meta-Analysis, Review]. *Cochrane Database of Systematic Reviews*(8), CD001059.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Hypertension

n=15,739

Cochrane review; 13 studies

Review of the Cochrane Pregnancy and Childbirth Group Register searched in May 2010, to assess the effect of calcium supplementation on hypertensive disorders of pregnancy and related maternal and child outcomes. 13 studies were included. Authors conclude that calcium supplementation halves the risk of pre-eclampsia, reduces the risk of preterm birth, and reduces the occurrence of the composite outcome of "death or serious morbidity" (detailed statistics are available in the article). Effect was greatest in those at high risk of preeclampsia and those with low calcium intake. Those benefits were assessed to outweigh the small increase in hemolysis, elevated liver enzymes, and lowered platelets (HELLP) syndrome. One RCT included (n=514) assessed reduction in occurrence of childhood blood pressure at or above the 95th percentile, for which calcium supplementation was found effective. Further research is indicated.

Hutcheon, J. A., Lisonkova, S., Magee, L. A., Von Dadelszen, P., Woo, H. L., Liu, S., & Joseph, K. S. (2011). Optimal timing of delivery in pregnancies with pre-existing hypertension. [Research Support, Non-U.S. Gov't]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 118(1), 49-54. doi: <http://dx.doi.org/10.1111/j.1471-0528.2010.02754.x>

Impact Factor: 3.41  
 Quality of Evidence: Acceptable  
 Condition: Hypertension

n= 171,660

USA Population-based Cohort Study 1995-2005

This study assessed the week-specific risks of stillbirth between 36-41 weeks of gestation and contrasted those risks with the week-specific risk of neonatal mortality and serious neonatal morbidity among births following induction of labor. Study subjects were women with pre-existing (chronic) hypertension, singleton pregnancies, and without renal, cardiac, or diabetic complications. Serious neonatal morbidity was inclusive of either neonatal seizure, severe respiratory morbidity, or a 5 minute Apgar score of 3 or less.

Results: The risk of stillbirth remained stable at 1.0-1.1 per thousand ongoing pregnancies until 38 weeks, rising steadily to 3.5 per thousand at 41 weeks. Risk of serious neonatal morbidity or mortality decreased sharply between 36 and 38 weeks from 137 to 26 per 1000 induced births, before stabilizing beyond 39 weeks.

Conclusion: Elective delivery at 38-39 weeks of gestation provides the optimal time window for women with pre-existing hypertension and otherwise-uncomplicated pregnancies.

Ijas, H., Vaarasmaki, M., Morin-Papunen, L., Keravuo, R., Ebeling, T., Saarela, T., & Raudaskoski, T. (2011). Metformin should be considered in the treatment of gestational diabetes: a prospective randomised study. [Randomized Controlled Trial, Research

Support, Non-U.S. Gov't]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 118(7), 880-885. doi: <http://dx.doi.org/10.1111/j.1471-0528.2010.02763.x>

Impact Factor: 3.41  
Quality of Evidence: Acceptable  
Condition: Diabetes/Obesity

n=100 (50 insulin/50 oral metformin)

Randomized Control Study

Open label prospective randomized controlled study. There was no statistically significant difference Large for Gestational Age (LGA) , mean birthweight, mean cord artery pH, or neonatal morbidity between insulin and metformin. 15 clients needed insulin in addition to metformin. Caesarean section was higher in the metformin group. The study concluded that metformin was suitable for prevention of fetal adverse outcomes.

Imdad, A., & Bhutta, Z. A. (2012). Effects of calcium supplementation during pregnancy on maternal, fetal and birth outcomes. *Paediatric and Perinatal Epidemiology*, 26 Suppl 1, 138-152. doi: <http://dx.doi.org/10.1111/j.1365-3016.2012.01274.x>

Impact Factor: 1.95  
Quality of Evidence: Limited  
Condition: Preeclampsia/Eclampsia, Hypertension

n=Not Specified

Review of literature, RCTs-15

Review of literature to evaluate the preventive effect of calcium sulfate during pregnancy on gestational hypertensive disorders. Only RCTs were included; primary outcomes were preeclampsia, preterm birth and birth weight. Secondary outcomes were neonatal mortality, small for gestational age, and low birth weight. Calcium supplementation was significant in reducing the risk of maternal mortality/severe morbidity, and is associated with a reduction in the risk of gestational hypertensive disorders.

This literature review was also conducted to assess the preventive effects of calcium supplementation (dose and frequency varied) on gestational hypertensive disorders. There were 4,260 publications initially identified, from which 15 RCTs conducted between 1989 and 2009 were analyzed after all exclusionary criteria were applied. RCTs were conducted in both developing and industrialized countries. In the RCTs, supplementation was given orally vs. either placebo or no intervention. Measured outcomes were a 52% reduction in the risk of preeclampsia and a 25% reduction in the risk of severe preeclampsia, and no reduction in the risk of eclampsia. Other measured outcomes were "significant" reduction in the risk of maternal mortality/severe morbidity, and risk of pre-term birth. Additionally, there was a gain of an extra 85g in the treatment vs. control group, but no effect on perinatal mortality. There was statistically non-significant increase in the risk of kidney stones.

Ioscovich, A. M., Goldszmidt, E., Fadeev, A. V., Grisar-Granovsky, S., & Halpern, S. H. (2009). Peripartum anesthetic management of patients with aortic valve stenosis: a retrospective study and literature review. [Meta-Analysis, Review]. *International Journal of Obstetric Anesthesia*, 18(4), 379-386.

Impact Factor: 1.85  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n=12

#### Case and Series Review

Report discussed peripartum anesthetic management of patients with moderate and severe aortic stenosis (AS) in context with a systematic review of previously reported cases. Patients with mild or non-valvular AS were excluded. Of the 12 patients, 6 had moderate and 6 had severe AS. All patients had non-invasive monitoring of blood pressure (B/P) and EKG. One patient had an arterial line to measure B/P. Moderate AS: 4 vaginal and 2 cesarean deliveries. Epidural or combined spinal epidural analgesia was used for pain relief. Severe AS: 3 vaginal and 3 elective cesarean deliveries. Labor analgesia for the vaginal deliveries with severe AS: I.V. morphine, epidural lidocaine, and continuous epidural. Cesarean deliveries: 2 had general and 1 had epidural anesthesia. None of the patients experienced significant morbidity or died. Mode of delivery should be determined on the basis of obstetrical indications and with team input from the obstetrician, cardiologist, anesthesiologist and neonatologist. Carefully titrated regional analgesia is usually tolerated in patients undergoing vaginal delivery. Co-morbidities, indications for cesarean delivery and patient choice factor in the decision to administer neuraxial or general anesthesia for cesarean delivery. It is possible to use neuraxial anesthesia with sufficient time to titrate the desired effect. General anesthesia may be necessary in patients with critical AS or uncompensated failure.

Jeejeebhoy, F. M., Zelop, C. M., Windrim, R., Carvalho, J. C. A., Dorian, P., & Morrison, L. J. (2011). Management of cardiac arrest in pregnancy: a systematic review. [Review]. *Resuscitation*, 82(7), 801-809.

Impact Factor: 2.71  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n=Not Specified

#### Systematic review of literature

Systematic review of literature conducted to describe consensus on science for the resuscitation of the pregnant patient who experiences cardiac arrest. Five out of 1305 identified articles were selected for further review. Based upon this review it was determined that there were no RCTs that evaluated resuscitation techniques during cardiac arrest of the pregnant woman. The review noted that it is suggested that women should be tilted prior to chest compressions. This raised concerns with respect to: degree of tilt, resuscitation science and maternal physiology, and minimizing interruptions in chest compressions. Although the review noted that maternal and neonatal survival had been documented with perimortem cesarean section, it also noted that the procedure is rarely performed within the recommended 5 minutes of cardiac arrest. It was concluded that there is a lack of research on optimal resuscitation techniques for the pregnant woman and that additional study is needed.

John, A. S., Gurley, F., Schaff, H. V., Warnes, C. A., Phillips, S. D., Arendt, K. W., . . . Connolly, H. M. (2011). Cardiopulmonary bypass during pregnancy. *Annals of Thoracic Surgery*, 91(4), 1191-1196.

Impact Factor: 3.74  
 Quality of Evidence: limited  
 Condition: Cardiac Disease

n=21 pregnant women who had cardiothoracic surgery performed between 1976 and 2009.

#### Case Review

Study conducted to determine maternal/neonatal outcomes of cardio-pulmonary bypass during surgery. The operations included 8 aortic valve replacements, 6 mitral valve repair-replacements, 2 myxoma excisions, 2 aortic aneurysm repairs, 1 patent foramen ovale closure, 1 myectomy, and 1 prosthetic aortic valve thrombectomy. Median cardiopulmonary bypass time was 53 minutes. All patients demonstrated improvement to New York Heart Association functional class I or II. There was one maternal death 2 days after emergent mechanical aortic valve thrombectomy and 3 late maternal deaths that occurred 2, 10, and 19 years postoperatively. Three fetal deaths were reported in mothers with additional medical co-morbidities. Patients with congenital heart disease had higher rates of preterm deliveries and required emergent surgery more frequently. Fetal losses occurred with the urgent surgeries performed at an early gestational age. Although it was concluded that cardiothoracic surgery can be performed with relative safety during pregnancy, there are factors that should be taken into account: the surgery should be considered only after medical therapy has failed; normothermia, high flow cardio-pulmonary bypass and avoidance of surgery at an early gestational age should be attempted in order to minimize fetal complications; elective delivery prior to surgery should also be considered. In order to ensure the best outcome for mother and baby, patients should be managed by a multidisciplinary team including cardiologists, surgeons, maternal fetal medicine specialists, anesthesiologists, and neonatologists.

Jones, H. E., Kaltenbach, K., Heil, S. H., Stine, S. M., Coyle, M. G., Arria, A. M., . . . Fischer, G. (2010). Neonatal abstinence syndrome after methadone or buprenorphine exposure. [Historical Article, Randomized Controlled Trial, Research Support, N.I.H., Extramural]. *New England Journal of Medicine*, 363(24), 2320-2331.

Impact Factor: 53.3  
 Quality of Evidence: Acceptable  
 Condition: Psychiatric/Mental Health

n=175

Double-blind, double-dummy, flexible-dosing, randomized, controlled study.

Opioid dependence during pregnancy is typically treated with Methadone. Prenatal exposure to Methadone has been known to result in neonatal abstinence syndrome (NAS). Buprenorphine has been identified as an alternative treatment to methadone for opioid dependence during pregnancy. This study was conducted to review the following primary outcomes of treatment with buprenorphine vs. methadone: number of neonates requiring treatment for NAS, the peak NAS score, the total amount of morphine needed to treat NAS, the length of the hospital stay for neonates, and neonatal head circumference. Additional neonatal outcomes evaluated: the number of medication treatment days for NAS, weight and length at birth, preterm birth (defined as birth at <37 weeks of gestation), gestational age at delivery and 1 and 5-minute Apgar scores. 131 mothers completed the study through the end of pregnancy. 16 of 89 in the methadone group and 28 of 86 in the buprenorphine group discontinued treatment. Overall the results demonstrated positive outcomes for the group treated with buprenorphine for the following: significantly less morphine required (mean dose, 1.1 mg vs. 10.4 mg) and shorter hospital stay



(4.1 days vs. 9.9 days). The results were not significantly different for the remaining primary outcomes. A significant difference was demonstrated only in one of the secondary outcomes, a shorter duration of treatment for NAS (4.1 days vs. 9.9 days). The authors concluded that the demonstrated benefits of treatment with buprenorphine in reducing the severity of NAS in neonates suggest that it should be considered a first-line treatment option for mothers with opioid dependency during pregnancy.

Joseph, J. G., El-Mohandes, A. A. E., Kiely, M., El-Khorazaty, M. N., Gantz, M. G., Johnson, A. A., . . . Subramanian, S. (2009). Reducing psychosocial and behavioral pregnancy risk factors: results of a randomized clinical trial among high-risk pregnant african american women. [Multicenter Study, Randomized Controlled Trial, Research Support, N.I.H., Extramural]. *American Journal of Public Health, 99*(6), 1053-1061.

Impact Factor: 4.73

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=1044

#### Randomized Clinical Trial

This study reviewed clinic based interventions focused on 4 psychosocial risk factors associated with poor pregnancy outcomes for pregnant African-American women. The risk factors studied were: cigarette smoking, secondhand smoke exposure, depression, and intimate partner violence (IPV). The interventions were individualized, focused on the targeted psychosocial and behavioral risks, and were designed to be provided in prenatal care clinics. Although eight prenatal sessions were required to deliver the complete intervention, a minimum of 4 sessions were estimated to be adequate. The majority of the 452 women in the intervention group (60.2%) dealt with multiple risk factors. With consideration of risk factors in isolation, secondhand smoke exposure was the most common risk targeted (28.2%), and cigarette smoking was least common (1.6%). More than half (53.9%) of the enrolled women attended at least 4 intervention sessions, the mean number of sessions attended was 3.9. The overall results demonstrated that 58.0% of the women assigned to the intervention group resolved some or all of their risks, only 48.2% of those receiving usual care did so. Although larger studies are needed to extend the findings, the authors concluded that this study provided evidence that clinic-based behavioral interventions resulted in reductions in selected risk factors for poor reproductive outcomes.

Jovanovic, L., Savas, H., Mehta, M., Trujillo, A., & Pettitt, D. J. (2011). Frequent monitoring of A1C during pregnancy as a treatment tool to guide therapy. *Diabetes Care, 34*(1), 53-54.

Impact Factor: 8.09

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=24

#### Observational study of Latina women

Seeking rate of A1C decline in women with Gestational Diabetes Mellitus. The hypothesis was supported when researchers noted a declined in A1C when vigorous normoglycemia is instituted and achieved.

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Kayem, G., Kurinczuk, J. J., Alfirevic, Z., Spark, P., Brocklehurst, P., & Knight, M. (2011). Specific second-line therapies for postpartum haemorrhage: a national cohort study. [Multicenter Study, Research Support, Non-U.S. Gov't]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 118(7), 856-864. doi: <http://dx.doi.org/10.1111/j.1471-0528.2011.02921.x>

Impact Factor: 3.41  
Quality of Evidence: Acceptable  
Condition: Hemorrhage

n=272

Population-based Descriptive Study

This study focused on measuring the success and effectiveness of specific second-line therapies for postpartum hemorrhage. These second-line therapies included uterine compression sutures, pelvic vessel ligation, interventional radiology and rFVIIa, as well as hysterectomies. Overall uterine compression sutures and interventional radiology procedures had a higher success rate, 75% and 86% respectively, than rFVIIa and pelvic vessel ligation, 31% and 36% respectively. The rates of success did not differ significantly when used after uterotonic agents alone or after uterotonic agents and intrauterine tamponade combined.

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Klemmensen, A., Tabor, A., Osterdal, M. L., Knudsen, V. K., Halldorsson, T. I., Mikkelsen, T. B., & Olsen, S. F. (2009). Intake of vitamin C and E in pregnancy and risk of pre-eclampsia: prospective study among 57 346 women. [Research Support, Non-U.S. Gov't]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 116(7), 964-974.

Impact Factor: 3.97  
Quality of Evidence: Limited  
Condition: Preeclampsia/Eclampsia

n=57,346

Prospective Cohort Study

The article reviews a prospective Cohort study reviewing the intake of vitamin C and E and the risk of preeclampsia in pregnant women. Intake of diet was recorded for four weeks. Preeclampsia population was obtained from the Danish National Patient Registry. The incidence of preeclampsia or severe eclampsia did not correlate with any dietary vitamin C and E intake. A decreasing trend did occur in the incidence of severe eclampsia with increasing dietary vitamin C intake greater than 130-170 mg/day. The authors concluded overall, there was no relationship of vitamin C intake and preeclampsia. However, when severe complications with preeclampsia were considered, there was a trend towards an increased incidence in these conditions in women with low dietary vitamin C intake.

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Koopmans, C. M., Bijlenga, D., Groen, H., Vijgen, S. M. C., Aarnoudse, J. G., Bekedam, D. J., . . . group, H. s. (2009). Induction of labour versus expectant monitoring for gestational hypertension or mild pre-eclampsia after 36 weeks' gestation (HYPITAT): a multicentre, open-label randomised controlled trial. [Comparative Study, Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *Lancet*, 374(9694), 979-988.

Impact Factor:38.28  
 Quality of Evidence: Acceptable  
 Condition: Hypertension

n=756

RCT

This RCT was conducted at 38 hospitals in the Netherlands from October 2005 through March 2008 among women at 36-41 weeks gestation with singleton pregnancies complicated by gestational hypertension or mild preeclampsia. Subjects were assigned to either expectant monitoring or induction of labor. 31% of the labor induction group and 44% of the expectant monitoring group developed poor maternal outcome, defined as either maternal mortality, maternal morbidity (eclampsia, HELLP syndrome, pulmonary edema, thromboembolic disease, or placental abruption), severe hypertension or proteinuria, or major postpartum hemorrhage of >1000 ccs. Authors conclude that induction of labor is associated with improved maternal outcome and should be offered to women with mild hypertensive disease beyond 37 weeks gestation.

Landon, M. B., Spong, C. Y., Thom, E., Carpenter, M. W., Ramin, S. M., Casey, B., . . . Human Development Maternal-Fetal Medicine Units, N. (2009). A multicenter, randomized trial of treatment for mild gestational diabetes. [Multicenter Study, Randomized Controlled Trial, Research Support, N.I.H., Extramural]. *New England Journal of Medicine*, 361(14), 1339-1348.

Impact Factor: 47.05  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=958

Randomized Controlled Trial

Measured outcome was still born or perinatal death and neonatal complications, including hypobileremia, hypoglycemia, hyperinsulinemia and birth trauma. Treatment consisted of dietary interventions, self monitoring of blood glucose, and insulin therapy if necessary. No treatment of mild gestational diabetes was found to significantly reduce the frequency of death. Treatment did lower the secondary outcomes such as a reduction in fetal overgrowth, shoulder dystocia, cesarean delivery and preeclampsia. This supported the findings from the ACHOIS trial.

Leduc, D., Senikas, V., Lalonde, A. B., Ballerman, C., Biringer, A., Delaney, M., . . . Gynaecologists of, C. (2009). Active management of the third stage of labour: prevention and treatment of postpartum hemorrhage. [Practice Guideline, Research Support, Non-U.S. Gov't, Review]. *Journal of Obstetrics & Gynaecology Canada: JOGC*, 31(10), 980-993.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

This is a guideline written by the Society of Obstetricians and Gynaecologists of Canada (SOGC) that provides guidelines for the prevention and management of postpartum hemorrhage. The quality of evidence was rated with use of criteria described by the Canadian Task Force on Preventative Health Care.

Relevant recommendations for the prevention of postpartum hemorrhage are:

- 10 IU of oxytocin administered intramuscularly in low risk vaginal deliveries (I-A)
- Ergonovine is second choice to oxytocin use, due to adverse effects (I-A)
- Carbetocin, 100 µg should be given as an IV bolus over 1 minute during an elective cesarean section for prevention of postpartum hemorrhage and to reduce the need for additional uterotonics. (I-B)
- Women delivering vaginally with one risk factor for post partum hemorrhage (PPH) should be administered carbetocin 100 µg (I-B)
- Delaying cord clamping by at least 60 seconds is preferred to clamping earlier in premature newborns (I-A)
- Intraumbilical cord injection of misoprostol (800 µg) or oxytocin (10 µg to 30 IU) can be considered. (II-2C)

Relevant treatment recommendations are as follows:

- Management of PPH requires a multidisciplinary approach (III-C)
- Uterine tamponade can be considered when PPH is caused by uterine atony and there has been no response to other medical therapy (III-L)
- Surgical techniques should be used for the management of intractable PPH unresponsive to medical therapy (III-B)

Lee, H. Y., Shin, J. H., Kim, J., Yoon, H.-K., Ko, G.-Y., Won, H.-S., . . . Sung, K.-B. (2012). Primary postpartum hemorrhage: outcome of pelvic arterial embolization in 251 patients at a single institution. *Radiology*, 264(3), 903-909.

Impact Factor: 6.34

Quality of Evidence: Limited

Condition: Hemorrhage

n=251

Retrospective Single Center Study

This study assessed the outcome of pelvic arterial embolization in primary postpartum hemorrhage. Pelvic arterial embolization had a clinical success rate of 89.5%. Overall, the study found that pelvic arterial embolization is a safe and effective intervention for managing primary postpartum hemorrhage.

Livingston, J. C., Livingston, L. W., Ramsey, R., Mabie, B. C., & Sibai, B. M. (2003). Magnesium sulfate in women with mild preeclampsia: a randomized controlled trial. [Clinical Trial, Comment, Comparative Study, Randomized Controlled Trial]. *Obstetrics & Gynecology*, 101(2), 217-220.

Impact Factor: 4.73

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n=222

RCT

The article reviews a RCT for IV Magnesium Sulfate or matched placebo for patients with mild preeclampsia with blood pressure of 140/90. Patients with hypertension previous to pregnancy were excluded. Magnesium sulfate was not found to have any effect on major disease progression from mild preeclampsia to severe preeclampsia. No differences were found in caesarean rate, infection, hemorrhage or neonatal depression, demonstrated by APGAR scores.

Louie, J. C. Y., Markovic, T. P., Perera, N., Foote, D., Petocz, P., Ross, G. P., & Brand-Miller, J. C. (2011). A randomized controlled trial investigating the effects of a low-glycemic index diet on pregnancy outcomes in gestational diabetes mellitus. [Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *Diabetes Care*, 34(11), 2341-2346.

Impact Factor: 8.09

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=98

Randomized Controlled Trial

Investigation of the low glycemic index (LGI) to modify the diet versus conventional high fiber diet. The measurement was pregnancy outcomes such as: average birth weight, birth weight percentile, and ponderal index were all within healthy norms in both groups.

Magee, L. A., & Duley, L. (2003). Oral beta-blockers for mild to moderate hypertension during pregnancy. [Review]. *Cochrane Database of Systematic Reviews*(3), CD002863.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Hypertension

n= Not Specified

Cochrane Pregnancy and Childbirth Group Trials Register

This review of the Cochrane Pregnancy and Childbirth Group Trials Register was done in 2004 and updated in 2012 to elicit whether oral beta blockers were more effective than placebo, no intervention, or other antihypertensives in controlling mild to moderate gestational hypertension. Oral beta-blockers decrease the risk of severe hypertension (11 trials n=1128) and the need for additional anti-hypertensives (7 trials n= 856) by an increase in small-for-gestational-age infants (n= 1136, 12 trials). Authors conclude that there is no benefit in using oral beta-blockers and large RCT's are needed.

McDonald, S., Abbott, J. M., & Higgins, S. P. (2004). Prophylactic ergometrine-oxytocin versus oxytocin for the third stage of labour. [Review]. *Cochrane Database of Systematic Reviews*(1), CD000201.

Impact Factor: 5.72

Quality of Evidence: Acceptable  
Condition: Hemorrhage

n=9332

Cochrane Systematic Review; RCTs=6

The review compared the effects of syntometrine and oxytocin in reducing the risk of postpartum hemorrhage (blood loss of at least 500 ml) and other maternal and neonatal outcomes. The results demonstrated a significant reduction in the risk of postpartum hemorrhage for the women who were administered syntometrine when compared to oxytocin for blood loss of 500 ml or more. However, there was no significant difference in blood loss of 1000 ml or more. There was a reduction in the additional use of uterotonics with the administration of syntometrine. A downfall to syntometrine when compared to oxytocin is that it is associated with more side effects such as nausea and vomiting. As for neonatal outcomes, two of the trials reported on neonatal outcomes which included: Apgar score and jaundice. The outcomes had no significant differences between syntometrine and oxytocin. There were differences reported for maternal outcomes either.

The authors did note that the the decision of which uterotonic drug depends on how much importance the clinician, or obstetrical center places on:

- (a) "the lower category of blood loss (at least 500 ml)"
- (b) "the higher category of blood loss ( at least 1000 ml)"
- (c) "maternal morbidity associated with side effects of vomiting and hypertension"
- (d) "the setting in which maternity care is being undertaken"

McLintock, C., McCowan, L. M. E., & North, R. A. (2009). Maternal complications and pregnancy outcome in women with mechanical prosthetic heart valves treated with enoxaparin. [Multicenter Study]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 116(12), 1585-1592.

Impact Factor: 3.41

Quality of Evidence: Limited

Condition: Cardiac Disease

n= 31 women, 47 pregnancies.

Retrospective Audit

Study conducted to review maternal/fetal outcomes in women with mechanical heart valves managed with enoxaparin during pregnancy. Study involved a retrospective audit of pregnant women with mechanical heart valves treated with enoxaparin at any stage during pregnancy with deliveries between January 1997 and July 2008 at two tertiary referral hospitals in New Zealand. The outcome of the 47 pregnancies is as follows:

At  $\leq$  12 weeks there were 7 miscarriages and 1 termination of pregnancy.

From 12 - 19 weeks there was 1 miscarriage and 3 pregnancy terminations.

35 pregnancies survived > 20 weeks.

Thromboembolic complications occurred in 7 pregnancies and they were associated with enoxaparin therapy. There were 8 pregnancies with hemorrhagic complications. Overall the data suggested that administration of therapeutic dose enoxaparin in combination with low-dose aspirin can be used for prevention of valve thrombosis in pregnant women with mechanical heart valves. Close clinical follow-up by a multidisciplinary team is crucial if enoxaparin is the chosen anticoagulant.

Mecacci, F., Carignani, L., Cioni, R., Bartoli, E., Parretti, E., La Torre, P., . . . Mello, G. (2003). Maternal metabolic control and perinatal outcome in women with gestational diabetes treated with regular or lispro insulin: comparison with non-diabetic pregnant women. [Clinical Trial, Comparative Study, Randomized Controlled Trial]. *European Journal of Obstetrics, Gynecology, & Reproductive Biology*, 111(1), 19-24.

Impact Factor: 1.97

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n= 49

Randomized Controlled Trial

Maternal metabolic control with regular vs. lispro insulin. Maternal glucose was managed better (considered by nine determinants of fast/ pre-prandial, 1 and 2 hour post prandial levels). Babies from the regular insulin group had larger cranial-thoracic circumference ratio.

Mian, A. I. (2005). Depression in pregnancy and the postpartum period: balancing adverse effects of untreated illness with treatment risks. [Review]. *Journal of Psychiatric Practice*, 11(6), 389-396.

Impact Factor: 2.16

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=Unspecified

Literature Search

PubMed and safety data were searched; as in other reviews of this type and subject, no trials were found. Therefore, case reports, animal data, and retrospective case series were included in reviewing the risks and benefits of untreated maternal depression during pregnancy and the post-natal period and its effects on well-being of the mother and infant. There is a review of the harmful effects of untreated maternal depression on infants; no specific associated data is provided, other than bibliographic reference, to substantiate conclusions, which appear at times to be author opinion. The next section summarizes findings related to anti-depressant medication use (again, there are no controlled studies):

- Tricyclic antidepressants – there are two case reports of withdrawal seizures and some neonatal anticholinergic symptoms reported.
  - Selective serotonin reuptake inhibitors (SSRIs) – Questionable slightly increased risk of miscarriage (2 studies), increased risk of major malformation with paroxetine use, inconsistent results for other drugs.
  - SSRI exposure also causes increased neurobehavioral problems in newborns.
- Use of pharmacologic agents during lactation has not been extensively studied, but small series and case reports suggest no significant effects of exposure through breast milk on breastfed newborns.

Authors reference the Expert Consensus Guidelines on the Treatment of Depression in Women (2001) and note the recommendation for the use of psychotherapy in milder cases of depression, with the use of medication reserved for failure cases and those with severe depression. Authors conclude that adequate prenatal screening for depressive illness is warranted, since maternal depressive illness can have adverse effects on neonatal behavioral outcomes.

Misri, S., & Kendrick, K. (2007). Treatment of perinatal mood and anxiety disorders: a review. [Review]. *Canadian Journal of Psychiatry - Revue Canadienne de Psychiatrie*, 52(8), 489-498.

Impact Factor: 2.42  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=Unspecified  
 Literature Review

This review of PubMed and Medline was conducted to review treatment modalities for prenatal mood and anxiety disorders. There is discussion of the findings of studies as they relate to effects of untreated mental illness, both maternal and neonatal effects. There is review of non-pharmacological treatment (psychotherapy), with most studies finding that 1) cognitive behavioral therapy is effective in reducing maternal symptoms and improving maternal/infant bonding, and 2) interpersonal therapy was largely effective in improving depressive symptoms prenatally and postpartum. Other adjunctive therapies have been assessed in small studies and while light therapy, acupuncture, herbal remedies and massage are promising, further research is needed.

There is a review of pharmacological treatment, by drug class and drug. There is no drug or drug class that has been associated with a total absence of side effects for the neonate, but again, evidence is at times contradictory, depending on study design, definitions, and confounding factors. There are also adverse effects for mothers and babies when medications are suddenly stopped; withdrawal symptoms are common. Authors conclude that anti-depressive medication use in pregnancy, while effective, has caused clinical concerns, and the evidence for psychotherapies and alternative therapies is insufficient to recommend them as first-line treatments. Best practice is therefore presenting patients with current knowledge, engaging them in treatment decisions, and monitoring them closely, whichever treatment is chosen.

Moore, L. E., Briery, C. M., Clokey, D., Martin, R. W., Williford, N. J., Bofill, J. A., & Morrison, J. C. (2007). Metformin and insulin in the management of gestational diabetes mellitus: preliminary results of a comparison. [Randomized Controlled Trial]. *Journal of Reproductive Medicine*, 52(11), 1011-1015.

Impact Factor: 0.69  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n= 63  
 Randomized Clinical Trial  
 Metformin vs. Insulin, outcomes were compared.

Outcomes compared fasting glucose and post prandial glucose of mothers. Neonatal outcomes compared include birthweight, APGAR score, NICU admission, hypoglycemia, respiratory distress, and hypobileremia. No statistical difference was found. Metformin is a safe alternative to insulin.



Moore, T. R. (2007). Glyburide for the treatment of gestational diabetes. A critical appraisal. [Review]. *Diabetes Care*, 30 Suppl 2, S209-213.

Impact Factor: 8.09  
Quality of Evidence: Limited  
Condition: Diabetes/Obesity

n= 404

Randomized Controlled Trial

This author supports the statistical power of the Glyburide RCT's. These established from the review include:

- 1The rate of glyburide failure is small in most clinical populations.
- 2.The rate of neonatal hypoglycemia/hypobileremia is increased with glyburide compared to insulin
3. Maternal fasting and post prandial glucose are lower with glyburide

Conclusions state that use of oral hypoglycemic agents are safe in this pregnant population, along with growing evidence to support the use of oral agents combined with insulin.

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Mori, R., Nardin, J. M., Yamamoto, N., Carroli, G., & Weeks, A. (2012). Umbilical vein injection for the routine management of third stage of labour. [Meta-Analysis, Research Support, Non-U.S. Gov't, Review]. *Cochrane Database of Systematic Reviews*, 3, CD006176.

Impact Factor: 5.72  
Quality of Evidence: Limited  
Condition: Hemorrhage

n=1,118

Cochrane Review, RCTS=6

The objective of the review was to analyze 9 studies and compare the effects of umbilical vein injection of any uterotonic agent, saline solution, expectant management or any other method of routine management of the third stage of labor on maternal and perinatal outcomes. The findings demonstrated that injection of a saline solution plus oxytocin, versus an injection of saline solution alone, did not improve or change the amount of blood lost. The author concluded routine use of oxytocin or any other uterotonics with normal saline via umbilical vein injection is not recommended until new evidence is available. Further research should be conducted to show effectiveness of oxytocin with normal saline via umbilical vein injection."

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Mukhopadhyay, A., Farrell, T., Fraser, R. B., & Ola, B. (2007). Continuous subcutaneous insulin infusion vs intensive conventional insulin therapy in pregnant diabetic women: a systematic review and metaanalysis of randomized, controlled trials. [Comparative Study, Meta-Analysis, Review]. *American Journal of Obstetrics & Gynecology*, 197(5), 447-456.

Impact Factor: 3.28  
Quality of Evidence: Limited  
Condition: Diabetes/Obesity

n= Not Specified

68 Randomized Control Trials

Systematic review on Insulin infusion vs. conventional insulin therapy. Included 6 primary studies which include Coustan above. Conclusion was that there were no significant differences in birth weight with differing types of insulin. Still birth was unchanged. Insulin pumps raised issues with cost, and patient acceptability. Authors could not conclude a clear cut benefit to the use of insulin infusions.

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Murphy, H. R., Rayman, G., Lewis, K., Kelly, S., Johal, B., Duffield, K., . . . Temple, R. C. (2008). Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. [Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *BMJ*, 337, a1680. doi: <http://dx.doi.org/10.1136/bmj.a1680>

Impact Factor: 13.66  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= 71

Randomized Controlled Trial

Evaluation of continuous glucose monitoring. Type I and Type II diabetes were segmented out. The researchers evaluated maternal glycemic control and HgB A1C. Mothers who had continuous monitoring had lower mean A1C, (5.8%). Neonatal birthweight was also decreased with a standard deviation score of 0.9 vs. 1.6 effect size 0.7 SD, 95% CI 0.0 to 1.3). This is associated with improved glycemic control in the third trimester, with an outcome of lower birthweight and reduced risk of macrosomia.

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Nelson, W. L., & O'Brien, J. M. (2007). The uterine sandwich for persistent uterine atony: combining the B-Lynch compression suture and an intrauterine Bakri balloon. *American Journal of Obstetrics & Gynecology*, 196(5), e9-10.

Impact Factor: 3.28  
 Quality of Evidence: Limited  
 Condition: Hemorrhage

n=5

Retrospective Review of Cases

This study, between May 2003 and May 2006, assessed the effectiveness of the combination of the B-Lynch compression suture and an intrauterine Bakri balloon tamponade. The uterine sandwich technique, which is the combination of the B-lynch suture and the intrauterine balloon, was successful in all cases to obviate the need for a hysterectomy, and further blood loss was stopped.

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Newport, D. J., Viguera, A. C., Beach, A. J., Ritchie, J. C., Cohen, L. S., & Stowe, Z. N. (2005). Lithium placental passage and obstetrical outcome: implications for clinical management during late pregnancy. [Research Support, N.I.H., Extramural]. *American Journal of Psychiatry*, 162(11), 2162-2170.

Impact Factor: 12.54  
 Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=42

#### Report of Studies

A very small study (n=10) of participants was combined with published results of other studies (n=32) assessing the effects of maternal lithium levels at delivery on perinatal events, to determine if lithium levels at delivery can be lowered by briefly suspending lithium administration, and to quantify the rate of lithium passage. It was found that lower 1-minute Apgar scores, longer hospital stays, and increased nervous system and neuromuscular complications were seen in infants with higher lithium concentrations at delivery. It was also found that withholding lithium 24-48 hours prior to delivery resulted in a lower lithium concentration in the neonate at delivery. Based upon their findings the authors propose the following guidelines are proposed:

- Monitor lithium concentrations and use the lowest effective dose.
- Lower lithium dose if maternal complications arise.
- Briefly suspend lithium administration 24-48 hours before scheduled delivery or at the onset of labor for unscheduled deliveries.
- Administer fluids throughout labor and delivery; check maternal lithium levels if toxicity appears present.
- Reinstatement lithium at the pre-conception dose when medically stable after delivery.

Nguyen, H. T. T., Sharma, V., & McIntyre, R. S. (2009). Teratogenesis associated with antibipolar agents. [Review]. *Advances in Therapy*, 26(3), 281-294.

Impact Factor: 2.11

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=Not Specified

#### Literature review.

Published articles from January 1966 - December 2008. Sources also included manual review of articles and information obtained from the clinical trial repository, the FDA web page, and several pregnancy registries. Review conducted to assess the teratogenic effects associated with use of approved agents for bipolar disorder. The drugs reviewed were: valproate, lamotrigine, carbamazepine, lithium, and antipsychotics. The teratogenic effects that were reviewed included: CV=cardiovascular; GIT=gastrointestinal; Neuro=neurological; OF=orofacial; UG=urogenital. Adverse effects were reported in all areas for the following drugs: valproate, lamotrigine, and carbamazepine. With the exception of CV effects, there was insufficient data for Lithium and antipsychotics for the other noted categories. Developmental delays were reported in children exposed to valproate, lamotrigine, and carbamazepine. There was no reported effect for Lithium and insufficient data for antipsychotics. Overall, safe and appropriate treatment of bipolar disorder during pregnancy must consider the need to balance the risk of recurrence with the hazards of teratogenic effects attributable to antibipolar agents. The authors acknowledge a lack of data on the teratogenesis of antibipolar agents and express the need for more research with an emphasis on treatment during pregnancy.

Nij Bijvank, S. W. A., & Duvekot, J. J. (2010). Nicardipine for the treatment of severe hypertension in pregnancy: a review of the literature. [Review]. *Obstetrical & Gynecological Survey*, 65(5), 341-347.

Impact Factor: Not Available  
Quality of Evidence: Limited  
Condition: Hypertension

n= 147

Literature review (CME article) 5 studies (1 RCT; 4 observational or retrospective)

Review of Medline and Cochrane literature was undertaken to determine the effectiveness of nicardipine in lowering blood pressure among women with pre-existing or gestational hypertension. All patients experienced lowering of blood pressure; 87% had either a 20% reduction in arterial pressure or systolic/diastolic blood pressure. Target blood pressure was reached within 23 minutes in 70% of patients.

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Nirmala, K., Zainuddin, A. A., Ghani, N. A. A., Zulkifli, S., & Jamil, M. A. (2009). Carbetocin versus syntometrine in prevention of post-partum hemorrhage following vaginal delivery. [Comparative Study, Randomized Controlled Trial]. *Journal of Obstetrics & Gynaecology Research*, 35(1), 48-54.

Impact Factor: 0.94  
Quality of Evidence: Acceptable  
Condition: Hemorrhage

n=120

Prospective, Randomized Controlled Study

The study assessed the effectiveness of a single dose of 100 µg intramuscular carbetocin to a single dose of intramuscular syntometrine in preventing postpartum hemorrhage in patients that delivered vaginally, who were at high risk for post partum hemorrhage. The results showed a lower estimated blood loss in the carbetocin group than the syntometrine group. The carbetocin group also had a reduced drop in hemoglobin in comparison to the syntometrine group. Overall, a single 100 µg intramuscular dose of carbetocin may be more effective than a single intramuscular syntometrine in reducing postpartum hemorrhage after a vaginal delivery.

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Ouahba, J., Piketty, M., Huel, C., Azarian, M., Feraud, O., Luton, D., . . . Oury, J. F. (2007). Uterine compression sutures for postpartum bleeding with uterine atony. *BJOG: An International Journal of Obstetrics & Gynaecology*, 114(5), 619-622.

Impact Factor: 3.41  
Quality of Evidence: Limited  
Condition: Hemorrhage

n=20

Retrospective Study

This retrospective study assessed the effectiveness of uterine compression suturing technique in reducing postpartum hemorrhage in women with uterine atony and postpartum bleeding that did not react to usual medical management. In 95% of the women, the uterine compression

sutures immediately stopped the bleeding. There were no documented complications related to the suturing.

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Owe, K. M., Nystad, W., & Bo, K. (2009). Association between regular exercise and excessive newborn birth weight. [Research Support, N.I.H., Extramural, Research Support, Non-U.S. Gov't]. *Obstetrics & Gynecology*, 114(4), 770-776.

Impact Factor: 4.73

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=36,869

Norwegian Mother and Child Cohort Study

The article reviewed effects of regular exercise and excessive newborn birth weight.

Questionnaires were reviewed about maternal lifestyle, previous disease and the use of medication during pregnancy. No outcomes determined to affect maternal fetal morbidity or mortality.

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Oyebode, F., Rastogi, A., Berrisford, G., & Coccia, F. (2012). Psychotropics in pregnancy: safety and other considerations. *Pharmacology & Therapeutics*, 135(1), 71-77.

Impact Factor: 8.9

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=Unspecified

Systematic literature review

Review of electronic literature published between 2000 and August 2011 was undertaken to assess the effects of psychotropic medication use in pregnancy. Anticonvulsants were excluded. There was consensus that pregnant mothers exposed to antidepressants are more likely to have spontaneous abortions, stillbirths, and preterm deliveries (9 studies, n=unstated). There is considerable evidence that 1) fetuses exposed to anti-depressants are delivered small for gestational age (4 studies), and 2) fetuses exposed to anti-depressants in the third trimester are associated with lower 5-minute Apgar scores, respiratory distress syndrome, convulsions, jaundice and other disorders (8 studies). However, the risk of major malformations does not appear to be elevated (7 studies). There is inconclusive evidence of the effect of exposure on subsequent infant and childhood mental development, with most studies reporting no noticeable effect (6 studies). There follows a summary of the adverse effects identified with administration of specific drugs such as lithium and clozapine. Authors conclude that the current evidence cannot serve as a basis for a guideline or treatment algorithm, but certain medications should be avoided and there needs to be a balance between the risks and benefits of medication in treating depressed pregnant patients.

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Patton, S. W., Misri, S., Corral, M. R., Perry, K. F., & Kuan, A. J. (2002). Antipsychotic medication during pregnancy and lactation in women with schizophrenia: evaluating the risk. [Review]. *Canadian Journal of Psychiatry - Revue Canadienne de Psychiatrie*, 47(10), 959-965.

Impact Factor: 2.42  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=Unspecified

Literature Review

Review of Medline articles published from 1966-2001 was undertaken to assess whether exposure to antipsychotic medications during pregnancy and lactation was associated with increased teratogenicity, or neonatal or later behavioral sequelae, whether schizophrenia affects pregnancy outcome, and whether schizophrenia symptoms are altered by pregnancy and lactation. Included are case reports; few studies exist and those that do lack detail. Authors conclude that women with schizophrenia are at increased risk for poor outcomes, including preterm delivery, low birth weight and small-for-gestational age, based on a Danish 20 year retrospective review. They also conclude that infants exposed to phenothiazines in utero at weeks 4 to 10 of gestation carry an increased risk of congenital malformations. Authors call for further studies.

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Peitsidis, P., & Kadir, R. A. (2011). Antifibrinolytic therapy with tranexamic acid in pregnancy and postpartum. [Meta-Analysis, Review]. *Expert Opinion on Pharmacotherapy*, 12(4), 503-516.

Impact Factor: 3.2  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

n=912

Systematic Review;

A systematic review, yielding 35 articles (studies dating from 1976 to 2010) was conducted analyzing the evidence on the use, efficacy, and safety of tranexamic acid in the management of hemorrhage during pregnancy and for the treatment and prevention of postpartum hemorrhage. Findings were that tranexamic acid reduces the amount of blood loss after both cesarean sections and vaginal deliveries and reduces the requirement for blood transfusions. It was also deemed safe and effective in the prevention and management of bleeding during pregnancy, thus reducing the risk of a miscarriage. Tranexamic acid has also been shown to reduce bleeding for women with antepartum hemorrhage due to placenta abruption or placenta previa. The study noted that there have not been any significant reports of maternal or neonatal adverse outcomes.

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Pereira, T. V., Rudnicki, M., Soler, J. M. P., & Krieger, J. E. (2006). Meta-analysis of aspirin for the prevention of preeclampsia: do the main randomized controlled trials support an association between low-dose aspirin and a reduced risk of developing preeclampsia? [Comment, Letter]. *Clinics (Sao Paulo, Brazil)*, 61(2), 179-182.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Preeclampsia/Eclampsia

n=16, 898

Meta analysis, RCT=14

Meta analysis was conducted reviewing studies that examined the use of aspirin (ASA) for prevention of preeclampsia. When 14 RCTs were compared, it was found that the earlier trials that provided evidence of improvement in preeclampsia had smaller populations. This provided the community with an impression of improved outcomes, which may not be generalizable to the population. Methodology was reviewed and it was determined that heterogeneity may have affected the results. The authors concluded that the relationship between ASA treatment and the reduction of preeclampsia remains an unresolved issue.

Peters, N. C. J., & Duvekot, J. J. (2009). Carbetocin for the prevention of postpartum hemorrhage: a systematic review. [Review]. *Obstetrical & Gynecological Survey*, 64(2), 129-135.

Impact Factor: 2.51  
 Quality of Evidence: Limited  
 Condition: Hemorrhage

n=1,163

Systematic Review, RCT-Double-Blinded=4

The study analyzed 5 trials that focused on the efficacy of carbetocin in the management of postpartum hemorrhage. Outcome measured was blood loss. The review concluded that carbetocin probably is as effective as oxytocin or syntometrine in the prophylactic management of postpartum hemorrhage.

Poston, L., Briley, A. L., Seed, P. T., Kelly, F. J., Shennan, A. H., & Vitamins in Pre-eclampsia Trial, C. (2006). Vitamin C and vitamin E in pregnant women at risk for pre-eclampsia (VIP trial): randomised placebo-controlled trial. [Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *Lancet*, 367(9517), 1145-1154.

Impact Factor: 23.46  
 Quality of Evidence: Limited  
 Condition: Preeclampsia/Eclampsia

n= 2410

RCT

Women from 25 hospitals who were at an increased risk of preeclampsia were entered into the trial. There was random assignment of 1000mg of Vitamin C and 400 IU of Vitamin E, versus a matched placebo. The primary measured outcomes were preeclampsia and low birth weight, or small for gestational age. Preeclampsia incidence was similar in both groups; no statistical difference was found. More low birth weight babies were born to women who took Vitamin C and Vitamin E than to the controls, but incidence of small for gestational age did not differ in either group.

Price, N., Bartlett, C., & Gillmer, M. (2007). Use of insulin glargine during pregnancy: a case-control pilot study. *BJOG: An International Journal of Obstetrics & Gynaecology*, 114(4), 453-457.

Impact Factor: 3.34  
 Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=64

Case Control Study

Examining use of insulin in pregnancy to reduce macrosomia. Compared insulin glargine with intermediate-acting human insulin (isophane or insulin zinc suspension) . Outcomes measured were weight, height, gestation at delivery, parity , fetal sex, duration of insulin use in pregnancy, glycemc control in third trimester by HgB A1C.

No difference was found in rate of fetal macrosomia.

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Rahimi, R., Nikfar, S., Rezaie, A., & Abdollahi, M. (2009). A meta-analysis on the efficacy and safety of combined vitamin C and E supplementation in preeclamptic women. [Meta-Analysis, Research Support, Non-U.S. Gov't]. *Hypertension in Pregnancy*, 28(4), 417-434.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n=5969

Meta analysis, RCT= 7

A meta analysis was conducted for the efficacy and safety of combined Vitamin C and E supplementation in women who were at risk for preeclampsia, and thus subject to adverse maternal and neonatal disorders. Seven studies were reviewed for gestational hypertension, preeclampsia, preterm delivery, small for gestational age, and low birth weight. The authors found that the combined Vitamin C and E supplementation not only had no benefit in reducing the incidence of poor maternal and neonatal outcomes, but it increased the risk of gestational hypertension in woman at risk for preeclampsia and low birth weight.

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Rath, W. (2009). Prevention of postpartum haemorrhage with the oxytocin analogue carbetocin. [Research Support, Non-U.S. Gov't, Review]. *European Journal of Obstetrics, Gynecology, & Reproductive Biology*, 147(1), 15-20.

Impact Factor: 1.97

Quality of Evidence: Acceptable

Condition: Hemorrhage

n=1,510

Review, 5 Randomized Controlled Trials

Review of the efficacy of carbetocin in the prevention of postpartum hemorrhage. Three randomized controlled trials found that when compared to a placebo or intravenous oxytocin, a single intravenous injection of 100 µg of carbetocin was shown to significantly reduce the need for additional uterotonic agents or uterine massage to prevent excessive bleeding. Review findings also suggested that carbetocin could be used as an alternative uterotonic agent for prevention of postpartum hemorrhage after vaginal deliveries in high risk women; this is due to carbetocin's capability to act for longer period of time when compared to intravenous oxytocin.

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Rath, W., Hackethal, A., & Bohlmann, M. K. (2012). Second-line treatment of postpartum haemorrhage (PPH). *Archives of Gynecology & Obstetrics*, 286(3), 549-561.

Impact Factor: 0.91

Quality of Evidence: Limited

Condition: Hemorrhage

n=Not Specified

Literature Review

Review of second-line treatments for postpartum hemorrhage, including uterine tamponade, selective arterial embolization, surgical procedures, uterine sutures, arterial ligation, and peripartum hysterectomy. Findings of the uterine tamponade suggested it may be an effective treatment after vaginal delivery when the cause of hemorrhage is uterine atony. Case series that were reviewed and a systemic review that was analyzed reported success rates of 71 to 100% and 84%, for the use of uterine balloon tamponade. If arterial embolization is unsuccessful, surgical interventions may be considered and have also been shown to be effective. Uterine compression sutures have been recommended as a first-line measure, preventing hysterectomy in patients with uterine atony who respond to bimanual compression; this intervention requires less skill and is associated with fewer complications -therefore it may be more effective than arterial ligation. Uterine compression sutures are mostly used in cesarean sections. A systematic review reported a success rate of 91.7% for various uterine compression sutures. Internal iliac artery ligation has been replaced by other procedures, due to its difficulty and not being more effective than other procedures; it also requires more advanced and skilled surgical personnel, and carries an increased risk of venous, ureteral and nervous damage. As for a hysterectomy, the procedure should be performed before catastrophe derived from massive blood loss hemodynamic instability, and significant coagulopathy, which is inevitable.

Rayburn, W. F., & Bogenschutz, M. P. (2004). Pharmacotherapy for pregnant women with addictions. [Research Support, Non-U.S. Gov't, Review]. *American Journal of Obstetrics & Gynecology*, 191(6), 1885-1897.

Impact Factor: 3.47

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=Unspecified

Systematic Literature Review

The stated purpose of this review was to summarize the literature related to pharmacotherapy for pregnant women with addictions. Studies are difficult to design and most information comes from animal studies, adverse event reports and case reports; confounders such as adverse lifestyles and multiple addictions are common in reported occurrences. The fetal effects reported in more than 2 studies were listed for alcohol, cigarettes, cannabis, nervous system stimulants, and narcotics. Principles of treatment are a blend of psychological and pharmacological therapy, the latter of which is divided into 2 approaches – detoxification, and maintenance to avoid relapse. There follows a series of reports not limited to pregnant patients and inclusive of animal studies that detail adverse fetal effects from various abused substances and the medications used to treat them. Authors conclude that a trial of psychosocial treatment should be done before pharmacotherapy for alcohol or nicotine dependence, but opioid

dependence and moderate-to-severe alcohol withdrawal should be treated more aggressively with pharmacotherapy. Specialized, integrated treatment programs are recommended.

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Ronnberg, A. K., & Nilsson, K. (2010). Interventions during pregnancy to reduce excessive gestational weight gain: a systematic review assessing current clinical evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system. [Research Support, Non-U.S. Gov't, Review]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 117(11), 1327-1334. doi: <http://dx.doi.org/10.1111/j.1471-0528.2010.02619.x>

Impact Factor: 3.34  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= Not Specified

4 Randomized Controlled Trials

Investigation of current clinical evidence of interventions during pregnancy to reduce excessive weight gain. Extracted data from four RCT studies were evaluated using the GRADE system. Evidence resulted in mixed results for reducing weight gain during pregnancy. To reduce total weight gain that was in excess of the IOM recommendations is the national challenge. None of the trials were able to result in successful outcomes.

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Rossi, A. C., & Mullin, P. M. (2011). Prevention of pre-eclampsia with low-dose aspirin or vitamins C and E in women at high or low risk: a systematic review with meta-analysis. [Meta-Analysis, Review]. *European Journal of Obstetrics, Gynecology, & Reproductive Biology*, 158(1), 9-16.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Preeclampsia/Eclampsia

n=5027

Systematic review with meta analysis, RCTs=15

The authors conducted a systematic review with meta analysis of reduction of preeclampsia with low dose aspirin (ASA), dose not specific, or Vitamins C and E. Low dose ASA did not decrease the incidence of preeclampsia in high risk patients. Vitamins C and E did not reduce the incidence of preeclampsia in high risk or low risk women vs. placebo. Prenatal outcomes were not improved by use of low dose ASA or Vitamins C or E. There is no evidence to support use of these agents to prevent preeclampsia.

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Rowan, J. A., Gao, W., Hague, W. M., & McIntyre, H. D. (2010). Glycemia and its relationship to outcomes in the metformin in gestational diabetes trial. [Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *Diabetes Care*, 33(1), 9-16.

Impact Factor: 8.09  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n=724

Review of MiGs Trial

Randomized Control Trial data

Measuring oral glucose tolerance test (OGTT) baseline glucose tolerance test results and A1C, along with fasting capillary glucose to predict neonatal complications. A1C Predicted LGA infants, fasting capillary glucose predicted neonatal complications, post prandial glucose predicted preeclampsia and LGA. Obesity did not influence outcomes.

Prevention of fasting capillary glucose <4.9 mmol/l, or higher when 2 hour post prandial glucose was 5.9-6.4 mmol/l or lower will reduce neonatal morbidity and mortality.

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Rowan, J. A., Hague, W. M., Gao, W., Battin, M. R., Moore, M. P., & Mi, G. T. I. (2008). Metformin versus insulin for the treatment of gestational diabetes.[Erratum appears in N Engl J Med. 2008 Jul 3;359(1):106]. [Comparative Study, Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *New England Journal of Medicine*, 358(19), 2003-2015.

Impact Factor: 47.05

Quality of Evidence: Acceptable

Condition: Diabetes/Obesity

n= 751

Randomized Controlled Trial

Metformin compared with insulin, to measure primarily neonatal hypoglycemia, respiratory distress, need to phototherapy, birth trauma, 5 minute APGAR score of <7. Secondary outcome was anthropometric measurements, maternal glycemic control, maternal hypertensive complications, postpartum glucose tolerance, and acceptability of treatment. Trial resulted in no associated increase in perinatal complications, when compared to insulin. The women preferred metformin over insulin due to its oral delivery.

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Rowan, J. A., & Mi, G. I. (2007). A trial in progress: gestational diabetes. Treatment with metformin compared with insulin (the Metformin in Gestational Diabetes [MiG] trial).[Erratum appears in Diabetes Care. 2007 Dec;30(12):3154]. [Comparative Study, Multicenter Study, Randomized Controlled Trial]. *Diabetes Care*, 30 Suppl 2, S214-219.

Impact Factor: 8.09

Quality of Evidence: Acceptable

Condition: Diabetes/Obesity

n=550

Prospective Randomized Controlled Trial

Prospective RCT with pregnant women testing metformin outcomes vs. insulin outcomes of baby. Long-term follow up will re-examine the babies at 2 years of age, and again later by the Australian Clinical Trials Registry. This article reveals the inconsistency with other trials in that they are not measuring the same outcomes consistently. They aim to consistently measure outcomes on neonates, primary outcome morbidity, prevention of fetal hyperinsulinemia and consequences. Secondary outcomes analyzed metformin influence in fetal adipoinular axis. This was done by anthropometric and cord blood measurements at birth. Future work with incidence of type 2 NIDDM in offspring is recommended.

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Royall, D. (2006). Nutrition counselling for gestational diabetes. [Comment, Editorial]. *Canadian Journal of Dietetic Practice & Research*, 67(4), 168.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= 1000

Randomized Control Trial

Review of the public policy statement recommended by Canadian Diabetes Association, Dieticians of Canada, Diabete Quebec and the Ordre Professionnel des diététistes du Québec. Nutrition counseling was recommended (Grade A) for diabetic mothers. This was echoed by the American Diabetes Association Position Statement.

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Ruano, R., Fontes, R. S., & Zugaib, M. (2005). Prevention of preeclampsia with low-dose aspirin -- a systematic review and meta-analysis of the main randomized controlled trials. [Meta-Analysis, Review]. *Clinics (Sao Paulo, Brazil)*, 60(5), 407-414.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Preeclampsia/Eclampsia

n=16,700

Meta analysis, RCT=5

This article reviewed a meta analysis of the prevention of preeclampsia with low dose aspirin (ASA). This report criticizes the work done by Pereira (2006). This author disagrees with the conclusion that ASA is not necessarily beneficial; evaluation of RCTs best answers the question regarding the reduction in the risk for preeclampsia with use of low dose aspirin.

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Rumbold, A. R., Crowther, C. A., Haslam, R. R., Dekker, G. A., Robinson, J. S., & Group, A. S. (2006). Vitamins C and E and the risks of preeclampsia and perinatal complications. [Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *New England Journal of Medicine*, 354(17), 1796-1806.

Impact Factor: 53.30  
 Quality of Evidence: Limited  
 Condition: Hypertension

n=1877

RCT

A multi-centered RCT was conducted among nulliparous Australian women to assess the effects of combined therapy with 1000 mg Vitamin C and 400 IU vitamin E daily vs. placebo on the occurrence of preeclampsia and Perinatal complications. No difference among groups was found in any measured outcome.

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Rumiris, D., Purwosunu, Y., Wibowo, N., Farina, A., & Sekizawa, A. (2006). Lower rate of preeclampsia after antioxidant supplementation in pregnant women with low antioxidant status. [Randomized Controlled Trial]. *Hypertension in Pregnancy*, 25(3), 241-253.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Preeclampsia/Eclampsia

n= 60

RCT

RCT of daily supplementation with antioxidants early in pregnancy (estimated 8-12 weeks), in patients who were at risk for preeclampsia, detected by low antioxidant concentration. At delivery, blood pressure and rate of preeclampsia was significantly lower in the treatment group, compared with the placebo group. Authors conclude the administration of the antioxidant decreased incidence of preeclampsia. Limitations include the small sample size and inability to restrict participant's diets.

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Salles, A. M. R., Galvao, T. F., Silva, M. T., Motta, L. C. D., & Pereira, M. G. (2012). Antioxidants for preventing preeclampsia: a systematic review. [Research Support, Non-U.S. Gov't]. *TheScientificWorldJournal*, 2012, 243476.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Preeclampsia/Eclampsia

n=21,012

Systematic Review ,RCTs=15

This is a systematic review of antioxidants versus placebo for preventing preeclampsia. No statistical difference was found between the two groups. The authors do not support the use of antioxidants over placebo therapy. Antioxidants showed no significance for prevention of eclampsia as well.

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Shields, L. E., Smalarz, K., Reffigee, L., Mugg, S., Burdumy, T. J., & Propst, M. (2011). Comprehensive maternal hemorrhage protocols improve patient safety and reduce utilization of blood products. *American Journal of Obstetrics & Gynecology*, 205(4), 368.e361-368.

Impact Factor: 3.28  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

n=Not Specified

Retrospective and Prospective Study

The objective of the study was to implement a comprehensive protocol for the treatment of postpartum hemorrhage, then to evaluate whether this protocol reduced the severity of obstetric hemorrhage. Also, did this early intervention reduce the number of patients in need of transfusion or number of units transfused. There were four noted outcomes from this study: patients were treated with a lower amount of hemorrhage, therefore experiencing less blood loss; fewer blood products were administered; early intervention yielded fewer patients

experiencing life-threatening disseminated intravascular coagulation; and the hospital staff reported improved clinical knowledge and comfort levels when response to a obstetrical hemorrhage situation arose.

Skupski, D., Lowenwirt, I., Weinbaum, F., Brodsky, D., Danek, M., & Eglinton, G. (2006). Improving Hospital Systems for the Care of Women With Major Obstetric Hemorrhage. *Obstetrics & Gynecology*, 107(5), 977-983.

Impact Factor: 4.73

Quality of Evidence: Acceptable

Condition: Hemorrhage

Outcomes were compared retrospectively after an introduction for a patient safety program was in place for protecting major hemorrhage ob patients. Rapid Response team was formed, using the cardiac arrest team model. Protocols for early diagnosis, assessment, and management of patients at high risk for major ob hemorrhage was developed and communicated to staff. Population of hemorrhage cases increased in the assessment period while new team approach was initiated. Improvement in mortality due to a decrease in the maternal mortality rates from hemorrhage was found, as well as improved patient safety was determined with data was comparison.

Sloan, N. L., Durocher, J., Aldrich, T., Blum, J., & Winikoff, B. (2010). What measured blood loss tells us about postpartum bleeding: a systematic review. [Meta-Analysis, Research Support, Non-U.S. Gov't, Review]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 117(7), 788-800.

Impact Factor: 3.41

Quality of Evidence: Acceptable

Condition: Hemorrhage

n=Not Specified

Meta-Analysis; RCTs=19

A meta-analysis of 29 articles measured postpartum blood loss with and without prophylactic uterotonics for prevention of postpartum hemorrhage. Women who did not receive uterotonic prophylaxis had the highest average blood loss. For three prophylactic uterotonics that were looked at (oxytocin, misoprostol, and ergometrine) the blood loss measured was similar. All three prophylactic uterotonics, compared with expectant management, were associated with a reduction in mean blood loss and reduced severe postpartum hemorrhage. The study concluded that oxytocin is the preferable uterotonic to use in the hospital; however, misoprostol substantially reduces postpartum hemorrhage and severe postpartum hemorrhage when compared to expectant management and when used in developing countries.

Spinnato, J. A., 2nd, Freire, S., Pinto E Silva, J. L., Cunha Rudge, M. V., Martins-Costa, S., Koch, M. A., . . . Sibai, B. M. (2007). Antioxidant therapy to prevent preeclampsia: a randomized controlled trial. [Multicenter Study, Randomized Controlled Trial, Research Support, N.I.H., Extramural]. *Obstetrics & Gynecology*, 110(6), 1311-1318.

Impact Factor: 4.73

Quality of Evidence: Limited  
Condition: Preeclampsia/Eclampsia

n= 739  
RCT

This article reviewed a RCT of women with gestational hypertension who were given daily treatment with Vitamin C and Vitamin E. No reduction in the rate of preeclampsia was found when compared with placebo. There was no difference in mean gestational age at delivery, rate of perinatal mortality, abruptio placenta, preterm delivery, small for gestational age, or low birth weight. There is no benefit for antioxidant supplementation to reduce the incidence of preeclampsia. The study suggested separating patients who have prior eclampsia, from those patients who have gestational hypertensive in future treatment groups

Su, L.-L., Chong, Y.-S., & Samuel, M. (2012). Carbetocin for preventing postpartum haemorrhage. [Meta-Analysis, Research Support, Non-U.S. Gov't, Review]. *Cochrane Database of Systematic Reviews*, 4, CD005457.

Impact Factor: 5.72  
Quality of Evidence: Acceptable  
Condition: Hemorrhage

n=2,635

Cochrane Review, RCTs=11

The review analyzed 11 studies that focused on the effectiveness of carbetocin as an uterotonic agent for the prevention of postpartum hemorrhage and evaluated the best routes of administration and optimal doses. Findings demonstrated that carbetocin resulted in a statistically significant reduction in need for additional uterotonics in comparison to oxytocin; however, it did not reduce the incidence of postpartum hemorrhage. Intramuscular injected carbetocin does have a longer duration than intravenously administered oxytocin. Carbetocin, when compared to syntometrine, was associated with less blood loss and fewer adverse effects in women who delivered vaginally. However, carbetocin is not more effective in preventing postpartum hemorrhage than syntometrine. No data was reported regarding the use of carbetocin and neonatal outcomes.

Tanentsapf, I., Heitmann, B. L., & Adegboye, A. R. A. (2011). Systematic review of clinical trials on dietary interventions to prevent excessive weight gain during pregnancy among normal weight, overweight and obese women. [Review]. *BMC Pregnancy & Childbirth*, 11, 81.

Impact Factor: Not Available  
Quality of Evidence: Acceptable  
Condition: Diabetes/Obesity

n= Not Specified

Cochrane Review

Systematic review of clinical trials on dietary interventions to prevent excessive weight gain, measured post partum. 13 studies were reviewed. Dietary interventions did reduce incidence of weight sentential at 6 months post partum

Thangaratnam, S., Rogozinska, E., Jolly, K., Glinkowski, S., Roseboom, T., Tomlinson, J. W., . . . Khan, K. S. (2012). Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. [Meta-Analysis, Research Support, Non-U.S. Gov't]. *BMJ*, *344*, e2088. doi: <http://dx.doi.org/10.1136/bmj.e2088>

Impact Factor: 13.66  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= 7278

RCTs=44

Review of 44 relevant RCTs that evaluated interventions such as: diet, physical activity, and mixed approaches on healthy and obese women. No statistical difference was found in birth weight, LGA. By itself, physical activity reduced birth weight, but associated with SGA. Intervention groups were associated with preeclampsia, and shoulder dystocia. Dietary intervention was associated with the smallest amount of maternal weight gain, and was not associated with adverse outcomes on the neonate.

Thornton, Y. S., Smarkola, C., Kopacz, S. M., & Ishaof, S. B. (2009). Perinatal outcomes in nutritionally monitored obese pregnant women: a randomized clinical trial. [Randomized Controlled Trial]. *Journal of the National Medical Association*, *101*(6), 569-577.

Impact Factor: 1.16  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n=257

Randomized Controlled Trial

Perinatal outcomes were measured in two groups, one conventional parental dietary management, and the study group which is balanced nutritional regimen and recording all food in a diary. Statistical differences found indicated the control group gained more weight, (about 10 pounds average) had greater incidence of preeclampsia (9.5% vs. 6.0%), and hypertension (8.6% vs. 2.6%). However, the study group had a greater incidence of macrosomia (3.4% vs. 7.8%).

Tita, A. T. N., Szychowski, J. M., Rouse, D. J., Bean, C. M., Chapman, V., Nothorn, A., . . . Hauth, J. C. (2012). Higher-dose oxytocin and hemorrhage after vaginal delivery: a randomized controlled trial. [Randomized Controlled Trial, Research Support, N.I.H., Extramural, Research Support, Non-U.S. Gov't]. *Obstetrics & Gynecology*, *119*(2 Pt 1), 293-300.

Impact Factor: 4.73  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

n=1,798

Double-masked, Randomized Controlled Trial

This randomized trial evaluated whether two higher-dose (80 units and 40 units) oxytocin



regimens were more effective than lower-dose (10 units) oxytocin to prevent postpartum hemorrhage after vaginal delivery. Prophylactic oxytocin was administered in 500 mL over 1 hour after placental delivery. The results revealed that, after the first hour, women who received the higher dose (80 units) of oxytocin needed additional oxytocin less frequently. There was also a decrease in low hematocrit with higher doses of oxytocin. Overall postpartum hemorrhage was not reduced with 10 units, 40 units, or 80 units of prophylactic oxytocin when given after a vaginal delivery; however a higher dose (80 units) did decrease the need for additional oxytocin.

Tobler, D., Fernandes, S. M., Wald, R. M., Landzberg, M., Salehian, O., Siu, S. C., . . . Silversides, C. K. (2010). Pregnancy outcomes in women with transposition of the great arteries and arterial switch operation. [Multicenter Study, Research Support, Non-U.S. Gov't]. *American Journal of Cardiology*, 106(3), 417-420.

Impact Factor: 1.04  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n=74

Retrospective Chart Review

Review of women of child-bearing age with transposition of the great arteries (TGA) who had undergone an arterial switch operation (ASO). Retrospective chart review identified 9 women who had 17 pregnancies from 2000 - 2009. Four of the pregnancies resulted in miscarriage. Six women had clinically important valve and ventricular lesions before the index pregnancy. Two women developed cardiac complications during pregnancy. There were no maternal deaths. This study is a snapshot of an early cohort of women who underwent ASO for TGA in the 1980's. As such, they represent a more complex group than what is expected in the future. Larger studies are necessary to determine predictors of adverse pregnancy outcome for these women. In the meantime, coordinated care is recommended between a congenital heart disease specialist and a high-risk obstetrician.

Trivedi, N. A. (2011). A meta-analysis of low-dose aspirin for prevention of preeclampsia. [Meta-Analysis]. *Journal of Postgraduate Medicine*, 57(2), 91-95.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Preeclampsia/Eclampsia

n=28,237

Meta analysis, RCTs=19,

Meta analysis of low dose aspirin (ASA) 40-160 mg/day for prevention of preeclampsia. Trial subjects were divided into low risk (16550) and high risk (11687) groups. Preeclampsia was the measured outcome; the overall rate was 7.4%. Within the low risk ASA group, the rate was reduced to 6.9%. Within the low risk placebo group the rate was 7.8%. Within the high risk group, there was a 27% reduction in risk when ASA was used. The authors concluded that ASA has a small effect in preventing preeclampsia for the high risk group, but not a significant difference for the low risk group. The studies also found a 6% reduction in the risk of prenatal death and post partum hemorrhage.

Trumbo, P. R., & Ellwood, K. C. (2007). Supplemental calcium and risk reduction of hypertension, pregnancy-induced hypertension, and preeclampsia: an evidence-based review by the US Food and Drug Administration. [Review]. *Nutrition Reviews*, 65(2), 78-87.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

Evidence- based review

Evidence-based review by the United States Food and Drug Administration for use of calcium supplementation to reduce risk of hypertension by conducting a science review of health claims. This review evaluated the human interventional and observational studies that evaluated the role of calcium in reducing all hypertension, pregnancy induced hypertension and preeclampsia. This review concluded that there is not enough evidence, evidence is inconsistent and inconclusive, and the relationship between calcium supplementation and reduced risk of pregnancy induced hypertension and preeclampsia is highly unlikely.

Tuccori, M., Testi, A., Antonioli, L., Fornai, M., Montagnani, S., Ghisu, N., . . . Del Tacca, M. (2009). Safety concerns associated with the use of serotonin reuptake inhibitors and other serotonergic/noradrenergic antidepressants during pregnancy: a review. [Review]. *Clinical Therapeutics*, 31 Pt 1, 1426-1453.

Impact Factor: 3.25

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n= variable by measured outcome

Literature Review

This review of observational studies and meta-analyses was undertaken to determine the safety of selective serotonin reuptake inhibitors (SSRIs) and other anti-depressants when used in pregnancy. Findings respecting measured outcomes:

- Major congenital malformation – there is a statistical association between paroxetine use and major malformation in the newborn reported in recent large population-based studies.(27 studies, 5 meta-analyses of 42 studies, n=>100,000).
- Miscarriage – Pregnancy loss did not differ significantly in study and control groups (9 studies).
- Neonatal behavioral syndrome – (18 case reports, 19 studies) – Available evidence supports an association between third trimester use of SSRIs and symptoms of neonatal behavioral syndrome, some evidence for venlafaxine association; studies of other drugs warranted.
- Persistent pulmonary hypertension of the newborn (PPHN) – n=unstated in studies that did not identify an increased risk of PPHN among anti-depressant users vs. normal controls.
- Neurobehavioral development - 4 small, low-n studies of children age 15 months through 4 years revealed the need for more well-designed studies.
  - Neonatal Bleeding – (4 case reports, 2 studies, n=>25,000) No association between drug use and abnormal neonatal bleeding was demonstrated, but more studies are needed.

- Prolonged QTc interval – 1 study, n=104, was inconclusive. Authors conclude that SSRIs and other anti-depressants should be used with caution during pregnancy, with careful follow-up of exposed infants needed.

Tuncalp, O., Hofmeyr, G. J., & Gulmezoglu, A. M. (2012). Prostaglandins for preventing postpartum haemorrhage.[Update of Cochrane Database Syst Rev. 2007;(3):CD000494; PMID: 17636640]. [Research Support, Non-U.S. Gov't]. *Cochrane Database of Systematic Reviews*, 8, CD000494.

Impact Factor: 5.75

Quality of Evidence: Acceptable

Condition: Hemorrhage

n=52,678

Cochrane Review, RCTs=72

A review of the use of prophylactic prostaglandins in the third stage of labor. Findings revealed that misoprostol is effective in reducing severe hemorrhage and the need for blood transfusions, however it is not more effective than oxytocin and is accompanied by more side effects. The author's concluded that oxytocin is the uterotonic of choice (10 IU) administered intravenously or intramuscularly. Misoprostol is thought to be effective in low resource settings where there is low access to facilities and skilled healthcare workers. Overall, intramuscular prostaglandins are not preferable to conventional uterotonics in the routine management of the third stage of labor, especially for low risk women.

Udechuku, A., Nguyen, T., Hill, R., & Szego, K. (2010). Antidepressants in pregnancy: a systematic review. [Review]. *Australian & New Zealand Journal of Psychiatry*, 44(11), 978-996.

Impact Factor: 2.93

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=variable by outcome assessed

Literature Review

This is a systematic literature review of the effects of antidepressant use during pregnancy. By measured outcomes:

Congenital malformation (n=159,618) was statistically associated with fluoxetine or paroxetine use in the first trimester in only a small percentage of the 45 studies done (meta-analyses and cohort studies). The conclusion is that anti-depressants, as a class and as individual drugs, are unlikely to be teratogenic

Pregnancy outcome – 35 articles found, n=>25000 total, the risk of preterm birth is elevated, but there is limited and contradictory evidence related to the occurrence of spontaneous abortion, and weak association to other outcomes such as birth weight.

Neonatal outcomes – Mild to moderate neonatal adaptation difficulties, evidenced by increased rates of NICU admission have been reported in a series of studies flawed by inadequate controls for confounders and inconsistent medications studied.

Persistent pulmonary hypertension of the newborn (PPHN) – Significant methodological weaknesses also exist in the 3 studies (variable n) to date on PPHN; authors conclude there is insufficient evidence to contraindicate use of SSRIs in late pregnancy.

Long-term developmental outcomes – Seven studies, each with  $n < 100$ , have employed various models for measuring developmental delays, but none have identified increased risk for late developmental delays among children exposed to SSRIs in utero.

Authors conclude there is no evidence to support the use of one class of anti-depressants over another.

Vadillo-Ortega, F., Perichart-Perera, O., Espino, S., Avila-Vergara, M. A., Ibarra, I., Ahued, R., . . . Strauss, J. F. (2011). Effect of supplementation during pregnancy with L-arginine and antioxidant vitamins in medical food on pre-eclampsia in high risk population: randomised controlled trial. [Randomized Controlled Trial, Research Support, N.I.H., Extramural, Research Support, Non-U.S. Gov't, Research Support, U.S. Gov't, P.H.S.]. *BMJ*, 342, d2901. doi: <http://dx.doi.org/10.1136/bmj.d2901>

Impact Factor: 13.66

Quality of Evidence: Acceptable

Condition: Preeclampsia/Eclampsia

n=450

RCT

This study was done in Mexico City to test the hypothesis for a relative deficiency in L-arginine, which is required for the synthesis of the vasodilatory gas nitric oxide. This gas may be associated with the development of preeclampsia in the population at high risk. There were 222 in the placebo group who received Vitamins C and E, and 228 women received L-arginine plus antioxidant vitamins. The study concluded that medical food containing both L-arginine and antioxidant vitamins reduced the incidence of preeclampsia in populations at high risk for the condition.

Wise, A., & Clark, V. (2008). Strategies to manage major obstetric haemorrhage. [Review]. *Current Opinion in Anaesthesiology*, 21(3), 281-287.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Hemorrhage

n=Not Specified

Literature Review

This article reviewed literature to provide a summary of the prevention, management and treatment of obstetric hemorrhage. To manage postpartum hemorrhage a combination of uterotonics, early cord clamping and controlled cord traction should be used. Pharmacological treatment (oxytocin, ergometrine and prostaglandins) of uterine atony has not changed much. However, the use of misoprostol has increased especially in low-resource settings because it is an agent that can be administered without being a skilled health professional. Use of a uterine balloon tamponade has been shown to be effective and less invasive. Uterine compression sutures have also been reported to produce successful subsequent pregnancies. Interventional radiology has also yielded successful pregnancies and provides an intervention to reduce blood loss. Cell salvage and recombinant factor VIIa are additional interventions that can aid in the management and treatment of postpartum hemorrhage. Anesthesia services may also be of use in cases with placenta praevia.

Wisner, K. L., Sit, D. K. Y., Hanusa, B. H., Moses-Kolko, E. L., Bogen, D. L., Hunker, D. F., . . . Singer, L. T. (2009). Major depression and antidepressant treatment: impact on pregnancy and neonatal outcomes. [Research Support, N.I.H., Extramural]. *American Journal of Psychiatry*, 166(5), 557-566.

Impact Factor: 12.54

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=238

Prospective observational study

The study objective was determination of adverse maternal or neonatal outcomes related to exposure to depression during pregnancy or exposure to selective serotonin reuptake inhibitors (SSRIs), used to treat depression. Subjects were divided into 3 groups – SSRIs, major depression, or no SSRI, no depression. Outcomes were that neither SSRIs nor depression had any effect on the occurrence of minor physical anomalies or reduced maternal weight gain, but infants exposed to either depression or SSRIs continuously across gestation were more likely to be born preterm than infants with partial or no exposure to either. Birth weights and other neonatal outcomes were similar in all groups, except for 5 minute Apgars, which were lower in the SSRI and depression groups. For depressed pregnant women, both continuous SSRI exposure and continuous untreated depression were associated with preterm birth rates exceeding 20%.

Wong, S., Ordean, A., Kahan, M., Maternal Fetal Medicine, C., Family Physicians Advisory, C., Medico-Legal, C., . . . Gynaecologists of, C. (2011). Substance use in pregnancy. [Practice Guideline, Research Support, N.I.H., Extramural, Research Support, Non-U.S. Gov't]. *Journal of Obstetrics & Gynaecology Canada: JOGC*, 33(4), 367-384.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Psychiatric/Mental Health

n=Not Applicable

Society of Obstetricians and Gynaecologists of Canada (SOGC) Clinical Practice Guideline

This guideline document is intended to improve awareness and knowledge of substance use in pregnancy and to provide recommendations for management. The guidelines recommend screening of all pregnant women for alcohol, tobacco, and prescription and illicit drug use. It is noted that pregnant women with substance abuse problems face a number of barriers to receiving optimal prenatal care. It is therefore recommended that care providers employ a flexible approach to the care of women who have substance use problems, and the use of all available community resources should be encouraged. Harm reduction is an important component of care for substance abuse in pregnant women. This is captured in recommendations that include counseling about the risks of drug use and smoking cessation counseling which should be considered a first-line intervention for pregnant smokers. For pregnant women who are opioid dependent, opioid detoxification is not advisable due to the high rate of relapse. Opiate substitution therapy is considered the standard of care and is captured in a guideline recommendation for methadone maintenance treatment, or consideration of other slow-release opioid preparations if methadone is not available. Neonatal abstinence syndrome (NAS) can occur with any regular daily antenatal opioid use. For this

reason, it is recommended that opiate-dependent women are informed that neonates exposed to opioids during pregnancy will be monitored closely for signs and symptoms of neonatal withdrawal. The range of evidence for the recommendations noted in this summary is I-A to III-B with the smoking cessation counseling recommendation having the greatest level of evidence. The authors acknowledged that problematic substance use in pregnancy is prevalent in the Canadian population. Perinatal health care providers play a key role in the care of pregnant women with substance abuse problems. It was concluded that ongoing education and comprehensive care models still need to be developed in meeting the care needs of these challenging patients.

Xu, H., Perez-Cuevas, R., Xiong, X., Reyes, H., Roy, C., Julien, P., . . . group, I. s. (2010). An international trial of antioxidants in the prevention of preeclampsia (INTAPP). [Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *American Journal of Obstetrics & Gynecology*, 202(3), 239.e231-239.e210.

Impact Factor: 1.04  
 Quality of Evidence: Limited  
 Condition: Preeclampsia/Eclampsia

n= 2647

International RCT

This article reviewed an international RCT, with subjects stratified by risk status for preeclampsia. Subjects were assigned to daily treatment with Vitamin C and Vitamin E, or placebo. The measured outcome was development of gestational hypertension. Vitamin supplementation did not reduce the rate of gestational hypertension, nor of subsequent preeclampsia. There was an increase in the risk of fetal loss, perinatal death, and preterm, prelabor rupture of membranes. The trial was prematurely stopped for ethical reasons.

Yinon, Y., Siu, S. C., Warshafsky, C., Maxwell, C., McLeod, A., Colman, J. M., . . . Silversides, C. K. (2009). Use of low molecular weight heparin in pregnant women with mechanical heart valves. [Research Support, Non-U.S. Gov't]. *American Journal of Cardiology*, 104(9), 1259-1263.

Impact Factor: 1.04  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n = 17 women, 23 pregnancies

Sub study of larger prospective cohort study.

Prospective study conducted to determine maternal thromboembolic complications in women with mechanical valves treated with low-molecular weight heparin (LMWH) throughout pregnancy. This was a sub-study of a larger cohort study of pregnant women with heart disease from 1998 to 2008. The study included women who were treated with LMWH and low-dose aspirin. There were 15 pregnancies in women with mechanical mitral valves, 9 pregnancies in women with mechanical aortic valves, and 1 pregnancy in a woman with both. Outcomes demonstrated during this study: 1 maternal thromboembolic event resulting in maternal and fetal death. Five women developed other adverse cardiac events. Nine pregnancies had fetal or neonatal adverse events, 5 of which had favorable outcomes. Postpartum hemorrhage occurred in three pregnancies. Although this study concluded that

carefully monitored LMWH may be a suitable anticoagulation strategy in pregnant women with mechanical heart valves, this group of women remains at risk for maternal cardiac and fetal complications.

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Yu, C. K. H., Papageorgiou, A. T., Parra, M., Palma Dias, R., Nicolaides, K. H., & Fetal Medicine Foundation Second Trimester Screening, G. (2003). Randomized controlled trial using low-dose aspirin in the prevention of pre-eclampsia in women with abnormal uterine artery Doppler at 23 weeks' gestation. [Clinical Trial, Multicenter Study, Randomized Controlled Trial, Research Support, Non-U.S. Gov't]. *Ultrasound in Obstetrics & Gynecology*, 22(3), 233-239.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Preeclampsia/Eclampsia

n= 19,950

Randomized Control Trials

Color Doppler was used to measure blood flow in the uterine arteries at 22-24 weeks gestation.

Those subjects with arteries that had an impedance of flow were randomized to aspirin (ASA) 150 mg trial vs. placebo. There was no difference found in either group in the incidence of preeclampsia, preterm delivery, birth weight, perinatal death, or placental abruption.

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### III. Research Question 2

**Highlight which of the six conditions have been used as evidence-based guidelines or quality measures.**

#### Summary

The second research question is designed to elicit the findings and recommendations from review of the literature related to the previous six specific high-risk conditions that have been used as evidence-based guidelines or quality measures.

#### Diabetes/Obesity

The search methodology yielded three articles examining the evidence regarding interventions to reduce morbidity and mortality in obese high risk obstetrical patients. All the following interventions as cited by The Society of Obstetricians and Gynaecologists of Canada (SOGC) are found to be beneficial in the care of high risk obstetrical patients with obesity. These include recommended daily exercise, nutritional counseling and dietary management to all be beneficial interventions in the care of obese pregnant women (Davis et al., 2010). A systematic review assessing energy and protein restrictions found that these were successful in avoiding adverse maternal outcomes, but found to be harmful to the fetus. An anesthesia consult is advisable for obese patients to reduce incidence of airway management during delivery.

Acceptable weight gain was revised by the Institute of Medicine (IOM) guideline following findings from an observational study that weight should be limited to 11-12 pounds for women with a body mass index (BMI) greater than 30kg/m<sup>2</sup>. This study resulted in a decreased incidence of cesarean deliveries, as well as pregnancy induced hypertension (Einerson et al., 2011).

Revisions for recommended weight gain have also been addressed in the Cedergren (2007) article as written by Potti et al., (2010). Limited weight gain has been shown, in another study, to produce a decrease in risk for adverse obstetrical and neonatal outcomes, such as macrosomia and cesarean delivery rates. It was determined in the study that the group that followed the Cedergren study, had lower gestational weight gain than the women who gained weight according to the older IOM recommendations (Potti et al., 2010). After implementation of the recommended weight gain, it was determined that the ideal weight gain for obese pregnant women would be between the IOM and the Cedergren recommendations. The search methodology yielded two guidelines that address the topic of gestational diabetes mellitus (GDM) in the high risk obstetrical patient. There is a paucity of studies and evidence regarding the use of oral hypoglycemic agents in pregnancy. The advantages and outcomes with the use of glyburide and metformin, as found in the literature examined in Part II of this document are supported as well. One study reviewed found that glyburide improved glucose control analogous to insulin; glyburide also was not associated with any adverse maternal or neonatal complications. Metformin is commonly used for glucose control in pregnancy, however, its effects in utero have not been well investigated (Bulletins, A. C. o. P. (2005).

American College of Obstetrics and Gynecologists (ACOG) (2005) *Clinical Management Guidelines for Obstetrician-Gynecologist: Pregestational Diabetes Mellitus*.

Based on limited or inconsistent scientific level of evidence (Level of Evidence B\*\*):

- “Suspected fetal macrosomia is not an indication for induction of labor, because induction does not improve maternal or fetal outcomes.”



- “Adequate maternal glucose control should be maintained near physiologic levels before conception and throughout pregnancy to decrease the likelihood of spontaneous abortion, fetal malformation, fetal macrosomia, intrauterine fetal death, and neonatal morbidity.”
- “The use of oral agents for control of Type 2 diabetes mellitus during pregnancy should be limited and individualized until data regarding the safety and efficacy of these drugs become available.”
- “To prevent traumatic birth injury, cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 grams in women with diabetes.”

American College of Obstetrics and Gynecologists (ACOG) (2001) *Clinical Management Guidelines for Obstetrician-Gynecologist: Gestational Diabetes*.

The bulletin provides management guidelines for gestational diabetes mellitus (GDM).

Based on limited or inconsistent scientific level of evidence (Level of Evidence B) the following has been recommended:

- “Does not support a recommendation for or against moderate caloric restriction in obese women with GDM.”
- “When medical nutritional therapy has not resulted in fasting glucose less than 95 mg/dL, or 1-hour postprandial values less than 130-140 mg/dL, or 2-hour postprandial values less than 120 mg/dL, insulin should be considered.”

It was noted that oral antidiabetic agents have been contraindicated for this population.

However, glyburide was compared to insulin in a randomized controlled trial including women with gestational diabetes mellitus who did not achieve optimally glycemic control with diet. The study yielded results that glyburide had similar glucose control as insulin; furthermore pregnancy outcomes were similar to insulin as well. (Bulletins, 2005)

Australian Diabetes in Pregnancy Society (ADIPS) consensus guidelines for the management of Type 1 and Type 2 diabetes in pregnancy.

- Management of diabetes during pregnancy should be overseen by a multidisciplinary team that has experience with diabetes and pregnancy.
- Women with Type 1 and Type 2 diabetes need mandatory blood glucose monitoring. HbA1c levels should be monitored and managed

Other oral hypoglycemic agents, similar to other guidelines and studies, are not recommended for use during pregnancy due to the lack of evidence regarding safe use in pregnancy (Hoffman et al., 1998).

Bismuth et al., (2012) reviewed the guidelines of the French-Speaking Diabetes Society Recommendations were not graded and include:

- Dietary Management Insulin therapy
- Glycemic control and monitor of HbA1c.
- Fasting BS 60-90- post AC <140 mg/dL, <120 mg/dL 2 hr post AC.
- Insulin lispro is recommended.
- Insulin aspart is recommended.
- Insulin glulisine not recommended.
- Insulin glargine not recommended.
- Use of Insulin pumps reviewed on case by case.

All the guidelines reviewed, as well as the review provided by Bismuth et al., (2012) appear to be congruent with the recommendations for the management and treatment of diabetic or obese

high risk obstetrical diabetic patients. The guidelines also appear to be aligned with the interventions reviewed in Part II of this document. Interventions regarding a healthy exercise regimen are consistently recommended, as well as limitations in weight gain, and nutritional counseling for obese high risk obstetrical patients. If these actions fail to control fasting glucose readings, insulin is recommended, as well as oral antidiabetic medications.

### **Cardiac Disease**

The search methodology used for this literature review yielded two sets of guidelines, ESC (European Society of Cardiology) Guidelines on the Management of Cardiovascular Diseases during Pregnancy and JCS (Japanese Circulation Society) Guidelines for Indication and Management of Pregnancy and Delivery in Women with Heart Disease.

*ESC Guidelines on the Management of Cardiovascular Diseases during Pregnancy* (European Society et al., 2011)

The guidelines included 9 tables of recommendations which included the following cardiovascular conditions:

- Congenital heart disease
- Aortic disease
- Valvular heart disease
- Coronary artery disease
- Heart failure
- Arrhythmias

Pre-pregnancy counseling and testing was noted throughout the guideline recommendations. For the pregnant woman with cardiovascular disease the guidelines stressed the importance of specialized care rendered by a multidisciplinary team. Individualized care and symptom management was a common theme throughout the guidelines. Medication management and surgical interventions were also included. The importance of close maternal-fetal monitoring was noted in addition to consideration of the appropriate timing for delivery given the mother's condition and potential for optimal fetal outcome.

*Guidelines for Indication and Management of Pregnancy and Delivery in Women with Heart Disease* (Group, 2012)

The guidelines discussed the following specific maternal conditions:

- Congenital heart disease
- Pulmonary hypertension
- Valvular heart disease
- Aortic Disease
- Cardiomyopathy
- Arrhythmias
- Ischemic Heart Disease
- Heart Failure
- Hypertension

Pre-pregnancy assessment and testing were recommended in order to predict the risk of pregnancy-related complications. The guidelines addressed a number of congenital heart diseases/conditions, i.e., Down Syndrome, Duchenne muscular dystrophy, etc. that would

require careful monitoring during pregnancy. Also noted was the importance of genetic counseling and attention to psychosocial issues that may arise. For monitoring during pregnancy the guidelines stressed the importance of involvement by a multidisciplinary team consisting of obstetricians, cardiologists, anesthesiologists, and nurses. The need for frequent hemo-dynamic assessment during pregnancy was addressed. With respect to medications used during pregnancy, the guidelines stated that drugs should be selected with consideration of the risk-benefit balance for the mother and fetus. It was specifically noted that angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers are contraindicated in the second and third trimester of pregnancy. If invasive treatment is a consideration during pregnancy, disease progression should be a determining factor. The following were also noted: termination of pregnancy may be necessary if maternal health becomes a life-threatening situation. Timing of delivery should address the potential for infant survival; body weight (< 1,000g) and gestation (less than 28 weeks) are factors for consideration. Vaginal delivery and epidural anesthesia are preferable.

Both guidelines above are consistent with the overall previously-identified recommendations for the care of the pregnant women with cardiac disease. These guidelines focus on specialized care rendered by a multidisciplinary team, pre-pregnancy counseling, continuous maternal-fetal monitoring, caution with medication management and invasive interventions, and evaluation of maternal-fetal risks for decision making regarding timing of delivery.

### **Preeclampsia/Eclampsia**

The search methodology yielded one guideline from the American College of Obstetricians and Gynecologists that focused on the diagnosis and management of hypertensive disorders unique to pregnancy.

The following recommendations are based on good and consistent scientific evidence (Level of Evidence A):

- "Magnesium sulfate should be used for the prevention and treatment of seizures in women with severe preeclampsia or eclampsia."
- "If analgesia/anesthesia is required, regional or neuraxial analgesia/anesthesia should be used because it is efficacious and safe for intrapartum management of women with severe preeclampsia in the absence of coagulopathy."
- "Low-dose aspirin has not been shown to prevent preeclampsia in women who are at low risk for preeclampsia and, therefore is not recommended."
- "Daily calcium supplementation has not been shown to prevent preeclampsia and, therefore, is not recommended."

The following recommendations are based on limited or inconsistent scientific evidence (Level of Evidence B):

- "The management of a woman with severe preeclampsia remote from term is best accomplished in a tertiary care setting or in consultation with an obstetrician–gynecologist with training, experience, and demonstrated competence in the management of high-risk pregnancies, such as a maternal–fetal medicine subspecialist."

These recommendations from the American College of Obstetricians and Gynecologists appear to be aligned with the information obtained from Part II of this document. Limited data and evidence is available to strongly recommend the use of calcium supplementation, antioxidant therapy and low-dose aspirin, while magnesium sulfate has been proven to be effective in the prevention and treatment of seizures in women with severe preeclampsia or eclampsia.

## Hypertension

The search methodology used for this literature review yielded two guidelines addressing the topic of chronic hypertension in pregnancy and one on the topic of hypertension during pregnancy. Two of the guidelines were from the American College of Obstetricians and Gynecologists (ACOG) 2001 and 2012. The ACOG guideline from February 2012 replaced the ACOG guideline from July 2001, therefore, the 2012 guideline will be summarized. The other guideline came from the European Society of Cardiology and focused on the management of cardiovascular diseases during pregnancy.

The American College of Obstetrics and Gynecology Practice Bulletin provided the following recommendation based on good and consistent scientific evidence (Level of Evidence: A):

- “Angiotensin-converting enzyme inhibitors (ACEI) are contraindicated during pregnancy and are associated with fetal and neonatal renal failure and death.”

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level of Evidence: B):

- “Women with severe hypertension require antihypertensive medications for acute elevation of blood pressure.”
- “Labetalol was suggested to be a good option for the first-line treatment of chronic hypertension in pregnancy.”

The ACOG bulletin indicated that labetalol is increasingly prescribed during pregnancy and is most likely due to its low rate of adverse effects. Methyldopa was also suggested to be safe for treatment of hypertension in pregnancy, however, it was noted to be associated with significant maternal sedation. Therefore, methyldopa provides limited use for treatment of hypertension in pregnant women.

The European Society of Cardiology recommends for severe hypertension, medication treatment with intravenous labetalol or oral methyldopa or nifedipine (Level of Evidence: I-C).

Both of these, ACOG (2012) and European Society of Cardiology guidelines, recommended labetalol as a first line treatment for hypertension during pregnancy. However, there were no recommendations for elective late-term delivery, dietary calcium or vitamin supplementations, or bed rest which were three interventions that were discussed earlier in Part II of this document.

## Psychiatric/Mental Health

The search methodology used for this literature review yielded three sets of guidelines, two by the Society of Obstetricians and Gynecologists of Canada (SOGC), and an ACOG (American College of Obstetricians and Gynecologists) Practice Bulletin Clinical Management Guidelines for Obstetrician-Gynecologists: Use of Psychiatric Medication during Pregnancy and Lactation.

*Alcohol Use and Pregnancy Consensus Clinical Guidelines* (Carson et al., 2010)

The recommendations from these guidelines, focused on the following interventions:

- Universal screening for alcohol consumption should be done periodically for all pregnant women and women of child-bearing age. Ideally, at-risk drinking could be identified before pregnancy, allowing for change. (II-2B)
- Brief interventions are effective and should be provided by health care providers for women with at-risk drinking. (II-2B)

- If a woman continues to use alcohol during pregnancy, harm reduction/treatment strategies should be encouraged. (II-2B)
- Pregnant women should be given priority access to withdrawal management and treatment. (III-A)

SOGC Clinical Practice Guidelines *Substance Use in Pregnancy* (Wong et al., 2011)

The recommendations from these guidelines, focused on the following interventions:

- All pregnant women and women of childbearing age should be screened periodically for alcohol, tobacco, prescription, and illicit drug use. (III-A)
- Health care providers should employ a flexible approach to the care of women who have substance use problems, and they should encourage the use of all available community resources. (II-2B)
- Women should be counseled about the risks of periconception, antepartum, and postpartum drug use. (III-B)
- Smoking cessation counseling should be considered as a first-line intervention for pregnant smokers. (I-A) Nicotine replacement therapy and/or pharmacotherapy can be considered if counseling is not successful. (I-A)
- Methadone maintenance treatment should be standard of care for opioid-dependent women during pregnancy. (II-IA) Other slow-release opioid preparations may be considered if methadone is not available. (II-2B)
- Opioid detoxification should be reserved for selected women because of the high risk of relapse to opioids. (II-2B)
- Opiate-dependent women should be informed that neonates exposed to heroin, prescription opioids, methadone, or buprenorphine during pregnancy are monitored closely for symptoms and signs of neonatal withdrawal (neonatal abstinence syndrome). (II-2B) Hospitals providing obstetric care should develop a protocol for assessment and management of neonates exposed to opiates during pregnancy. (III-B)

The ACOG Practice Bulletin Clinical Management Guidelines for Obstetrician-Gynecologists: *Use of Psychiatric Medication during Pregnancy and Lactation* (Bulletins--Obstetrics, 2008)

The recommendations and conclusions that were focused on interventions are as follows:

Level A scientific evidence:

- Lithium exposure in pregnancy may be associated with a small increase in congenital cardiac malformations.
- Valproate exposure in pregnancy is associated with increased risk of fetal anomalies. It should be avoided in pregnancy, if possible, especially during the first trimesters.
- Carbamazepine exposure in pregnancy is associated with fetal carbamazepine syndrome. It should be avoided in pregnancy, if possible, especially during the first trimester.
- Maternal benzodiazepine use shortly before delivery is associated with floppy infant syndrome.

Level B scientific evidence:

- Paroxetine use in pregnant women and women planning pregnancy should be avoided, if possible. Fetal echocardiography should be considered for women who are exposed to paroxetine in early pregnancy.
- Lamotrigine is a potential maintenance therapy option for pregnant women with bipolar disorder because of its protective effects against bipolar depression, general tolerability, and a growing reproductive safety profile relative to alternative mood stabilizers.

- Maternal psychiatric illness, if inadequately treated or untreated, may result in poor compliance with prenatal care, inadequate nutrition, exposure to additional medication or herbal remedies, increased alcohol and tobacco use, deficits in mother–infant bonding, and disruptions within the family environment.

Level C consensus and expert opinion:

- Whenever possible, multidisciplinary management involving the patient's obstetrician, mental health clinician, primary health care provider, and pediatrician is recommended to facilitate care.
- Use of a single medication at a higher dose is favored over the use of multiple medications for the treatment of psychiatric illness during pregnancy.
- Treatment with all SSRIs (selective serotonin reuptake inhibitors) or selective norepinephrine reuptake inhibitors, or both during pregnancy should be individualized.

The guidelines acknowledge the challenges in managing the care of pregnant women with mental health illnesses. For those with substance abuse problems, interventions focus on the major components of assessment and feedback, goal setting, positive reinforcement, and education. Harm reduction is a key intervention noted in both SOGC guidelines. In recognition that total abstinence of alcohol or drugs may not be realistic; the guidelines stress the importance of withdrawal management/treatment, and methadone maintenance treatment for opioid-dependent women during pregnancy.

The recommendations noted in the ACOG Bulletin are consistent with the interventions previously cited in this document. Multidisciplinary management is crucial whenever possible; pharmacological therapy should be individualized with consideration of risks vs. benefits, and there should be careful monitoring of the mother and infant development throughout the pregnancy.

### **Hemorrhage**

The search methodology used for this literature review yielded two guidelines, American College of Obstetrics and Gynecology and the Society of Obstetricians and Gynaecologists of Canada, addressing the topic of postpartum hemorrhage.

The American College of Obstetrics and Gynecology (ACOG) practice bulletin, (2006), provided recommendations for the etiology, evaluation and management of postpartum hemorrhage. The recommendations are based primarily on consensus and expert opinion (Level of Evidence C):

- When uterine atony is the cause of postpartum hemorrhage, uterotonic agents should be the first-line of treatment.
- A multidisciplinary approach is recommended in the management and treatment of postpartum hemorrhage.
- Exploratory laparotomy should be considered if medical management by uterotonics is unsuccessful in the prevention of hemorrhage and blood loss.

The Society of Obstetricians and Gynaecologists of Canada (SOGC) (2009) provides guidelines for the prevention and management of postpartum hemorrhage. The quality of evidence was rated with use of criteria described by the Canadian Task Force on Preventative Health Care. Relevant recommendations for the prevention of postpartum hemorrhage are:

- Active management is strongly recommended for all women and reduces the risk of postpartum hemorrhage (Level of Evidence: I-A)

- 10 IU of oxytocin administered intramuscularly in low risk vaginal deliveries (Level of Evidence: I-A)
- Ergonovine is second choice to oxytocin use, due to adverse effects (Level of Evidence: I-A)
- Carbetocin, 100 µg should be given as an IV bolus over 1 minute during an elective cesarean section for prevention of postpartum hemorrhage and to reduce the need for additional uterotonics. (Level of Evidence: I-B)
- Women delivering vaginally with one risk factor for post partum hemorrhage (PPH) should be administered carbetocin 100 µg (Level of Evidence: I-B)
- Delaying cord clamping by at least 60 seconds is preferred to clamping earlier in premature newborns (Level of Evidence: I-A)
- Intraumbilical cord injection of misoprostol (800 µg) or oxytocin (10 µg to 30 IU) can be considered. (Level of Evidence: II-2C)

Relevant treatment recommendations are as follows:

- Management of PPH requires a multidisciplinary approach (Level of Evidence: III-C)
- Uterine tamponade can be considered when PPH is caused by uterine atony and there has been no response to other medical therapy (Level of Evidence: III-L)
- Surgical techniques should be used for the management of intractable postpartum hemorrhage unresponsive to medical therapy (Level of Evidence: III-B)

Both SOGC and ACOG guidelines appear to be congruent with their recommendations for the prevention, management and treatment of obstetric hemorrhage, specifically postpartum hemorrhage. The guidelines also appear to be aligned with the interventions reviewed in Part II of this document.

\*\*Note: Refer to appendix D for tables including level of evidence.

## Bibliography

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American College of Obstetricians & Gynecologists Committee on Practice, B.-O. (2001). ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologists. Number 30, September 2001 (replaces Technical Bulletin Number 200, December 1994). Gestational diabetes. [Guideline Practice Guideline]. *Obstetrics & Gynecology*, 98(3), 525-538.

Impact Factor: 4.36

Quality of Evidence: Acceptable

Condition: Diabetes/Obesity

The bulletin provides management guidelines for gestational diabetes mellitus (GDM). Based on limited or inconsistent scientific evidence (Level B) the following has been recommended:

- “Does not support a recommendation for or against moderate caloric restriction in obese women with GDM.”
- “For women with GDM and an estimated fetal weight of 4,500 grams or more, cesarean delivery may be considered because it may reduce the likelihood of permanent brachial plexus injury in the infant”

- "When medical nutritional therapy has not resulted in fasting glucose less than 95 mg/dL, or 1-hour postprandial values less than 130-140 mg/dL, or 2-hour postprandial values less than 120 mg/dL, insulin should be considered."

The bulletin reported that antepartum fetal testing is recommended for women with preexisting diabetes, as well as women with poorly controlled gestational diabetes. Exercise is often recommended for individuals with diabetes.

It was noted that oral antidiabetic agents have been contraindicated in pregnancy. However, glyburide was compared to insulin in a randomized controlled trial including women with gestational diabetes mellitus who did not achieve optimally glycemic control with diet. The study yielded results that glyburide had similar glucose control as insulin; furthermore pregnancy outcomes were similar to insulin as well. Contrary to the bulletin for preexisting diabetes in pregnancy, there are no other oral antidiabetic agents recommended for use in women with gestational diabetes mellitus.

American College of Obstetricians & Gynecologists. (2006). ACOG Practice Bulletin: Clinical Management Guidelines for Obstetrician-Gynecologists Number 76, October 2006: postpartum hemorrhage. [Practice Guideline]. *Obstetrics & Gynecology*, 108(4), 1039-1047.

Impact Factor: 4.36

Quality of Evidence: Acceptable

Condition: Hemorrhage

The bulletin reviewed the etiology, evaluation and management of postpartum hemorrhage. Based primarily on consensus and expert opinion (Level C) the following has been recommended and concluded:

- "Uterotonic agents should be the first-line treatment for postpartum hemorrhage due to uterine atony."
- "Management may vary greatly among patients, depending on etiology and available treatment options, and often a multidisciplinary approach is required."
- "When uterotonics fail following vaginal delivery, exploratory laparotomy is the next step."

It was also noted a multidisciplinary team may be required. Also, less-invasive methods should be used initially.

Proposed performance measure: "If hysterectomy is performed for uterine atony, there should be documentation of other therapy attempts."

American College of Obstetricians & Gynecologists. (2012). ACOG Practice Bulletin No. 125: Chronic hypertension in pregnancy. [Practice Guideline]. *Obstetrics & Gynecology*, 119(2 Pt 1), 396-407.

Impact Factor: 4.36

Quality of Evidence: Acceptable

Condition: Hypertension



Antihypertensive therapy has been shown to reduce the risk of a severe maternal hypertensive crisis, but has not been shown to improve overall perinatal outcome. A meta-analysis of randomized trials of antihypertensive therapy included 2,409 women with mild to moderate hypertension during pregnancy. This study reported a 50% decreased risk in developing severe hypertension, but no reduction in the risk of superimposed preeclampsia, perinatal mortality, preterm birth or small for gestational age (SGA) infants.

Labetalol was suggested to be a good option for the first-line treatment of chronic hypertension in pregnancy.

Methyldopa was also suggested to be safe for treatment of hypertension in pregnancy.

In a systematic review of 2,949 pregnant women were investigated along with the use of different antihypertensive agents; this study concluded that the women's blood pressure was lowered due to the antihypertensive therapy. However, it was unclear which agent provided the best results.

Studies reviewed have shown that increased morbidity associated with chronic hypertension in pregnancy is secondary to superimposed preeclampsia or intrauterine growth restrictions, it is recommended that a baseline ultrasonography be obtained followed up by regular ultrasonography for fetal growth. This monitoring may include nonstress testing or biophysical profile testing, and the use of umbilical vessel Doppler velocimetry. These tests have been shown not to improve outcomes when there is no fetal growth restriction or superimposed preeclampsia.

The following recommendations are based on good and consistent scientific evidence (Level A):

- “Angiotensin-converting enzyme inhibitors and angiotensin receptor block are contraindicated in all trimesters of pregnancy.”

The guideline did provide a proposed performance measure:

“In women with chronic hypertension, documentation of discussion of risks of chronic hypertension in pregnancy, documentation of baseline proteinuria, and documentation of plan for evaluation for fetal growth.”

Bismuth, E., Bouche, C., Caliman, C., Lepercq, J., Lubin, V., Rouge, D., . . . Vambergue, A. (2012). Management of pregnancy in women with type 1 diabetes mellitus: Guidelines of the French-Speaking Diabetes Society (Societe francophone du diabete [SFD]). *Diabetes & Metabolism*, 38(3), 205-216.

Impact Factor: 2.43

Quality of Evidence: Limited

Condition: Diabetes/Obesity

This review analyzed the clinical guidelines by the French-Speaking Diabetes Society for the management of pregnancy in women with Type 1 diabetes mellitus (T1DM). “T1DM during pregnancy has an impact on the fetus and embryo and may have increased the risk of spontaneous miscarriages, malformations, premature births, and fetal and neonatal complications.” However, tight glycemic control, planning and management can help improve outcomes for the fetus.

Continuous subcutaneous infusion of insulin (CSII), using an external pump, provides better control of blood glucose levels, especially in women with Type 1 diabetes mellitus who have poor control of blood glucose levels with multiple daily insulin injections, and are early in their pregnancy. The article stated that there is no evidence that suggests fetal prognosis is improved by treatment with the CSII. The article also references the recommendation of obstetric monitoring by physicians and midwives. Close management of diabetes during pregnancy is necessary for better outcomes of women with Type 1 diabetes mellitus.

Interventions included were:

- Avoidance of ACE inhibitors for antihypertensive agents.
- Avoidance of Diuretics
- Preferable to use calcium inhibitors as first line therapy
- Preferred use of labetalol
- No statin use during pregnancy
- Low dose ASA limited
- Dietary Management
- Insulin therapy
- Glycemic control and monitor of HbA1C.
- Fasting blood sugar 60-90- post AC <140 mg/dL, <120 mg/dL 2 hr post AC.
- Insulin lispro is recommended
- Insulin aspart is recommended
- Insulin glulisine not recommended
- Insulin glargine not recommended
- Insulin detemir safety and efficacy was reviewed
- insulin pumps reviewed on case by case

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Blackwell, S. C. (2011). Staying with old guidelines. *American Journal of Obstetrics & Gynecology*, 204(5), 371-372.

Impact Factor: 3.47

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=Not Specified

Debate Summary at 31<sup>st</sup> annual meeting of the Society for Maternal-Fetal Medicine (See Rouse (2011) for opposing summary debate)

The International Association of Diabetes in Pregnancy Study Group recommends a 1-stage screening and diagnosis method that includes a 75-gram, 2-hour glucose tolerance test based off the results of a Hypoglycemia and Adverse Pregnancy Outcome (HAPO) study and two randomized trials. The author argues against the expansion of the diagnostic criteria for gestational diabetes mellitus (GDM). He cites that the incidence of GDM will increase from 4-7% to 16-18%. Some feel diagnosing GDM in so many patients is not cost effective, there is over utilization of healthcare services, cesarean deliveries, and unnecessary therapies. The author goes on to comment that such a change in diagnostic criteria should only be considered after level I evidence and well-conducted interventional trials have become available, and provide the results and positive incomes that support this diagnostic change.

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Bomken, C., Mathai, S., Biss, T., Loughney, A., & Hanley, J. (2009). Recombinant Activated Factor VII (rFVIIa) in the Management of Major Obstetric Haemorrhage: A Case Series and a Proposed Guideline for Use. *Obstetrics & Gynecology International*, 2009, 364843.

Impact Factor: Not Available  
Quality of Evidence: Limited  
Condition: Hemorrhage

n=15

Retrospective Review

This study was a retrospective review, between July 2004 and February 2007, of the use of Recombinant Activated Factor VII (rFVIIa) in major obstetric hemorrhage. This study resulted in further support for the safety and efficacy of rFVIIa. Suggests that rFVIIa be given early and prior to hysterectomy, or vessel ligation could be used as a supplementary agent to obstetric and surgical interventions. rFVIIa is not recommended to be used as sole intervention, however it has been documented to slow the rate of bleeding and prevent further deterioration by delaying disseminated intravascular coagulation (DIC) and by reducing exposure to blood products.

Bulletins, A. C. o. P. (2001). ACOG Practice Bulletin. Chronic hypertension in pregnancy. ACOG Committee on Practice Bulletins. [Guideline, Practice Guideline]. *Obstetrics & Gynecology*, 98(1), suppl 177-185.

Impact Factor: 4.36  
Quality of Evidence: Acceptable  
Condition: Hypertension

n=Not Specified

Clinical Practice Guideline

The practice bulletin provided information on chronic hypertension in pregnancy, but this summary focuses on the evidence review of treatment options for this condition. The following recommendations are based on good and consistent scientific evidence (Level A):

- Angiotensin-converting enzyme inhibitors and angiotensin receptor blockers are contraindicated in all trimesters of pregnancy.

Based on limited or inconsistent scientific evidence (Level B):

- Antihypertensive therapy should be used in pregnant with women with severe hypertension.
- "Methyldopa and labetalol are appropriate first-line antihypertensive therapies."
- "Treatment of women with uncomplicated mild hypertension is not beneficial because it does not improve the perinatal outcomes."
- Atenolol is not recommended for use in pregnancy.

Bulletins, A. C. o. P. (2005). ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists. Number 60, March 2005. Pregestational diabetes mellitus. [Guideline Practice Guideline]. *Obstetrics & Gynecology*, 105(3), 675-685.

Impact Factor: 4.36  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n=Not Specified

Clinical Practice Guideline

The bulletin suggests management guidelines for pregestational diabetes mellitus through pregnancy.

Insulin can be administered by the use of a continuous subcutaneous insulin infusion pump, and this therapy can decrease severe hypoglycemia, as well as provide better control of hyperglycemia. There have not been many studies and evidence regarding oral hypoglycemic agents in pregnancy. However, there has been use of glyburide and metformin. A study reviewed found that glyburide improved glucose control analogous to insulin; glyburide also was not associated with any adverse maternal or neonatal complications. Metformin is commonly used for glucose control in pregnancy; however, its effects in utero have not been well investigated. An ultrasound is recommended for fetal assessment. Also the use of fetal movement counting, the nonstress test, the biophysical profile and the contraction stress test can be used to monitor during the pregnancy. Testing is appropriate at 32-34 weeks gestation for most patients.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- “Suspected fetal macrosomia is not an indication for induction of labor because induction does not improve maternal or fetal outcomes.”
- “Antepartum fetal monitoring, including fetal movement counting, the nonstress test, the biophysical profile, and the contraction stress test when performed at appropriate intervals, is a valuable approach and can be used to monitor the pregnancies of women with pregestational diabetes mellitus.”
- “Adequate maternal glucose control should be maintained near physiologic levels before conception and throughout pregnancy to decrease the likelihood of spontaneous abortion, fetal malformation, fetal macrosomia, intrauterine fetal death, and neonatal morbidity.”
- “Patients and their families should be taught how to respond quickly and appropriately to hypoglycemia.”
- “Preconceptional counseling for women with pregestational diabetes mellitus has been reported to be beneficial and cost-effective and should be encouraged.”
- “The use of oral agents for control of type 2 diabetes mellitus during pregnancy should be limited and individualized until data regarding the safety and efficacy of these drugs become available.”
- “To prevent traumatic birth injury, cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 gm in women with diabetes.”

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Bulletins--Obstetrics, A. C. o. P. (2002). ACOG practice bulletin. Diagnosis and management of preeclampsia and eclampsia. Number 33, January 2002. [Guideline, Practice Guideline]. *Obstetrics & Gynecology*, 99(1), 159-167.

Impact Factor: 4.36  
 Quality of Evidence: Acceptable  
 Condition: Preeclampsia

n=Not Specified

#### Clinical Practice Guideline

The bulletin focuses on guidelines for the diagnosis and management of hypertensive disorders unique to pregnancy.

The following recommendations are based on good and consistent scientific evidence (Level A):

- "Magnesium sulfate should be used for the prevention and treatment of seizures in women with severe preeclampsia or eclampsia."
- "If analgesia/anesthesia is required, regional or neuraxial analgesia/anesthesia should be used because it is efficacious and safe for intrapartum management of women with severe preeclampsia in the absence of coagulopathy."
- "Low-dose aspirin has not been shown to prevent preeclampsia in women at low risk and, therefore is not recommended."
- "Daily calcium supplementation has not been shown to prevent preeclampsia and, therefore, is not recommended."

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- "The management of a woman with severe preeclampsia remote from term is best accomplished in a tertiary care setting or in consultation with an obstetrician–gynecologist with training, experience, and demonstrated competence in the management of high-risk pregnancies, such as a maternal–fetal medicine subspecialist."
- "Practitioners should be aware that although various laboratory tests may be useful in the management of women with preeclampsia, to date there is no reliable predictive test for preeclampsia."
- "Invasive hemodynamic monitoring should be considered in preeclamptic women with severe cardiac disease, renal disease, refractory hypertension, pulmonary edema, or unexplained oliguria."

Bulletins--Obstetrics, A. C. o. P. (2008). ACOG Practice Bulletin: Clinical management guidelines for obstetrician-gynecologists number 92, April 2008 (replaces practice bulletin number 87, November 2007). Use of psychiatric medications during pregnancy and lactation. [Practice Guideline Review]. *Obstetrics & Gynecology*, 111(4), 1001-1020.

Impact Factor: 4.36

Quality of Evidence: Acceptable

Condition: Psychiatric/ Mental Health

n=Not Specified

#### Clinical Practice Guideline

The practice bulletin presents current evidence on the risks and benefits of treatment of certain psychiatric illnesses during pregnancy.

Based on good and consistent scientific evidence (Level A) the following has been recommended and concluded:

- "Lithium exposure in pregnancy may be associated with a small increase in congenital cardiac malformations",
- "Valproate exposure in pregnancy is associated with increased risk of fetal anomalies. It should be avoided in pregnancy, if possible, especially during the first trimesters."

- "Carbamazepine exposure in pregnancy is associated with fetal carbamazepine syndrome. It should be avoided in pregnancy, if possible, especially during the first trimester."
- "Maternal benzodiazepine use shortly before delivery is associated with floppy infant syndrome."

Based on limited or inconsistent scientific evidence (Level B) the following has been recommended and concluded:

- "Paroxetine use in pregnant women and women planning pregnancy should be avoided, if possible. Fetal echocardiography should be considered for women who are exposed to paroxetine in early pregnancy."
- "Lamotrigine is a potential maintenance therapy option for pregnant women with bipolar disorder because of its protective effects against bipolar depression, general tolerability, and a growing reproductive safety profile relative to alternative mood stabilizers."
- "Maternal psychiatric illness, if inadequately treated or untreated, may result in poor compliance with prenatal care, inadequate nutrition, exposure to additional medication or herbal remedies, increased alcohol and tobacco use, deficits in mother–infant bonding, and disruptions within the family environment."

Based primarily on consensus and expert opinion (Level C) the following has been recommended and concluded:

- "Whenever possible, multidisciplinary management involving the patient's obstetrician, mental health clinician, primary health care provider, and pediatrician is recommended to facilitate care."
- "Use of a single medication at a higher dose is favored over the use of multiple medications for the treatment of psychiatric illness during pregnancy."
- "Fetal assessment with fetal echocardiogram should be considered in pregnant women exposed to lithium in the first trimester."

Carson, G., Cox, L. V., Crane, J., Croteau, P., Graves, L., Kluka, S., . . . Gynaecologists of, C. (2010). Alcohol use and pregnancy consensus clinical guidelines. [Practice Guideline Research Support, Non-U.S. Gov't]. *Journal of Obstetrics & Gynaecology Canada: JOGC*, 32(8 Suppl 3), S1-31.

Impact Factor: Not Applicable

Quality of Evidence: Acceptable

Condition: Psychiatric/ Mental Health

n=Not Applicable

Clinical Consensus Guidelines on Alcohol Use and Pregnancy

This document provides clinical guidelines on alcohol use and pregnancy with a focus of providing a basis for assessment, counseling, and intervention for women who are pregnant and consume alcohol. The guidelines note the importance of screening to improve maternal and child health outcomes through early identification and reduction of maternal alcohol consumption and early identification of infants at potentially high risk for fetal alcohol spectrum disorder (FASD). Research supports the effectiveness of brief interventions and the guidelines recommend they be provided. Brief interventions consist of 4 components: assessment and feedback, goal setting, positive reinforcement, and education. Harm reduction is another guideline recommendation. This involves reducing the harms associated with alcohol use by

promoting a reduction in consumption in working toward abstinence. Noting that women who are alcohol dependent experience difficulty to stop drinking during pregnancy, it is recognized that they require intense and specialized counseling and support. Medical support is essential during the process of withdrawal. Therefore, the guidelines also recommend that priority access to withdrawal management and treatment should be given to pregnant women. The range of evidence for the recommendations noted in this summary is II-2B to III-A

Churchill, D. (2001). The new American guidelines on the hypertensive disorders of pregnancy. *Journal of Human Hypertension*, 15(9), 583-585.

Impact Factor: 2.24

Quality of Evidence: Limited

Condition: Hypertension

n=Not Specified

Commentary

The article reviews a 2000 report that the National High Blood Pressure Education Program Working Group, sponsored by the National Institute of Health (NIH), constructed on hypertensive disorders of pregnancy.

In high-risk pregnant women the use of low dose aspirin and other anti-platelet agents has been helpful. The lack of reporting on umbilical artery Doppler ultrasound is critiqued because it has been shown through randomized controlled clinical trials that utilization of the Doppler ultrasound of the umbilical artery reduces perinatal mortality. The author disagrees with the suggestion of fetal movement monitoring because of the lack of evidence and it is an outdated technique. The author does recommend the use of "fetal heart rate monitoring and biophysical profile to monitor at-risk pregnancies." As for the treatment of hypertensive disorders, the NIH recommends methyldopa is the first drug of choice and then labetalol can be considered as an alternative if needed.

Churchill describes this report as an effective tool for the management of hypertension in pregnancy.

Cohen, L. S., Heller, V. L., & Rosenbaum, J. F. (1989). Treatment guidelines for psychotropic drug use in pregnancy. [Review]. *Psychosomatics*, 30(1), 25-33.

Impact Factor: 1.71

Quality of Evidence: Limited

Condition: Psychiatric/ Mental Health

n=Not Specified

Informational Review

This article provided proposed recommendations on guidelines for managing psychiatric disorders. The article provides a table of 24 recommendations for psychotropic drug use during pregnancy. It highlights management in psychosis, mania, depression, and anxiety disorders.

Cutchie, W. A., Cheung, N. W., & Simmons, D. (2006). Comparison of international and New Zealand guidelines for the care of pregnant women with diabetes. [Comparative Study Review]. *Diabetic Medicine*, 23(5), 460-468.

Impact Factor: 2.87  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=Not Specified

Literature Review of National and International Guidelines

The article compared international guidelines for the care of women with diabetes and pregnancy with the current practice among New Zealand healthcare centers. Stated there was variation between guidelines for the management of diabetes in pregnancy. There is less agreement for the management of gestational diabetes. There needs to be an international consensus.

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Dalvi, B. V., Chaudhuri, A., Kulkarni, H. L., & Kale, P. A. (1992). Therapeutic guidelines for congenital complete heart block presenting in pregnancy. [Case Reports]. *Obstetrics & Gynecology*, 79(5 ( Pt 2)), 802-804.

Impact Factor: 4.36  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n=3

Case Reports

Congenital complete heart block is rare and can be very serious in pregnancy. There are no guidelines on the use of temporary or permanent pacemakers during pregnancy. This study examined three cases of congenital complete heart block. All three patients delivered normally with temporary pacing support during labor. The article suggests that women that present with symptoms in the first and second trimesters receive permanent pacemaker implantation, while women who present with symptoms at or near term receive temporary pacing with induction of labor as early as possible. The symptomatic status of the patient should be assessed postpartum; if symptoms remain after weaning the patient off temporary pacing, a permanent pacemaker should be placed.

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Davies, G. A. L., Maxwell, C., McLeod, L., Gagnon, R., Basso, M., Bos, H., . . . Gynaecologists of, C. (2010). SOGC Clinical Practice Guidelines: Obesity in pregnancy. No. 239, February 2010. [Practice Guideline]. *International Journal of Gynaecology & Obstetrics*, 110(2), 167-173.

Impact Factor: 1.14  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=Not Specified

Clinical Practice Guideline

Obese women should be encouraged to exercise regularly during pregnancy. Nutritional counseling and dietary management may be beneficial. The article cited a systematic review that assessed energy and protein restriction as preventive strategies to avoid adverse perinatal outcomes; it was found that energy and protein restrictions may not be beneficial and actually pose harm to the fetus.



Additionally, it was suggested that a consult with an anesthesiologist should be considered when planning care during delivery.

Recommendations:

- “Obese pregnant women should receive counseling about weight gain, nutrition, and food choices.” (Level of Evidence: II-2B)
- “Obese women should be advised that they are at risk for medical complications such as cardiac disease, pulmonary disease, gestational hypertension, gestational diabetes, and obstructive sleep apnea. Regular exercise during pregnancy may help to reduce some of these risks.” (Level of Evidence: II-2B)
- “Antenatal consultation with an anaesthesiologist should be considered to review analgesic options and to ensure a plan is in place should a regional anaesthetic be chosen.” (Level of Evidence: III-B)

Duffy, M. R. (2007). Guidelines for use of recombinant factor VIIa in life-threatening post-partum haemorrhage. [Comment Letter]. *International Journal of Obstetric Anesthesia*, 16(3), 299-300; author reply 300.

Impact Factor: 1.85

Quality of Evidence: Limited

Condition: Hemorrhage

n=Not Specified

Comment Letter

The commentary discussed the use of recombinant activated factor VIIa (rFVIIa) for treatment in massive post-partum hemorrhage. Reviews the consensus guidelines proposed by Vincent et al (2006), these guidelines suggest that rFVIIa should not be the only intervention or therapy used for the treatment of post-partum hemorrhage. Additionally, all other conventional methods of interventions should be utilized before the use of rFVIIa is considered. Guidelines that are developed and address the use of rFVIIa need randomized controlled trials, and at the time of release of this letter there were no scheduled trials. An audit of use of rFVIIa nationally and internationally is suggested, and also suggests that guidelines developed need to not have any linkage to a pharmaceutical company.

Einerson, B. D., Huffman, J. K., Istwan, N. B., Rhea, D. J., & Joy, S. D. (2011). New gestational weight gain guidelines: an observational study of pregnancy outcomes in obese women. [Comparative Study]. *Obesity*, 19(12), 2361-2364. doi: <http://dx.doi.org/10.1038/oby.2011.67>

Impact Factor: 3.37

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=691

Retrospective Analysis

The article compared the updated 2009 Institute of Medicine weight gain guidelines with the criteria of the previous version of the guidelines. The change made in the 2009 guidelines was the recommendation of gestational weight gain of 11-12 pounds for women with a pre-pregnancy BMI greater than 30 kg/m<sup>2</sup> (the traditional recommendation was 23-35 pounds). This

study investigated the effect on perinatal outcomes of weight gain within the new guidelines and those who gained above the recommended amount.

There was no statistical difference in maternal and neonatal outcomes between the obese women that gained weight according to the new IOM guidelines and those who gained weight per the traditional recommendations. However, the results demonstrated a decrease in cesarean deliveries and cases of pregnancy-related hypertension for women who gained weight within the new guidelines. There was also no increase in the number of low birth weight infants.

European Society of, G., Association for European Paediatric, C., German Society for Gender, M., Authors/Task Force, M., Regitz-Zagrosek, V., Blomstrom Lundqvist, C., . . . Warnes, C. (2011). ESC Guidelines on the management of cardiovascular diseases during pregnancy: the Task Force on the Management of Cardiovascular Diseases during Pregnancy of the European Society of Cardiology (ESC). [Practice Guideline]. *Eur Heart J*, 32(24), 3147-3197.

Impact Factor: 9.80

Quality of Evidence: Acceptable

Condition: Cardiac Disease/Hypertension

n=Not Specified

Practice Guidelines

These guidelines address the management of cardiovascular disease in pregnant women. Within the guidelines there a number of procedures that can aid in the diagnosis and management; a few are electrocardiography, echocardiography, exercise testing, and cardiac catheterization. Fetal assessment is included, which recommends specific tests to monitor the fetus as well as optimal times to screen and assess the fetus. The guidelines noted that if an intervention is necessary it is best to intervene after the fourth month in the second trimester. Management of the timing of delivery should be individualized. A multi-disciplinary team should be a part of the care plan. Treatment should be done in specialized centers, along with specialized health care professionals performing the services. If an echocardiograph is inconclusive an MRI (without gadolinium) should be considered. CT and electrophysiological studies may be considered. When conservative and medical therapy has failed, the situation is life-threatening and cannot be treated with percutaneous treatment; coronary bypass surgery or valvular surgery may be considered.

Group, J. C. S. J. W. (2012). Guidelines for Indication and Management of Pregnancy and Delivery in Women with Heart Disease (JCS 2010): digest version. [Practice Guideline]. *Circulation Journal*, 76(1), 240-260.

Impact Factor: 9.80

Quality of Evidence: Acceptable

Condition: Cardiac Disease

n=Not Specified

Practice Guidelines

This guideline focused on the management of pregnancy and delivery in women with heart disease.

The mother and fetus must be continuously monitored by a multidisciplinary team when the

mother has heart disease. The mother and fetus should be monitored for arrhythmia, heart failure and thrombosis during the pregnancy. There should also be communication between the team members (cardiologist to obstetrician) regarding the monitoring progress/results and background. Hemodynamic assessment should be evaluated by echocardiography. Fetal health should be monitored using fetal heart rate monitoring and ultrasonic methods. Women with high-risk pregnancy should be monitored in a tertiary care facility by obstetricians, heart disease specialists, anesthesiologists and neonatologists.

Guideline Development, G. (2008). Management of diabetes from preconception to the postnatal period: summary of NICE guidance. [Research Support, Non-U.S. Gov't Review]. *BMJ*, 336(7646), 714-717.

Impact Factor: 13.66  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n=Not Specified

Summary of Guidelines

Management of diabetes based on the NICE guidelines.

Pregnant women with pre-existing diabetes should be offered retinal and renal assessments because diabetic retinopathy and nephropathy may add complications to the pregnancy.

For women with gestational diabetes, hypoglycemic therapy should be considered, if diet and exercise cannot maintain normal blood glucose levels. Hypoglycemic therapy should also be considered if there is evidence of incipient fetal macrosomia.

Pregnant women with diabetes should be put in contact with joint diabetes and antenatal clinic and a diabetes care team. Anesthetic assessment should occur in the third trimester for pregnant women with additional co-morbidities.

Hoffman, L., Nolan, C., Wilson, J. D., Oats, J. J., & Simmons, D. (1998). Gestational diabetes mellitus--management guidelines. The Australasian Diabetes in Pregnancy Society. [Consensus Development Conference Guideline Review]. *Medical Journal of Australia*, 169(2), 93-97.

Impact Factor: 2.89  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=Not Specified

Consensus Statement

The article provides recommendations for the management of gestational diabetes mellitus by the Australasian Diabetes in Pregnancy Society.

A multidisciplinary team is the best approach when managing pregnant women with gestational diabetes. Patient education is also very important. To provide glycemic control, dietary therapy (preferably from a skilled dietitian), self and laboratory monitoring of blood glucose levels, insulin therapy, and fetal surveillance should be implemented.

It is noted that insulin therapy should be considered “if the glucose goals are exceeded on two or more occasions within a 1 to 2 week interval, particularly in association with clinical or investigation suspicious of macrosomia.”

Oral hypoglycemic agents are contraindicated for treatment of gestational diabetes mellitus.

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Hollander, M. H., Paarlberg, K. M., & Huisjes, A. J. M. (2007). Gestational diabetes: a review of the current literature and guidelines. [Review]. *Obstetrical & Gynecological Survey*, 62(2), 125-136.

Impact Factor: 3.1

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=Not Specified

Review of Literature and Guidelines

There still is no worldwide consensus on diagnosis, management, and adverse effects of gestational diabetes mellitus (GDM). No randomized control clinical trials provide conclusive evidence that treatment of gestational diabetes mellitus (diet, exercise, and/or insulin) improves the outcomes for mothers and fetuses.

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Howland, R. H. (2009). Prescribing psychotropic medications during pregnancy and lactation: principles and guidelines. [Review]. *Journal of Psychosocial Nursing & Mental Health Services*, 47(5), 19-23.

Impact Factor: 0.71

Quality of Evidence: Limited

Condition: Psychiatric/ Mental Health

n=Not Specified

Review

A multidisciplinary team is beneficial for the success of treatment during pregnancy. Mother and fetus should be closely monitored throughout pregnancy. Use of psychotropic medications should be administered in the lowest effective drug dose. The article had similar consensus on which psychotropic medication were safe and not safe during pregnancy, as other articles. Antidepressants and anti-psychotic have deemed generally safe while benzodiazepines, lithium and anticonvulsants drugs should be avoided if possible.

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lung, B. (2012). Heart disease in pregnant women: recent ESC guidelines. [Editorial]. *Arch Cardiovasc Dis*, 105(2), 57-59.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Cardiac Disease

n=Not Specified

Scientific Editorial

Reviewed the European Society of Cardiology 2011 guidelines for management of cardiovascular disease during pregnancy.

This review concludes that the European Society of Cardiology guidelines are useful for healthcare providers in "facilitating an overall and disease-specific approach." The guidelines emphasize multidisciplinary management throughout the whole pregnancy, which should involve cardiologists, obstetricians, and anesthesiologists. Women with high risk cardiac issues should be managed in specialized centers.

Jovanovic-Peterson, L., & Peterson, C. M. (1992). Pregnancy in the diabetic woman. Guidelines for a successful outcome. [Review]. *Endocrinology & Metabolism Clinics of North America*, 21(2), 433-456.

Impact Factor: 3.56

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=Not Specified

Review

This article recommends that any woman with fasting plasma glucose about 105 mg/dL requires insulin about four injections per day. Recommends diet and exercise. Suggests education of patients to achieve optimal plasma glucose levels. Glycosylated hemoglobin should not be used to screen for gestational diabetes, however, it can be used to monitor control of gestational diabetes. The use of human insulin or pure pork insulin is recommended because human insulins are less immunogenic than mixed beef-pork insulins. Delivery should occur electively between 35 and 38 weeks and to reduce neonatal morbidity, delivery should be delayed until pulmonary maturity, when possible.

Kappy, M. S. (1991). Diabetes in pregnancy: rationale and guidelines for care. [Review]. *Comprehensive Therapy*, 17(7), 50-56.

Impact Factor: 1.32

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=Not Specified

Review

A multidisciplinary team is crucial for the management of pregnant women with diabetes. The team should include a perinatologist, diabetologist, perinatologist/obstetrician, diabetes nurse, dietician, neonatologist, mother's family physician, infant's primary care provider, and specialists which can include ophthalmologists, nephrologists, psychiatrists or psychologists, and social workers. Dietary management should be implemented and consultation by a dietician may be beneficial. Insulin therapy is recommended to achieve pre-prandial blood glucose level 70-90 mg/dl and 2-hour postprandial blood glucose level less than 140 mg/dl. To achieve this, the article suggests three daily insulin injections. Pregnant women with diabetes and fetuses should be monitored. The fetus should be monitored with nonstress tests, maternal serum alpha fetoprotein concentrations, ultrasounds, and amniocentesis. Delivery should occur when metabolic conditions are stable and the maternal blood glucose level is around 100 mg/dl. The article also notes that it is crucial to achieve metabolic normalcy preconception, because

this helps avoid congenital malformations and death in the infants. The multidisciplinary team is crucial in reducing maternal and perinatal morbidity and mortality.

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Karakash, S. D., & Einstein, F. H. (2011). Diabetes in pregnancy: glycemia control guidelines and rationale. [Research Support, N.I.H., Extramural Review]. *Current Opinion in Endocrinology, Diabetes & Obesity*, 18(2), 99-103.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=Not Specified

Review

Clinical guidelines for the diagnosis of gestational diabetes mellitus will be changing in the future due to the results of studies which have shown that treatment of mild gestational diabetes reduces certain adverse perinatal and maternal outcomes.

Two studies that the article reviewed provided details that gestational diabetes mellitus incurs significant risk of adverse maternal and fetal perinatal outcome and interventions can help with reducing the risks. These two key studies support the need for a consensus on interventions for mild maternal hyperglycemia, because there are improved outcomes with treatment.

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Kim, D. R., O'Reardon, J. P., & Epperson, C. N. (2010). Guidelines for the management of depression during pregnancy. *Current Psychiatry Reports*, 12(4), 279-281.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=Not Specified

Commentary on Guidelines

Provides commentary on guidelines for the management of depression during pregnancy, as published by the American Psychiatric Association and the American College of Obstetricians and Gynecologists. This article supported the recommendation of the guidelines and emphasized the importance for clinicians that treat women who become pregnant to be aware of these guidelines.

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Leduc, D., Senikas, V., Lalonde, A. B., Ballerman, C., Biringier, A., Delaney, M., . . . Gynaecologists of, C. (2009). Active management of the third stage of labour: prevention and treatment of postpartum hemorrhage. [Practice Guideline, Research Support, Non-U.S. Gov't, Review]. *Journal of Obstetrics & Gynaecology Canada: JOGC*, 31(10), 980-993.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

n=Not Specified

Practice Guidelines

This is a guideline written by the Society of Obstetricians and Gynaecologists of Canada (SOGC) that provides guidelines for the prevention and management of postpartum hemorrhage. The quality of evidence was rated with use of criteria described by the Canadian Task Force on Preventative Health Care. Relevant recommendations for the prevention of postpartum hemorrhage are:

- 10 IU of oxytocin administered intramuscularly in low risk vaginal deliveries (I-A)
- Ergonovine is second choice to oxytocin use, due to adverse effects (I-A)
- Carbetocin, 100 µg should be given as an IV bolus over 1 minute during an elective cesarean section for prevention of postpartum hemorrhage and to reduce the need for additional uterotonics. (I-B)
- Women delivering vaginally with one risk factor for post partum hemorrhage (PPH) should be administered carbetocin 100 µg (I-B)
- Delaying cord clamping by at least 60 seconds is preferred to clamping earlier in premature newborns (I-A)
- Intraumbilical cord injection of misoprostol (800 µg) or oxytocin (10 µg to 30 IU) can be considered. (II-2C)

Relevant treatment recommendations are as follows:

- Management of post-partum hemorrhage (PPH) requires a multidisciplinary approach (III-C)
- Uterine tamponade can be considered when PPH is caused by uterine atony and there has been no response to other medical therapy (III-L)
- Surgical techniques should be used for the management of intractable PPH unresponsive to medical therapy (III-B)

Lowe, S. A., Brown, M. A., Dekker, G. A., Gatt, S., McLintock, C. K., McMahon, L. P., . . . New, Z. (2009). Guidelines for the management of hypertensive disorders of pregnancy 2008. [Practice Guideline]. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 49(3), 242-246.

Impact Factor: 1.32

Quality of Evidence: Limited

Condition: Hypertension

n=Not Specified

Executive Summary for Updated Guidelines

This article is a summary of the updated guidelines for the management of hypertensive diseases of pregnancy, developed by the Society of Obstetric Medicine of Australia and New Zealand. A team approach in the management of gestational hypertension and pre-eclampsia provides optimal outcomes for mother and the newborn. Recommends that anesthesia should be offered for women with severe pre-eclampsia. Also an epidural analgesia during labor and delivery can be useful as an antihypertensive therapy.

Marcus, S. M., Barry, K. L., Flynn, H. A., Tandon, R., & Greden, J. F. (2001). Treatment guidelines for depression in pregnancy. [Review]. *International Journal of Gynaecology & Obstetrics*, 72(1), 61-70.

Impact Factor: 1.41

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n=Not Specified

Review

Provides treatment guidelines for depression in pregnancy and postpartum. Selective serotonin reuptake inhibitors have been shown to be safe for the mother and fetus during pregnancy. Tricyclics have also been shown not to have any association with congenital malformations. However, monoamine oxidase inhibitors are contraindicated during pregnancy. Benzodiazepines have been suggested to contribute to cleft palate, however cleft palate in the general population only occurs in about 0.064%, therefore the level of risk that benzodiazepines contributes to the outcome of cleft palate is difficult to determine. Mood stabilizers such as lithium have been associated with anomalies in pregnant women and neonatal morbidity and toxicity. Selective serotonin reuptake inhibitors and secondary amine tricyclic antidepressants are the choice of drugs in pregnancy. MAOIs are contraindicated during pregnancy. "Electroconvulsive therapy should be considered for severe debilitating depression with nutritional compromise."

Pregnant women with bipolar illness that experience mood liability, insomnia, nutritional compromise, or risk taking behavior should be put on mood stabilizers; however, they are contraindicated in the first trimester. Lithium is preferred in the first trimester because the risk for Ebstein's anomaly is relatively small. At weeks 16-18 an ultrasound of the fetus should be performed to assess for congenital anomalies. A pediatric team should be arranged to be present during the delivery to help with care of the neonate. Lithium should also be delivered in multiple doses throughout the day. If necessary, electroconvulsive therapy is indicated.

Mathai, M., Gulmezoglu, A. M., & Hill, S. (2007). Saving women's lives: evidence-based recommendations for the prevention of postpartum haemorrhage. *Bulletin of the World Health Organization*, 85(4), 322-323.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Hemorrhage

n=Not Specified

Article

This article contains evidence-based recommendations for the prevention of postpartum hemorrhage. Recommends oxytocin as the most advantageous drug for the prevention of atonic post-partum hemorrhage (PPH).

Mathiesen, E. R., & Damm, P. (2008). Commentary from Copenhagen on the NICE guideline on management of diabetes and its complications from preconception to the postnatal period. *Diabetic Medicine*, 25(9), 1028-1029.

Impact Factor: 2.87

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=Not Specified

Commentary



This article commented on the NICE guidelines on management of diabetes. The MiG study (Rowan 2008) assessed the efficacy and safety of the use of metformin during pregnancy; it was shown that in the last half of pregnancy, metformin is a safe and efficient method of treatment comparable to insulin. However, this commentary advises caution because metformin does cross the placenta and there have not been any follow-up studies. The insulin analogues were also recommended. However, there was not any solid evidence supporting this recommendation. The authors were surprised that the guidelines did not recommend monitoring women's glycated hemoglobin in pregnancy, because this practice is widely used and it has been proven to be predictive of poor pregnancy outcomes. The NICE guidelines do not recommend antenatal fetal testing until 38 weeks. This is also a surprise because antenatal cardiotochography is viewed as a significant tool by clinicians for monitoring. The authors recommend that cardiotochography be performed at least once weekly from week 32 to 34 in women with pre-gestational diabetes. Overall the NICE guidelines will be of use but there are issues with some of the recommendations and lack of recommendations.

McElduff, A., Cheung, N. W., McIntyre, H. D., Lagstrom, J. A., Oats, J. J. N., Ross, G. P., . . . Australasian Diabetes in Pregnancy, S. (2005). The Australasian Diabetes in Pregnancy Society consensus guidelines for the management of type 1 and type 2 diabetes in relation to pregnancy. [Guideline Practice Guideline]. *Medical Journal of Australia*, 183(7), 373-377.

Impact Factor: 2.89

Quality of Evidence : Limited

Condition: Diabetes/Obesity

n=Not Specified

Consensus Guidelines

Australasian Diabetes in Pregnancy Society (ADIPS) consensus guidelines for the management of type 1 and type 2 diabetes in pregnancy.

- Management of diabetes during pregnancy should be overseen by a multidisciplinary team that has experience with diabetes and pregnancy.
- Women with type 1 and type 2 diabetes need mandatory blood glucose monitoring. A1C levels should be monitored and managed. Proteinuria should also be assessed at regular intervals.
- Ultrasound should be performed for fetal growth and morphology.

Oral hypoglycemic agents, similarly to other guidelines and studies, are not recommended for use during pregnancy due to the lack of evidence regarding safety in pregnancy.

Anti-hypertensive therapy in pregnancy has been reviewed and guidelines developed by the Australasian Society for the Study of Hypertension in Pregnancy. Angiotensin-converting enzyme inhibitors should be avoided in pregnancy; they adversely affect the fetus. There is evidence that supports the use of methyldopa, oxprenolol, clonidine, labetalol, prazosin and nifedipine during pregnancy.

Menzies, J., Magee, L. A., Li, J., MacNab, Y. C., Yin, R., Stuart, H., . . . Preeclampsia Integrated Estimate of RiSk Study, G. (2007). Instituting surveillance guidelines and adverse outcomes in preeclampsia. [Evaluation Studies, Research Support, Non-U.S. Gov't]. *Obstetrics & Gynecology*, 110(1), 121-127.

Impact Factor: 4.36  
 Quality of Evidence: Acceptable  
 Condition: Preeclampsia

n=Not Specified

Retrospective and Prospective Cohort Comparison Study

The study concluded that instituting a standardized initial assessment and ongoing surveillance of women admitted to the hospital with preeclampsia resulted in a reduced incidence of adverse maternal outcomes.

Mulholland, C., Njoroge, T., Mersereau, P., & Williams, J. (2007). Comparison of guidelines available in the United States for diagnosis and management of diabetes before, during, and after pregnancy. [Comparative Study, Review]. *Journal of Women's Health*, 16(6), 790-801.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=Not Specified

Comparative Study, Review

Gestational Diabetes:

This article reviewed six guidelines for gestational diabetes mellitus: American College of Obstetricians and Gynecologists (ACOG), American Diabetes Association (ADA), Joslin Diabetes Center (Joslin), International Diabetes Center, World Health Organization (WHO), and U.S. Preventive Services Task Force. All but the U.S. Preventive Services Task Force recommend assessing the risk for gestational diabetes for all women. There is little homogeneity regarding target blood glucose levels during pregnancy. Joslin Diabetes Center and the ADA recommend that insulin therapy be started when blood glucose levels are greater than 105 g/dL. None of the guidelines recommend the use of oral hypoglycemic agents. The ACOG guidelines note that there is not sufficient evidence regarding oral hypoglycemic agents.

Additionally, the guidelines do not provide a consensus regarding the frequency of blood sugar monitoring; some recommend one test a day, while other recommend up to seven tests a day. Delivery practices are also varied.

Preexisting diabetes mellitus:

The study also reviewed three guidelines for the management of pre-existing diabetes: ACOG, ADA, and Joslin. There was a general consensus between the three guidelines that the management is done by a multidisciplinary team of specialists. The guidelines differ on target blood glucose values, monitoring frequency, management of labor and delivery, and postpartum instructions.

Muzik, M., Marcus, S. M., Heringhausen, J. E., & Flynn, H. (2009). When depression complicates childbearing: guidelines for screening and treatment during antenatal and postpartum obstetric care. *Obstetrics & Gynecology Clinics of North America*, 36(4), 771-788, ix-x.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=Not Specified  
 Guideline

The article addressed depression during pregnancy. Recommended some of the general guidelines that ACOG suggests in their Practice Bulletin from 2008 entitled "Use of psychiatric medications during pregnancy and lactation." Research reviewed in the article suggests that use of selective serotonin reuptake inhibitors (SSRIs) is associated with risks for the fetuses. However, the risk is assessed as being small and therefore the medications are seen as being safe for use during pregnancy. Interpersonal psychotherapy and cognitive behavioral therapy are recommended for treatment of unipolar depression. Another nonpharmacologic treatment that is deemed safe and effective, when necessary, is electroconvulsive therapy. For the treatment of postpartum depression, antidepressant medication and psychotherapy are key clinical tools. Interpersonal psychotherapy and cognitive behavioral therapy are also recommended for postpartum depression.

Nurnberg, H. G., & Prudic, J. (1984). Guidelines for treatment of psychosis during pregnancy. *Hospital & Community Psychiatry*, 35(1), 67-71.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=Not Specified  
 Guidelines

This paper discussed the treatment of pregnant psychotic women in the last six months of pregnancy and presented some guidelines on treatment. At this time, there was no evidence that guaranteed fetal safety, so the general rule of pharmacology is to be applied: "use drugs in pregnancy only when the risk to the mother and fetus of not using drugs outweighs the risk of drug treatment."

Guidelines for treatment were given for the acutely psychotic pregnant patient:

- "To determine the need for medication, the pregnant psychotic patient should be hospitalized when florid symptomatology is manifested. The patient should first be evaluated off medication; such evaluation may be possible only with the structure and supervision an inpatient unit provides
- If medication is needed, use perphenazine or haloperidol at the lowest effective dosage. Complete resolution of all symptoms may not be a feasible goal.
- If possible, all other medications should be avoided.
- Psychotropic medications should be discontinued as soon as possible.
- Support systems are very important from caseworker, family support and healthcare workers. Need close relationships. May need to plan for alternate care for the infant.
- After birth, the "initiation of the medications should be delayed until the mother's physiological fluid homeostasis is reestablished."

Perez-Cuevas, R., Morales, H. R., Doubova, S. V., & Murillo, V. V. (2007). Development and use of quality of care indicators for obstetric care in women with preeclampsia, severe preeclampsia, and severe morbidity. *Hypertension in Pregnancy*, 26(3), 241-257.

Impact Factor: 1.37

Quality of Evidence: Limited

Condition: Preeclampsia

n=432

Two-Staged Study Design

Evaluated the quality of care using four indicators developed by an expert group. The indicators were: availability of intensive care, completeness of laboratory tests, appropriateness of drug treatment at admission/before delivery, gestational age at which pregnancy should be interrupted, and type of delivery. The results demonstrated that women with severe preeclampsia received better quality of care, than women with mild or less preeclampsia. Also suggested that improving the way clinical information is being documented and passed along among hospital sites and healthcare workers, and processes of care at admission/before delivery, may help improve maternal outcome.

Potti, S., Sliwinski, C. S., Jain, N. J., & Dandolu, V. (2010). Obstetric outcomes in normal weight and obese women in relation to gestational weight gain: comparison between Institute of Medicine guidelines and Cedergren criteria. [Comparative Study]. *American Journal of Perinatology*, 27(5), 415-420.

Impact Factor: 1.13

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=9125

Comparative Study

This study compared the obstetric outcomes of normal weight and obese women using the Institute of Medicine (IOM) guidelines and newly recommended Cedergren Criteria. The Cedergren Criteria proposes tighter gestational weight gain ranges. The revised weight gain ranges in the Cedergren Criteria have been shown, in another study, to produce a decrease in risk for adverse obstetric and neonatal outcomes in women who had lower gestational weight, than the women who gained weight according to the older IOM recommendations. In this study, using the Cedergren Criteria for both the normal weight and obese women it revealed improved outcomes for macrosomia and cesarean delivery rates, however the rates of preterm deliveries, low birth weight, and NICU admissions were higher when compared to the IOM guidelines. These finding differed from the author's original hypothesis which was with less weight gain with the Cedergren Criteria there would be improved outcomes in both maternal and neonates. From this study the authors deducted the conclusion that the ideal weight gain for each category of weight is between the IOM and Cedergren's guidelines.

Reader, D., Splett, P., Gunderson, E. P., Diabetes, C., & Education Dietetic Practice, G. (2006). Impact of gestational diabetes mellitus nutrition practice guidelines implemented by registered dietitians on pregnancy outcomes. [Multicenter Study, Randomized Controlled Trial]. *Journal of the American Dietetic Association*, 106(9), 1426-1433.

Impact Factor: 3.13  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=215  
 RCT

They study assessed the impact of gestational diabetes mellitus nutrition practice guidelines on pregnancy outcomes when implemented by registered dietitians. The study concluded that nutrition practice guidelines for gestational diabetes did not improve outcomes in diabetic clinics, possibly due to the expertise, experience and knowledge of the registered dietitians. The implementation and use of these guidelines at obstetric and other clinics demonstrated a higher impact on pregnancy outcomes.

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Redman, C. W. G. (2011). Hypertension in pregnancy: the NICE guidelines. *Heart*, 97(23), 1967-1969.

Impact Factor: 5.39  
 Quality of Evidence: Limited  
 Condition: Hypertension

n=Not Specified  
 Review of Guidelines

This article reviewed the NICE guidelines on hypertension in pregnancy. The article addresses key points of the guidelines. Women who are at high risk of preeclampsia should be advised to take 75 mg of aspirin daily from 12 weeks until birth. ACE inhibitors or angiotensin II receptor blockers are not recommended for use during pregnancy. Women should be offered an integrated package of care. Also stated the guidelines should not be accepted uncritically, because there are weaknesses, although weaknesses are not stated in the guidelines.

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Rouse, D. J. (2011). Marry old and new guidelines. *American Journal of Obstetrics & Gynecology*, 204(5), 371-372.

Impact Factor: 3.47  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=Not Specified

Debate Summary at 31<sup>st</sup> annual meeting of the Society for Maternal-Fetal Medicine (See Blackwell (2011) for opposing summary debate)

The International Association of Diabetes in Pregnancy Study Group recommends a 1-stage screening and diagnosis method that includes a 75-gram 2-hour glucose tolerance test based off the results of a hyperglycemia and adverse pregnancy outcomes (HAPO) study and 2 randomized trials.

The author makes the argument for the acceptance of these proposed guidelines. This diagnostic expansion will increase the amount of women diagnosed with gestational diabetes mellitus, however, 80-90% will be able to be treated by diet. The author notes that proper implementation of the proposed screening and diagnosis recommendations will yield better maternal and infant health.

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Scollan-Koliopoulos, M., Guadagno, S., & Walker, E. A. (2006). Gestational diabetes management: guidelines to a healthy pregnancy. [Review]. *Nurse Practitioner*, 31(6), 14-23; quiz 24-15.

Impact Factor: Not Available  
Quality of Evidence: Limited  
Condition: Diabetes/Obesity

n=Not Specified

Review

Similar to other guidelines, when diet and exercise fail to maintain normal blood glucose values, insulin therapy may be implemented. Recommended the ACOG and ADA blood glucose values which are a fasting plasma glucose value of 95 mg/dL or below, 1-hr postprandial values less than 130 to 140 mg/dL, and 2-hr postprandial less than 120 mg/dL. Tight glycemic control has been associated with a reduction in fetal macrosomia. Insulin therapy 4 times a day has been shown to provide tighter control of glycemic levels. Also based on other studies, insulin analogs have been proven effective. Analogs also allow more control to maintain healthy glucose levels. Oral agents have also been used for treatment of gestational diabetes.

Steel, J. M., & Johnstone, F. D. (1996). Guidelines for the management of insulin-dependent diabetes mellitus in pregnancy. [Review]. *Drugs*, 52(1), 60-70.

Impact Factor: 4.73  
Quality of Evidence: Limited  
Condition: Diabetes/Obesity

n=Not Specified

Review

Suggests that during pregnancy, blood glucose levels should be monitored. Patients should be educated on the dangers and risks that may affect them. Insulin should be adjusted as the pregnancy progresses. Dietary management should be implemented. All women should have regular retinal examinations and if needed, kidney assessments.

Surveillance of the fetus should include ultrasounds, alpha-fetoprotein, and fetal monitoring. Fetal monitoring should become more frequent towards the end of the pregnancy and if diabetic control is poor, it can lead to significant maternal vascular disease, or abnormal fetal growth. Overall the article suggests that if the recommendations are followed, there will be an increased likelihood of a successful pregnancy.

Visintin, C., Mugglestone, M. A., Almerie, M. Q., Nherera, L. M., James, D., Walkinshaw, S., & Guideline Development, G. (2010). Management of hypertensive disorders during pregnancy: summary of NICE guidance. [Research Support, Non-U.S. Gov't]. *BMJ*, 341, c2207. doi: <http://dx.doi.org/10.1136/bmj.c2207>

Impact Factor: 13.66  
Quality of Evidence: Limited  
Condition: Hypertension

n=Not Specified

### Summary of Guidelines

Provides a summary of the NICE guidelines.

- Seek immediate advice from a healthcare professional if experience symptoms of preeclampsia.
- Management of gestational hypertension: Offer integrated care in hospital with healthcare professionals trained in managing hypertensive disorders, hospital admission if necessary, and treatment and monitoring of blood pressure, proteinuria and blood tests.
- Schedule antenatal consultations on the basis of the woman and her baby's need.
- For pregnant women with chronic hypertension, fetal monitoring should be provided by an ultrasound assessment. During labor, women with mild or moderate hypertension may need hematological and biochemical tests.
- For the management of severe hypertension (or severe preeclampsia) women should be referred to critical care, and the mode of birth should be decided based on clinical situation and the patient's preference.
- Vitamin and nutrient supplements have been analyzed as preventative treatments for hypertensive disorders; however there has been no evidence that proves the benefit of these.

von Dadelszen, P., Menzies, J., Gilgoff, S., Xie, F., Douglas, M. J., Sawchuck, D., & Magee, L. A. (2007). Evidence-based management for preeclampsia. [Review]. *Frontiers in Bioscience*, 12, 2876-2889.

Impact Factor: 3.74

Quality of Evidence: Limited

Condition: Preeclampsia

n=Not Specified

### Review

To manage severe preeclampsia, if possible, oral antihypertensive treatments should be considered. Blood pressure should be monitored every 15 minutes for at least 4 hours until it has stabilized, then every 30 minutes. Nifedipine is a drug of choice for women who develop severe hypertension. Labetalol and Methyldopa are also recommended. Women who are considered to have severe preeclampsia should receive magnesium sulfate.

When intravenous fluids are administered, urine should be collected with an indwelling catheter and should be measured and tested for proteinuria. Fetal assessment by way of a baseline non-stress test should be performed. Thromboprophylaxis interventions should be indicated such as anti-embolic stockings and/or heparin.

It is recommended that an anesthesiologist be involved in the plan of care, because these services may be needed during the delivery. Epidural, combined spinal epidural, and spinal anesthesia are not contraindicated for pregnant women with preeclampsia, barring no other complications. Central venous pressure monitoring may be indicated if there is excessive blood loss during delivery.

Walker, J. D. (2008). NICE guidance on diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period. NICE clinical guideline 63. London, March 2008. [Review]. *Diabetic Medicine*, 25(9), 1025-1027.

Impact Factor: 2.87  
Quality of Evidence: Limited  
Condition: Diabetes/Obesity

n=Not Specified

Review

Reviews the NICE guidelines on diabetes and pregnancy.

Supports the use and recommendations of the NICE guidelines. The guidelines provide a framework that healthcare providers can use to provide quality care to pregnant women with diabetes.

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Welsh, A., McLintock, C., Gatt, S., Somerset, D., Popham, P., & Ogle, R. (2008). Guidelines for the use of recombinant activated factor VII in massive obstetric haemorrhage. [Practice Guideline]. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 48(1), 12-16.

Impact Factor: 1.32  
Quality of Evidence: Acceptable  
Condition: Hemorrhage

n=Not Specified

Practice Guideline

As of 2008 there were not any guidelines published for the use of recombinant activated factor VII( rFVIIa) for post-partum hemorrhage (PPH). These guidelines are to provide information on the use of rFVIIa. The guidelines states "Once all surgical and non-surgical definitive hemostasis procedures to arrest active bleeding have been attempted, and bleeding continues with between 8 and 12 U of PRBC transfusion, and prior to hysterectomy, rFVIIa (NovoSeven) could be considered." The administering of rFVIIa should be overseen by a multidisciplinary team of clinicians, as well as a local transfusion specialist.

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Wong, S., Ordean, A., Kahan, M., Society of, O., & Gynecologists of, C. (2011). SOGC clinical practice guidelines: Substance use in pregnancy: no. 256, April 2011. [Practice Guideline, Research Support, N.I.H., Extramural]. *International Journal of Gynaecology & Obstetrics*, 114(2), 190-202.

Impact Factor: 0.43  
Quality of Evidence: Acceptable  
Condition: Psychiatric/Mental Health

n=Not Specified

Clinical Practice Guideline

Society of Obstetricians and Gynaecologists of Canada (SOGC) Clinical Practice Guideline

This guideline document is intended to improve awareness and knowledge of substance use in pregnancy and to provide recommendations for management. The guidelines recommend screening of all pregnant women for alcohol, tobacco, and prescription and illicit drug use. It is



noted that pregnant women with substance abuse problems face a number of barriers to receiving optimal prenatal care. It is therefore recommended that care providers employ a flexible approach to the care of women who have substance use problems, and the use of all available community resources should be encouraged. Harm reduction is an important component of care for substance abuse in pregnant women. This is captured in recommendations that include counseling about the risks of drug use and smoking cessation counseling which should be considered a first-line intervention for pregnant smokers. For pregnant women who are opioid dependent, opioid detoxification is not advisable due to the high rate of relapse. Opiate substitution therapy is considered the standard of care and is captured in a guideline recommendation for methadone maintenance treatment, or consideration of other slow-release opioid preparations if methadone is not available. Neonatal abstinence syndrome (NAS) can occur with any regular daily antenatal opioid use. For this reason, it is recommended that opiate-dependent women are informed that neonates exposed to opioids during pregnancy will be monitored closely for signs and symptoms of neonatal withdrawal. The range of evidence for the recommendations noted in this summary is I-A to III-B with the smoking cessation counseling recommendation having the greatest level of evidence. The authors acknowledged that problematic substance use in pregnancy is prevalent in the Canadian population. Perinatal health care providers play a key role in the care of pregnant women with substance abuse problems. It was concluded that ongoing education and comprehensive care models still need to be developed in meeting the care needs of these challenging patients.

Yee, L. M., Cheng, Y. W., Inturrisi, M., & Caughey, A. B. (2011). Effect of gestational weight gain on perinatal outcomes in women with type 2 diabetes mellitus using the 2009 Institute of Medicine guidelines. [Research Support, N.I.H., Extramural, Research Support, Non-U.S. Gov't]. *American Journal of Obstetrics & Gynecology*, 205(3), 257.e251-256.

Impact Factor: 3.47  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n=2310

Retrospective Cohort Study

The study included women with Type 2 diabetes mellitus (T2DM) who were either overweight or obese, assessed whether the revised 2009 Institute of Medicine (IOM) guidelines for pregnancy weight gain apply to, and are predictive of adverse perinatal outcomes in women with T2DM. The study concluded that 2009 IOM guidelines are applicable to women with T2DM who are either overweight or obese.

Yonkers, K. A., Wisner, K. L., Stewart, D. E., Oberlander, T. F., Dell, D. L., Stotland, N., . . . Lockwood, C. (2009). The management of depression during pregnancy: a report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists. [Review]. *General Hospital Psychiatry*, 31(5), 403-413.

Impact Factor: 2.67  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=Not Specified

#### Review

The article addressed the maternal and neonatal risks of both depression and antidepressant exposure and provided management recommendations during pregnancy. It was noted that fetal malformations are associated with the use of antidepressant medications during the first trimester. Psychotherapy is indicated as an appropriate treatment for pregnant women. However, medications may be needed to efficiently treat the patient. Electroconvulsive therapy is also indicated as being a safe and effective treatment when the patient has severe depression, or medications are ineffective in relieving symptoms. Psychotherapy may be beneficial to pregnant women who want to avoid medication, residual symptoms, high risk of relapse, and those with co-morbid conditions.

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Zeck, W., Panzitt, T., Schlembach, D., Lang, U., & McIntyre, D. (2007). Management of diabetes in pregnancy: comparison of guidelines with current practice at Austrian and Australian obstetric center. [Comparative Study]. *Croatian Medical Journal*, 48(6), 831-841.

Impact Factor: 1.8

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=Not Specified

#### Comparative Study

Reviewed an Australian and an Austrian obstetric center and compared and contrasted the management and screening of diabetes in pregnancy, as well as the adherence of current practice to guidelines. The study found more variation in management in gestational diabetes than pre-gestational diabetes. It also recommended that a multidisciplinary approach should be taken to manage diabetes in pregnancy. A noteworthy discussion point was the Austrian obstetric center using amniocentesis for insulin treatment decision making. This has been suggested as a reliable practice to detect fetal hyperinsulinism. However, there are no guidelines published in the English language that recommends this practice.

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## IV. Research Question 3

**Evidence for the use of the following availability services in obstetrics: 24 hour obstetric availability, 24 hour anesthesia availability, access to maternal fetal medicine specialist, access to subspecialty care, and access to multidisciplinary care.**

### Summary

The final research question defines specific obstetric services – availability of 24 hour obstetric and anesthesia services, and access to maternal/fetal medicine specialists, subspecialty care and multidisciplinary care – that have been addressed in the professional literature, and the impact of varying availability and accessibility on fetal and maternal morbidity and mortality.

### 24 hour Obstetrical Care

There is very little evidence found in this literature review examining the availability of 24 hour obstetrical services. It was determined that lack of specialty providers during the off hours may have a causative effect on the rates of neonatal death (Pasumpathy et al., 2010). In a very large (n=1,039,560) retrospective examination of neonatal deaths in Scotland, it was determined that intra partum anoxia, which contributed to increased neonatal deaths, occurred at a greater rate during off hours.

### 24 hour Anesthesia

The Guidelines for Perinatal Care 6<sup>th</sup> Ed (2007), examine the staff requirements for anesthesiology in facilities that contain nurseries at levels I, II, and III. This guideline recommended that level II and level III nurseries require a director of the obstetrical anesthesia team to be board- certified in anesthesia and have training and experience. Currently, the guideline states that anesthesia practitioners with privileges should be available according to hospital policy.

The effect on the anesthesia workforce to provide “immediate” availability of services for all vaginal birth after cesarean (VBAC) deliveries has been assessed (Birnbach et al., 2010). Areas of concern are: the current availability of anesthesia services in the United States, the workforce estimate of staffing for the future, and barriers to providing immediate availability in all hospitals that provide obstetrical care.

The demand for 24 hour anesthesia presence has led to a reduction in VBAC deliveries in smaller organizations. Consolidation of obstetrical services, improving patient education on the topic and demand for VBAC, and the development of protocols and guidelines to manage the care of VBAC patients is estimated to reduce the risk of uterine rupture while attempting VBAC. Process improvements in the area of VBAC and anesthesia staffing can reduce facility patient care safety concerns. Efforts to increase the organization of the work force of anesthesia providers should be considered for those institutions providing care to high risk obstetrical patients, and investigation of training of new providers by use of simulation along with further research in this area is recommended (Birnbach et al., 2010).

## Access to Maternal-Fetal Medicine Specialist

The Guidelines for Perinatal Care 6<sup>th</sup> Ed (2007) examines staff requirements for specialty care providers such as maternal fetal specialists for facilities that contain a level III nursery. Care of high risk patients should occur in a setting with a level III nursery, and patients should be cared for by appropriately-trained and qualified providers. The literature does not define who those providers must be, however it is strongly recommended that all high risk obstetrical patients have access to a maternal-fetal medicine specialist, as defined by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

Facilities that serve high risk obstetrical patients must have a full time, board certified maternal – fetal medicine specialist acting as director of maternal-fetal medicine, and providing subspecialty care. The level III newborn intensive care unit (NICU) that receives the neonate upon birth should have a medical director who is a full time, board certified pediatrician, with subspecialty certification in neonatal /perinatal medicine, and should have a director of perinatal and neonatal nursing services. Physicians caring for neonates in NICU must have a maternal /fetal medicine specialty, as well as a neonatology specialty, and those clinicians must be continuously available for consultation 24 hrs of the day (Guidelines for Perinatal Care 6<sup>th</sup> Ed, 2007).

Common themes regarding the availability of maternal-fetal specialists and perinatal outcomes were reviewed in this search. Themes included: rural residents and access to care providers, lack of specialty care provider, lack of insurance and increased mortality rates, increases in specialty care resulting in improved outcomes, and the unequal distribution of care providers and unchanged fetal outcomes.

Rural areas have been studied by Grzbowski et al., (2011) Nesbitt and Baldwin (1993), and Yawn et al., (1995). Grzbowski et al., (2011) reviewed retrospective data on 49,402 patients to assess newborn and maternal outcomes as they related to distance traveled for maternity services and high risk services. In this study, data from the British Columbia Perinatal Health Program (BCPHP) was analyzed. It was determined that those patients who lived two to four hours away, or one to two hours away, from a specialty care provider more often had babies that generated an admission to the Neonatal Intensive Care Unit (NICU) compared to those who had access to specialty services locally.

The lack of number of specialty providers has affected the neonatal mortality rate in rural areas (Nesbitt and Baldwin, 1993). The same phenomenon of lack of number of providers was explored again in the urban patient populations and a correlation between lack of insurance and an increase in mortality rates was also found. This was most associated with the limitations in the ability for those patients to pay for maternal specialty care. The authors found a parallel relationship between the availability of specialty care and an increase in adverse outcomes of the neonate. They determined that good perinatal care results in decreased adverse events. However, they continue to question if a lack of availability of care resulted in an increase in maternal/ fetal morbidity and mortality.

Maternal and fetal outcomes are improved when more specialty care is available and provided (Nguyen, et al., 1991). When the National Health Service Corps responded to reported data showing an increase in perinatal mortality rates, obstetricians and pediatricians were deployed to serve the Dade County Florida area (1987-1989). There had been a reported decrease in the number of providers servicing specialty care obstetrics, resulting in an increase in perinatal deaths. After implementation, it was determined that when additional providers are able to

service the population, a 45% reduction in the mortality rate of fetal and neonatal lives can be achieved. Sullivan and Hill (2005) found a similar outcome when they examined the Centers for Disease Control (CDC) – State Maternity Mortality ratio in 1994-2001. Upon addition of five maternal –fetal medicine specialists per 10,000 live births, a statistical difference was noted in reducing maternity mortality outcomes.

Availability of specialty care practitioners was also analyzed by Yawn et al.(1995). In her study, the team telephonically questioned 669 providers from Minnesota’s obstetrical services on their availability to provide care for obstetrical services. The survey found that 27% of rural providers had a restriction on their care practices limiting obstetrical services. When asked why they restricted their services, most identified Medicaid reimbursement as a leading cause. Further data concluded that new providers were less in number than those lost for this state. It was identified that 12 communities would be functioning in Minnesota without provider availability. Surprisingly, the perinatal outcomes such as low birth weight, or late perinatal care were not different from those communities with adequate providers.

### **Access to multidisciplinary care providers**

Access and availability to a multidisciplinary care team such as those listed above and defined by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists was also examined in this literature review. All personal qualified to manage obstetric or neonatal emergencies should be in- house and available (Guidelines for Perinatal Care 6<sup>th</sup> Ed, 2007).

Communication and coordination of care is the common theme found when examining the literature regarding multidisciplinary care providers for high risk obstetrical services. The literature does not conclude that an increase in communication and care coordination improves maternal fetal outcomes, nor does differing types of care provider models improve outcomes. Additionally, the theory of adding additional advance practice nursing to relieve the disproportionate workloads of neonatal intensivists was examined; it was found this only relieved those healthier obstetrical patients, and had no effect on the high risk population. The use of midwifery in the healthy obstetrical population has reduced mortality in the past. Current use of midwifery for the high risk obstetrical population is under consideration.

“High Reliability perinatal units” where all team members work together, such as The Seton Family Hospitals system that created a service entitled *The Perinatal Safety Initiative*, facilitated team communication with all providers. Team members facilitated a program review wherein they learned to recognize early fetal distress, reassess fetal distress, implement timely cesarean sections, properly resuscitate a depressed baby, properly administer Oxytocin, and assist or conduct vacuum or forceps assisted deliveries when necessary (Reisner and Landers, 2010). Only in “High Reliability perinatal units” does the research conclude with improvements in perinatal outcomes and reductions in adverse events, such as a drop in the elective inductions, after the essential team mates improve their communication and coordination of care.

A study by Lowry and Beikrich (1998) compared two models of care. Outcomes of maternal care from one multidisciplinary tertiary care clinics were compared with a similar population that was served by public health clinics. Those public health clinics did not collaborate with multiple levels of care providers. When care was managed by obstetrical services exclusively, in the public health clinic, there was a significant difference in outcomes that were found in the public health group. Those differences included: less incidence of low gestational age, an increase in

maternal risk factors prior to delivery, and a decrease in infant complications in the public health clinic.

Type of care provider models for the multidisciplinary anesthesia care team serving the high risk obstetrical population were reviewed by Needleman and Minnick (2009), Simonson and Ahern (2007) and Angel et al., (2009). When large populations that were served with differing anesthesia care provider models were explored, no difference in perinatal outcomes was found. Studies analyzed the use of teams consisting of Certified Registered Nurse Anesthetists (CRNAs) with a team of medical doctors (MDs) specializing in anesthesiology. Disproportionately heavy workloads of neonatal intensivists are a predictor of poor outcomes for the high risk population (Downing et al., 2004). Ways to alleviate the workloads of intensivists by dispersing patient needs with use of midwifery will reduce mortality. The authors conclude that the high risk population remains unaffected when the healthy obstetrical population is cared for by advanced practice nurses.

### **Access to subspecialty care provider**

Access to a subspecialty care provider was examined with respect to the six conditions as defined by the research questions for this literature review team. Each condition has been reviewed, and it has been determined that the literature has limited discussion regarding the availability or accessibility of the services or interventions that are determined to be grounded in evidence. Below are the six conditions referenced:

#### **Cardiac Disease**

The *Journal of Gynecology and Obstetrics* reviewed the American College of Obstetrical and Gynecological guidelines regarding cardiac care in pregnant women (ACOG, 1993) it was determined that early access to care providers is essential. Those providers, too, must have the capability to identify and refer these high risk patients to subspecialty care. Access to multidisciplinary care teams and assessment regarding early vascular intervention has been found to ensure hemodynamic stability. Development of a national risk assessment tool is recommended. Availability for early antenatal hospitalization with access to emergency interventions for hemodynamic stability is recommended to increase maternal and fetal outcomes.

It is generally accepted that obstetrical facilities accepting high risk cardiac patients have multidisciplinary care teams; Perinatology, neonatology, cardiology and anesthesiology are recommended. Appropriate access to immediate interventions should be available to address hemodynamic instability should it occur. Ante partum care on the obstetrical unit should strive for management of care by the entire care team. Morbidity and mortality will continue to occur regardless of interventions in some cardiac populations due to the nature of the cardiac deficiencies (Lasswell et al., 2010).

Congenital heart diseases require multidisciplinary care for early intervention. Discussion regarding subspecialty services necessary to appropriately care for those OB patients includes the availability of a comprehensive team approach consisting of cardiologist, obstetricians, anesthetists, pediatricians, clinical nurse specialists, and clinical geneticists. (Kaftka et al., 2006). Emergency cesarean section should always be available during labor and delivery of patients with congenital heart diseases. Anesthesia management with epidural anesthesia should be considered, and discussion regarding a controlled elective cesarean section is

essential. In areas where such a team is not readily available, it will be necessary to refer the medium and high risk patients to specialty care centers.

Systematic risk assessment is needed to properly identify those high risk cardiac patients prior to crises (Piper, 2012). The identification of this fragile population is necessary so that they may receive interventions during pregnancy management with a multidisciplinary team. Case studies of women who did not receive consultative cardiology care have been examined and it was established that without interventions by cardiology care, further detriments occurred to their health, causing deterioration in their cardiac status post partum. All women at risk should have at least one consultative appointment with the subspecialty provider.

A small retrospective study (n=9) found success in treatment of pulmonary hypertension patients when early introduction of targeted pulmonary vascular therapy and early planned delivery under anesthesia was available. In this procedure, a right heart catheterization is performed during pregnancy, pulmonary hemodynamic testing is assessed and intervention for revascularization is done immediately (Kiely, et al, 2010). Of all the cardiac disabilities examined, pulmonary hypertension has the highest rate of maternal mortality in pregnant women at 30-56%. Risk of mortality is so high in this high risk population, that most clinicians recommend counseling women with regard to termination of pregnancy.

### **Psychiatric/Mental Health**

Access to multiple disciplinary care teams are discussed in the literature review focusing on the high risk mental health and psychiatric obstetrical population. Acute and chronic mental illness and drug addiction during pregnancy are reviewed in this population as well. Common themes included the availability of the psychiatric liaison nurse on the obstetrical unit, as well as the availability of a multidisciplinary care team who has been previously educated by the mental health clinician staff.

The use of a model including a psychiatric liaison nurse on the obstetrical unit is recommended to integrate the mental health issues considered in the obstetrical service department (D'Afflitti, 2005). Clinician education for staff on the unit must be utilized to incorporate individual psychiatric needs during crises or response to pregnancy. Clinician-to-clinician orientation is optimal, as is availability for private locations for appointments and emergency consultation on the antenatal unit. It is essential that all high risk mental health patients have available a consultation and referral to psychiatric and psychological clinicians for management of mood disorders, acute and chronic psychosis, pregnancy loss, unwanted pregnancy and substance abuse and chronic pain (Dunnis and Smith, 1996). The team approach allows psychiatric consultants to concentrate on psychosocial interventions rather than psychopharmacological interventions when appropriate, thus reducing unintended consequences from pharmacotherapy and increasing positive outcomes.

### **Diabetes/obesity.**

Maternal morbidity from gestational diabetes is associated with diabetic ketoacidosis, preeclampsia, hypertension, nephropathy, hydroamniosis, retinopathy and pyelonephritis (Bailey et al., 1996). Availability of subspecialties is the most effective method of reducing perinatal morbidity and mortality (Quinlivan et al., 2011).

All materials recommend the availability of subspecialty teams who are experienced. Team members should include the patient, significant other, perinatologist, dietician/certified diabetic

educator, diabetes nurse clinician, certified diabetes educator two, perinatal case manager, genetic counselor, social worker and retina-vitreous physician specialist. No further conclusion can be made regarding the availability of subspecialists for obese patients from the identified articles.

### **Hypertension and Preeclampsia/Eclampsia**

Availability of subspecialty care for the hypertensive patient consisting of the need for a subspecialty antenatal unit to reduce morbidity and mortality was examined (Kirshon et al., 1990). In this large RCT (n= 95,684), no conclusive evidence for improved outcomes was found when patients were cared for on an exclusive subspecialty antenatal unit.

### **Hemorrhage**

The formation of a rapid response team for management of major hemorrhage in obstetrical patients can reduce the mortality rates. Outcomes were compared retrospectively after introduction of a patient safety program focused on protecting obstetric patients from major hemorrhage. A Rapid Response team was formed, using the cardiac arrest team model (Skupski et al., 2006). A decrease in the maternal mortality rates from hemorrhage was found, as well as improved patient safety.

Protocols for early diagnosis, assessment, and management of patients at high risk for major obstetrical hemorrhage need further development. Staff communication is essential as well. The availability of services such as blood transfusion, anesthesia, and state of the art operating facilities will increase the likelihood of the appropriate management for those at risk during the active phase of labor (Brown et al., 2012). The availability of interventional radiology has increased outcomes in the management of embolization during hemorrhagic emergencies, primarily used in persistent moderate hemorrhage (King and Scrutton, 2011).

### **Summary**

This literature review examined the evidence for the use of the following availability measures in obstetrics: 24 hour obstetrical availability, 24 hr anesthesia availability, access to maternal fetal medicine specialist, access to subspecialty care, and access to multidisciplinary care. It was determined that when 24 hour obstetrical services are not available, there may be an increase in morbidity and mortality as the incidence of intra partum anoxia may increase. Twenty four hour availability of anesthesia for high risk obstetrical deliveries has caused a great deal of discussion among the medical community. Concerns lie in the current availability of anesthesia services in the United States, the workforce estimate of staffing for the future, and the barriers to providing immediate availability in all hospitals that provide obstetrical care. The assessment of availability of maternal-fetal specialists included geographic location limitations with respect to the access to subspecialty care providers, the lack of subspecialty care providers, the lack of insurance to access subspecialty care providers and the subsequent increased mortality rates. The literature found an improvement in perinatal outcomes when there was an increase in specialty care. Fetal outcomes were unchanged when unequal distribution of care providers was found.

Communication and coordination of care is the common theme found when examining the literature regarding multidisciplinary care providers for high risk obstetrical services. The literature does not conclude that an increase in communication and care coordination improves maternal fetal outcomes, unless the "High Reliability" model is used. There an improvement in



outcomes when differing types of care provider models were used. There was no improvement in outcomes when advance practice nurses were added to the high risk obstetrical teams.

## Bibliography

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ACOG. (1993). Cardiac disease in pregnancy. ACOG technical bulletin number 168–June 1992. [Guideline, Practice Guideline]. *International Journal of Gynaecology & Obstetrics*, 41(3), 298-306.

Impact Factor: 2.05  
 Quality of Evidence: Acceptable  
 Condition: Cardiac Disease

n= Not Specified  
 Guideline

Multiple cardiac diseases are discussed with risk during pregnancy and future mortality. Hospitalization during the end of the pregnancy is discussed with pulmonary HTN with cardiac disease and modifications during labor. Summary includes appropriate facilities for antepartum care in OB patients with cardiac disorders, as well as the indication that even with meticulous care, some morbidity and mortality will continue to occur. Multidisciplinary care team will assist in ensuring optimal care.

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Angel P, L., C., Murthy, Y., and Cino, P. (2009). Key issues and barriers to obstetrical anesthesia care in Ontario community hospitals with fewer than 2,000 deliveries annually. *Canadian Journal of Anesthesia* 56, 667-677.

Impact Factor: 4.19  
 Quality of Evidence: Limited  
 Condition: Not Specified

n= Not Specified

Cochrane Review (1995-2010)

Secondary analysis of qualitative data from 18 anesthesiologists and family practitioners who had participated in a large provincial study. Physicians identified barriers encountered including lack of time, need for CME's, need for hospital infrastructure, need for development of "best practice protocols", and need for mentorship supports. The study reconfirmed the shortage in obstetrical services was related to the lack of Family Practitioners /General Practitioner anesthetists in the rural communities.

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Bailey, B. K., & Cardwell, M. S. (1996). A team approach to managing preexisting diabetes complicated by pregnancy. *Diabetes Educator*, 22(2), 111-112, 115.

Impact Factor: 1.96  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= Not Specified  
 Article

This article reviews the benefit of a teamwork approach for every visit at the clinic for identified high risk diabetic mothers. Outcomes measured Hemoglobin (Hgb) A1C, and found an average drop of 6.5% in their clinic patients. Patients were seen weekly.

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Bergel, Eduardo, Carroli, Guillermo, & Althabe, Fernando. (2012). Ambulatory versus conventional methods for monitoring blood pressure during pregnancy. *Cochrane Database of Systematic Reviews*(4).

Impact Factor: 5.72

Quality of Evidence: Limited

Condition: Hypertension

n= Not Specified

Article

The article reviewed a comparison of other work relating to the benefit in hypertension management when one compares clinic blood pressure monitoring services by staff, to a quick noninvasive ambulatory automated device. No further mortality was measured. Conclusion, there is no evidence to assess the effectiveness of the low cost convenience of the automated blood pressure monitoring.

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Bimbach, D., Bucklin, B., and Dexter, F. (2010). Impact of Anesthesiologists on the Incidence of Vaginal Birth After Cesarean in the United States: Role of Anesthesia Availability, Productivity, Guidelines, and Patient Safety. *Seminole of Perinatology*, 34, 318-324.

Impact Factor: 3.61

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Article

This article reviews the availability of anesthesia for vaginal birth after cesarean delivery (VBAC). Three areas are determined to be concerning to the authors. Those are: the current availability of anesthesia services in the United States to provide "immediate" availability for VBAC at all deliveries, the workforce estimate of this staffing for the future, and the barriers to providing immediate availability in all hospitals that provide obstetrical (OB) care. The authors review mathematical and statistical data concluding the staffing of the immediately available anesthesia has reduced VBAC in smaller organizations. Authors suggest consolidation of OB services, improving patient education, developing protocols and guidelines to allow for risk of rupture and organization of work force, improving the process of safe patient care by use of simulation and further research.

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Berkowitz, R. L. (2011). Of parachutes and patient care: a call to action. *Am J Obstet Gynecol*, 205(1), 7-9. Doi: 10.1016/j.ajog.2010.12.020

Impact Factor: 3.28

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Article

This article focuses on risk management, specifically relaying safety initiatives and the reduction in law suits. The author reviews poor obstetric outcomes contributing to the rising cost of health care. Quality initiatives and error reporting are discussed as well. The authors suggest clinical protocols, and checklist use to guide improved outcomes.

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Brown, Haywood, & Small, Maria. (2012). The Role of the Maternal–Fetal Medicine Subspecialist in Review and Prevention of Maternal Deaths. *Seminars in Perinatology*, 36(1), 27-30. Doi: 10.1053/j.semperi.2011.09.006

Impact Factor: 0.95

Quality of Evidence: Limited

Condition: Not specified

n= Not Specified

Article

The article reviews post mortem maternal deaths and discusses the indirect approach at preserving maternal care in maternal fetal care management. Services discussed are the use of modern obstetrical facilities, having priority in preparation for postpartum major hemorrhage. Services such as blood transfusion service, anesthesia, and operating facilities are appropriate management for those at risk during the active phase in labor.

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Chappell, Lucy C. (2009). Commentary: Complex medical conditions in pregnancy need appropriate multidisciplinary input. *BMJ*, 339, b5179.

Impact Factor: 13.66

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Article

The use of appropriate imaging, appropriate communication and information from specialist, and interpretations of images for high risk patients to avoid morbidity and mortality is discussed.

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Cleary-Goldman, J., & Malone, F. (2005). Advances in prenatal diagnosis. *Applied Radiology*, 34(9), 8.

Impact Factor: 28.9

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Article

This article describes new radiology imaging for a defined at risk obstetrical population.

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Committee on Fetus and Newborn (2004). Levels of neonatal care. *American Academy of Pediatrics*, 114; 1341-1347.

Impact Factor: 3.56  
 Quality of Evidence: Limited  
 Condition: Not Specified

n= Not Specified

Article

The diversity in the definitions and application of levels of care has complicated the delivery of care for neonates. This reviews the information needed for classification of levels of care.

Level 1 – basic needs of care

Level 2- specialty care

Level 3- critically ill or require surgery

Coskun, Demet, Mahli, Ahmet, Korkmaz, Sibel, Demir, Figen S., Inan, Gozde Karaca, Erer, Dilek, & Ozdogan, M. Emin. (2009). Anaesthesia for caesarean section in the presence of multivalvular heart disease and severe pulmonary hypertension: a case report. *Cases journal*, 2, 9383

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n= Not Specified

Case Report

These authors provide insight on their management of cases with heart disease and pulmonary hypertension. Cases that present such as this, require multidisciplinary care. Adequate monitoring during labor and caesarean delivery is essential.

D'Afflitti, Judith Gregorie. (2005). A psychiatric clinical nurse specialist as liaison to OB/GYN practice. *JOGNN – Journal of Obstetric, Gynecologic, & Neonatal Nursing*, 34(2), 280-285.

Impact Factor: 3.41  
 Quality of Evidence: Acceptable  
 Condition: Psychiatric/Mental Health

n= Not Specified

Article

This article discusses a model of a liaison psychiatric nurse on the Obstetrics unit. An important note to the success was to integrate the mental health worker into the Obstetrics/Gynecology (OB/GYN) service department. Clinician to clinician orientation is optimal, as well as a private facility for appointments. Emergency consultation was also successful. Referrals listed for each pregnancy mental health condition such as mood disorder, psychosis, pregnancy loss, unwanted pregnancy and chronic pain are also discussed.

Dineen, K., Rossi, M., Lia-Hoagberg, B., & Keller, L. O. (1992). Antepartum home-care services for high-risk women. *JOGNN – Journal of Obstetric, Gynecologic, & Neonatal Nursing*, 21(2), 121-125.

Impact Factor: 0.95  
 Quality of Evidence: Limited  
 Condition: Not Specified

n= 219

Non Randomized Control Trial

Comparison of private versus public ante-partum home-care services- type of agencies, the nursing personnel, and the nursing services provided. Nursing interventions were compared with the two populations, public consisted of patient education and private consisted of more use of technical skills.

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Downing, J. W., Ramasubramanian, R., Johnson, R. F., Minzter, B. H., Paschall, R. L., Sundell, H. W., . . . Lewis, R. (2004). Hypothesis: selective phosphodiesterase-5 inhibition improves outcome in preeclampsia. *Medical Hypotheses*, 63(6), 1057-1064.

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Preeclampsia

n= Not Specified

Article

This article discusses the disproportionate work loads of neonatal intensivists, and ways to alleviate the work loads. It provides insight as to how work load averages with midwifery will reduce anxiety and concern among health care workers, regarding mortality.

The article supports the use of Phosphodiesterase-5 to protect the fetus from preeclampsia aberrant changes in the placenta. The authors in turn hypothesize that this will alter the course of care in this high risk population. The authors presume that workloads for special high risk providers will lighten, and financial impact on this previous daunting population will be relieved. No support for this conclusion is provided.

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Dunsis, A., & Smith, G. C. (1996). Consultation-liaison psychiatry in an obstetric service. *Australian & New Zealand Journal of Psychiatry*, 30(1), 63-73.

Impact Factor: 2.93  
 Quality of Evidence: Acceptable  
 Condition: Psychiatric/Mental Health

n=90

Non Randomized Control Trial

This article reviewed the work of a consultant liaison for psychiatry service in an obstetrical inpatient unit. They found that patients that needed psychiatric care had an increased length of stay, +3 days. Referrals and the liaison component were used for management of diagnosed psychiatric disorders, and to decrease length of stay. The effective working relationship

between Obstetrics and Psychiatry, with the increase in community services is associated with implications for future mental health. No measureable increase in outcomes.

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Finkler, M. D., & Wirtschafter, D. D. (1991). Cost-effectiveness and obstetric services. *Medical Care*, 29(10), 951-963.

Impact Factor: 2.34

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Analysis

A logistic regression analysis of the probability of a cesarean section was done on a set of clinical indicators. This study concludes that cost management should focus on staffing levels, or mix of practitioners, and practice patterns. There was no display of data comparing type of care giver or service provided.

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Gabbe, Steven G., & Graves, Cornelia R. (2003). Management of diabetes mellitus complicating pregnancy. *Obstetrics & Gynecology*, 102(4), 857-868.

Impact Factor: 3.28

Quality of Evidence: Acceptable

Condition: Diabetes/Obesity

n= Not Specified

Article

This article summarizes the need for obstetrician, maternal-fetal specialist, endocrinologist and other members of the obstetrical health care team, to be involved in all gestational diabetes mellitus (GDM) deliveries, balancing fetal health and reducing maternal risk. The authors discuss a rise in predicted rates of GDM with rising obesity in the United States. GDM patients with valculopathy require even more intense therapy, and therefore more team members, such as OB, maternal-fetal specialist, and/or endocrinology, cardiology, and other support members as well.

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Good, R. S., & Jenkins, C. D. (1995). How can new behavioral knowledge and proven aids to treatment enter the teaching and practice of obstetrics? *Behavioral Medicine*, 21(3), 123-129.

Impact Factor: 1.14

Quality of Evidence: Limited

Condition: Psychiatric/Mental Health

n= Not Specified

Interview

Interview with Good states there is a lack of funding to develop services of psychiatric obstetrics in the United States.

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Goodman, D. C. (2009). Unwarranted variation in pediatric medical care. *Pediatr Clin North Am*, 56(4), 745-755. Doi: 10.1016/j.pcl.2009.05.007

Impact Factor: 2.25  
Quality of Evidence: Acceptable  
Condition: Not Specified

n= Vermont Oxford Network- database on all infants 401-1500 grams in 750 Neonatal Intensive Care Units.

Population Cohort Study

Medical care variations are needed to improve child health in the United States. There is not enough evidence to support changes to the current system providing pediatric services. Information is provided on variations of children's services.

Variations of care can be parsed into three categories:

1. Variation in effective care
2. Variation in preference-sensitive care
3. Variation in supply-sensitive care

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Grumbach, K. (2002). Specialists, technology, and newborns – Too much of a good thing. *New England Journal of Medicine*, 346(20), 1574-1575. Doi: 10.1056/nejm200205163462012

Impact Factor: 53.3  
Quality of Evidence: Acceptable  
Condition: Not Specified

n= Not Specified

Article

Discussion revolves around the variation of the supply of neonatology services. Regions of high demand have a high rate of professionals. This is interesting as the variations were compared to outcomes; there was no correlation on the number of low birth weight babies, to the availability of services. There was also no correlation between the number of neonatologists and a decrease of mortality, or increase in better outcomes. The study concluded that not all variations in outcomes were observed, such as increased functionality of the infant after treatment from a specialist, were not observed, or compared.

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Grzybowski, S., Stoll, K., & Kornelsen, J. (2011). Distance matters: a population based study examining access to maternity services for rural women. *BMC Health Serv Res*, 11, 147. Doi: 10.1186/1472-6963-11-147

Impact Factor: Not Available  
Quality of Evidence: Acceptable  
Condition: Not Specified

n= 49,402  
Retrospective study.

The purpose is to document newborn and maternal outcomes as they relate to distance to travel to access for maternity services in British Columbia. Previous, lack of access to care in rural areas has led to a decrease in perinatal positive outcomes. Data from the British Columbia Perinatal Health Program (BCPHP) was analyzed, and more than 5% of women lived more than one hour travel time away from services. This study continues to support that distance from access to care is associated with adverse outcomes. Distance from supportive care relates to an increase in 2 or 3 days longer stay in the Neonatal Intensive Care Unit (NICU).

Hameed, Afshan B., & Sklansky, Mark S. (2007). Pregnancy: maternal and fetal heart disease. *Current Problems in Cardiology*, 32(8), 419-494.

Impact Factor: 3.96

Quality of Evidence: Limited

Condition: Cardiac Disease

n= Not Specified

Article

Managing those patients with heart disease during pregnancy is much the same as the non-pregnant patient. Close communication between maternal fetal medicine, cardiology, anesthesia, neonatology, OB/GYN, and nursing is important. Management may involve services relating to diagnostics, and or surgical intervention. Complications of the fetus revolving around heart disease in pregnant women include spontaneous abortion, cardiac anomaly, preterm labor, low birth weight, intrauterine growth restriction. High risk patients should be offered termination of pregnancy. Invasive monitoring is necessary in some conditions. Narcotic epidural is optimal, as well as prophylactic antibiotics for cesarean section. Avoiding hypotension is essential.

Homko, C. J., Santamore, W. P., Whiteman, V., Bower, M., Berger, P., Geifman-Holtzman, O., & Bove, A. A. (2007). Use of an internet-based telemedicine system to manage underserved women with gestational diabetes mellitus. *Diabetes technology & therapeutics*, 9(3), 297-306.

Impact Factor: 1.93

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=32

Randomized Control Trial

This trial used a website and internet communication for the intervention group for monitoring their blood sugars. The comparison group received traditional office visit care. Results included no difference between average glucose levels. There was no difference in pregnancy outcomes. Women in the intervention group self-reported higher feelings of self efficacy.

Horvath, J. S., Phippard, A., Smart, D. H., Korda, A., Duggin, G. G., Hall, B. M., & Tiller, D. J. (1983). High risk hypertensive pregnancies: maternal and foetal outcome. *Clinical & Experimental Hypertension – Part B, Hypertension in Pregnancy*, 2(1), 21-28.

Impact Factor: 1.29



Quality of Evidence: Limited  
Condition: Hypertension

n= 236

Non Randomized Control Trial

Pregnant women were referred to the study population due to their hypertension and or renal disease. All patients were hospitalized and at bed rest. Drug therapy was initiated. Maternal survival was 97%.

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Kaemmerer, H., Bauer, U., Stein, J. I., Lemp, S., Bartmus, D., Hoffmann, A., . . . Hess, J. (2003). Pregnancy in congenital cardiac disease: an increasing challenge for cardiologists and obstetricians – a prospective multicenter study. *Zeitschrift fur Kardiologie*, 92(1), 16-23.

Impact Factor: 0.97

Quality of Evidence: Limited  
Condition: Cardiac Disease

n= 122

Prospective unspecified study

The article reviews a prospective German multicenter medical study for cardiac OB patients. Results concluded that with intervention, most women with Congenital Cardiac Disease (CCD) can tolerate pregnancy and delivery and continue with a Function Class of I or II.

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Kafka, Henryk, Johnson, Mark R., & Gatzoulis, Michael A. (2006). The team approach to pregnancy and congenital heart disease. *Cardiology Clinics*, 24(4), 587-605, vi.

Impact Factor: 1.25

Quality of Evidence: Acceptable  
Condition: Cardiac Disease

n= Not Specified

Article

This article discussed the services necessary to appropriately care for those OB patients with Congenital Heart Disease (CDH). During labor and delivery, it notes the need for constant availability of staff and facilities to handle emergency cesarean section, 24 hours per day. Anesthesia management with epidural anesthesia is supported, as well as the consideration of elective cesarean section for this population.

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Karlowicz, M.G., and McMurry J.L. (2000). Comparison of neonatal nurse practitioners' and pediatric residents' care of extremely low-birth-weight infants. *Ach of Pediatric Adolescent Medicine*, 154, 1123-1126.

Impact Factor: 3.73

Quality of Evidence: Acceptable  
Condition: Not Specified

n= 201

Retrospective Study.

This article compares outcomes in babies who are treated by neonatal nurse practitioners versus pediatric residents. The survival, length of stay and total charges were measured. Data resulted in no significant difference.

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Kiely, D. G., Condliffe, R., Webster, V., Mills, G. H., Wrench, I., Gandhi, S. V., . . . Elliot, C. A. (2010). Improved survival in pregnancy and pulmonary hypertension using a multiprofessional approach. *BJOG: An International Journal of Obstetrics & Gynaecology*, 117(5), 565-574. Doi: 10.1111/j.1471-0528.2009.02492.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Hypertension

n= 9

Retrospective Observational Study.

Pregnancy in women with Pulmonary Hypertension (PH) has carried a maternal mortality rate of 30-56%. New intervention providing a service of early introduction of targeted pulmonary vascular therapy and early planned delivery under anesthesia improves outcomes. Right heart catheterization was performed during pregnancy, pulmonary hemodynamic's were assessed. All 9 women delivered healthy babies, 8 women survived, one women died due to refusal for continued treatment.

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King, S., & Scrutton, M. (2011). Obstetric emergencies. *Anaesthesia and Intensive Care Medicine*, 12(3), 102-107. Doi: <http://dx.doi.org/10.1016/j.mpaic.2010.12.003>

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Article

This article discusses multiple OB emergencies and recommends the type of care needed. The focus is on the risk for obstetrical hemorrhage. Use of interventional radiology is discussed in the management of embolization during hemorrhagic emergencies, and primarily persistent moderate hemorrhage. Transfer to intensive care unit is necessary post stabilization in the interventional radiology lab.

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Kirshon, B., Hinkley, C. M., Cotton, D. B., & Miller, J. (1990). Maternal mortality in a maternal-fetal medicine intensive care unit. *Journal of Reproductive Medicine*, 35(1), 25-28.

Impact Factor: 0.7

Quality of Evidence: Acceptable

Condition: Hypertension

n= 95,684

Randomized Control Trial, 6 hospitals 1981-1987

This article investigates pregnancy induced hypertensive deaths. Multidisciplinary team of maternal fetal medicine is suggested. Obstetrical anesthesiology provides best level of care for the patient requiring cardiac care unit.

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Kivnick, S. G., Fachnie, J. D., & Lee, C. Y. (1983). Current management of pregnancy in the diabetic: a team approach. *Henry Ford Hospital Medical Journal*, 31(2), 84-90.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Diabetes/Obesity

n=89

Retrospective Review

This is a retrospective review of 89 deliveries. Although many interventions for diabetes were done, the perinatal mortality rate of 4% compared favorably with reports from all other centers. No other key interventions were listed that led to an improvement of the outcomes.

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Lasswell, S., Barfield, W., Rochat, R., and Blackmon, L. (2010). Perinatal Regionalization for Very Low-Birth-Weight and Very Preterm Infants. *JAMA*, 304(9), 992-999.

Impact Factor: 28.9

Quality of Evidence: Acceptable

Condition: Not Specified

n= Not Specified

Meta analysis

Meta analysis was done to evaluate published works on associations between nursery care versus neonatal intensive care unit (NICU) care and pre discharge mortality for very low birth weight (VLBW) and very preterm infants. A 30 year analysis of data was reviewed. Birth occurring outside of the NICU is associated with death.

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Lavin, J., DiPasquale, L., Crane, S., and Stewart, J. (2002). A state-wide assessment of the obstetric, anesthesia, and operative team personnel who are available to manage the labors and deliveries and to treat the complications of women who attempt vaginal birth after cesarean delivery. *American Journal of Obstetrics and Gynecology*, 187(3), 611-614.

Impact Factor: 3.56

Quality of Evidence: Acceptable

Condition: Not Specified

n= Not Specified

Article

This article analyzes the qualified range of obstetric anesthesia and surgical team who were "immediately" available to manage the labor and deliveries of women attempting vaginal birth after cesarean (VBAC). Those institutions that performed VBAC's had immediately available Obstetrical staff at the following percentages: Level I (27.3 %), Level II (62.9%), and Level III

(100%). Anesthesia was available at the following respective percentages: (39%), (100%) and (100%). Surgical team was available at the following respective percentages: (35.1%), (97.1%) and (100%). Level III organizations had all aspects of necessary care for VBAC 100% of the time. Most level I and some Level II institutions do not have the optimal qualified staff “immediately” available for VBAC’s.

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Lee, Shoo K., Lee, David S. C., Andrews, Wayne L., Baboolal, Ranjit, Pendray, Margaret, Stewart, Shawn, & the Canadian Neonatal, Network. (2003). Higher mortality rates among inborn infants admitted to neonatal intensive care units at night. *The Journal of Pediatrics*, 143(5), 592-597. Doi: 10.1067/s0022-3476(03)00367-6

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Not Specified

n=5192

Non Randomized Control Trial= 17 Tertiary Care Centers

Population included all neonates born at < 32 weeks gestation admitted to Neonatal Intensive Care Units (NICU). This author examined the circadian variation of deaths in the NICU. Risk adjusted odds were 60% higher for death in infants born after 5 pm. There was no breakdown of the six diseases discussed for analysis in this review.

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Levin, M. E., Rigg, L. A., & Marshall, R. E. (1986). Pregnancy and diabetes. Team approach. *Archives of Internal Medicine*, 146(4), 758-767.

Impact Factor: 8.0  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n= Not Specified

Articles

The role of the team is essential in caring for diabetic pregnant mothers. Such teams should consist of the family physician, internist, diabetologist, and obstetricians, as well as specially trained nursing. Outcome reduction was noted in diabetic pregnant women with normal Hgb A1c’s, and this was found to decrease the incidence of fetal malformation.

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Lowry, L. W., & Beikirch, P. (1998). Effect of comprehensive care on pregnancy outcomes. *Applied nursing research : ANR*, 11(2), 55-61.

Impact Factor: 1.22  
 Quality of Evidence: Acceptable  
 Condition: Not Specified

n= Not Specified

Article

This article compares the outcomes of maternal care in multidisciplinary tertiary care clinics with the same population who were served by public health clinics. There was a significant difference

found in the public health population, who had less low gestational age, as well as an increase in maternal risk factors, and decrease in infant complications. However, birth weight and APGAR scores were unchanged upon delivery. All women delivered in the same hospital.

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Martinez-Diaz, Jorge L. (2008). Valvular heart disease in pregnancy: a review of the literature. *Boletin – Asociacion Medica de Puerto Rico, 100*(4), 55-59

Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Cardiac Disease

n= Not Specified

Review of Literature

The therapeutic anticoagulation services required for safe delivery of women with valvular heart disease is discussed, no outcome analysis of morbidity or mortality was found. No discussion on the availability of these clinics throughout the United States.

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Miller, W. H., Jr., Bloom, J. D., & Resnick, M. P. (1992). Chronic mental illness and perinatal outcome. *General Hospital Psychiatry, 14*(3), 171-176.

Impact Factor: 2.67  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=101

Retrospective Study

This was a retrospective study reviewing outcome of birth via birth statistics. Two groups were compared, one from a large state psychiatric facility, and one acute university psychiatric facility. No major difference was found in the outcomes.

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Needleman, J., & Minnick, A. F. (2009). Anesthesia provider model, hospital resources, and maternal outcomes. *Health Serv Res, 44*(2 Pt 1), 464-482. Doi: 10.1111/j.1475-6773.2008.00919.x

Impact Factor: 2.41  
 Quality of Evidence: Limited  
 Condition: Not Specified

n=1,141,641

Retrospective Study

This was a retrospective analysis, to explain maternal outcome variation with respect to a specific anesthesia provider model. Descriptive statistics were used to analyze data, no difference was found with Certified Registered Nurse Anesthetists (CRNA) when compared with a medical doctor (MD).

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Nelson-Piercy, Catherine, Mackillop, Lucy, Williams, David J., Williamson, Catherine, de Swiet, Michael, & Redman, Christopher. (2011). Maternal mortality in the UK and the need for obstetric physicians. *BMJ*, 343, d4993. Doi: <http://dx.doi.org/10.1136/bmj.d4993>

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Article

Morbidity and mortality was assessed. The article proposes changes in morbidity and mortality this is due to the increased demand for more Obstetric physicians. No specified high risk population was assessed. There was no evidence to support the authors' assumption that changes in morbidity and mortality were related to the demand for more Obstetric physicians.

Nesbitt, T. S., & Baldwin, L. M. (1993). Access to obstetric care. *Primary Care; Clinics in Office Practice*, 20(3), 509-522.

Impact Factor: 0.81

Quality of Evidence: Acceptable

Condition: Not Specified

n= Not Specified

Article

This article identified a rate of 14% mortality in perinatal patients, from low provider rural areas. This was found to be a consequence of a lack of obstetricians. Lack of insurance had similar consequences to health of babies in urban area as well. There was a direct relationship between the availability of care and its' related poor outcomes of neonates.

This supports the understanding that good care results in decreased adverse events, but does lack of care result in increased morbidity and mortality? This was not established.

Access to care is the essential element to any solution to improving outcomes. Midwives and primary care are targeted solutions, but not the answer to the complex problem needed to improve high risk OB care. This article discusses liability issues as well. Further discussion on the American Medical Association (AMA) involvement with tort reform, and reimbursement for low income care is needed.

Nguyen, H. N., O'Sullivan, M. J., & Fournier, A. M. (1991). The impact of National Health Service Corps physicians in the lowering perinatal mortality rate in Dade County, Florida.[Retraction in Nguyen HN, O'Sullivan MJ, Fournier AM. *Obstet Gynecol*. 1991 Nov;78(5 Pt 1):888; PMID: 1923217]. *Obstetrics & Gynecology*, 78(3 Pt 1), 385-390.

Impact Factor: 4.36

Quality of Evidence: Acceptable

Condition: Not Specified

n= Not Specified

Article

The National Health Service Corps obstetricians and pediatricians serviced the inner city medically need patients from 1987-1989 in Dade County Florida. Reports of this data was compared and it was determined that this program reduced the mortality rate in both maternal and fetal populations, and subsequently saved lives. Barriers to access to service are discussed. The additional practitioners servicing the inner city populations, can provide insight and model new changes for the rest of the country.

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Pasupathy, D., Wood, A. M., Pell, J. P., Fleming, M., & Smith, G. C. (2010). Time of birth and risk of neonatal death at term: retrospective cohort study. *BMJ*, 341. Doi: 10.1136/bmj.c3498

Impact Factor: Not available  
 Quality of Evidence: Acceptable  
 Condition: Not Specified

n= 1,039,560.

Retrospective Cohort Study

This article describes a population based retrospective cohort study in Scotland. The authors analyzed deaths of newborns, singleton, with a cephalic presentation from the Scottish National Records. The risk of death rose from 4.2 to 5.6 during the off hours(not specified) on weekends and at night. This article questioned the lack of cesarean sections during off hours. It was determined that the increased risk of anoxia during the off hours contributed to the deaths.

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Phillips, N., & Dennerstein, L. (1993). The psychiatrist in an obstetric/gynaecology hospital: establishing a consultation-liaison service. *Australian & New Zealand Journal of Psychiatry*, 27(3), 464-471.

Impact Factor: 2.25  
 Quality of Evidence: Limited  
 Condition: Psychiatric/Mental Health

n=134

Non Randomized Control Trial

A new consulting psychiatric liaison service was established in Australia at the OB/GYN hospital. This program began with post natal psychiatric treatment. Expansion of the program included the development of inpatient units. The authors noted the plan to grow the services, with further research work and teaching. Multiple disciplines have now been added to expand the program. Evaluation of service usage was yet to be determined. No morbidity or mortality was measured.

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Phillips, N., Dennerstein, L., & Farish, S. (1996). Psychological morbidity in obstetric-gynaecology patients: testing the need for expanded psychiatry services in obstetric-gynaecology facilities.[Erratum appears in Aust N Z J Psychiatry 1996 Apr;30(2):308]. *Australian & New Zealand Journal of Psychiatry*, 30(1), 74-81.

Impact Factor: 1.24  
 Quality of Evidence: Limited

Condition: Psychiatric/ Mental Health

n=134

Article

Questionnaires were filled out for anxiety inventory, depression scale and patient satisfaction service. Findings concluded with high levels of anxiety with 1/3 patients above the 75<sup>th</sup> percentile for anxiety levels. This study concluded the need for increased awareness and further research to determine the psychological needs of OB/GYN patients. This study was limited to self-rated instruments, as well as poor study design, including poor response rate.

Pieper, P. G. (2012). The pregnant woman with heart disease: management of pregnancy and delivery. *Netherlands Heart Journal*, 20(1), 33-37.

Impact Factor: NA

Quality of Evidence: Limited

Condition: Cardiac Disease

n= Not Specified

Article

A system for risk assessment is reviewed to include the importance of identification of this fragile population, so that they may receive interventions during pregnancy, as well as management with a multidisciplinary team. A case study of women who did not receive consultative cardiology care and had further detriment to their co morbid condition post partum was reviewed. All women at risk should have at least one consultative appointment.

Pratt, S. D., Mann, S., Salisbury, M., Greenberg, P., Marcus, R., Stabile, B., . . . Sachs, B. P. (2007). John M. Eisenberg Patient Safety and Quality Awards. Impact of CRM-based training on obstetric outcomes and clinicians' patient safety attitudes. *Jt Comm J Qual Patient Saf*, 33(12), 720-725.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Not Specified

n= Not Specified

Article

Crew Resource Management- a new method to improve communication, and patient safety. Example of effect is OB unit at Beth Israel Medical Center. Root Cause Analysis by Harvard's Risk Management Foundation reviewed communication errors that caused a death. A communication plan was carried out that decreased the overall frequency and severity of adverse events and malpractice claims.

Quevedo, S. F., & Coustan, D. R. (1989). Diabetes and pregnancy. Use of an integrated "team" approach provides the necessary comprehensive care. *Rhode Island Medical Journal (Providence, RI)*, 72(4), 129-132.



Impact Factor: Not Available  
 Quality of Evidence: Limited  
 Condition: Diabetes/Obesity

n= Not Specified

Non Randomized Trial

In this study, the use of self glucose monitoring greatly improved the care of the diabetic mothers. It improved outpatient efficiency of insulin regimes. No measurement of outcome for morbidity or mortality was followed; also there was no measurement on availability of this type of service.

Quinlivan, J. A., Lam, L. T., & Fisher, J. (2011). A neonatologist trial of a four-step multidisciplinary approach to the antenatal care of obese pregnant women. *The Australian & New Zealand journal of obstetrics & gynaecology*, 51(2), 141-146.

Impact Factor: 1.24  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

n= 132

Randomized Control Trial: sample of body mass index (BMI) of >25%, Pregnant women. This study indicated that providing a consultative service to high risk obese OB patients with a four step intervention, reduced the incidence of gestational diabetes and maternal weight gain in pregnancy.

Reisner, Dale P., & Landers, Susan. (2010). Collaboration between obstetricians and neonatologists: perinatal safety programs and improved clinical outcomes. *Clinics in Perinatology*, 37(1), 179-188.

Impact Factor: 1.54  
 Quality of Evidence: Acceptable  
 Condition: Not Specified

n= Not Specified

Article

Examination of Seton Family Hospital's that created a service called "The Perinatal Safety Initiatives". The initiative involved four hospitals. They created a "High Reliability Perinatal Unit". High ability to recognize fetal distress, reassessing fetal distress, implementation of timely cesareans sections, properly resuscitating a depressed baby, proper use of Oxytocin, and vacuum or forceps assisted deliveries was all improved. The focus was on communication and coordination of care. Elective inductions dropped, and quality of care improved. Outcomes were not measured. New protocols were written.

Resnick, S., Jacques, A., Patole, S., & Simmer, K. (2011). Does after-hours in-house senior physician cover improve standard of care and outcomes in high-risk preterm neonates? A retrospective cohort study. *J Paediatr Child Health*, 47(11), 795-801. Doi: 10.1111/j.1440-1754.2011.02028.x

Impact Factor: 2.46  
 Quality of Evidence: Limited  
 Condition: Not Specified

n=235 Epoch 1

n=245 Epoch 2

Randomized Control Trial

Subjects <32 weeks gestation, placed in NICU, N= 235 in Epoch 1, N= 245 in Epoch 2

Outcomes did not show significant improvement after presence of senior house physician as compared with a less experienced clinician. It was concluded that the senior staff physicians ordered interventions more often and sooner.

Ridley, D. M., & Smiley, R. M. (1998). The parturient with cardiac disease. *Anesthesiology Clinics of North America*, 16(2), 419-440.

Impact Factor: 1.7  
 Quality of Evidence: Acceptable  
 Condition: Cardiac Disease

n= Not Specified

Article

Several types of heart disease are discussed in the article, as well as the role for specialty care. Importance is stressed on the use of anesthesiology, the complexity of the hemodynamic status of these patients, and the problems associated with labor.

Roman, L. A., Lindsay, J. K., Moore, J. S., Duthie, P. A., Peck, C., Barton, L. R., . . . Baer, L. J. (2007). Addressing mental health and stress in Medicaid-insured pregnant women using a nurse-community health worker home visiting team. *Public health nursing (Boston, Mass.)*, 24(3), 239-248.

Impact Factor: 0.56  
 Quality of Evidence: Acceptable  
 Condition: Not Specified

n=530. (Medicaid eligible pregnant women)

Article

The article aimed to describe the framework of the nursing community health worker (CHW) nursing interventions. Standard care was compared to CHW team care. This program reached women who had barriers to access to more intensive services. No outcome was found to differ at this time.

Shannon, D. (2011). Obstetrical team training: how the response to a tragic event revolutionized care across the country. *Physician Exec*, 37(2), 4-11.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Not Specified

n= Not Specified

Article

Beth Israel Medical Center had a tragic event that caused the crew resource management (CRM) or CRM report noted in Pratt's article. This article notes the communication gaps that occur in obstetrical medicine and the subsequent medical errors. All parties of the multidisciplinary team had equal input in developing the new plan of communication. The following recommendations were made based on the success of the above program.

1. Train the Trainer
2. Train the staff
3. Team Meetings
4. Team Huddles
5. Briefings
6. Debriefings

Sheikh, L., Zuberi, N., Riaz, R., & Rizvi, J. (2006). Massive primary postpartum hemorrhage: setting up standards of care.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Hemorrhage

Protocol development for massive post partum hemorrhage, began with cross-sectional study data at Aga Khan University Hospital in Karachi from Jan 2003- Jul 2004. Maternal mortality and morbidities including mode of delivery, cause of post partum hemorrhage and medical and surgical interventions were reviewed. Hemorrhage rate was 56% of total deliveries, (18/32). Interventions to evaluate and control bleeding were relatively aggressive, while new less invasive options were not utilized. Authors anticipated improvement on care after their introduction of evidence based management protocols was developed.

Simonson, D. C., Ahern, M. M., & Hendryx, M. S. (2007). Anesthesia staffing and anesthetic complications during cesarean delivery: a retrospective analysis. *Nursing Research*, 56(1), 9-17.

Impact Factor: 1.8

Quality of Evidence: Acceptable

Condition: Not Specified

n= 965

Observational

The author sought to assess anesthesia complications in hospitals that use Certified Registered Nurse Anesthetists (CRNA)'s and compared this with anesthesia medical doctor (MD) only teams. Results indicated that hospitals with CRNA-only staffing had a lower rate of anesthetic complications than those with anesthesiology only staffing. Statistical difference was not significant. Authors concluded no difference in rate of complications when CRNA model is used. Limitations of the study included the use of ICD-9 code for population identification. Complications were present, however, no difference was found when comparing providers. Geographic differences were analyzed and an increase in the use of CRNA's specifically rural systems, teaching, urgent admissions, and very young patients was identified. CRNA only

hospitals that combined team efforts with reviewing anesthesia, were typically smaller, or large tertiary care sized hospitals, and predominantly Medicaid patient populations.

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Skupski, Daniel W., Lowenwirt, Isaac P., Weinbaum, Fredric I., Brodsky, Dana, Danek, Margaret, & Eglinton, Gary S. (2006). Improving hospital systems for the care of women with major obstetric hemorrhage. *Obstetrics & Gynecology*, 107(5), 977-983.

Impact Factor: 4.36  
 Quality of Evidence: Acceptable  
 Condition: Hemorrhage

n= Not Specified

Article

Outcomes were compared retrospectively after an introduction for a patient safety program was in place for protecting major hemorrhage obstetrical patients. A Response team was formed, using the cardiac arrest team model. Improvement in mortality due to hemorrhage was found when data was compared.

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Sullivan, S. A., Hill, E. G., Newman, R. B., & Menard, M. K. (2005). Maternal-fetal medicine specialist density is inversely associated with maternal mortality ratios. *Am J Obstet Gynecol*, 193(3 Pt 2), 1083-1088. Doi: 10.1016/j.ajog.2005.05.085

Impact Factor: 3.28  
 Quality of Evidence: Acceptable  
 Condition: Not Specified

n= Not Specified

CDC- State Maternity Mortality ratio 1994-2001.

This study shows the statistical difference when there are 5 maternal-fetal specialists per 10,000 live births. This translates to a 27% reduction in the risk of maternal death. Study results support the regionalization of specialties in obstetrics to have optimal densities for specific states and regions.

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Tabassum, F., Saghvi, H., Merialdi, M., Dadelszen, P. (2011). Pre-eclampsia in low and middle income countries. *Best Practice & Research Clinical Obstetrics and Gynaecology*, 25, 537-548.

Impact Factor: 1.73  
 Quality of Evidence: Limited  
 Condition: Preeclampsia

n= Not Specified

Article

This article reviews PRE-EMPT, a knowledge translation tool to effect outcomes such as life ending, life threatening, and life altering maternal and perinatal complications of preeclampsia and eclampsia. This can be used to guide national service at many differing health care levels. The mix in licensed personal and regional need is limiting the services available in this area.

The author sites the use of "Task Shifting" to relieve the burden on some over used high level clinicians.

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Waldenstrom, U., McLachlan, H., Forster, D., Brennecke, S., & Brown, S. (2001). Team midwife care: maternal and infant outcomes. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 41(3), 257-264.

Impact Factor: 1.24

Quality of Evidence: Limited

Condition: Not Specified

n= Not Specified

Article

This study shows no statistical difference between team midwife care and standard physician based care.

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Yawn, B., Wellever, A., Hartley, D., Casey, M., Krein, S., & Moscovice, I. (1995). Availability of rural Minnesota obstetric services: is it a problem? *Journal of Rural Health*, 11(3), 192-203.

Impact Factor: 1.11

Quality of Evidence: Acceptable

Condition: Not Specified

n=669

Survey analysis

A telephone survey to obstetrical providers to document the number of locations and specialty of rural locations, their practice limitations and plans for future practice. A decrease in services was noted with more family practitioners who had stopped providing obstetrical services. Most identified Medicaid reimbursement as the leading cause as to why they stopped providing service.

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## V. Grey Literature

### Summary

The following bibliographies summarize relevant information regarding high risk obstetrics with a focus on the six noted conditions-diabetes and obesity, cardiac disease, preeclampsia and eclampsia, hypertension, psychiatric and mental health, and hemorrhage. These articles resulted from the search methodology referenced in Part I of this document.

### Bibliography

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.ROI Evidence Base: Studies on High-Risk Pregnancy. (2007) *The ROI Evidence Base: Identifying Quality Improvement Strategies with Cost-Saving Potential in Medicaid*. Princeton, NJ: Center for Health Care Strategies.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Not Specified

High-Risk pregnancy studies reporting decreases in cost/utilization.

Residential drug treatment followed by intensive outpatient day treatment services through labor and delivery showed a 62% reduction in NICU admissions for newborns.

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Juhl, A., Hansen, M., Sifford, A., Vellinga-Wilkinson, G., & Tolliver, R. (2010). Gestational Diabetes in Colorado: Pregnancy Risk Assessment Monitoring System (PRAMS), 2006-2008 *Health Watch* (pp. 6). Denver.

Impact Factor: Not Available

Quality of Evidence: Limited

Condition: Diabetes/Obesity

The first purpose of this report is to describe who has Gestational Diabetes Mellitus (GDM) in Colorado and identify subgroups of women at higher risk for GDM. The second purpose of this report is to compare women with and without GDM on outcomes associated with GDM and on recommended preventive postpartum behaviors.

The results of this report show that Colorado women ages 35 years and older, are Hispanic/Latino or Asian, have only 12 years of education, are from households earning less than \$35,000, have an overweight or obese prepregnancy BMI, and who gain weight during pregnancy above or below the appropriate range have a higher probability of developing GDM. In summary, screening, early detection, and management can greatly improve outcomes for women with GDM and their offspring. In addition to counseling women with GDM on management during pregnancy, women with GDM need to be informed that glucose intolerance may not be temporary and continued health care after pregnancy is important. Postpartum and interconception care needs to highlight risks for depression and for developing type 2 diabetes.

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National Guideline, C. *Diabetes in pregnancy. In: Prevention, detection and treatment of diabetes in adults. 4th edition.* Rockville MD: Agency for Healthcare Research and Quality (AHRQ) Retrieved from <http://www.guideline.gov>.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

Provides recommendations for good practice that are based on the best available evidence for clinical and cost effectiveness.  
 During pregnancy, women with pre-existing diabetes should be offered retinal assessment and contact with a diabetes care team for assessment of glycemic control every 1-2 weeks throughout pregnancy. These women should also be offered an anesthetic assessment in the third trimester of pregnancy.

National Guideline, C. *Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period.* Rockville MD: Agency for Healthcare Research and Quality (AHRQ) Retrieved from <http://www.guideline.gov>.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

#### Major Recommendations:

Education and empowerment for women to take control of their care during pregnancy is advised. Good glycemic control before conception is essential to reduce risk of miscarriage, congenital malformations, still birth, and neonatal death. Risks can be reduced, but may still occur.

Information and Education should cover-

1. the role of dietary, body weight and exercise
2. the risk of hypoglycemia and hypoglycemia awareness during pregnancy
3. how nausea and vomiting in pregnancy affects glycemic control
4. increase incidence of large for gestational age babies increases the likelihood of birth trauma, induction of labor and cesarean section
5. assessment of diabetic retinopathy before and during pregnancy
6. assessment of diabetic nephropathy before and during pregnancy
7. the importance of maternal glycemic control during labor, and birth, and early feeding of the baby, to reduce neonatal hypoglycemia
- 8 assessments for transient morbidity in the baby during the neonatal period, possible admission to the neonatal unit
- 9 awareness of development for childhood and adult diabetes and obesity later in life

#### Dietary advice for Obese or Diabetic Obstetrical Patients

Individual dietary advice should be given

Body mass index above 27 kg/m<sup>2</sup> should follow advice for weight loss plan during pregnancy, referral to NICE clinical guidance

Additional folic acid (5mg/day)

Target Range for Blood Glucose: Hgb A1C below 6.1%, if greater than 10%, pregnancy should be avoided

Medication advice referred to NICE guidance

Self Management referred to NICE guidance

Retinal Assessment during preconception care, via digital imaging, with mydriasis using tropicamide in line with the UK National Screening Committee.

Renal Assessment to include measurement of microalbuminuria before discontinuing contraception. Recommended creatinine 120 micromol/liter or more, or estimated glomerular filtration rate (eGFR) less than 45 ml/minute/1.73 m<sup>2</sup>, referral to nephrology.

Risk assessment for gestational diabetes including BMI, previous history of gestational diabetes, or diabetes or macrosomic baby weighing 4.5 kg or greater.

Screening diagnosis and treatment for gestational diabetes referred to NICE guidance

Intrapartum care referred to NICE guidance

National Guideline, C. *Hypertension in pregnancy. The management of hypertensive disorders during pregnancy.* Rockville MD: Agency for Healthcare Research and Quality (AHRQ)  
Retrieved from <http://www.guideline.gov>.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Hypertension

Major Recommendations:

Antiplatelet agents are advised for high risk, or more than one risk preeclampsia patients, dosed at 75mg of aspirin daily from 12 weeks until the birth of the baby.

Other pharmacological agents not recommended are nitric oxide donors, progesterone, diuretics and low molecular weight heparin.

Nutritional supplements not recommended for prevention of hypertensive disorders during pregnancy included magnesium, folic acid, antioxidants, fish or algal oil, and garlic.

Diet and lifestyle changes were deferred to the NICE guidelines.

Management of pregnancy with gestational hypertension was deferred to the NICE guidelines.

Management of Pregnancy with preeclampsia was deferred to the NICE guidelines.

Fetal Monitoring for Gestational hypertension

Ultrasound with assessment of fetal growth, amniotic fluid volume, and umbilical artery Doppler velocimetry between 28-30 weeks and between 32-34 weeks is recommended.

Cardiotocography is recommended for any abnormal ultrasound assessment findings, as well as for all patients with severe gestational hypertension or preeclampsia.

Intensive Care Management is specific to patient presentation.

Potential benefits outweigh harm in medical management of hypertension.



Potential harms include risk of adverse effects with administration of the antihypertensive drugs Atenolol, Labetalol, Methyldopa, and Metoprolol. Contraindications include risk of adverse effects with antihypertensive drugs: Nifedipine, Captopril, and Enalapril.

National Guideline, C. *Obesity in pregnancy*. Rockville MD: Agency for Healthcare Research and Quality (AHRQ) Retrieved from <http://www.guideline.gov>.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Diabetes/Obesity

Provides recommendations for counseling and management of obese parturients.

Interventions and practices considered:

1. Periodic health examinations to encourage healthy weight
2. Body mass index (BMI) calculation
3. Counseling regarding weight gain, nutrition, food choices, exercise and medical complications
4. Screening for congenital abnormalities
5. Consider body mass index when arranging fetal anatomic assessment
6. Antenatal consultation with anesthesiologist
7. Assess risk for thromboembolism and consider thromboprophylaxis if appropriate
8. Counseling and consultation with an obesity surgery specialist

Antenatal consultation with an anesthesiologist should be considered to review analgesic options and to ensure a plan is in place should a regional anesthetic be chosen.

National Guideline, C. *Systemic diseases in pregnancy*. Rockville MD: Agency for Healthcare Research and Quality (AHRQ) Retrieved from <http://www.guideline.gov>.

Impact Factor: Not Available  
 Quality of Evidence: Acceptable  
 Condition: Cardiac Diseases

Major recommendations with level of evidence (A-D): Interventions and practices considered include:

Heart and valve disease:

Frequent and early assessment of cardiac output, and notation of increases in circulatory burden.

Collaboration between the prenatal clinic and maternity ward in the hospital.

Place on left lateral recumbent position for every examination or treatment of significant duration.

Assess for functional capacity (heart classifications)

Hypertension:

Intervene to maintain arterial blood pressure less than 140/90 mmHg.

Monitor for fetal risk associated with placental insufficiency

Close monitoring of the pregnancy in the outpatient clinic

Admit to hospital if albuminuria is present

Administer antihypertensive drugs; beta blockers are the most useful with labetalol being the drug of choice. Second choice is nifedipine.

Angiotensin-converting enzymes are forbidden during pregnancy

**Diabetes/Obesity:**

Diabetic control of Type I diabetic pregnancy should be concentrated at university and central hospitals.

Prevent diabetes with good preconception glucose balance

Cooperation between internist and obstetrician

Assess for maternal renal failure, aggravation of diabetic retinopathy, disturbances in glucose balance, risk for preeclampsia, and polyhydramnios

Assess for fetal malformations, spontaneous abortion and premature labor, intrauterine death, macrosomia and shoulder dystocia, and Erb's paresis.

Assess for neonatal adaptation problems, including hypoglycemia, hypocalcaemia, hypobilirubinemia, and respiratory distress syndrome

Insulin therapy recommended in multiple injections

Perioral treatment with antidiabetic drugs are not possible due to fetal malformation risk

Reduce presentational body weight to less than 90kg

Assess patient for thromboembolic complications

Assess the fetus for macrosomia and prevention of shoulder dystocia

Ensure weight gain during pregnancy does not exceed 4-9 kg

**Psychiatric:**

Some psychiatric drugs decrease the likelihood of conception

Assess for psychological distress

Review the need for oral drug therapy

Assess for fetal malformations

Assess neonate for withdrawal symptoms

**Levels of Evidence Noted:**

Selective serotonin reuptake inhibitors given in late pregnancy seem to have subtle adverse effects on the newborn, but there is insufficient evidence from high-quality trials (Lattimore et al., 2005) [D].

Some selective serotonin-reuptake inhibitors may increase the risks for some specific defects, but the specific

defects implicated are rare and the absolute risks are small (Louik et al., 2007) [C]

National Guideline, C. *Use of psychiatric medications during pregnancy and lactation*. Rockville MD: Agency for Healthcare Research and Quality (AHRQ) Retrieved from <http://www.guideline.gov>.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Psychiatric/Mental Health

Lithium exposure in pregnancy may be associated with a small increase in congenital cardiac malformations.

Valproate exposure in pregnancy is associated with increased risk of fetal anomalies.

Cabamazepine exposure in pregnancy is associated with fetal carbamazepine syndrome.

Maternal benzodiazepine use shortly before delivery is associated with floppy infant syndrome.

National Guideline, C. *WHO recommendations for the prevention of postpartum haemorrhage*. Rockville MD: Agency for Healthcare Research and Quality (AHRQ) Retrieved from <http://www.guideline.gov>.

Impact Factor: Not Available

Quality of Evidence: Acceptable

Condition: Hemorrhage

Major Recommendations graded: (Very low, low, moderate, high) with strength (weak, strong)

1. "Active management of the third state of labor is offered by skilled attendants to all women (Strong recommendation, moderate quality of evidence).
2. In the context of active management of the third state of labor, if all injectable uterotonic drugs are available:
  - Skilled attendants should offer oxytocin to all women for prevention of PPH in preference to ergometrine/methylergometrine (Strong recommendations, low quality evidence).
  - If oxytocin is not available:
    - Skilled attendants should offer ergometrine/methylegometrine or the fixed drug combination of oxytocin and ergometrine to women without hypertension, or heart disease for prevention of PPH. (Strong recommendation, low quality of evidence).
3. Skilled attendants should offer oxytocin for prevention of PPH in preference to oral misoprostol (600 mcg). (Strong recommendations, high quality of evidence).
4. Skilled attendants should not offer sublingual misoprostol for prevention of PPH in preference to oxytocin. (Strong recommendations, very low quality of evidence).
  - Further research is needed to define the role of sublingual misoprostol administration for prevention of PPH.
5. Skilled attendants should not offer rectal misoprostol for prevention of PPH in preference to oxytocin. (Strong recommendations, low quality of evidence).
6. Skilled attendants should not offer carboprost/sulprostone for prevention of PPH in preference to oxytocin. (Strong recommendation, very low quality of evidence).
7. In the absence of active management of the third stage of labor, an uterotonic drug (oxytocin or misoprostol) should be offered by a health worker trained in its use for prevention of PPH. (Strong recommendation, moderate quality of evidence ).
8. Because of the benefit to the baby, the cord should not be clamped earlier than is necessary for applying cord traction in the active management of the third stage of labor. (Weak recommendation, low quality of evidence).
9. Given the current evidence for active management includes cord traction, the panel does not recommend any change in the current practice, further research is needed. (Strong recommendations, very low quality of evidence).

## Guideline References

The following guidelines did not yield in the original search methodology. However, the full-text review referenced these guidelines that were deemed to be of significance.

Altshuler, L., Cohen, L., Moline, M., Kahn, D., Carpenter, D., & Docherty, J. (2001). The Expert Consensus Guideline Series: Treatment of Depression in Women 2001. *Postgraduate Medicine Special Report*.

American Heart, A. (2006). 2005 American Heart Association (AHA) guidelines for cardiopulmonary resuscitation (CPR) and emergency cardiovascular care (ECC) of pediatric and neonatal patients: pediatric basic life support. *Pediatrics*, 117(5), e989-1004. doi: 10.1542/peds.2006-0219

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- Metzger, B. E., Buchanan, T. A., Coustan, D. R., de Leiva, A., Dunger, D. B., Hadden, D. R., . . . Zoupas, C. (2007). Summary and recommendations of the Fifth International Workshop-Conference on Gestational Diabetes Mellitus. [Practice Guideline]. *Diabetes Care*, 30 Suppl 2, S251-260. doi: 10.2337/dc07-s225

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## VI. Appendices

### Appendix A High Risk Obstetric Services (HROB) Question 1 Search Methodology and Terms

1,736 results were yielded for Part II after clinical experts and the Mount Sinai Scientific Team refined the original search results

#### HROB Q1 Complete Focused

#### OvidSP

1,657 results on 9/22/12

1. exp Pregnancy in Diabetics/ or exp \*Diabetes, Gestational/
2. exp Pregnancy Complications, Cardiovascular/ and (heart or cardiac).tw.
3. \*Hypertension, Pregnancy-Induced/
4. \*Eclampsia/ or \*HELLP syndrome/ or \*Pre-eclampsia/
5. exp Postpartum Hemorrhage/
6. 1 or 2 or 3 or 4 or 5
7. exp Obesity/
8. exp Heart Diseases/ or exp Hypertension, Pulmonary/
9. Hypertension/
10. exp Hemorrhage/
11. exp Mental Disorders/ or exp Depression/
12. (7 or 8 or 9 or 10 or 11) and (exp \*Pregnancy Complications/ or exp Pregnancy Outcome/)
13. (6 or 12) and Female/
14. ("gestational diabet\*" or preeclampsia or eclampsia or "pre eclampsia" or HELLP or "postpartum hemorrhage\*" or "postpartum haemorrhage").tw.
15. ((pregnancy adj2 complications) or (pregnancy adj2 outcom\*) or puerperal or postpartum or prenatal or perinatal or labor or labour).tw.
16. (diabetes or diabetic\* or "glucose intolerance" or obesity or obese).tw.
17. ("heart disease\*" or "cardiac disease\*").tw.

18. hypertension.tw.
19. ("mental illness\*" or "psychiatric illness\*" or "psychiatric disorder\*" or schizophrenia or bipolar or "major depression" or "major depressive").tw.
20. (alcoholism or "alcohol abus\*" or alcoholic\* or addict\* or "substance abus\*").tw.
21. (hemorrhage or haemorrhage).tw.
22. 15 and (16 or 17 or 18 or 19 or 20 or 21)
23. (14 or 22) not medline.st.
24. (13 or 23) not (Animals/ not Humans/)
25. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
26. 24 not 25
27. limit 26 to english language
28. (th or tu).xs. or bed rest/ or exp drug therapy/ or emergency treatment/ or exp resuscitation/ or exp diet therapy/ or anesthesia/ or anesthesia, obstetrical/ or exp delivery, obstetric/ or cesarean section/ or episiotomy/ or labor, induced/ or watchful waiting/ or exp health education/
29. exp counseling/ or exp directive counseling/ or psychotherapy/ or exp behavior therapy/ or exp psychotherapy, brief/ or exp psychotherapy, group/ or exp "Tobacco Use Cessation"/
30. (therap\* or treatment\* or counseling or psychotherapy or education).tw. not medline.st.
31. (diagnosis or ultrasonography).fs. or diagnosis/ or diagnosis, differential/ or exp diagnostic errors/ or "diagnostic techniques and procedures"/ or clinical laboratory techniques/ or diagnostic imaging/ or "diagnostic techniques, obstetrical and gynecological"/ or exp fetal monitoring/ or electrocardiography/ or mass screening/ or blood pressure monitoring, ambulatory/ or uterine monitoring/
32. (diagnos\* or screening).tw. not medline.st.
33. education.fs. or critical pathways/ or "quality of health care"/ or clinical competence/ or guideline adherence/ or exp quality assurance, health care/ or benchmarking/ or total quality management/ or quality improvement/ or "standard of care"/
34. ((quality adj3 care) or standard\* or benchmark\* or pathway\* or competenc\*).tw. not medline.st.
35. og.xs. or exp "costs and cost analysis"/ or exp policy/ or health services administration/ or exp "organization and administration"/ or exp "delivery of health care"/



36. (organization or administration or management or (cost\* adj3 benefit\*)).tw. not medline.st.
37. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38. Pregnancy Outcome/ or Survival Rate/ or exp survival analysis/
39. exp death/ or mortality/ or cause of death/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/ or stillbirth/ or exp suicide/ or exp abortion, spontaneous/ or mortality.fs.
40. exp Morbidity/ or exp Obstetric Labor Complications/ or exp cesarean section/ or diabetes, gestational/ or depression, postpartum/ or pre-eclampsia/ or eclampsia/
41. (((pre-eclampsia or eclampsia) and seizure\*) or hellp).mp.
42. exp Hysterectomy/ or exp Postoperative Complications/ or exp Blood Transfusion/
43. exp heart failure/ or exp arrhythmias, cardiac/ or "heart failure".tw. or arrhythmia\*.tw.
44. exp birth injuries/ or exp congenital abnormalities/ or fetal macrosomia/ or exp infant, low birth weight/ or infant, premature/ or exp premature birth/ or apgar score/ or fetal growth retardation/
45. ((complication\* adj2 (pregnancy or labor or labour or postpartum)) or gestational diabetes or depression or postpartum hemorrhage or pre-eclampsia or eclampsia).tw. not medline.st.
46. (stillbirth\* or stillborn or miscarriage\*).tw. not medline.st.
47. ((prematur\* or preterm) adj2 birth).tw. not medline.st.
48. ((low adj3 "birth weight\*") or "small for gestational age" or sga).tw. not medline.st.
49. ((maternal or perinatal) adj2 (morbidity or mortality)).tw.
50. (macrocephaly or macrosomia or "large for gestational age" or shoulder dystocia).mp.
51. exp hospitalization/ or exp "Costs and Cost Analysis"/ or patient safety/ or patient satisfaction/
52. cochrane.mp.
53. 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52
54. (clinical trial or comparative study or controlled clinical trial or evaluation studies or multicenter study or randomized controlled trial).pt.
55. (randomized or randomised or randomly or placebo or trial or groups).tw.

56. cross-over studies/ or meta-analysis as topic/ or retrospective studies/ or prospective studies/ or cross-sectional studies/
57. (((retrospective or prospective) adj2 stud\*) or odds ratio\* or relative risk\*).tw. not medline.st.
58. ((search\* or design or methods or method) and (results or findings)).ab.
59. 54 or 55 or 56 or 57 or 58
60. limit 59 to "core clinical journals (aim)"
61. ("journal of perinatology" or academic pediatrics or diabetes care).jn. and 59
62. 60 or 61
63. limit 62 to yr="2007 -Current"
64. limit 59 to evidence based medicine reviews
65. (search\* or "systematic review" or "evidence based review").tw. or exp evidence based practice/
66. cochrane.mp.
67. meta analysis.pt,tw. or meta-analysis as topic/
68. 64 or 65 or 66 or 67
69. limit 68 to yr="2002 -Current"
70. 63 or 69
71. 37 and 53 and 70
72. 27 and 71

## Cardiac Disease

### OvidSP

186 results on 9/22/12

1. exp Pregnancy Complications, Cardiovascular/ and (heart or cardiac).ti,ab.

2. (exp Heart Diseases/ or exp Hypertension, Pulmonary/) and (exp \*Pregnancy Complications/ or exp Pregnancy Outcome/)
3. (1 or 2) and female/
4. ((pregnancy adj2 complications) or (pregnancy adj2 outcom\*) or puerperal or postpartum or prenatal or perinatal or labor or labour or gestational).tw.
5. ("heart disease\*" or "cardiac disease\*").tw.
6. 4 and 5
7. 6 not medline.st.
8. (3 or 7) not (Animals/ not Humans/)
9. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
10. 8 not 9
11. limit 10 to english language
12. (th or tu).xs. or bed rest/ or exp drug therapy/ or emergency treatment/ or exp resuscitation/ or exp diet therapy/ or anesthesia/ or anesthesia, obstetrical/ or exp delivery, obstetric/ or cesarean section/ or episiotomy/ or labor, induced/ or watchful waiting/ or exp health education/
13. exp counseling/ or exp directive counseling/ or psychotherapy/ or exp behavior therapy/ or exp psychotherapy, brief/ or exp psychotherapy, group/ or exp "Tobacco Use Cessation"/
14. (therap\* or treatment\* or counseling or psychotherapy or education).tw. not medline.st.
15. (diagnosis or ultrasonography).fs. or diagnosis/ or diagnosis, differential/ or exp diagnostic errors/ or "diagnostic techniques and procedures"/ or clinical laboratory techniques/ or diagnostic imaging/ or "diagnostic techniques, obstetrical and gynecological"/ or exp fetal monitoring/ or electrocardiography/ or mass screening/ or blood pressure monitoring, ambulatory/ or uterine monitoring/

16. (diagnos\* or screening).tw. not medline.st.
17. education.fs. or critical pathways/ or "quality of health care"/ or clinical competence/ or guideline adherence/ or exp quality assurance, health care/ or benchmarking/ or total quality management/ or quality improvement/ or "standard of care"/
18. ((quality adj3 care) or standard\* or benchmark\* or pathway\* or competenc\*).tw. not medline.st.
19. og.xs. or exp "costs and cost analysis"/ or exp policy/ or health services administration/ or exp "organization and administration"/ or exp "delivery of health care"/
20. (organization or administration or management or (cost\* adj3 benefit\*)).tw. not medline.st.
21. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
22. Pregnancy Outcome/ or Survival Rate/ or exp survival analysis/
23. exp death/ or mortality/ or cause of death/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/ or stillbirth/ or exp suicide/ or exp abortion, spontaneous/ or mortality.fs.
24. exp Morbidity/ or exp Obstetric Labor Complications/ or exp cesarean section/ or diabetes, gestational/ or depression, postpartum/ or pre-eclampsia/ or eclampsia/
25. (((pre-eclampsia or eclampsia) and seizure\*) or hellp).mp.
26. exp Hysterectomy/ or exp Postoperative Complications/ or exp Blood Transfusion/
27. exp heart failure/ or exp arrhythmias, cardiac/ or "heart failure".tw. or arrhythmia\*.tw.
28. exp birth injuries/ or exp congenital abnormalities/ or fetal macrosomia/ or exp infant, low birth weight/ or infant, premature/ or exp premature birth/ or apgar score/ or fetal growth retardation/
29. ((complication\* adj2 (pregnancy or labor or labour or postpartum)) or gestational diabetes or depression or postpartum hemorrhage or pre-eclampsia or eclampsia).tw. not medline.st.
30. (stillbirth\* or stillborn or miscarriage\*).tw. not medline.st.
31. ((prematu\* or preterm) adj2 birth).tw. not medline.st.

32. ((low adj3 "birth weight\*") or "small for gestational age" or sga).tw. not medline.st.
33. ((maternal or perinatal) adj2 (morbidity or mortality)).tw.
34. (macrocephaly or macrosomia or "large for gestational age" or shoulder dystocia).mp.
35. exp hospitalization/ or exp "Costs and Cost Analysis"/ or patient safety/ or patient satisfaction/
36. cochrane.mp.
37. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38. (clinical trial or comparative study or controlled clinical trial or evaluation studies or multicenter study or randomized controlled trial).pt.
39. (randomized or randomised or randomly or placebo or trial or groups).tw.
40. cross-over studies/ or meta-analysis as topic/ or retrospective studies/ or prospective studies/ or cross-sectional studies/
41. (((retrospective or prospective) adj2 stud\*) or odds ratio\* or relative risk\*).tw. not medline.st.
42. ((search\* or design or methods or method) and (results or findings)).ab.
43. 38 or 39 or 40 or 41 or 42
44. limit 43 to "core clinical journals (aim)"
45. ("journal of perinatology" or academic pediatrics or diabetes care).jn. and 43
46. 44 or 45
47. limit 46 to yr="2007 -Current"
48. limit 43 to evidence based medicine reviews
49. (search\* or "systematic review" or "evidence based review").tw. or exp evidence based practice/
50. cochrane.mp.
51. meta analysis.pt,tw. or meta-analysis as topic/
52. 48 or 49 or 50 or 51
53. limit 52 to yr="2002 -Current"

54. 47 or 53

55. 21 and 37 and 54

56. 11 and 55

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Diabetes/Obesity

OvidSP

386 results on 9/22/12

1. exp \*Pregnancy in Diabetics/ or exp \*Diabetes, Gestational/
2. exp \*Obesity/ and (exp \*Pregnancy Complications/ or exp Pregnancy Outcome/)
3. (1 or 2) and Female/
4. "gestational diabet\*".tw.
5. ((pregnancy adj2 complications) or (pregnancy adj2 outcom\*) or puerperal or postpartum or prenatal or perinatal or labor or labour).tw.
6. (diabetes or diabetic\* or "glucose intolerance" or obesity or obese).tw.
7. 5 and 6
8. (4 or 7) not medline.st.
9. (3 or 8) not (Animals/ not Humans/)
10. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
11. 9 not 10
12. limit 11 to english language
13. (th or tu).xs. or bed rest/ or exp drug therapy/ or emergency treatment/ or exp resuscitation/ or exp diet therapy/ or anesthesia/ or anesthesia, obstetrical/ or exp delivery, obstetric/ or

- cesarean section/ or episiotomy/ or labor, induced/ or watchful waiting/ or exp health education/
14. exp counseling/ or exp directive counseling/ or psychotherapy/ or exp behavior therapy/ or exp psychotherapy, brief/ or exp psychotherapy, group/ or exp "Tobacco Use Cessation"/
15. (therap\* or treatment\* or counseling or psychotherapy or education).tw. not medline.st.
16. (diagnosis or ultrasonography).fs. or diagnosis/ or diagnosis, differential/ or exp diagnostic errors/ or "diagnostic techniques and procedures"/ or clinical laboratory techniques/ or diagnostic imaging/ or "diagnostic techniques, obstetrical and gynecological"/ or exp fetal monitoring/ or electrocardiography/ or mass screening/ or blood pressure monitoring, ambulatory/ or uterine monitoring/
17. (diagnos\* or screening).tw. not medline.st.
18. education.fs. or critical pathways/ or "quality of health care"/ or clinical competence/ or guideline adherence/ or exp quality assurance, health care/ or benchmarking/ or total quality management/ or quality improvement/ or "standard of care"/
19. ((quality adj3 care) or standard\* or benchmark\* or pathway\* or competenc\*).tw. not medline.st.
20. og.xs. or exp "costs and cost analysis"/ or exp policy/ or health services administration/ or exp "organization and administration"/ or exp "delivery of health care"/
21. (organization or administration or management or (cost\* adj3 benefit\*)).tw. not medline.st.
22. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23. Pregnancy Outcome/ or Survival Rate/ or exp survival analysis/
24. exp death/ or mortality/ or cause of death/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/ or stillbirth/ or exp suicide/ or exp abortion, spontaneous/ or mortality.fs.
25. exp Morbidity/ or exp Obstetric Labor Complications/ or exp cesarean section/ or diabetes, gestational/ or depression, postpartum/ or pre-eclampsia/ or eclampsia/

26. (((pre-eclampsia or eclampsia) and seizure\*) or hellp).mp.
27. exp Hysterectomy/ or exp Postoperative Complications/ or exp Blood Transfusion/
28. exp heart failure/ or exp arrhythmias, cardiac/ or "heart failure".tw. or arrhythmia\*.tw.
29. exp birth injuries/ or exp congenital abnormalities/ or fetal macrosomia/ or exp infant, low birth weight/ or infant, premature/ or exp premature birth/ or apgar score/ or fetal growth retardation/
30. ((complication\* adj2 (pregnancy or labor or labour or postpartum)) or gestational diabetes or depression or postpartum hemorrhage or pre-eclampsia or eclampsia).tw. not medline.st.
31. (stillbirth\* or stillborn or miscarriage\*).tw. not medline.st.
32. ((premat\* or preterm) adj2 birth).tw. not medline.st.
33. ((low adj3 "birth weight\*") or "small for gestational age" or sga).tw. not medline.st.
34. ((maternal or perinatal) adj2 (morbidity or mortality)).tw.
35. (macrocephaly or macrosomia or "large for gestational age" or shoulder dystocia).mp.
36. exp hospitalization/ or exp "Costs and Cost Analysis"/ or patient safety/ or patient satisfaction/
37. cochrane.mp.
38. 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37
39. (clinical trial or comparative study or controlled clinical trial or evaluation studies or multicenter study or randomized controlled trial).pt.
40. (randomized or randomised or randomly or placebo or trial or groups).tw.
41. cross-over studies/ or meta-analysis as topic/ or retrospective studies/ or prospective studies/ or cross-sectional studies/
42. (((retrospective or prospective) adj2 stud\*) or odds ratio\* or relative risk\*).tw. not medline.st.
43. ((search\* or design or methods or method) and (results or findings)).ab.
44. 39 or 40 or 41 or 42 or 43
45. limit 44 to "core clinical journals (aim)"



46. ("journal of perinatology" or academic pediatrics or diabetes care).jn. and 44
  47. 45 or 46
  48. limit 47 to yr="2007 -Current"
  49. limit 44 to evidence based medicine reviews
  50. (search\* or "systematic review" or "evidence based review").tw. or exp evidence based practice/
  51. cochrane.mp.
  52. meta analysis.pt,tw. or meta-analysis as topic/
  53. 49 or 50 or 51 or 52
  54. limit 53 to yr="2002 -Current"
  55. 48 or 54
  56. 22 and 38 and 55
  57. 12 and 56
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### Hemorrhage

#### OvidSP

317 results on 9/22/12

1. exp Postpartum Hemorrhage/
2. exp Hemorrhage/ and (exp \*Pregnancy Complications/ or exp Pregnancy Outcome/)
3. (1 or 2) and Female/
4. ("postpartum hemorrhage\*" or "postpartum haemorrhage").tw.
5. ((pregnancy adj2 complications) or (pregnancy adj2 outcom\*) or puerperal or postpartum or prenatal or perinatal or labor or labour).tw.
6. (hemorrhage or haemorrhage).tw.
7. 5 and 6

8. (4 or 7) not medline.st.
9. (3 or 8) not (Animals/ not Humans/)
10. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
11. 9 not 10
12. limit 11 to english language
13. (th or tu).xs. or bed rest/ or exp drug therapy/ or emergency treatment/ or exp resuscitation/ or exp diet therapy/ or anesthesia/ or anesthesia, obstetrical/ or exp delivery, obstetric/ or cesarean section/ or episiotomy/ or labor, induced/ or watchful waiting/ or exp health education/
14. exp counseling/ or exp directive counseling/ or psychotherapy/ or exp behavior therapy/ or exp psychotherapy, brief/ or exp psychotherapy, group/ or exp "Tobacco Use Cessation"/
15. (therap\* or treatment\* or counseling or psychotherapy or education).tw. not medline.st.
16. (diagnosis or ultrasonography).fs. or diagnosis/ or diagnosis, differential/ or exp diagnostic errors/ or "diagnostic techniques and procedures"/ or clinical laboratory techniques/ or diagnostic imaging/ or "diagnostic techniques, obstetrical and gynecological"/ or exp fetal monitoring/ or electrocardiography/ or mass screening/ or blood pressure monitoring, ambulatory/ or uterine monitoring/
17. (diagnos\* or screening).tw. not medline.st.
18. education.fs. or critical pathways/ or "quality of health care"/ or clinical competence/ or guideline adherence/ or exp quality assurance, health care/ or benchmarking/ or total quality management/ or quality improvement/ or "standard of care"/
19. ((quality adj3 care) or standard\* or benchmark\* or pathway\* or competenc\*).tw. not medline.st.

20. og.xs. or exp "costs and cost analysis"/ or exp policy/ or health services administration/ or exp "organization and administration"/ or exp "delivery of health care"/
21. (organization or administration or management or (cost\* adj3 benefit\*)).tw. not medline.st.
22. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23. Pregnancy Outcome/ or Survival Rate/ or exp survival analysis/
24. exp death/ or mortality/ or cause of death/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/ or stillbirth/ or exp suicide/ or exp abortion, spontaneous/ or mortality.fs.
25. exp Morbidity/ or exp Obstetric Labor Complications/ or exp cesarean section/ or diabetes, gestational/ or depression, postpartum/ or pre-eclampsia/ or eclampsia/
26. (((pre-eclampsia or eclampsia) and seizure\*) or hellp).mp.
27. exp Hysterectomy/ or exp Postoperative Complications/ or exp Blood Transfusion/
28. exp heart failure/ or exp arrhythmias, cardiac/ or "heart failure".tw. or arrhythmia\*.tw.
29. exp birth injuries/ or exp congenital abnormalities/ or fetal macrosomia/ or exp infant, low birth weight/ or infant, premature/ or exp premature birth/ or apgar score/ or fetal growth retardation/
30. ((complication\* adj2 (pregnancy or labor or labour or postpartum)) or gestational diabetes or depression or postpartum hemorrhage or pre-eclampsia or eclampsia).tw. not medline.st.
31. (stillbirth\* or stillborn or miscarriage\*).tw. not medline.st.
32. ((premat\* or preterm) adj2 birth).tw. not medline.st.
33. ((low adj3 "birth weight\*") or "small for gestational age" or sga).tw. not medline.st.
34. ((maternal or perinatal) adj2 (morbidity or mortality)).tw.
35. (macrocephaly or macrosomia or "large for gestational age" or shoulder dystocia).mp.
36. exp hospitalization/ or exp "Costs and Cost Analysis"/ or patient safety/ or patient satisfaction/

37. cochrane.mp.
  38. 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37
  39. (clinical trial or comparative study or controlled clinical trial or evaluation studies or multicenter study or randomized controlled trial).pt.
  40. (randomized or randomised or randomly or placebo or trial or groups).tw.
  41. cross-over studies/ or meta-analysis as topic/ or retrospective studies/ or prospective studies/ or cross-sectional studies/
  42. (((retrospective or prospective) adj2 stud\*) or odds ratio\* or relative risk\*).tw. not medline.st.
  43. ((search\* or design or methods or method) and (results or findings)).ab.
  44. 39 or 40 or 41 or 42 or 43
  45. limit 44 to "core clinical journals (aim)"
  46. ("journal of perinatology" or academic pediatrics or diabetes care).jn. and 44
  47. 45 or 46
  48. limit 47 to yr="2007 -Current"
  49. limit 44 to evidence based medicine reviews
  50. (search\* or "systematic review" or "evidence based review").tw. or exp evidence based practice/
  51. cochrane.mp.
  52. meta analysis.pt,tw. or meta-analysis as topic/
  53. 49 or 50 or 51 or 52
  54. limit 53 to yr="2002 -Current"
  55. 48 or 54
  56. 22 and 38 and 55
  57. 12 and 56
-

HypertensionOvidSP

126 results on 9/22/12

1. \*Hypertension, Pregnancy-Induced/
2. Hypertension/ and (exp \*Pregnancy Complications/ or exp Pregnancy Outcome/)
3. (1 or 2) and female/
4. ((pregnancy adj2 complications) or (pregnancy adj2 outcom\*) or puerperal or postpartum or prenatal or perinatal or labor or labour or gestational).tw.
5. hypertension.tw.
6. (4 and 5) not medline.st.
7. (3 or 6) not (Animals/ not Humans/)
8. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
9. 7 not 8
10. limit 9 to english language
11. (th or tu).xs. or bed rest/ or exp drug therapy/ or emergency treatment/ or exp resuscitation/ or exp diet therapy/ or anesthesia/ or anesthesia, obstetrical/ or exp delivery, obstetric/ or cesarean section/ or episiotomy/ or labor, induced/ or watchful waiting/ or exp health education/
12. exp counseling/ or exp directive counseling/ or psychotherapy/ or exp behavior therapy/ or exp psychotherapy, brief/ or exp psychotherapy, group/ or exp "Tobacco Use Cessation"/
13. (therap\* or treatment\* or counseling or psychotherapy or education).tw. not medline.st.
14. (diagnosis or ultrasonography).fs. or diagnosis/ or diagnosis, differential/ or exp diagnostic errors/ or "diagnostic techniques and procedures"/ or clinical laboratory techniques/ or diagnostic imaging/ or "diagnostic techniques, obstetrical and gynecological"/ or exp fetal

monitoring/ or electrocardiography/ or mass screening/ or blood pressure monitoring,  
ambulatory/ or uterine monitoring/

15. (diagnos\* or screening).tw. not medline.st.
16. education.fs. or critical pathways/ or "quality of health care"/ or clinical competence/ or guideline adherence/ or exp quality assurance, health care/ or benchmarking/ or total quality management/ or quality improvement/ or "standard of care"/
17. ((quality adj3 care) or standard\* or benchmark\* or pathway\* or competenc\*).tw. not medline.st.
18. og.xs. or exp "costs and cost analysis"/ or exp policy/ or health services administration/ or exp "organization and administration"/ or exp "delivery of health care"/
19. (organization or administration or management or (cost\* adj3 benefit\*)).tw. not medline.st.
20. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. Pregnancy Outcome/ or Survival Rate/ or exp survival analysis/
22. exp death/ or mortality/ or cause of death/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/ or stillbirth/ or exp suicide/ or exp abortion, spontaneous/ or mortality.fs.
23. exp Morbidity/ or exp Obstetric Labor Complications/ or exp cesarean section/ or diabetes, gestational/ or depression, postpartum/ or pre-eclampsia/ or eclampsia/
24. (((pre-eclampsia or eclampsia) and seizure\*) or hellp).mp.
25. exp Hysterectomy/ or exp Postoperative Complications/ or exp Blood Transfusion/
26. exp heart failure/ or exp arrhythmias, cardiac/ or "heart failure".tw. or arrhythmia\*.tw.
27. exp birth injuries/ or exp congenital abnormalities/ or fetal macrosomia/ or exp infant, low birth weight/ or infant, premature/ or exp premature birth/ or apgar score/ or fetal growth retardation/
28. ((complication\* adj2 (pregnancy or labor or labour or postpartum)) or gestational diabetes or depression or postpartum hemorrhage or pre-eclampsia or eclampsia).tw. not medline.st.

29. (stillbirth\* or stillborn or miscarriage\*).tw. not medline.st.
30. ((prematu\* or preterm) adj2 birth).tw. not medline.st.
31. ((low adj3 "birth weight\*") or "small for gestational age" or sga).tw. not medline.st.
32. ((maternal or perinatal) adj2 (morbidity or mortality)).tw.
33. (macrocephaly or macrosomia or "large for gestational age" or shoulder dystocia).mp.
34. exp hospitalization/ or exp "Costs and Cost Analysis"/ or patient safety/ or patient satisfaction/
35. cochrane.mp.
36. 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35
37. (clinical trial or comparative study or controlled clinical trial or evaluation studies or multicenter study or randomized controlled trial).pt.
38. (randomized or randomised or randomly or placebo or trial or groups).tw.
39. cross-over studies/ or meta-analysis as topic/ or retrospective studies/ or prospective studies/ or cross-sectional studies/
40. (((retrospective or prospective) adj2 stud\*) or odds ratio\* or relative risk\*).tw. not medline.st.
41. ((search\* or design or methods or method) and (results or findings)).ab.
42. 37 or 38 or 39 or 40 or 41
43. limit 42 to "core clinical journals (aim)"
44. ("journal of perinatology" or academic pediatrics or diabetes care).jn. and 42
45. 43 or 44
46. limit 45 to yr="2007 -Current"
47. limit 42 to evidence based medicine reviews
48. (search\* or "systematic review" or "evidence based review").tw. or exp evidence based practice/
49. cochrane.mp.
50. meta analysis.pt,tw. or meta-analysis as topic/

51. 47 or 48 or 49 or 50

52. limit 51 to yr="2002 -Current"

53. 46 or 52

54. 20 and 36 and 53

55. 10 and 54

### Psychiatric/Mental Health

#### OvidSP

366 results on 9/22/12

1. (exp Mental Disorders/ or exp Depression/) and (exp \*Pregnancy Complications/ or exp Pregnancy Outcome/) and Female/
2. ((pregnancy adj2 complications) or (pregnancy adj2 outcom\*) or puerperal or postpartum or prenatal or perinatal or labor or labour).tw.
3. ("mental illness\*" or "psychiatric illness\*" or "psychiatric disorder\*" or schizophrenia or bipolar or "major depression" or "major depressive").tw.
4. (alcoholism or "alcohol abus\*" or alcoholic\* or addict\* or "substance abus\*").tw.
5. 2 and (3 or 4)
6. 5 not medline.st.
7. (1 or 6) not (Animals/ not Humans/)
8. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
9. 7 not 8
10. limit 9 to english language
11. (th or tu).xs. or bed rest/ or exp drug therapy/ or emergency treatment/ or exp resuscitation/ or exp diet therapy/ or anesthesia/ or anesthesia, obstetrical/ or exp delivery, obstetric/ or



- cesarean section/ or episiotomy/ or labor, induced/ or watchful waiting/ or exp health education/
12. exp counseling/ or exp directive counseling/ or psychotherapy/ or exp behavior therapy/ or exp psychotherapy, brief/ or exp psychotherapy, group/ or exp "Tobacco Use Cessation"/
13. (therap\* or treatment\* or counseling or psychotherapy or education).tw. not medline.st.
14. (diagnosis or ultrasonography).fs. or diagnosis/ or diagnosis, differential/ or exp diagnostic errors/ or "diagnostic techniques and procedures"/ or clinical laboratory techniques/ or diagnostic imaging/ or "diagnostic techniques, obstetrical and gynecological"/ or exp fetal monitoring/ or electrocardiography/ or mass screening/ or blood pressure monitoring, ambulatory/ or uterine monitoring/
15. (diagnos\* or screening).tw. not medline.st.
16. education.fs. or critical pathways/ or "quality of health care"/ or clinical competence/ or guideline adherence/ or exp quality assurance, health care/ or benchmarking/ or total quality management/ or quality improvement/ or "standard of care"/
17. ((quality adj3 care) or standard\* or benchmark\* or pathway\* or competenc\*).tw. not medline.st.
18. og.xs. or exp "costs and cost analysis"/ or exp policy/ or health services administration/ or exp "organization and administration"/ or exp "delivery of health care"/
19. (organization or administration or management or (cost\* adj3 benefit\*)).tw. not medline.st.
20. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. Pregnancy Outcome/ or Survival Rate/ or exp survival analysis/
22. exp death/ or mortality/ or cause of death/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/ or stillbirth/ or exp suicide/ or exp abortion, spontaneous/ or mortality.fs.
23. exp Morbidity/ or exp Obstetric Labor Complications/ or exp cesarean section/ or diabetes, gestational/ or depression, postpartum/ or pre-eclampsia/ or eclampsia/

24. (((pre-eclampsia or eclampsia) and seizure\*) or hellp).mp.
25. exp Hysterectomy/ or exp Postoperative Complications/ or exp Blood Transfusion/
26. exp heart failure/ or exp arrhythmias, cardiac/ or "heart failure".tw. or arrhythmia\*.tw.
27. exp birth injuries/ or exp congenital abnormalities/ or fetal macrosomia/ or exp infant, low birth weight/ or infant, premature/ or exp premature birth/ or apgar score/ or fetal growth retardation/
28. ((complication\* adj2 (pregnancy or labor or labour or postpartum)) or gestational diabetes or depression or postpartum hemorrhage or pre-eclampsia or eclampsia).tw. not medline.st.
29. (stillbirth\* or stillborn or miscarriage\*).tw. not medline.st.
30. ((premat\* or preterm) adj2 birth).tw. not medline.st.
31. ((low adj3 "birth weight\*") or "small for gestational age" or sga).tw. not medline.st
32. ((maternal or perinatal) adj2 (morbidity or mortality)).tw.
33. (macrocephaly or macrosomia or "large for gestational age" or shoulder dystocia).mp.
34. exp hospitalization/ or exp "Costs and Cost Analysis"/ or patient safety/ or patient satisfaction/
35. cochrane.mp.
36. 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35
37. (clinical trial or comparative study or controlled clinical trial or evaluation studies or multicenter study or randomized controlled trial).pt.
38. (randomized or randomised or randomly or placebo or trial or groups).tw.
39. cross-over studies/ or meta-analysis as topic/ or retrospective studies/ or prospective studies/ or cross-sectional studies/
40. (((retrospective or prospective) adj2 stud\*) or odds ratio\* or relative risk\*).tw. not medline.st.
41. ((search\* or design or methods or method) and (results or findings)).ab.
42. 37 or 38 or 39 or 40 or 41
43. limit 42 to "core clinical journals (aim)"

44. ("journal of perinatology" or academic pediatrics or diabetes care).jn. and 42
  45. 43 or 44
  46. limit 45 to yr="2007 -Current"
  47. limit 42 to evidence based medicine reviews
  48. (search\* or "systematic review" or "evidence based review").tw. or exp evidence based practice/
  49. cochrane.mp.
  50. meta analysis.pt,tw. or meta-analysis as topic/
  51. 47 or 48 or 49 or 50
  52. limit 51 to yr="2002 -Current"
  53. 46 or 52
  54. 20 and 36 and 53
  55. 10 and 54
- 

### Pre-eclampsia/Eclampsia

#### OvidSP

355 results on 9/22/12

1. (\*Eclampsia/ or \*HELLP syndrome/ or \*Pre-eclampsia/) and Female/
2. (preeclampsia or eclampsia or "pre eclampsia" or HELLP).tw.
3. 2 not medline.st.
4. (1 or 3) not (Animals/ not Humans/)
5. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
6. 4 not 5
7. limit 6 to english language

8. (th or tu).xs. or bed rest/ or exp drug therapy/ or emergency treatment/ or exp resuscitation/ or exp diet therapy/ or anesthesia/ or anesthesia, obstetrical/ or exp delivery, obstetric/ or cesarean section/ or episiotomy/ or labor, induced/ or watchful waiting/ or exp health education/
9. exp counseling/ or exp directive counseling/ or psychotherapy/ or exp behavior therapy/ or exp psychotherapy, brief/ or exp psychotherapy, group/ or exp "Tobacco Use Cessation"/
10. (therap\* or treatment\* or counseling or psychotherapy or education).tw. not medline.st.
11. (diagnosis or ultrasonography).fs. or diagnosis/ or diagnosis, differential/ or exp diagnostic errors/ or "diagnostic techniques and procedures"/ or clinical laboratory techniques/ or diagnostic imaging/ or "diagnostic techniques, obstetrical and gynecological"/ or exp fetal monitoring/ or electrocardiography/ or mass screening/ or blood pressure monitoring, ambulatory/ or uterine monitoring/
12. (diagnos\* or screening).tw. not medline.st.
13. education.fs. or critical pathways/ or "quality of health care"/ or clinical competence/ or guideline adherence/ or exp quality assurance, health care/ or benchmarking/ or total quality management/ or quality improvement/ or "standard of care"/
14. ((quality adj3 care) or standard\* or benchmark\* or pathway\* or competenc\*).tw. not medline.st.
15. og.xs. or exp "costs and cost analysis"/ or exp policy/ or health services administration/ or exp "organization and administration"/ or exp "delivery of health care"/
16. (organization or administration or management or (cost\* adj3 benefit\*)).tw. not medline.st.
17. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. Pregnancy Outcome/ or Survival Rate/ or exp survival analysis/
19. exp death/ or mortality/ or cause of death/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/ or stillbirth/ or exp suicide/ or exp abortion, spontaneous/ or mortality.fs.

20. exp Morbidity/ or exp Obstetric Labor Complications/ or exp cesarean section/ or diabetes, gestational/ or depression, postpartum/ or pre-eclampsia/ or eclampsia/
21. (((pre-eclampsia or eclampsia) and seizure\*) or hellp).mp.
22. exp Hysterectomy/ or exp Postoperative Complications/ or exp Blood Transfusion/
23. exp heart failure/ or exp arrhythmias, cardiac/ or "heart failure".tw. or arrhythmia\*.tw.
24. exp birth injuries/ or exp congenital abnormalities/ or fetal macrosomia/ or exp infant, low birth weight/ or infant, premature/ or exp premature birth/ or apgar score/ or fetal growth retardation/
25. ((complication\* adj2 (pregnancy or labor or labour or postpartum)) or gestational diabetes or depression or postpartum hemorrhage or pre-eclampsia or eclampsia).tw. not medline.st.
26. (stillbirth\* or stillborn or miscarriage\*).tw. not medline.st.
27. ((prematu\* or preterm) adj2 birth).tw. not medline.st.
28. ((low adj3 "birth weight\*") or "small for gestational age" or sga).tw. not medline.st.
29. ((maternal or perinatal) adj2 (morbidity or mortality)).tw.
30. (macrocephaly or macrosomia or "large for gestational age" or shoulder dystocia).mp.
31. exp hospitalization/ or exp "Costs and Cost Analysis"/ or patient safety/ or patient satisfaction/
32. cochrane.mp.
33. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
34. (clinical trial or comparative study or controlled clinical trial or evaluation studies or multicenter study or randomized controlled trial).pt.
35. (randomized or randomised or randomly or placebo or trial or groups).tw.
36. cross-over studies/ or meta-analysis as topic/ or retrospective studies/ or prospective studies/ or cross-sectional studies/
37. (((retrospective or prospective) adj2 stud\*) or odds ratio\* or relative risk\*).tw. not medline.st.
38. ((search\* or design or methods or method) and (results or findings)).ab.

39. 34 or 35 or 36 or 37 or 38
40. limit 39 to "core clinical journals (aim)"
41. ("journal of perinatology" or academic pediatrics or diabetes care).jn. and 39
42. 40 or 41
43. limit 42 to yr="2007 -Current"
44. limit 39 to evidence based medicine reviews
45. (search\* or "systematic review" or "evidence based review").tw. or exp evidence based practice/
46. cochrane.mp.
47. meta analysis.pt,tw. or meta-analysis as topic/
48. 44 or 45 or 46 or 47
49. limit 48 to yr="2002 -Current"
50. 43 or 49
51. 17 and 33 and 50
52. 7 and 51

**Appendix B**  
**High Risk Obstetric Services Question 2**  
**Search Methodology and Terms**

Medline/OVID SP

774 results on 8/9/12

1. exp \*Pregnancy in Diabetics/
2. exp \*Diabetes, Gestational/
3. exp \*Pregnancy Complications, Cardiovascular/ and (heart or cardiac).ti,ab.
4. exp \*Hypertension, Pregnancy-Induced/
5. exp \*Postpartum Hemorrhage/
6. 1 or 2 or 3 or 4 or 5
7. exp Obesity/
8. exp Heart Diseases/ or Heart Defects, Congenital/ or exp Cardiovascular Infections/
9. exp Hypertension, Pulmonary/ or exp Hypertension/
10. exp Hemorrhage/
11. exp Mental Disorders/
12. (7 or 8 or 9 or 10 or 11) and (exp \*Pregnancy Complications/ or exp \*Pregnancy Outcome/)
13. ("postpartum hemorrhage\*" or "postpartum haemorrhage" or preeclampsia or eclampsia or "pre eclampsia" or HELLP or "gestational diabet\*" or (pregnancy adj2 hypertension)).ti,ab.
14. ((pregnancy adj2 complications) or (pregnancy adj2 outcom\*) or (puerperal or postpartum or prenatal or perinatal or labor or labour)).ti,ab.
15. ("heart disease\*" or "cardiac disease\*" or hypertension).ti,ab.
16. (diabetes or diabetic\* or "glucose intolerance").ti,ab.
17. ("mental illness\*" or "psychiatric illness\*" or "psychiatric disorder\*" or schizophrenia or bipolar or "major depression" or "major depressive").ti,ab.
18. (obesity or obese).ti,ab.
19. (alcoholism or "alcohol abuse" or alcoholic\*).ti,ab.

20. (hemorrhage or haemorrhage).ti,ab.
21. 14 and (15 or 16 or 17 or 18 or 19 or 20)
22. (13 or 21) not medline.st.
23. (6 or 12 or 22) not (Animals/ not Humans/)
24. (exp africa/ or exp asia/ or exp south america/ or Developing Countries/) not (exp Developed Countries/ or exp canada/ or exp united states/ or exp australia/ or exp europe/ or exp new zealand/)
25. 23 not 24
26. limit 25 to english language
27. (consensus development conference or consensus development conference nih or guideline or practice guideline).pt.
28. (\*health facility administration/ or exp \*hospital administration/ or exp \*institutional management teams/ or exp \*management audit/ or \*mandatory programs/ or \*multi-institutional systems/ or exp \*personnel management/ or exp \*professional practice/ or \*safety management/ or exp total quality management/) and standards.fs.
29. (\*"delivery of health care"/ or \*after-hours care/ or exp \*"delivery of health care, integrated"/ or exp \*health care reform/ or exp \*health resources/ or \*health services accessibility/ or \*health care rationing/ or exp \*"health services needs and demand"/ or \*nurse's practice patterns/ or \*physician's practice patterns/ or \*uncompensated care/ or \*health care evaluation mechanisms/ or \*guideline adherence/ or exp \*"outcome and process assessment (health care)"/ or \*patient satisfaction/ or program evaluation/ or \*benchmarking/) and standards.fs.
30. exp guideline/ or exp practice guideline/ or guidelines as topic/ or practice guidelines as topic/ or \*guideline adherence/
31. exp \*Critical Pathways/
32. exp \*"Standard of Care"/



33. ("consensus statement" or "practice bulletin").ti,ab. not medline.st.
34. ("best practice\*" or (standard\* adj1 of adj1 care) or ((critical or clinical) adj2 pathway\*)).ti,ab.  
not medline.st.
35. (guideline\* or consensus or statement or bulletin or recommendation\*).ti.
36. 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35
37. "Quality of Health Care"/
38. \*Risk Management/
39. "risk management".ti,ab. not medline.st.
40. \*Benchmarking/
41. exp \*Clinical Audit/
42. \*Management Audit/
43. \*Quality Control/
44. quality indicators, health care/ or risk adjustment/ or exp "utilization review"/
45. ((quality or process) adj2 (Indicator\* or Measures)).ti,ab.
46. ("report card" or audit\* or dashboard\*).ti,ab.
47. (45 or 46) not medline.st.
48. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 47
49. exp "Centers for Medicare and Medicaid Services (U.S.)"/
50. exp "Joint Commission on Accreditation of Healthcare Organizations"/
51. ("National Committee for Quality Assurance" or NCQA).ti,ab.
52. ("Healthcare Effectiveness Data and Information Set" or HEDIS).ti,ab.
53. ("Joint Commission" or JCAHO).ti,ab.
54. ("Agency for Healthcare Research and Quality" or AHRQ).ti,ab.
55. ("Hospital Consumer Assessment of Healthcare Providers and Systems" or HCAHPS or  
CAHPS or "Press Ganey").ti,ab.
56. ("American college of obstetricians and gynecologists" or ACOG).au,ti.

57. 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56

58. 36 or 48 or 57

59. 26 and 58

**Appendix C**  
**High Risk Obstetric Services Question 3**  
**Search Methodology and Terms**

Medline/OvidSP

563 results on 8/5/12

1. exp Pregnancy/
2. exp Infant, Newborn/
3. 1 or 2
4. exp "health care facilities, manpower, and services"/ or exp "health care economics and organizations"/ or exp health services administration/ or exp "health care quality, access, and evaluation"/
5. 3 and 4
6. (pregnancy or pregnant or newborn\* or obstetric\*).ti,ab. not medline.st.
7. (labor or labour or perinatal or neonatal or maternal).ti,ab. not medline.st.
8. exp canada/ or exp united states/ or exp australia/ or exp europe/ or new zealand/
9. exp Asia/ or exp Africa/
10. 9 not 8
11. (5 not 10) or 6 or 7
12. exp After-Hours Care/
13. ("around the clock" or "24 7" or "after hours" or "out of hours").ti,ab. not medline.st.
14. 12 or 13
15. exp Obstetrics/ or obsetrician\*.ti,ab.
16. Anesthesiology/
17. (anesthesiologist\* or anaesthesiologist\* or anaesthetist\* or anesthetist\*).ti,ab. not medline.st.
18. 14 and (15 or 16 or 17)
19. neonatologist\*.ti,ab. not medline.st.

20. neonatologist\*.ti,ab. and Neonatology/
21. (perinatologist\* or "obstetric anesthesiologist\*" or "obstetric anaesthesiologist\*").ti,ab.
22. (hospitalist\*.ti,ab. not medline.st.) or intensivist\*.ti,ab. or Hospitalists/
23. \*Patient Care Team/ or multiprofessional.ti,ab.
24. ("care team\*" or multidisciplinary).ti,ab. not medline.st.
25. (("maternal-fetal" or "maternal-foetal") adj3 (special\* or subspecial\*)).ti,ab.
26. manpower.fs.
27. 12 or 13 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28. exp Birth Injuries/
29. exp Death/
30. mortality/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/
31. exp Morbidity/ or exp Obstetric Labor Complications/
32. exp Pregnancy Complications/
33. Stillbirth/ or Pregnancy Outcome/
34. (complication\* adj2 (pregnancy or labor or labour or postpartum)).ti,ab. not medline.st.
35. (mortality or morbidity or stillbirth\* or stillborn or miscarriage\*).ti,ab. not medline.st.
36. ((prematu\* or preterm) adj2 birth).ti,ab. not medline.st.
37. ((low adj3 "birth weight\*") or "small for gestational age" or sga).ti,ab. not medline.st.
38. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37
39. 11 and 27 and 38
40. limit 39 to english language

HROB Q3 Embase (OvidSP)

68 on 8/7/12

1. exp fetus mortality/ or exp infant mortality/ or exp maternal mortality/ or exp perinatal mortality/ or exp prenatal mortality/

2. exp maternal morbidity/ or exp perinatal morbidity/
3. exp health care quality/
4. 1 or 2 or 3
5. exp canada/ or exp united states/
6. exp Europe/
7. exp "Australia and New Zealand"/
8. 5 or 6 or 7
9. exp Asia/ or exp Africa/
10. 9 not 8
11. 4 not 10
12. ("after hours" or "after-hours" or "out of hours" or "around the clock" or "24 hours" or "24 7" or "24 x 7" or "twenty four hours").ti,ab. and exp work/
13. exp obstetric procedure/ or obstetric anesthesia/
14. (anesthesi\* or anaesthesi\*).ti,ab. and (exp pregnancy/ or exp pregnancy disorder/ or exp newborn disease/ or exp newborn/)
15. 12 and (13 or 14)
16. (hospitalist\* or intensivist\*).ti,ab.
17. (((team\* or specialist\*) adj3 multidisciplinary) or multiprofessional).ti,ab.
18. exp pregnancy/ or exp pregnancy disorder/ or exp newborn disease/ or exp newborn/
19. (16 or 17) and 18
20. (neonatologist\* or perinatologist\* or "obstetric anesthesiologist\*" or "obstetric anaesthesiologist\*" or (("maternal foetal" or "maternal fetal") adj2 (specialist\* or subspecialist\*))).ti,ab.
21. 15 or 19 or 20
22. 11 and 21
23. limit 22 to (english language and embase)

24. limit 23 to exclude medline journals

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HROB Q3 Cochrane Database of Systematic Reviews -Cochrane Library/OvidSP

4 results on 8/5/2012

1. (pregnancy or pregnant or newborn\* or infant\* or obstetric\*).ti,ab,kw.
2. (manpower or staffing or "24 hour" or "around the clock" or "24 7" or "twenty four hour" or "after hours care").ti,ab,kw.
3. (labor or labour or perinatal or neonatal).ti,ab,kw.
4. (obsetric\* or anesthesiolog\* or anaesthesiolog\* or anaesthetist\* or anesthetist\*).ti,ab,kw.
5. (3 or 4) and 2
6. (hospitalist\* or subspecial\* or "obstetric anesthesiologist\*" or "obstetric anaesthesthesiologist").ti,ab,kw.
7. "After-Hours Care".ti,ab,kw.
8. ("care team\*" or multidisciplinary or multiprofessional).ti,ab,kw.
9. (("maternal-fetal" or "maternal-faetal") adj3 (special\* or subspecial\*)).ti,ab,kw.
10. 5 or 6 or 7 or 8 or 9
11. (death or mortality or stillbirth or stillborn or miscarriage\* or "spontaneous abortion\*").ti,ab,kw.
12. (Morbidity or "pregnancy outcome\*" or "birth injur\*").ti,ab,kw.
13. (complication\* adj2 (pregnancy or labor or labour or postpartum)).ti,ab,kw.
14. ((prematu\* or preterm) adj2 birth).ti,ab,kw.
15. ((low adj3 "birth weight\*") or "small for gestational age" or sga).ti,ab,kw.
16. 11 or 12 or 13 or 14 or 15
17. 1 and 10 and 16

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HROB Q3 Central-Cochrane Library/OvidSP

51 results on 8/7/2012

1. exp Pregnancy/
2. exp Infant, Newborn/
3. exp canada/ or exp united states/ or exp australia/ or exp cities/ or exp europe/ or new zealand/
4. exp Asia/ or exp Africa/
5. 4 not 3
6. (1 or 2) not 3
7. (pregnancy or pregnant or newborn\* or obstetric\*).ti,ab.
8. 6 or 7
9. limit 8 to english language
10. exp After-Hours Care/ or ("around the clock" or "after hours care").ti,ab.
11. ("24 hour" or "24 7" or "twenty four hour\*").ti.
12. 10 or 11
13. exp Obstetrics/
14. Anesthesiology/
15. exp Neonatology/
16. exp Anesthesia Department, Hospital/
17. (labor or labour or perinatal or neonatal).ti,ab.
18. (obsetrician\* or anesthesiologist\* or anaesthesiologist\* or anaesthetist\* or anesthetist\*).ti,ab.
19. (13 or 14 or 15 or 17 or 18) and 12
20. ("obstetric anesthesiologist\*" or "obstetric anaesthesthesiologist\*").ti,ab.
21. (neonatologist\* or perinatologist\*).ti,ab.
22. Hospitalists/
23. Patient Care Team/

24. exp After-Hours Care/
25. ("care team\*" or multidisciplinary).ti,ab.
26. (("maternal-fetal" or "maternal-faetal") adj3 (special\* or subspecial\*)).ti,ab.
27. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28. exp Birth Injuries/
29. exp Death/
30. mortality/ or fetal mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/
31. exp Morbidity/
32. exp Obstetric Labor Complications/
33. exp Pregnancy Complications/
34. Pregnancy Outcome/
35. Stillbirth/
36. exp Abortion, Spontaneous/
37. (complication\* adj2 (pregnancy or labor or labour or postpartum)).ti,ab.
38. (mortality or morbidity or stillbirth\* or stillborn or miscarriage\*).ti,ab.
39. ((prematu\* or preterm) adj2 birth).ti,ab.
40. ((low adj3 "birth weight\*") or "small for gestational age" or sga).ti,ab.
41. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40
42. 9 and 27 and 41

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HROB Q3 DARE -Cochrane Library/OvidSP

8 results on 8/5/12

1. (pregnancy or pregnant or newborn\* or infant\* or obstetric\*).mp. [mp=title, full text, keywords]
2. (manpower or staffing or "24 hour" or "around the clock" or "24 7" or "twenty four hour" or "after hours care").mp. [mp=title, full text, keywords]
3. (labor or labour or perinatal or neonatal).mp. [mp=title, full text, keywords]



4. (obsetric\* or anesthesiolog\* or anaesthesiolog\* or anaesthetist\* or anesthetist\*).mp. [mp=title, full text, keywords]
5. (3 or 4) and 2
6. (hospitalist\* or subspecial\* or "obstetric anesthesiologist\*" or "obstetric anaesthesthesiologist").mp. [mp=title, full text, keywords]
7. "After-Hours Care".mp. [mp=title, full text, keywords]
8. ("care team\*" or multidisciplinary).mp. [mp=title, full text, keywords]
9. (("maternal-fetal" or "maternal-faetal") adj3 (special\* or subspecial\*)).mp. [mp=title, full text, keywords]
10. 5 or 6 or 7 or 8 or 9
11. (death or mortality or stillbirth or stillborn or miscarriage\* or "spontaneous abortion").mp. [mp=title, full text, keywords]
12. (Morbidity or "pregnancy outcome\*" or "birth injur\*").mp. [mp=title, full text, keywords]
13. (complication\* adj2 (pregnancy or labor or labour or postpartum)).mp. [mp=title, full text, keywords]
14. ((prematu\* or preterm) adj2 birth).mp. [mp=title, full text, keywords]
15. ((low adj3 "birth weight\*") or "small for gestational age" or sga).mp. [mp=title, full text, keywords]
16. 11 or 12 or 13 or 14 or 15
17. 1 and 10 and 16

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HROB Q3 CINAHL / EbscoHost

54 results on 8/5/2012

S76 S44 and S73 and S74

S75 S44 and S73 and S74

S74 S55 or S57 or S58 or S59 or S60 or S61

- S73 (morbidity OR mortality OR error\* OR outcome\*) AND (S62 or S63 or S64 or S65 or S66 or S67 or S68 or S69 or S70 or S71 or S72)
- S72 morbidity OR mortality OR error\* OR outcome\*
- S71 MW /CO
- S70 (MH "Treatment Errors")
- S69 (MH "Infant, Low Birth Weight") OR (MH "Infant, Premature")
- S68 (MH "Abortion, Spontaneous") OR (MH "Childbirth, Premature") OR (MH "Fetal Diseases") OR (MH "Labor, Premature")
- S67 (MH "Infant Death")
- S66 (MH "Health Services Research+")
- S65 (MH "Quality of Health Care") OR (MH "Outcomes (Health Care)")
- S64 (MH "Morbidity")
- S63 MW /MO
- S62 (MH "Mortality") OR (MH "Infant Mortality") OR (MH "Maternal Mortality") OR (MH "Perinatal Death") OR (MH "Hospital Mortality")
- S61 intensivist\*
- S60 neonatologist\* OR perinatologist\*
- S59 "obstetric anesthesiologist\*"
- S58 "maternal fetal specialist\*" OR "maternal fetal medicine"
- S57 (MH "Hospitalists")
- S56 S49 and S55
- S55 S50 or S51 or S52 or S53 or S54
- S54 (MH "Practice Patterns")
- S53 "around the clock" OR "24 hour" OR "24 X 7" OR "24 7" OR "after hours" OR "out of hours"
- S52 (MH "Night Care")

- S51 (MH "Personnel Staffing and Scheduling+")
- S50 MW /ma
- S49 S45 or S46 or S47 or S48
- S48 anesথে\* OR anaesথে\* OR obstetric\*
- S47 (MH "Anesthesiologists")
- S46 (MH "Obstetrics")
- S45 (MH "Obstetric Service") OR (MH "Anesthesiology Service")
- S44 (obstetrics OR maternal OR pregnancy OR childbirth OR labor OR labour OR delivery OR newborn OR neonat\*) AND (S39 or S40 or S41 or S42 or S43)
- S43 obstetrics OR maternal OR pregnancy OR childbirth OR labor OR labour OR delivery OR newborn OR neonat\*
- S42 (MH "Obstetrics")
- S41 (MH "Obstetric Care")
- S40 (MH "Infant, Newborn")
- S39 (MH "Pregnancy")
- S38 S6 and S35 and S36 54
- S37 S6 and S35 and S36
- S36 S17 or S19 or S20 or S21 or S22 or S23
- S35 (morbidity OR mortality OR error\* OR outcome\*) AND (S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34)
- S34 morbidity OR mortality OR error\* OR outcome\*
- S33 MW /CO
- S32 (MH "Treatment Errors")
- S31 (MH "Infant, Low Birth Weight") OR (MH "Infant, Premature")
- S30 (MH "Abortion, Spontaneous") OR (MH "Childbirth, Premature") OR (MH "Fetal Diseases") OR (MH "Labor, Premature")

- S29 (MH "Infant Death")
- S28 (MH "Health Services Research+")
- S27 (MH "Quality of Health Care") OR (MH "Outcomes (Health Care)")
- S26 (MH "Morbidity")
- S25 MW /MO
- S24 (MH "Mortality") OR (MH "Infant Mortality") OR (MH "Maternal Mortality") OR (MH "Perinatal Death") OR (MH "Hospital Mortality")
- S23 intensivist\*
- S22 neonatologist\* OR perinatologist\*
- S21 "obstetric anesthesiologist\*\*"
- S20 "maternal fetal specialist\*\*" OR "maternal fetal medicine"
- S19 (MH "Hospitalists")
- S18 S11 and S17
- S17 S12 or S13 or S14 or S15 or S16
- S16 (MH "Practice Patterns")
- S15 "around the clock" OR "24 hour" OR "24 X 7" OR "24 7" OR "after hours" OR "out of hours"
- S14 (MH "Night Care")
- S13 (MH "Personnel Staffing and Scheduling+")
- S12 MW /ma
- S11 S7 or S8 or S9 or S10
- S10 anesথে\* OR anaesথে\* OR obstetric\*
- S9 (MH "Anesthesiologists")
- S8 (MH "Obstetrics")
- S7 (MH "Obstetric Service") OR (MH "Anesthesiology Service")

S6 (obstetrics OR maternal OR pregnancy OR childbirth OR labor OR labour OR delivery  
OR newborn OR neonat\*) AND (S1 or S2 or S3 or S4 or S5)

S5 obstetrics OR maternal OR pregnancy OR childbirth OR labor OR labour OR delivery  
OR newborn OR neonat\*

S4 (MH "Obstetrics")

S3 (MH "Obstetric Care")

S2 (MH "Infant, Newborn")

S1 (MH "Pregnancy")

## Appendix D Tables for Level of Evidence

<b>The American College of Obstetricians and Gynecologists (ACOG)</b>
<p><b>I.</b> Evidence obtained from at least 1 properly designed randomized controlled trial.</p> <p><b>II-1.</b> Evidence obtained from well-designed controlled trials without randomization.</p> <p><b>II-2.</b> Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than 1 center or research group.</p> <p><b>II-3.</b> Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded at the type of evidence.</p> <p><b>III.</b> Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</p> <p><b>Level A-</b>Recommendations are based on good and consistent scientific evidence.</p> <p><b>Level B-</b> Recommendations are based on limited or inconsistent scientific evidence.</p> <p><b>Level C-</b> Recommendations are based primarily on consensus and expert opinion.</p>
<b>Society of Obstetricians and Gynaecologists of Canada (SOGC)</b>
<p>Quality of Evidence Assessment</p> <p><b>I:</b> Evidence obtained from at least one properly Randomized controlled trial.</p> <p><b>II-1:</b> Evidence from well-designed controlled trials without randomization</p> <p><b>II-2:</b> Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.</p> <p><b>II-3:</b> Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.</p> <p><b>III:</b> Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</p> <p>Classification of Recommendations</p> <p><b>A.</b> There is good evidence to recommend the clinical preventive action.</p> <p><b>B.</b> There is fair evidence to recommend the clinical preventive action.</p> <p><b>C.</b> The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-</p>

making.

**D.** There is fair evidence to recommend against the clinical preventive action.

**E.** There is good evidence to recommend against the clinical preventive action.

**L.** There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

### **U.S. Preventive Services Task Force (USPSTF)**

**I** Evidence obtained from at least one properly designed randomized controlled trial.

**II-1** Evidence obtained from well-designed controlled trials without randomization.

**II-2** Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

**II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

**III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

**Level A**—Recommendations are based on good and consistent scientific evidence.

**Level B**—Recommendations are based on limited or inconsistent scientific evidence.

**Level C**—Recommendations are based primarily on consensus and expert opinion.

### **National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Clinical Excellence (NICE).**

#### **Rating Scheme for the Strength of the Evidence**

#### **Levels of Evidence for Intervention Studies**

**1++** High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs) or RCTs with a very low risk of bias

**1+** Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

**1–** Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

**2++** High-quality systematic reviews of case-control or cohort studies; high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

**2+** Well-conducted case-control or cohort studies with a low risk of confounding, bias or

chance and a moderate probability that the relationship is causal

**2-** Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

**3** Non-analytical studies (e.g., case reports, case series)

**1+** Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

**1-** Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

**2++** High-quality systematic reviews of case-control or cohort studies; high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

**2+** Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

**2-** Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal **3** Non-analytical studies (e.g., case reports, case series)

**4** Expert opinion, formal consensus

### **Levels of Evidence for Studies of the Accuracy of Diagnostic Tests**

**Ia** - Systematic review (with homogeneity) a of level 1 studies b

**Ib** - Level 1 studies b

**II** - Level 2 studies c; systematic reviews of level 2 studies

**III** - Level 3 studies d; systematic reviews of level 3 studies

**IV** - Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or "first principles"

a Homogeneity means there are minor or no variations in the directions and degrees of results between individual studies that are included in the systematic review.

b Level 1 studies are studies that use a blind comparison of the test with a validated reference standard (gold standard) in a sample of patients that reflects the population to whom the test would apply.

c Level 2 studies are studies that have only one of the following:

- Narrow population (the sample does not reflect the population to whom the test would apply)
- Use a poor reference standard (defined as that where the "test" is included in the "reference", or where the "testing" affects the



- "reference")
- The comparison between the test and reference standard is not blind
- Case-control studies

d Level 3 studies are studies that have at least two or three of the features listed above.

### Finnish Medical Society Duodecim.

#### Levels of Evidence

##### A. Quality of Evidence: High

Further research is very unlikely to change confidence in the estimate of effect

- Several high-quality studies with consistent results
- In special cases: one large, high-quality multi-centre trial

##### B. Quality of Evidence: Moderate

Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

- One high-quality study
- Several studies with some limitations

##### C. Quality of Evidence: Low

Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.

- One or more studies with severe limitations

##### D. Quality of Evidence: Very Low

Any estimate of effect is very uncertain.

- Expert opinion
- No direct research evidence
- One or more studies with very severe limitations

#### Clinical Algorithm(s)

None provided

##### D. Quality of Evidence: Very Low

Any estimate of effect is very uncertain.

- Expert opinion
- No direct research evidence
- One or more studies with very severe limitations

### The World Health Organization (WHO)

#### GRADE Quality Assessment Criteria

**High-** Randomized Control Trial-

**Moderate**

**Low-** Observational study

**Very low-** any other evidence

#### Study Quality

Lower if:

- -1 Serious limitations
- -2 Very serious limitations
- -1 Important inconsistency

#### Directness:

- -1 Some uncertainty
- -2 Major uncertainty
- -1 Sparse data
- -1 High probability of reporting Bias

#### Study Association

Higher if:

- +1 Strong, no plausible confounders, consistent and direct evidence\*\*
- +2 Very strong, no major threats to validity and direct evidence \*\*\*
- +1 Evidence of a dose response gradient
- +1 All plausible confounders would have reduced the effect
- \*1 = move up or down one grade (for example, from high to intermediate); 2 = move up or down two grades (for example, from high to low)

\*\*A statistically significant relative risk of  $>2$  ( $<0.5$ ), based on consistent evidence from two or more observational studies, with no plausible confounders.

\*\*\*A statistically significant relative risk of  $>5$  ( $<0.2$ ) based on direct evidence with no major threats to validity.

## World Health Organization (WHO)

### Quality of Evidence

**1** Quality of evidence = Strong recommendations usually require higher quality evidence for all the critical outcomes.

**2.** Relative importance of the outcomes = Seek evidence about the relative and actual values that patients place on outcomes (critical; important but not critical; not important). Seek evidence about variability in preferences and values among patients and other stakeholders. The relative importance of the outcomes should be included in the considerations before recommendations are made. If values and preferences vary widely, a strong recommendation becomes less likely.

- a. benefits of therapy
- b. harm of treatment
- c. burdens of therapy

**3.** Baseline risks of outcomes = Consider the baseline risk for an outcome. Is the baseline risk going to make a difference? If yes, then consider making separate recommendations for different populations. The higher the baseline risk, the higher the magnitude of potential benefit and the higher the likelihood of a strong recommendation

- a. benefits of therapy
- b. harm of treatments
- c. burdens of therapy

**4.** Magnitude of relative risk = Consider the relative magnitude of the net effect. Large relative effects will lead to a higher likelihood of a strong recommendation if the balance of benefit, harms and burden go in the same direction. If they go in opposite directions and the relative magnitude of effects is large (large benefits coming with large risk of adverse effects), the recommendation is more likely to be weak.

- a. benefits (reduction in RR)
- b. harms (increase in RR)
- c. burden

**5.** Absolute magnitude of the effect = Large absolute effects are more likely to lead to strong recommendation

- a. benefits
- b. harms
- c. burden

**6.** Precision of the estimates of the effects = The greater the precision the more likely the recommendation is strong.

- a. benefits of therapy
- b. harms of treatments
- c. burdens of therapy

**7. Factors that modify effects in specific settings/Local factors that may affect translation of the evidence into practice=** The more similar the setting and patients for which one is making a recommendation to the setting and patients generating the evidence, the more likely the recommendation is strong.

**8. Costs=** Consider that important benefits should come at a reasonable cost. The higher the incremental cost, all else being equal, the less likely that the recommendation in favour of an intervention is strong.

### **Pre-eclampsia Community Guideline (PRECOG)**

#### **GRADING OF RECOMMENDATIONS AND EVIDENCE**

##### **Grading of recommendations**

**Grade A\*** Directly based on category I evidence

**Grade B** Directly based on category II evidence or extrapolated recommendation from category I evidence

**Grade C** Directly based on category III evidence or extrapolated recommendation from category I or II evidence

**Grade D** Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence

**Good practice point:** the view of the guideline development group.  
(Note the grading of recommendations follows that adopted in the NICE guideline and differs from recent RCOG recommendations: see “Evidence used to develop the PRECOG guideline” for further details).

\*The highest grade

##### **Grading of evidence**

##### **Level Evidence**

**1a\*** Evidence obtained from meta-analysis of randomised controlled trials

**1b** Evidence obtained from at least one randomised controlled trial

**IIa** Evidence obtained from at least one well-designed controlled study without randomisation. Includes cohort studies

**IIb** Evidence obtained from at least one other type of well-designed quasi-experimental study. Includes case control studies

**III** Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies

**IV** Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

\*The highest level of evidence

### Royall College of Obstetrics and Gynaecology (RCOG)

#### Classification of evidence levels

**1++** High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

**1+** Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

**1-** Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

**2++** High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

**2+** Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

**2-** Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

**3** Non-analytical studies; e.g. case reports, case series

**4** Expert opinion

#### Grades of recommendations

**A** =At least one meta-analysis, systematic reviews or randomised controlled trial rated as 1++ and directly applicable to the target population; or A systematic review of randomized controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results

**B** =A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+

**C** =A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++

**D** =Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

Good practice point =Recommended best practice based on the clinical experience of the guideline development group

### American Diabetic Association(ADA) evidence-grading system for clinical practice recommendations

#### Level of evidence

A. Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

Compelling nonexperimental evidence, i.e., the “all or none” rule developed by the Centre for Evidence-Based Medicine at Oxford Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

B. Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C. Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation E Expert consensus or clinical experience

### European Society of Cardiology

**Class I** Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.

**Class II** Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.

**Class IIa** Weight of evidence/opinion is in favour of usefulness/efficacy.

**Class IIb** Usefulness/efficacy is less well established by evidence/opinion.

**Class III** Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

**Level of evidence A**

Data derived from multiple randomized clinical trials or meta-analyses.

**Level of evidence B**

Data derived from a single randomized clinical trial or large non-randomized studies.

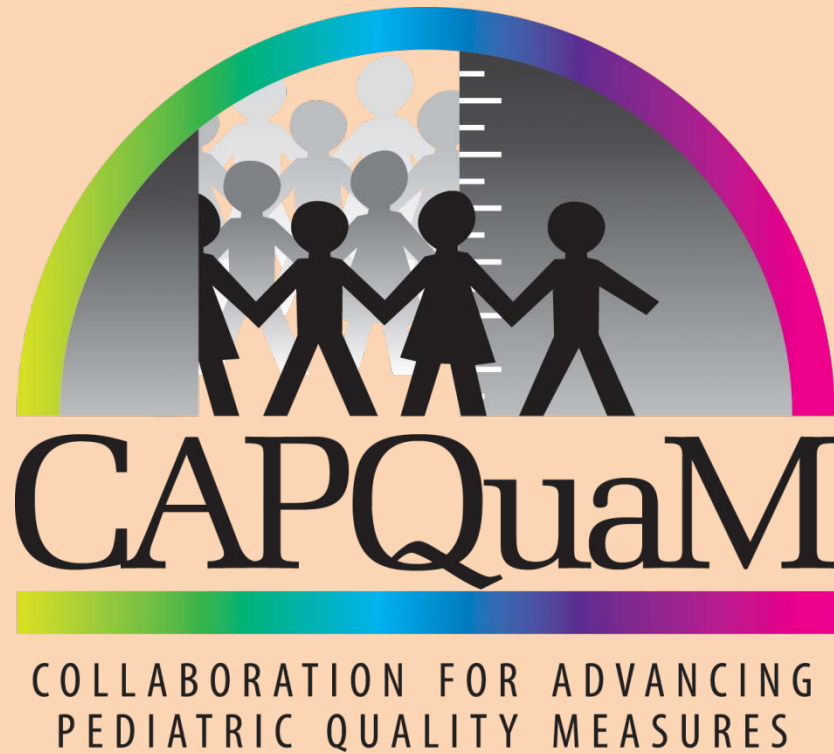
**Level of evidence C**

Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

## ***Appendix C***

*Powerpoint Presentation Orienting EP to the Process*





# CAPQuaM Expert Panel Orientation Presentation



Dr. Larry Kleinman, CAPQuaM PI

# Children Are Not Young Adults

- 4 D's Model (Forrest & Dougherty)
  - Changing **D**evelopmental Status of Children
  - **D**ifferences in epidemiological patterns of disease
  - Differing **D**emography of children compared to adults
  - **D**ependent upon their parents / caregivers
- More D's
  - Lack of a **D**ata Infrastructure equivalent to Medicare
  - Lack of strong financial **D**rivers for research

# Medicaid and the SCHIP Program

- Federal State partnership
- Major public insurance program for children
- Supplemented in late 1990's by State Child Health Insurance Program (CHIP or SCHIP)
  - For working poor who did not qualify for Medicaid
  - Benefits and eligibility vary by state
  - Could be Medicaid expansion or separate program

# Children's Health Insurance Program Reauthorization Act (CHIPRA), 2009

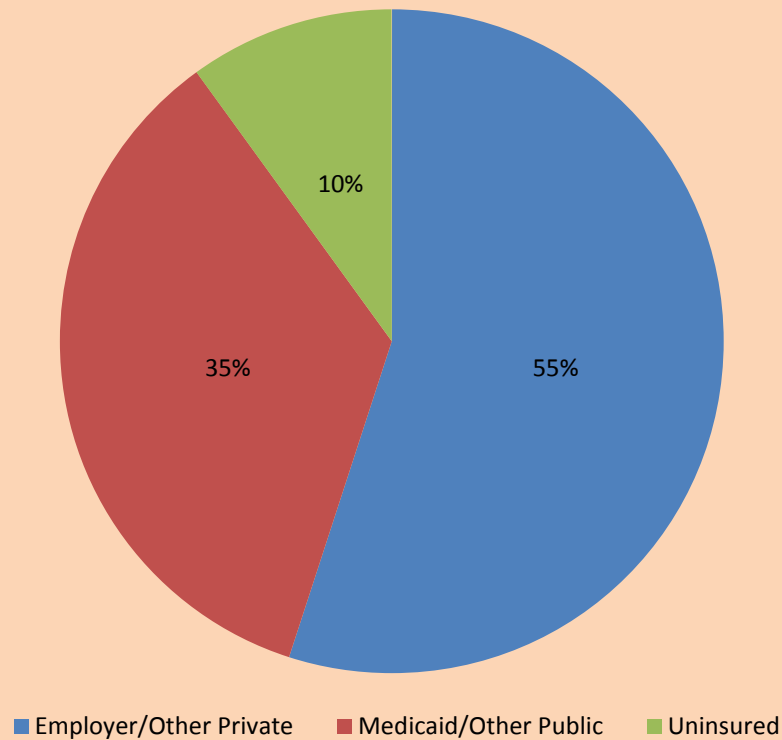
- CHIP = Children's Health Insurance Program
  - administered at the state level
  - insures low-income children whose parents do not qualify for Medicaid
  - reauthorizes CHIP through 2013
- Creates the Pediatric Quality Measures Program

# Background and Context

- CHIPRA's Title IV signals a new day for children's healthcare quality measurement in the U.S.
- AHRQ is partnering with CMS on identification and development of children's healthcare quality measures
  - Phase I-- Identification of an initial core measurement set for voluntary use by Medicaid and CHIP programs-- is completed
  - Phase II – the Pediatric Quality Measures Program (Sec. 1139A(b) of Title XI (42 USC 1301 et seq.) began in January 2011 (PQMP).
    - Improved core measures are to be published annually beginning January 1, 2013.

[www.ahrq.gov/CHIPRA](http://www.ahrq.gov/CHIPRA)

# Health Insurance for Children, 2009



# PQMP Goals

CHIPRA Title IV Sec. 401 which amended Title XI (42 USC 1301 et seq.) by adding the following new section: Sec. 1139A (b).

- The Secretary shall establish a pediatric quality measures program to:
  - **Improve and strengthen** ...children's health care quality measures;
  - **Expand on existing pediatric quality measures** .. and advance [their] development; and
  - **Increase the portfolio** of evidence-based, consensus pediatric quality measures available to public and private purchasers of children's health care services, providers, and consumers.

# Definitions of Quality

- IOM – The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
- Doing the right thing, well, for the right person, at the right time



# The Constituents of Quality

- Donabedian
  - Structure / System
  - Process
  - Outcomes
- Coordination of care
- Patient experience of care

# Attributes of Quality (IOM)

Health care should be:

- Safe
- Effective
- Patient-centered
- Timely
- Efficient
- Equitable

# Desirable Attributes of Quality Measures

- Individual Measures
  - Reliable
  - Valid
  - Well-specified
  - Usable/feasible
  - Useful/actionable
- Portfolio of Measures
  - enhance innovation
  - expose new clinical areas to measurement
  - Improve health and health care

# Purposes of Quality Measurement

- Accountability
- Quality Improvement
- Monitoring
- Learning

# Simple Model

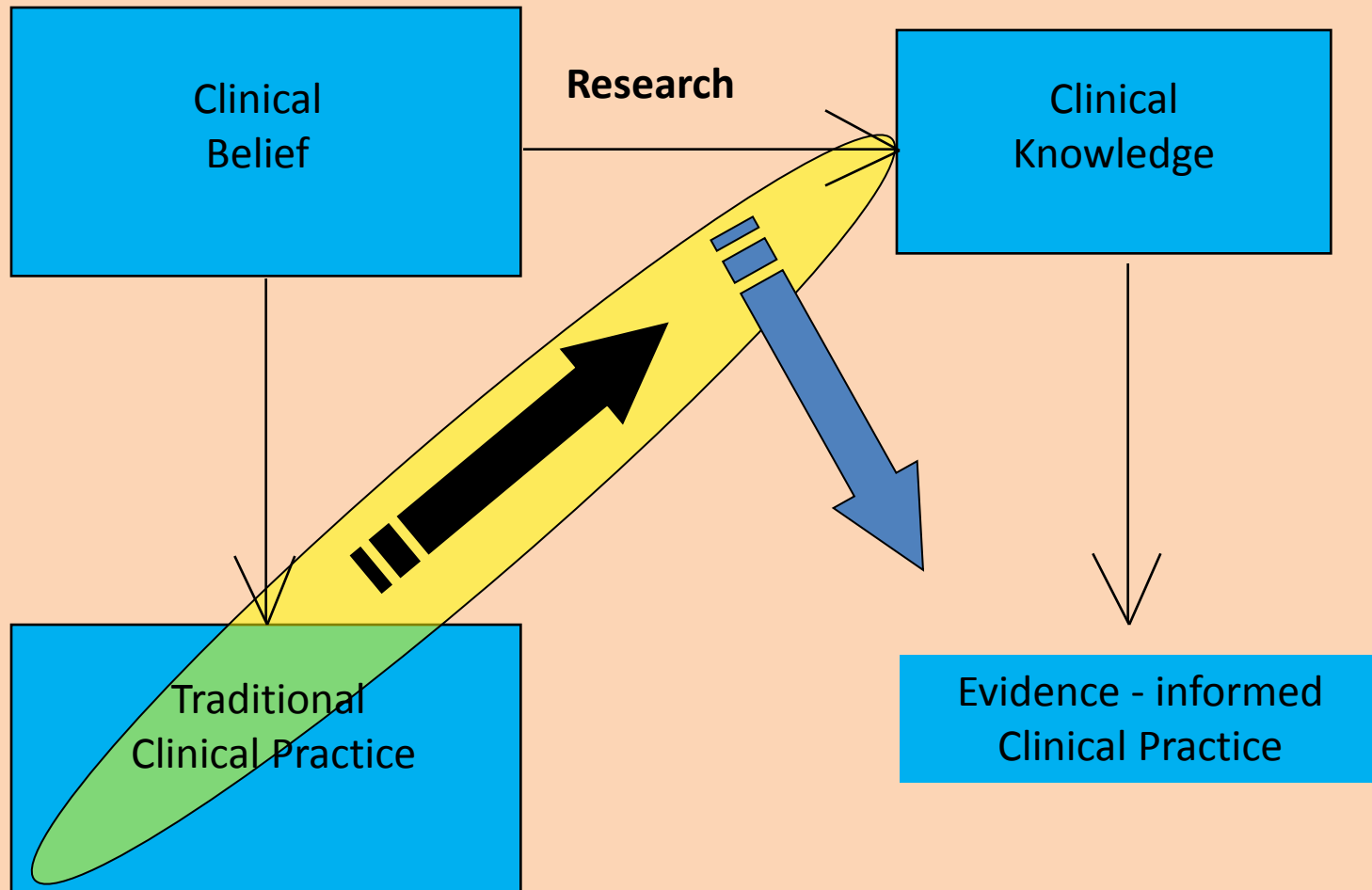


		Believed useful ?	
		Yes	No
Research Corroborated ?	Yes	a	b
	No	c	d

Evidenced based = a + b  
Traditional practice = a + c

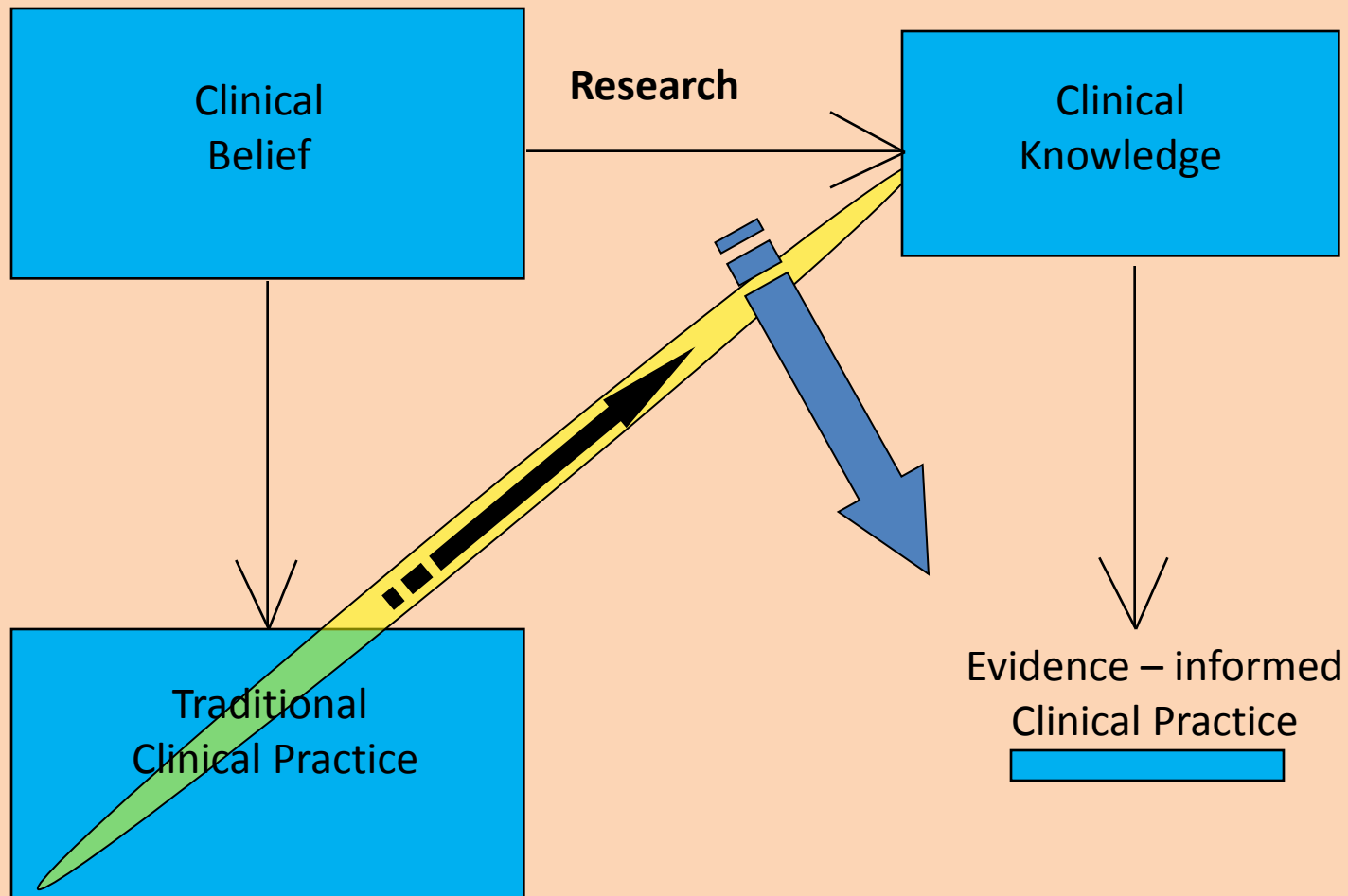
Popper: Confirming evidence should not count *except when it is the result of a genuine test of the theory*; [by] a serious but unsuccessful attempt to falsify the theory. (“I now speak in such cases of ‘corroborating evidence.’”)

# Adult Medicine

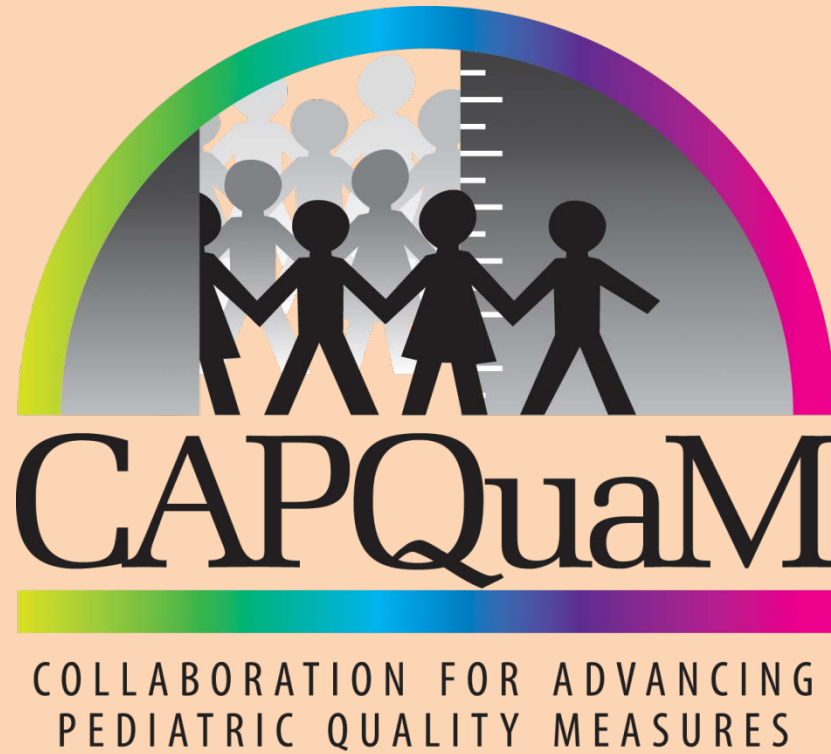


Kleinman LC, Am J Prev Med, 1998

# Evidence is particularly limited when it comes to pediatric care



# The Mount Sinai Collaboration for Advancing Pediatric Quality Measures (CAPQuaM)





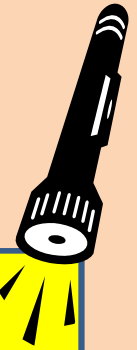
# CAPQuaM Principles

- It is possible to develop excellent quality measures even when there is meaningful uncertainty about clinical practice
- Medicine is a clinical practice for which the evidence is rarely dispositive for a specific patient
- There exist overuse, underuse, and misuse and all should be open to measurement

# Better Quality Measures are one of the keys to better health and health care



# Spectrum of Clinical Practice

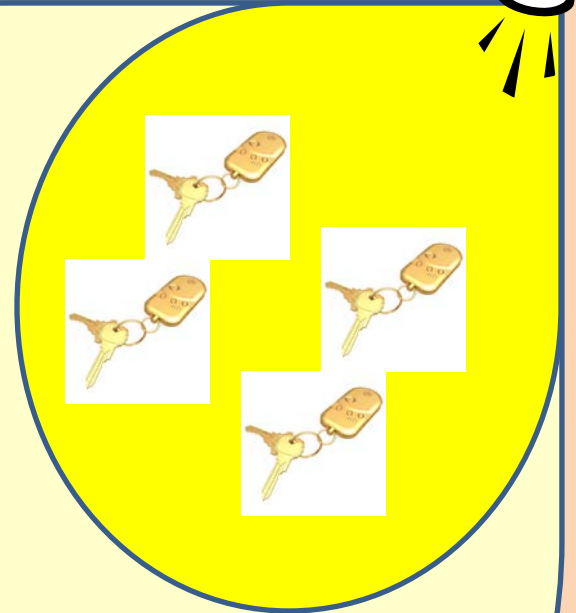
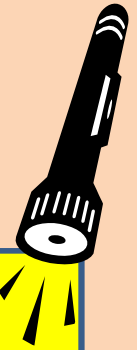


Very Limited or  
No Evidence

Some evidence

Strong  
Evidence

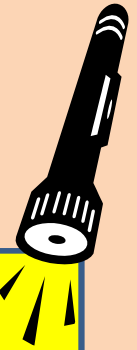
# Current State of QM



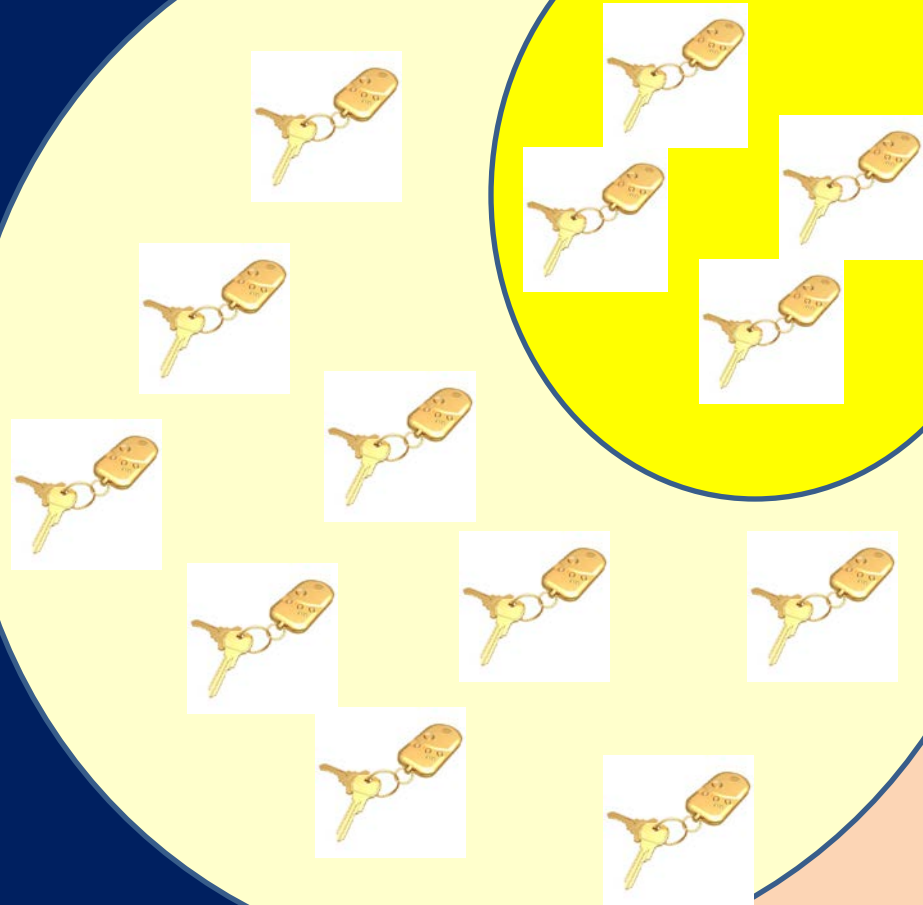
Very Limited or  
No Evidence

Some evidence

# CAPQuaM Vision



Very Limited or  
No Evidence



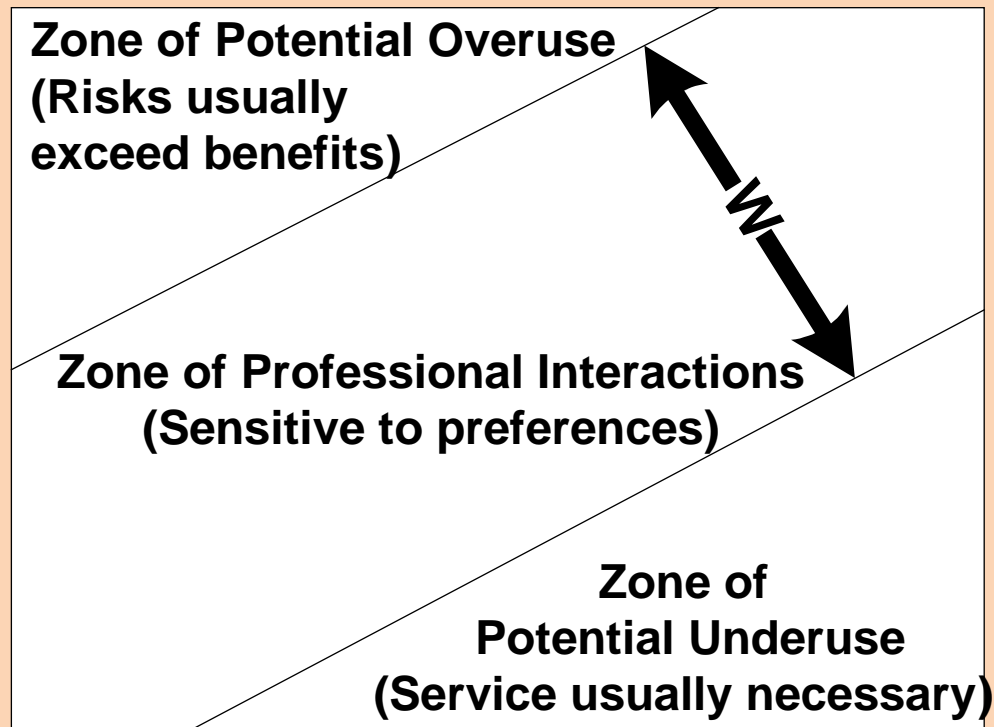
# Our Approach

- Build Coalition of Strong Institutional Partners
  - Accreditors (TJC, NCQA)
  - Clinicians (AAP, AAFP, ACOG)
  - Consumers (Consumer Reports, IPFCC, NAMI)
  - Insurers
- Offered things of opposing value(s)
  - Overuse on the one hand
  - Validation of clinical process on the other

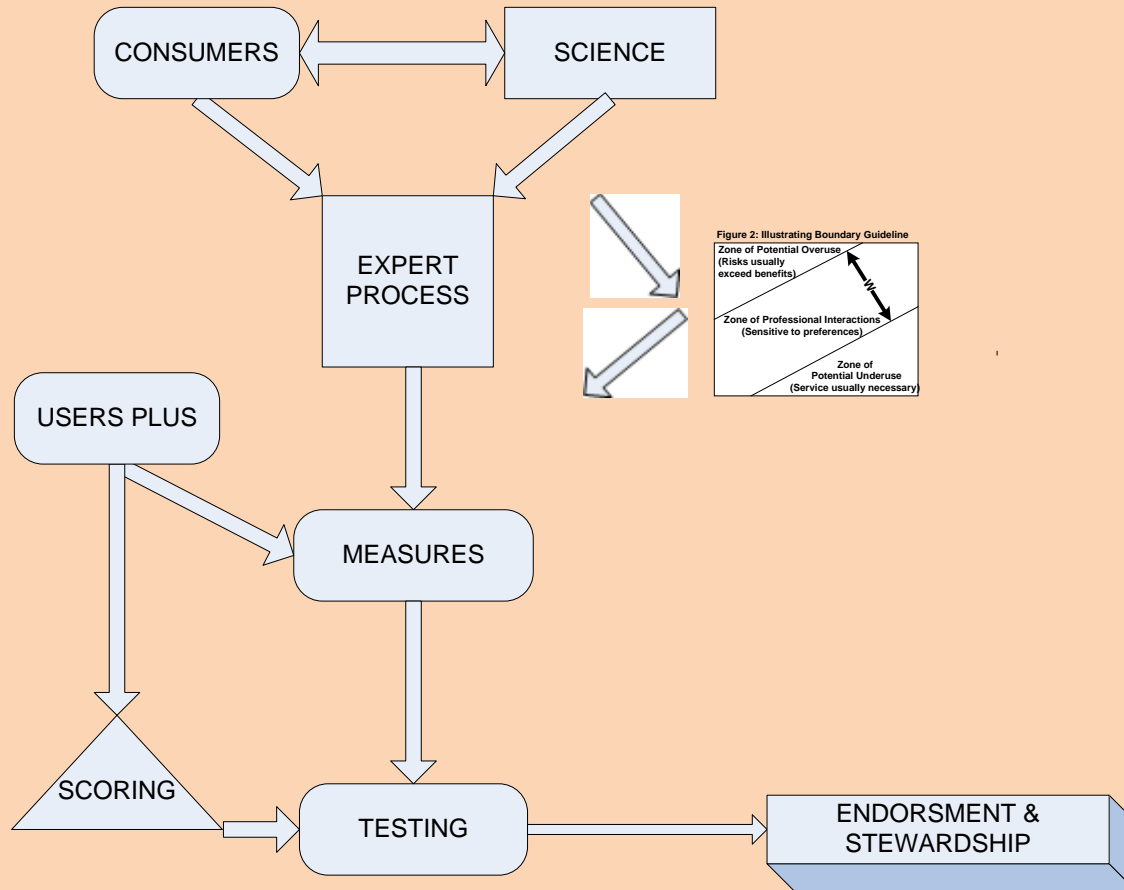
# Explicitly incorporate uncertainty

- Boundary Guideline
  - Incorporates evidence and uncertainty

Figure 2: Illustrating Boundary Guideline



# Develop Consensus around the Process, not the Measure





# Mount Sinai Collaboration for Advancing Pediatric Quality Measures (CAPQuaM)

Program & Methods Leadership

Principal Investigator  
Dr. Kleinman

Steering Committee: Site and Project PI's

Consortium

MSSM

Joint Commission

NCQA

AAP

AAFP

NICHQ

CAHMI

NU

NYS DOH

IPFCC  
ACOG

Stakeholders / Senior Advisory Board

Thought Leadership

Group Practices

Pediatricians

Family Physicians

Other Clinicians

Medicaid

Policy Makers

CHIP

Health Plans

Hospitals

Public Health

Advocates

Consumers

Health IT

Patients

Purchasers

Accrediting Orgs.

Other Stakeholders

<b>Table 2. MSSM CAPQuaM Steering Committee and Senior Advisors</b>			
<b>Steering Committee</b>	<b>Organization</b>	<b>Senior Advisors</b>	<b>Organization</b>
Christina Bethell, PhD, MBA, MPH	CAHMI, OHSU	Mark Chassin, MD, MPH, MPP	TJC
Marla Clayman, PhD	Northwestern	John Clarke, MD	ECRI, PA Patient Safety Authority
Foster C. Gesten, MD	OHIP, NYS DOH	Martin Hatlie, JD	Partnership 4 Pt. Safety, Consumers Advancing Pt Safety
Charles J. Homer, MD, MPH	NICHQ	Tony Hope, BM BCh, PhD	Oxford U.
Jerod M. Loeb, PhD	TJC	Beverly K. Johnson	Institute for Family Centered Care
Lynn Olson, PhD	AAP	Marilyn Kacica, MD	NYS DOH DFH
Wilson Pace, MD	AAFP	Steve Kairys, MD	AAP/QuIN
Mary Barton, MD	NCQA	Barbara Kupferman	UHC/Americhoice
Elizabeth Howell, MD	MSSM	Marc Lashley, MD,	Allied Pediatrics
Harold Kaplan, MD	MSSM	Gregory Pawlson, MD	BC/BS Association
Lawrence Kleinman, MD, MPH	MSSM	Laurel Pickering	Northeast BGH
Ira Nash, MD	MSSM	Harold Pincus, MD	Columbia U, NYPI
Eyal Shemesh, MD	MSSM	Eric A. Rose, MD	MSSM
<b>Senior Advisors</b>	<b>Organization</b>	Robert St. Peter, MD, MPH	Kansas Health Institute
Arthur Aufses, MD	MSSM	John Santa, MD	Consumers Union
Anne C. Beal, MD, MPH	Aetna Foundation	Shoshanna Sofaer, Dr PH	CUNY Baruch
David Baker, MD, MPH	Northwestern	Ruth Stein, MD	CH @ Montefiore
Scott Breidbart, MD	Empire BCBS	Jeff Terry	GE Healthcare
Wendy Brennan, MS	NAMI- NYC Metro	Paul Wise, MD	Stanford University

# Assigned Measures, Phase 1

- Availability of High Risk Ob Care
- Inpatient Perinatal
  - Temperature on admission to NICU
- ER Visits for Asthma
  - As an indicator of chronic asthma care
  - As an indicator of adequacy of primary care

# Stakeholder Engagement

- Consumer Stakeholders
  - Share their beliefs, priorities, values based upon relevant experiences (CFLR is novel)
- Clinician Stakeholders
  - Share their beliefs priorities, values and relevant experiences
  - Staff expert panels to develop criteria to support boundary guideline
- Organizational Stakeholders
  - Assist with specification of measures
  - Plan for interpretation of measures

# Institutional Stakeholder Contributions

- Advise & engage
- Assist with translating boundary guideline to measure specifications
- Inform the scoring process
- Prioritize data elements for collection and feasibility

# Expert Panel (EP) Contribution

- Integrates the input from the literature and stakeholders with their own expertise to
  - Define clinical standards / criteria
  - Assess the validity / importance of specific constructs within the clinical framework
  - Assess the value of specific items, measures, specifications, etc as appropriate
- The final arbiter on clinical decisions

# EP Composition

- Multidisciplinary
- Academic and Community Settings
- Geographically Diverse

# EP Method

- Adopted from the RAND UCLA Appropriateness Method (RUAM)
- RAND 2-round Modified Delphi Process
  - Round 1 Telephone
  - Round 2 Face-to-face
- CAPQuaM adds:
  - Input from clinician and consumer stakeholders
  - Post processing and potential third round (only if needed)



# EP Process

- Scientific Team organizes questions for discussion in the form of “scenarios”
- Scenarios may be true clinical circumstances, constructs or survey questions for rating importance, or other formulations that allow panel to assess validity, importance, or clinical judgment
- Scenarios may be organized into “chapters” and “verse” to help to promote efficient rating process

# EP Role in 360° Method

- EP owns the clinical importance of specific constructs
  - Provides expert judgment as a path to validity
  - Advise regarding editing/revising scenarios
  - May advise regarding specifications
- Stakeholders (Senior Advisors) own the final specifications and scoring strategies
- Scientific Team frames, interprets, organizes, provides feedback and organizes testing

# EP Member Role in the Process

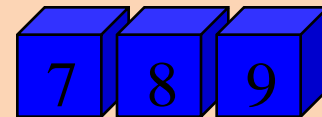
- Examine Literature Review
- Review Summary of Stakeholder Input
- Work with team to revise scenarios
- Incorporate your judgment
  - 2 stage rating: Telephone & In-Person
- Scenarios rated on 9 point scale



Low Rating



EQUIVOCAL



High Rating

# EP Voting Method

	C	D	E	J	K	L	M	M	U
1	CHAPTER TITLE	Heading 1	Heading 2						
2									0
3	First example indicator.	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	( 1 - 2 )					2
4									2
5	Second example indicator.	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	( 3 - 4 )					4
6									4
7	Third example indicator.	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	( 5 - 6 )					6
8									6
	Fourth example indicator. This one will be longer so we can see an example of								8

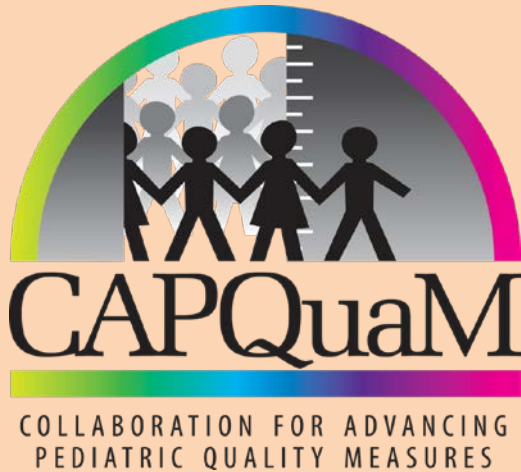
Indication xxxxxxxx	8	3	2	1	1				
	①	2	3	4	5	6	7	8	9

Ratings 1-9

Panelist vote is circled

Summary of votes:

- Eight votes for 1
- Three votes for 2
- Two votes for 3
- One vote for 5
- One vote for 6



Thank you for participating  
with the CAPQuaM on this  
important project

We will be in touch soon about the next call and  
in-person meeting details.

**Any questions?**

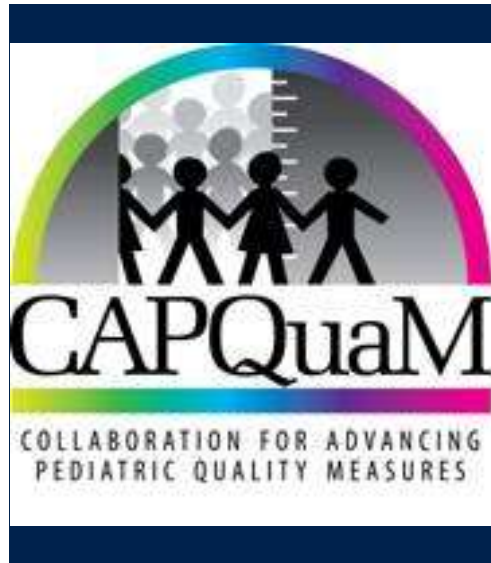
Please contact: [capquam@mountsinai.org](mailto:capquam@mountsinai.org)

Barbara Rabin 212-659-8396

Larry Kleinman [Lawrence.Kleinman@mssm.edu](mailto:Lawrence.Kleinman@mssm.edu)

## *Appendix D*

### *2<sup>nd</sup> Round EP Ratings Summary*



## High Risk Obstetric Services

Dr. Carter  
Dr. Caughey  
Dr. Dildy  
Dr. Dolan  
Dr. Gregory  
Dr. Grobman  
Dr. Mhyre  
Dr. Nielsen  
Dr. Troxler

## Chapter 1

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
1.00.01	MFM care is an essential component of high risk obstetrical services.	0	0	0	0	0	0	0	0	9	9	0.0
1.00.02	Cardiologists are an essential component of high risk obstetrical services for at least some women with heart disease.	0	0	0	0	0	0	1	0	8	9	0.2
1.00.03	Pulmonologists are an essential component of high risk obstetrical services for at least some women with asthma/pulmonary disease.	0	0	0	0	0	2	2	3	2	8	0.9
1.00.04	Endocrinologists/diabetologists are an essential component of high risk obstetrical services for some pregnant women.	0	0	0	0	0	1	0	4	4	8	0.7
1.00.05	Rheumatologists are an essential component of high risk obstetrical services for some pregnant women.	0	0	0	0	0	3	4	1	1	7	0.7
1.00.06	Infectious disease specialists are an essential component of high risk obstetrical services for women with HIV disease.	0	0	0	0	0	0	1	3	5	9	0.6
1.00.07	Neurologists are an essential component of high risk obstetrical services for at least some pregnant women.	0	0	0	0	1	1	3	2	2	7	1.0
1.00.08	Gastroenterologists are an essential component of high risk obstetrical services for some pregnant women.	0	0	0	0	1	1	4	2	1	7	0.8
1.00.09	Surgical consults are an essential component of high risk obstetrical services for some pregnant women.	0	0	0	0	0	3	1	1	4	8	1.2



		1	2	3	4	5	6	7	8	9		
1.00.10	Reproductive genetic services are an essential component of high risk obstetrical services in the community.	0	0	0	0	0	0	1	1	7	9	0.3
1.00.11	Advanced ultrasound services are an essential component of high risk obstetrical services.	0	0	0	0	0	0	0	0	9	9	0.0
1.00.12	Chorionic Villus sampling is an essential component of high risk obstetrical services.	0	0	0	0	0	0	5	3	1	7	0.6
1.00.13	Psychiatrists are an essential component of high risk obstetrical services.	0	0	0	0	0	0	1	2	6	9	0.4
1.00.14	Allied mental health professionals are an essential component of high risk obstetrical services.	0	0	0	0	0	0	3	3	3	8	0.7
1.00.15	Social work services are an essential component of high risk obstetrical services.	0	0	0	0	0	0	0	2	7	9	0.2
1.00.16	Multidisciplinary care is an essential component of high risk obstetrical care.	0	0	0	0	0	0	0	1	8	9	0.1
1.00.17	An anesthesiologist available for pre-labor consultation is an essential component of high risk obstetrical care.	0	0	0	0	1	0	2	3	3	8	0.9
1.00.18	Round the clock (24 hour) in-house availability of anesthesia at the delivery hospital is an essential component of high risk obstetrical care.	0	0	0	0	1	0	0	0	8	9	0.4
1.00.19	Having a neonatologist available for pre-delivery consultation is an essential component of high risk obstetrical care.	0	0	0	0	1	0	1	4	3	8	0.8

		1	2	3	4	5	6	7	8	9		
1.00.20	Round the clock (24 hour) in-house availability of neonatologists to attend the delivery is an essential component of high risk obstetrical care.	0	0	0	0	1	0	0	1	7	9	0.6
		1	2	3	4	5	6	7	8	9		
1.00.21	Round the clock (24 hour) in-house availability of a pediatrician to attend the delivery is an essential component of high risk obstetrical care.	0	0	1	0	2	0	0	4	2	8	1.4
		1	2	3	4	5	6	7	8	9		
1.00.22	Round the clock (24 hour) in-house availability of an obstetrician at the delivery hospital is an essential component of high risk obstetrical care.	0	0	0	0	1	0	0	1	7	9	0.6
		1	2	3	4	5	6	7	8	9		
1.00.23	Blood Bank/transfusion services are an essential component of high risk obstetrical services.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
1.00.24	Round the clock (24 hour) availability of urgent blood banking services is an essential component of high risk obstetrical care.	0	0	0	0	0	0	0	1	8	9	0.1
		1	2	3	4	5	6	7	8	9		
1.01.01	Women with preexisting hypertension require high risk obstetrical services.	0	0	0	0	0	0	2	3	4	8	0.7
		1	2	3	4	5	6	7	8	9		
1.01.02	Women with pregnancy-induced hypertension require high risk obstetrical services.	0	0	0	0	0	0	4	3	2	8	0.7
		1	2	3	4	5	6	7	8	9		
1.01.03	Women with preeclampsia require high risk obstetrical services.	0	0	0	0	0	0	2	4	3	8	0.6
		1	2	3	4	5	6	7	8	9		
1.01.04	Women with eclampsia require high risk obstetrical services.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
1.01.05	Women with preexisting cardiac disease require high risk obstetrical services.	0	0	0	0	0	0	0	3	6	9	0.3

		1	2	3	4	5	6	7	8	9		
1.01.06	Women with cardiomyopathy of pregnancy require high risk obstetrical services.	0	0	0	0	0	0	0	0	9	9	0.0
1.01.07	Women with HIV disease require high risk obstetrical services.	0	0	0	0	0	0	0	0	9	9	0.0
1.01.08	Women with non HIV chronic infections (e.g. TB and Hepatitis) require high risk obstetrical services.	0	0	0	0	0	1	0	1	7	9	0.4
1.01.09	Women with serious acute infection require high risk obstetrical services.	0	0	0	0	0	0	0	2	7	9	0.2
1.01.10	Women with depressive disorders require high risk obstetrical services.	0	0	1	0	1	2	2	1	2	7	1.4
1.01.11	Women with bipolar or psychotic disorders require high risk obstetrical services.	0	0	0	0	0	0	1	0	8	9	0.2
1.01.12	Women with bipolar prescription drug abuse require high risk obstetrical services.	0	0	0	0	0	1	1	2	5	9	0.8
1.01.13	Women with other substance abuse high risk obstetrical services.	0	0	0	0	0	0	4	0	5	9	0.9
1.01.14	Women with other psychiatric/behavioral health diagnoses require high risk obstetrical services.	1	0	0	1	0	2	3	0	2	7	1.7
1.01.15	Women with asthma/pulmonary disease require high risk obstetrical services.	0	0	0	0	1	0	5	1	2	7	0.8
1.01.16	Women with preexisting diabetes require high risk obstetrical services.	0	0	0	0	0	0	1	2	6	9	0.4
1.01.17	Women who are 40 - 50% BMI obese require high risk obstetrical services.	0	0	0	0	0	1	4	3	1	7	0.7

		1	2	3	4	5	6	7	8	9		
1.01.18	Women with gestational diabetes require high risk obstetrical services.	0	0	0	2	0	2	2	0	3	7	1.6
1.01.19	Women with a history of previous preterm delivery require high risk obstetrical services.	0	0	0	0	2	0	0	2	5	9	1.1
1.01.20	Women with a history of previous first trimester miscarriage require high risk obstetrical services.	1	0	3	3	1	1	0	0	0	4	1.0
1.01.21	Women with a history of previous second trimester miscarriage require high risk obstetrical services.	0	0	0	0	1	3	1	1	3	7	1.3
1.01.22	Women with a history of previous third trimester miscarriage or stillbirth require high risk obstetrical services.	0	0	0	0	0	2	3	2	2	7	0.9
1.01.23	Women with a previous c-section require high risk obstetrical services.	1	1	2	2	1	0	2	0	0	4	1.6
1.01.24	Women with a current abnormal placentation in this pregnancy require high risk obstetrical services.	0	0	0	0	0	2	0	4	3	8	0.8
1.01.25	Pregnant women with one chronic comorbidity require high risk obstetrical services.	1	0	0	1	1	2	1	1	2	6	1.9
1.01.26	Pregnant women with two chronic comorbidities require high risk obstetrical services.	1	0	0	0	1	1	2	1	3	7	1.8
1.01.27	Women with three or more chronic comorbidity require high risk obstetrical services.	1	0	0	0	0	0	1	2	5	9	1.3
1.01.28	Women with one acute illness requiring treatment require high risk obstetrical services.	1	0	1	1	2	2	1	0	1	5	1.7

		1	2	3	4	5	6	7	8	9		
1.01.29	Women with two or more acute illnesses requiring treatment require high risk obstetrical services.	1	0	0	0	2	1	4	0	1	7	1.4
1.01.30	Women who are on a teratogenic medicine at the time that they become pregnant require high risk obstetrical services.	0	0	0	0	1	0	2	1	5	9	1.0
1.01.31	Women who are on psychotropic drugs at the time that they become pregnant require high risk obstetrical services.	0	0	1	0	0	0	3	4	1	8	1.0
1.01.32	Women who are on MAO inhibitors at the time that they become pregnant require high risk obstetrical services.	0	0	1	0	0	0	5	2	1	7	0.9
1.01.33	Women who are on SSRI's at the time that they become pregnant require high risk obstetrical services.	0	0	1	0	1	2	4	0	1	7	1.1
1.01.34	Women who are on oral steroid medications at the time that they become pregnant require high risk obstetrical services.	0	0	1	0	1	1	3	1	2	7	1.3
1.01.35	Women who are on chronic NSAIDs at the time that they become pregnant require high risk obstetrical services.	0	0	1	0	3	2	2	0	1	6	1.2
1.01.36	Women who are on chronic opioid medications at the time that they become pregnant require high risk obstetrical services.	0	0	0	0	1	0	3	3	2	8	0.9
1.02.01	Amniocentesis is an essential component of high risk obstetrical services.	0	0	0	0	0	0	1	3	5	9	0.6
1.02.02	Invasive prenatal diagnosis is an essential component of high risk obstetrical services.	0	0	0	0	0	0	0	2	7	9	0.2

		1	2	3	4	5	6	7	8	9		
1.02.03	Access to first trimester screening is an essential component of high risk obstetrical services.	0	0	0	0	0	0	4	2	3	8	0.8
1.02.04	Access to second trimester serum screening is an essential component of high risk obstetrical services.	0	0	0	0	0	0	3	2	4	8	0.8
1.02.05	Access to an integrated screen is an essential component of high risk obstetrical services.	0	0	0	0	0	2	4	3	0	7	0.6
1.02.06	Documentation that screening/diagnostics was offered indicates fulfillment of the criteria.	0	0	0	0	0	0	0	2	7	9	0.2
1.02.07	For the purpose of this measure, it is meaningful to describe whether an appropriate OB clinician is available for emergency care in house.	0	0	0	0	2	0	0	1	6	9	1.0
1.02.08	For the purpose of this measure, it is meaningful to describe whether an appropriate OB clinician is available for emergency care within 0-15 minutes.	0	0	0	0	1	0	0	1	7	9	0.6
1.02.09	For the purpose of this measure, it is meaningful to describe whether an appropriate OB clinician is available for emergency care within 16-30 minutes.	2	0	0	0	0	0	3	0	4	7	2.2
1.02.10	For the purpose of this measure, it is meaningful to describe whether an appropriate OB clinician is available for emergency care within >30 minutes	2	1	1	0	1	0	1	0	3	5	3.0
1.02.11	For the purposes of this measure, it is meaningful to describe whether an emergency anesthesia clinical is available in house.	0	0	0	0	2	0	0	1	6	9	1.0

		1	2	3	4	5	6	7	8	9		
1.02.12	For the purposes of this measure, it is meaningful to describe whether an emergency anesthesia clinical is available within 0-15 minutes.	0	0	0	0	1	0	0	1	7	9	0.6
		1	2	3	4	5	6	7	8	9		
1.02.13	For the purposes of this measure, it is meaningful to describe whether an emergency anesthesia clinical is available within 16-30 minutes.	2	0	0	0	0	0	3	0	4	7	2.2
		1	2	3	4	5	6	7	8	9		
1.02.14	For the purposes of this measure, it is meaningful to describe whether an emergency anesthesia clinical is available within >30 minutes	2	1	1	0	1	0	1	0	3	5	3.0
		1	2	3	4	5	6	7	8	9		
1.02.15	For the purposes of this measure, it is meaningful to describe whether an emergency pediatric/neonatal clinician is available in house.	0	0	0	0	1	0	1	2	5	9	0.9
		1	2	3	4	5	6	7	8	9		
1.02.16	For the purposes of this measure, it is meaningful to describe whether an emergency pediatric/neonatal clinician is available within 0 - 15 minutes.	0	0	0	0	1	0	1	1	6	9	0.8
		1	2	3	4	5	6	7	8	9		
1.02.17	For the purposes of this measure, it is meaningful to describe whether an emergency pediatric/neonatal clinician is available within 16-30 minutes.	2	0	0	0	0	1	1	1	4	8	2.3
		1	2	3	4	5	6	7	8	9		
1.02.18	For the purposes of this measure, it is meaningful to describe whether an emergency pediatric/neonatal clinician is available within >30 minutes.	2	1	1	0	0	0	1	0	4	7	3.2
		1	2	3	4	5	6	7	8	9		
1.02.19	High risk obstetrical patients should be delivered within an organized system of regional care, including triage & transportation to an appropriate level of hospital.	0	0	0	0	0	0	2	1	6	9	0.6

		1	2	3	4	5	6	7	8	9		
1.02.20	High risk obstetrical patients should be delivered within an organized system of regional care, including triage & transportation to and from an appropriate level of hospital.	0	0	1	1	1	0	2	2	2	7	1.7
		1	2	3	4	5	6	7	8	9		
1.02.21	High risk obstetrical patients should be delivered at a hospital with the capacity to provide an emergency cesarean section within 0 - 15 minutes.	0	0	0	0	0	0	0	1	8	9	0.1
		1	2	3	4	5	6	7	8	9		
1.02.22	High risk obstetrical patients should be delivered at a hospital with the capacity to provide an emergency cesarean section within 16-30 minutes.	0	0	1	0	1	0	0	3	4	8	1.3
		1	2	3	4	5	6	7	8	9		
1.02.23	High risk obstetrical patients should be delivered at a hospital with the capacity to provide an emergency cesarean section within >30 minutes.	3	0	0	1	2	0	0	1	2	5	2.7
		1	2	3	4	5	6	7	8	9		
1.02.24	Women with a BMI <50% require high risk obstetrical services.	0	0	0	0	0	0	1	2	6	9	0.4
		1	2	3	4	5	6	7	8	9		
1.02.25	MFM care is an essential component of high risk obstetrical services for women with maternal complications	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
1.02.26	MFM care is an essential component of HROB services for women with fetal complications	0	0	0	0	0	0	0	1	8	9	0.1



## Chapter 2

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
2.00.01	Primary obstetrical provider is able to report accurately the availability of MFM care in his/her community.	0	0	0	0	0	0	0	0	9	9	0.0
2.00.02	Primary obstetrical provider is able to report accurately the availability of cardiologists capable of caring for high risk pregnant women in their community.	0	0	0	0	0	0	1	2	6	9	0.4
2.00.03	Primary obstetrical provider is able to report accurately the availability of pulmonologists capable of caring for high risk pregnant women in their community.	0	0	0	0	0	0	6	1	2	7	0.6
2.00.04	Primary obstetrical provider is able to report accurately the availability of endocrinologists/diabetologists capable of caring for high risk pregnant women in their community.	0	0	0	0	0	1	0	4	4	8	0.7
2.00.05	Primary obstetrical provider is able to report accurately the availability of rheumatologists capable of caring for high risk pregnant women in their community.	0	0	0	0	1	1	4	1	2	7	0.9
2.00.06	Primary obstetrical provider is able to report accurately the availability of infectious disease specialists capable of caring for HIV+ pregnant women in their community.	0	0	0	0	0	0	1	3	5	9	0.6
2.00.07	Primary obstetrical provider is able to report accurately the availability of neurologists capable of caring for high risk pregnant women in their community.	0	0	0	0	0	1	2	3	3	8	0.8

		1	2	3	4	5	6	7	8	9		
2.00.08	Primary obstetrical provider is able to report accurately the availability of gastroenterologists capable of caring for high risk pregnant women in their community.	0	0	0	0	0	1	4	2	2	7	0.8
		1	2	3	4	5	6	7	8	9		
2.00.09	Primary obstetrical provider is able to report accurately the availability of an appropriate surgical consult capable of caring for high risk pregnant women in their community.	0	0	0	0	0	0	1	1	7	9	0.3
		1	2	3	4	5	6	7	8	9		
2.00.10	Primary obstetrical provider is able to report accurately the availability of reproductive genetic services for high risk pregnant women in their community.	0	0	0	0	0	0	2	1	6	9	0.6
		1	2	3	4	5	6	7	8	9		
2.00.11	Primary obstetrical provider is able to report accurately the availability of advanced ultrasound services for high risk pregnant women in their community.	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
2.00.12	Primary OB clinicians who are caring for the subpopulation are able to report on the availability of care for the conditions indicated above, specifically for private insurance patients	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
2.00.13	Primary OB clinicians who are caring for the subpopulation are able to report on the availability of care for the conditions indicated above, specifically for medicaid patients	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
2.00.14	Primary OB clinicians who are caring for the subpopulation are able to report on the availability of care for the conditions indicated above, specifically for uninsured patients	0	0	0	0	0	1	0	1	7	9	0.4
		1	2	3	4	5	6	7	8	9		

		1	2	3	4	5	6	7	8	9		
2.00.15	Primary OB clinicians who are caring for the subpopulation are able to report on the availability of care for the conditions indicated above, specifically for managed care patients	0	0	0	0	1	0	0	1	7	9	0.6

		1	2	3	4	5	6	7	8	9		
2.00.16	Primary OB clinicians who are caring for the subpopulation are able to report on the availability of care for the conditions indicated above, specifically for undocumented patients	0	0	0	0	1	0	0	1	7	9	0.6

### Chapter 3

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
3.00.01	MFMs (MFMs) are capable of reporting accurately the capacity of their own practices to meet the needs of women needing high risk obstetrical care.	0	0	0	0	0	0	0	1	8	9	0.1
3.00.02	MFMs are capable of reporting accurately the availability of MFM care in their community.	0	0	0	0	0	0	0	1	8	9	0.1
3.00.03	MFMs are capable of reporting accurately the availability of MFM care in their community for subpopulations of women, such as those on Medicaid or the uninsured.	0	0	0	0	0	0	0	2	7	9	0.2
3.01.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with pre-existing hypertension.	0	0	0	0	0	0	0	0	9	9	0.0
3.01.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for pre-existing hypertension.	0	0	0	0	0	0	0	0	9	9	0.0
3.01.03	MFMs are capable of reporting accurately the availability of MFM care for pre-existing hypertension in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0
3.02.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with pregnancy induced hypertension.	0	0	0	0	0	0	0	0	9	9	0.0

		1	2	3	4	5	6	7	8	9		
3.02.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for pregnancy induced hypertension.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.02.03	MFMs are capable of reporting accurately the availability of MFM care for pregnancy induced hypertension in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.03.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with preeclampsia.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.03.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for preeclampsia.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.03.03	MFMs are capable of reporting accurately the availability of MFM care for preeclampsia in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.04.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with eclampsia	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.04.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for eclampsia.	0	0	0	0	0	0	0	0	9	9	0.0

		1	2	3	4	5	6	7	8	9		
3.04.03	MFMs are capable of reporting accurately the availability of MFM care for eclampsia in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.05.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with preexisting cardiac disease.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.05.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for preexisting cardiac disease.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.05.03	MFMs are capable of reporting accurately the availability of MFM care for preexisting cardiac disease in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	8	9	0.0
		1	2	3	4	5	6	7	8	9		
3.06.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with cardiomyopathy.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.06.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for cardiomyopathy.	0	0	0	0	0	0	0	0	9	9	0.0
		1	2	3	4	5	6	7	8	9		
3.06.03	MFMs are capable of reporting accurately the availability of MFM care for cardiomyopathy in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0

		1	2	3	4	5	6	7	8	9		
3.07.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with HIV.	0	0	0	0	0	0	0	0	9	9	0.0
3.07.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for HIV.	0	0	0	0	0	0	0	0	9	9	0.0
3.07.03	MFMs are capable of reporting accurately the availability of MFM care for HIV in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0
3.08.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with other infectious diseases.	0	0	0	0	0	0	1	1	7	9	0.3
3.08.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for other infectious diseases.	0	0	0	0	0	0	0	1	8	9	0.1
3.08.03	MFMs are capable of reporting accurately the availability of MFM care for other infectious diseases in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	2	7	9	0.2
3.09.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with psychiatry/mental health illness.	0	0	0	0	0	0	2	2	5	9	0.7
3.09.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for psychiatry/mental health illness	0	0	0	0	1	0	1	2	5	9	0.9

		1	2	3	4	5	6	7	8	9		
3.09.03	MFMs are capable of reporting accurately the availability of MFM care for psychiatry/mental health illness in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	1	0	0	0	1	2	5	9	1.1
		1	2	3	4	5	6	7	8	9		
3.10.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with substance abuse.	0	0	0	0	0	0	1	4	4	8	0.6
		1	2	3	4	5	6	7	8	9		
3.10.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for substance abuse	0	0	0	0	0	0	1	4	4	8	0.6
		1	2	3	4	5	6	7	8	9		
3.10.03	MFMs are capable of reporting accurately the availability of MFM care for substance abuse in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	1	4	4	8	0.6
		1	2	3	4	5	6	7	8	9		
3.11.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with asthma/pulmonary disease.	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
3.11.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for asthma/pulmonary disease.	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
3.11.03	MFMs are capable of reporting accurately the availability of MFM care for asthma/pulmonary disease in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	1	0	8	9	0.2



		1	2	3	4	5	6	7	8	9		
3.12.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with preexisting diabetes.	0	0	0	0	0	0	0	0	9	9	0.0
3.12.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for preexisting diabetes.	0	0	0	0	0	0	0	0	9	9	0.0
3.12.03	MFMs are capable of reporting accurately the availability of MFM care for this preexisting diabetes in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0
3.13.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with gestational diabetes.	0	0	0	0	0	0	0	1	8	9	0.1
3.13.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for gestational diabetes.	0	0	0	0	0	0	0	1	8	9	0.1
3.13.03	MFMs are capable of reporting accurately the availability of MFM care for gestational diabetes in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	1	8	9	0.1
3.14.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of obese women.	0	0	0	0	1	0	1	1	6	9	0.8
3.14.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for obese women.	0	0	0	0	1	0	2	1	5	9	1.0

		1	2	3	4	5	6	7	8	9		
3.14.03	MFMs are capable of reporting accurately the availability of MFM care for obese women in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	1	0	1	1	6	9	0.8
		1	2	3	4	5	6	7	8	9		
3.15.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with previous preterm delivery.	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
3.15.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for this previous preterm delivery.	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
3.15.03	MFMs are capable of reporting accurately the availability of MFM care for previous preterm delivery in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
3.16.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with a history of a previous C Section.	0	0	0	0	0	0	1	0	8	9	0.2
		1	2	3	4	5	6	7	8	9		
3.16.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for women with a history of a previous C Section.	0	0	0	0	0	0	1	0	8	9	0.2

		1	2	3	4	5	6	7	8	9		
3.16.03	MFMs are capable of reporting accurately the availability of MFM care for women with a history of a previous C Section in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	1	0	8	9	0.2
3.17.01	MFMs are capable of reporting accurately the capacity of their own practices to meet the needs of women with a history of a Abnormal Placentation.	0	0	0	0	0	0	0	0	9	9	0.0
3.17.02	MFMs are capable of accurately reflecting the availability of MFM care in their community for women with a history of a Abnormal Placentation.	0	0	0	0	0	0	0	0	9	9	0.0
3.17.03	MFMs are capable of reporting accurately the availability of MFM care for women with a history of a Abnormal Placentation in their community, including for subpopulations of women, such as those on Medicaid, or who are uninsured.	0	0	0	0	0	0	0	0	9	9	0.0

## Chapter 4

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
4.00.01	When estimating the extent to which MFMs are available for an initial consultation, an optimal way to ask the primary obstetrical provider is as a yes/no response.	0	0	0	0	0	0	2	1	6	9	0.6
4.00.02	When estimating the extent to which MFMs are available for an initial consultation, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is available.	2	0	1	0	1	0	3	1	1	7	2.3
4.00.03	When estimating the extent to which MFMs are available for an initial consultation, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is NOT available.	2	0	2	0	0	0	2	2	1	7	2.7
4.00.04	When estimating the extent to which MFMs are available for follow up of an initial consultation, an optimal way to ask the primary obstetrical provider is as a yes/no response.	0	0	0	0	1	0	1	1	6	9	0.8
4.00.05	When estimating the extent to which MFMs are available for follow up of an initial consultation, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is available.	2	0	0	0	2	0	3	1	1	7	2.1

		1	2	3	4	5	6	7	8	9		
4.00.06	When estimating the extent to which MFMs are available for follow up of an initial consultation, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is NOT available.	2	0	1	0	1	0	2	2	1	7	2.4
4.00.07	When estimating the extent to which MFMs are available to participate in obstetrical co-management, an optimal way to ask the primary obstetrical provider is as a yes/no response.	0	0	0	0	0	0	1	1	7	9	0.3
4.00.08	When estimating the extent to which MFMs are available to participate in obstetrical co-management, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is available.	2	0	0	0	2	0	2	1	2	7	2.3
4.00.09	When estimating the extent to which MFMs are available to participate in obstetrical co-management, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is NOT available.	2	0	1	0	1	0	1	2	2	7	2.7
4.00.10	When estimating the extent to which MFMs are available to accept referrals to take over primary obstetrical management, an optimal way to ask the primary obstetrical provider is as a yes/no response.	0	0	0	0	0	0	1	2	6	9	0.4

		1	2	3	4	5	6	7	8	9		
4.00.11	When estimating the extent to which MFMs are available to accept referrals to take over primary obstetrical management, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is available.	2	0	0	0	2	0	2	1	2	7	2.3
4.00.12	When estimating the extent to which MFM are available to accept referrals to take over primary obstetrical management, an optimal way to ask the primary obstetrical provider is to ask them to estimate the percentage of patients for whom it is NOT available.	2	0	1	0	1	0	1	1	3	7	2.8
4.01.01	MFM is available for initial consultation for women with pre-existing hypertension.	0	0	0	0	0	0	2	3	4	8	0.7
4.01.01a	An initial consultation with an MFM is necessary for women with pre-existing hypertension.	0	0	1	0	1	1	2	2	2	7	1.4
4.01.02	MFM is available for follow-up of initial consultation for women with pre-existing hypertension.	0	0	0	0	0	2	5	0	2	7	0.7
4.01.03	MFM is available to participate in obstetrical co-management for women with pre-existing hypertension.	0	0	0	0	0	2	3	3	1	7	0.8
4.01.04	MFM is available to accept referral to take over primary obstetrical management for women with pre-existing hypertension.	0	1	0	1	1	1	2	2	1	7	1.7
4.01.05	Clinical Genetic Services are available during the first trimester for women with pre-existing hypertension.	1	1	5	0	1	0	0	1	0	3	1.1

	1	2	3	4	5	6	7	8	9		
4.01.05a Clinical Genetic Services are necessary during the first trimester for women with pre-existing hypertension	3	4	1	0	0	0	0	0	1	2	1.2
4.01.06 Clinical Genetic Services are available prior to conception for women with pre-existing hypertension.	1	2	4	0	1	0	0	0	1	3	1.3
4.02.01 MFM is available for initial consultation for women with pregnancy-induced hypertension.	0	0	0	1	1	3	1	1	2	6	1.3
4.02.02 MFM is available for follow-up of initial consultation for women with pregnancy-induced hypertension.	0	0	1	1	1	2	2	1	1	6	1.4
4.02.03 MFM is available to participate in obstetrical co-management for women with pregnancy-induced hypertension.	0	0	0	1	0	3	3	1	1	7	1.0
4.02.04 MFM is available to accept referral to take over primary obstetrical management for women with pregnancy-induced hypertension for women with pregnancy-induced hypertension.	0	0	1	1	2	2	1	0	2	6	1.6
4.02.05 Clinical Genetic Services are available during the first trimester for women with pregnancy-induced hypertension.	7	0	1	0	0	0	0	1	0	1	1.0
4.02.06 Clinical Genetic Services are available prior to conception for women with pregnancy-induced hypertension.	6	0	2	0	0	0	0	1	0	1	1.2
4.03.01 MFM is available for initial consultation for women with preeclampsia.	0	0	0	0	0	1	2	1	5	9	0.9

		1	2	3	4	5	6	7	8	9		
4.03.01a	An initial consultation with an MFM is necessary for women with preeclampsia	2	1	1	0	0	2	2	0	1	6	2.4
4.03.02	MFM is available for follow-up of initial consultation for women with preeclampsia.	0	0	0	1	1	1	3	1	2	7	1.2
4.03.03	MFM is available to participate in obstetrical co-management for women with preeclampsia.	0	0	0	1	0	0	5	0	3	7	1.0
4.03.04	MFM is available to accept referral to take over primary obstetrical management for women with preeclampsia.	0	0	0	1	1	1	2	2	2	7	1.3
4.03.05	Clinical Genetic Services are available during the first trimester for women with preeclampsia.	6	0	2	0	0	1	0	0	0	1	1.0
4.03.06	Clinical Genetic Services are available prior to conception for women with preeclampsia.	6	0	2	0	0	1	0	0	0	1	1.0
4.04.01	MFM is available for initial consultation for women with eclampsia.	0	0	0	0	1	0	2	1	5	9	1.0
4.04.01a	An initial consultation with an MFM is necessary for women with eclampsia.	0	1	1	0	2	1	1	2	1	6	1.9
4.04.02	MFM is available for follow-up of initial consultation for women with eclampsia.	0	0	0	0	1	0	3	0	5	9	1.1
4.04.02a	A follow-up visit with an MFM is necessary for women with eclampsia	0	2	1	1	1	0	2	0	2	5	2.3
4.04.03	MFM is available to participate in obstetrical co-management for women with eclampsia.	0	0	0	0	1	0	3	1	4	8	1.1



	1	2	3	4	5	6	7	8	9		
4.04.03a MFM participation in obstetrical co-management is necessary for women with eclampsia	2	0	1	0	1	2	0	1	2	6	2.4
4.04.04 MFM is available to accept referral to take over primary obstetrical management for women with eclampsia.	0	0	0	1	1	0	2	1	4	8	1.4
4.04.04a Availability of an MFM to accept referral to take over primary obstetrical management is necessary for women with eclampsia.	1	0	2	1	1	2	0	0	2	5	2.1
4.04.05 Clinical Genetic Services are available during the first trimester for women with eclampsia.	7	0	1	0	1	0	0	0	0	1	0.7
4.04.06 Clinical Genetic Services are available prior to conception for women with eclampsia.	7	0	1	0	1	0	0	0	0	1	0.7
4.05.01 MFM is available for initial consultation for women with preexisting cardiac disease.	0	0	0	0	0	0	0	1	8	9	0.1
4.05.01a An initial consultation with an MFM is necessary for women with preexisting cardiac disease.	0	0	0	0	0	1	0	0	8	9	0.3
4.05.02 MFM is available for follow-up of initial consultation for women with preexisting cardiac disease.	0	0	0	0	0	1	0	2	6	9	0.6
4.05.02a A follow-up visit with an MFM is necessary for women with preexisting cardiac disease.	0	0	0	0	1	1	2	2	3	8	1.1
4.05.03 MFM is available to participate in obstetrical co-management for women with preexisting cardiac disease.	0	0	0	0	0	1	0	1	7	9	0.4

	1	2	3	4	5	6	7	8	9		
4.05.03a MFM participation in obstetrical co-management is necessary for women with preexisting cardiac disease.	0	0	0	0	0	2	1	3	3	8	0.9
	1	2	3	4	5	6	7	8	9		
4.05.04 MFM is available to accept referral to take over primary obstetrical management for women with preexisting cardiac disease.	0	0	0	0	0	1	0	1	7	9	0.4
	1	2	3	4	5	6	7	8	9		
4.05.04a Availability of an MFM to accept referral to take over primary obstetrical management is necessary for women with preexisting cardiac disease.	0	0	0	0	0	2	2	2	3	8	1.0
	1	2	3	4	5	6	7	8	9		
4.05.05 Clinical Genetic Services are available during the first trimester for women with preexisting cardiac disease.	0	0	0	0	1	0	0	5	3	8	0.7
	1	2	3	4	5	6	7	8	9		
4.05.05a Clinical Genetic Services during the first trimester are necessary for women with preexisting cardiac disease.	0	0	1	0	0	2	0	4	2	8	1.2
	1	2	3	4	5	6	7	8	9		
4.05.06 Clinical Genetic Services are available prior to conception for women with preexisting cardiac disease.	0	0	0	0	3	1	0	3	2	8	1.4
	1	2	3	4	5	6	7	8	9		
4.05.06a Clinical Genetic Services prior to conception are necessary for women with preexisting cardiac disease.	0	0	1	0	1	2	0	2	3	8	1.7
	1	2	3	4	5	6	7	8	9		
4.06.01 MFM is available for initial consultation for women with cardiomyopathy.	0	0	0	0	0	0	0	0	9	9	0.0
	1	2	3	4	5	6	7	8	9		
4.06.01a An initial consultation with an MFM is necessary for women with cardiomyopathy.	0	0	0	0	0	1	0	0	8	9	0.3

4.06.02	MFM is available for follow-up of initial consultation for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	9	0.1
4.06.02a	A follow-up visit with an MFM is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	8	0.9
4.06.03	MFM is available to participate in obstetrical co-management for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	9	0.2
4.06.03a	MFM participation in obstetrical co-management is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	9	0.9
4.06.04	MFM is available to accept referral to take over primary obstetrical management for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	9	0.4
4.06.04a	Availability of MFM to accept referral to take over primary obstetrical management is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	8	0.9
4.06.05	Clinical Genetic Services are available during the first trimester for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	5	2.4
4.06.06	Clinical Genetic Services are available prior to conception for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	5	2.4
4.07.01	MFM is available for initial consultation for women with HIV.	1	2	3	4	5	6	7	8	9	9	0.4
4.07.01a	An initial consultation with an MFM is necessary for women with HIV.	1	2	3	4	5	6	7	8	9	9	1.2
4.07.02	MFM is available for follow-up of initial consultation for women with HIV.	1	2	3	4	5	6	7	8	9	9	0.8

4.07.02a	A follow-up visit with an MFM is necessary for women with HIV	1	2	3	4	5	6	7	8	9	9	1.6
4.07.03	MFM is available to participate in obstetrical co-management for women with HIV.	1	2	3	4	5	6	7	8	9	9	0.9
4.07.03a	MFM participation in obstetrical co-management is necessary for women with HIV.	1	2	3	4	5	6	7	8	9	8	1.7
4.07.04	MFM is available to accept referral to take over primary obstetrical management for women with HIV.	1	2	3	4	5	6	7	8	9	8	1.2
4.07.04a	Availability of MFM to accept referral to take over primary obstetrical management is necessary for women with HIV.	1	2	3	4	5	6	7	8	9	7	1.6
4.07.05	Clinical Genetic Services are available during the first trimester for women with HIV.	1	2	3	4	5	6	7	8	9	5	3.0
4.07.05a	Clinical Genetic Services during the first trimester are necessary for women with HIV.	1	2	3	4	5	6	7	8	9	5	3.0
4.07.06	Clinical Genetic Services are available prior to conception for women with HIV.	1	2	3	4	5	6	7	8	9	5	3.0
4.07.06a	Clinical Genetic Services prior to conception are necessary for women with HIV.	1	2	3	4	5	6	7	8	9	5	3.0
4.08.01	MFM is available for initial consultation for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	8	0.7
4.08.01a	An initial consultation with an MFM is necessary for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	7	0.9

		1	2	3	4	5	6	7	8	9		
4.08.02	MFM is available for follow-up of initial consultation for women with other infectious diseases.	0	0	0	0	0	0	3	3	3	8	0.7
4.08.03	MFM is available to participate in obstetrical co-management for women with other infectious diseases.	0	0	0	0	0	0	5	2	2	7	0.7
4.08.04	MFM is available to accept referral to take over primary obstetrical management for women with other infectious diseases.	0	0	2	1	1	2	1	1	1	6	1.7
4.08.05	Clinical Genetic Services are available during the first trimester for women with other infectious diseases.	2	0	0	1	1	1	1	1	2	6	2.4
4.08.05a	Clinical Genetic Services during the first trimester are necessary for women with other infectious diseases.	2	2	0	0	3	1	0	0	1	5	2.1
4.08.06	Clinical Genetic Services are available prior to conception for women with other infectious diseases.	2	2	1	0	3	1	0	0	0	3	1.7
4.09.01	MFM is available for initial consultation for women with psychiatry/mental health illness.	0	1	0	1	0	0	1	4	2	8	1.4
4.09.01a	An initial consultation with an MFM is necessary for women with psychiatry/mental health illness.	2	1	0	0	2	2	1	0	1	5	2.1
4.09.02	MFM is available for follow-up of initial consultation for women with psychiatry/mental health illness.	0	1	1	0	1	2	2	0	2	6	1.8
4.09.03	MFM is available to participate in obstetrical co-management for women with psychiatry/mental health illness.	1	0	2	1	3	0	1	0	1	5	1.7

		1	2	3	4	5	6	7	8	9		
4.09.04	MFM is available to accept referral to take over primary obstetrical management for women with psychiatry/mental health illness.	2	1	3	0	1	0	0	0	2	3	2.1
		1	2	3	4	5	6	7	8	9		
4.09.05	Clinical Genetic Services are available during the first trimester for women with psychiatry/mental health illness.	3	2	0	0	2	0	1	0	1	2	2.3
		1	2	3	4	5	6	7	8	9		
4.09.06	Clinical Genetic Services are available prior to conception for women with psychiatry/mental health illness.	3	2	0	0	2	0	1	0	1	2	2.3
		1	2	3	4	5	6	7	8	9		
4.10.01	MFM is available for initial consultation for women with substance abuse.	0	0	1	1	0	0	2	3	2	8	1.4
		1	2	3	4	5	6	7	8	9		
4.10.01a	An initial consultation with an MFM is necessary for women with substance abuse.	2	1	0	0	0	3	2	0	1	6	2.1
		1	2	3	4	5	6	7	8	9		
4.10.02	MFM is available for follow-up of initial consultation for women with substance abuse.	0	0	2	0	0	2	2	0	3	7	1.8
		1	2	3	4	5	6	7	8	9		
4.10.03	MFM is available to participate in obstetrical co-management for women with substance abuse.	1	0	2	0	2	1	1	0	2	5	2.1
		1	2	3	4	5	6	7	8	9		
4.10.04	MFM is available to accept referral to take over primary obstetrical management for women with substance abuse.	1	0	3	1	1	0	1	0	2	4	2.2
		1	2	3	4	5	6	7	8	9		
4.10.05	Clinical Genetic Services are available during the first trimester for women with substance abuse.	2	3	0	0	2	0	0	1	1	2	2.3
		1	2	3	4	5	6	7	8	9		
4.10.06	Clinical Genetic Services are available prior to conception for women with substance abuse.	3	3	0	0	1	0	0	1	1	2	2.1

4.11.01	MFM is available for initial consultation for women with asthma/pulmonary disease.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	3	2	4	8	0.8	
4.11.01a	An initial consultation with an MFM is necessary for women with asthma/pulmonary disease.	1	2	3	4	5	6	7	8	9	0	0	1	0	1	0	4	1	2	7	1.2	
4.11.02	MFM is available for follow-up of initial consultation for women with asthma/pulmonary disease.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	3	4	1	1	7	0.7	
4.11.03	MFM is available to participate in obstetrical co-management for women with asthma/pulmonary disease.	1	2	3	4	5	6	7	8	9	0	0	0	1	1	2	3	1	1	7	1.1	
4.11.04	MFM is available to accept referral to take over primary obstetrical management for women with asthma/pulmonary disease.	1	2	3	4	5	6	7	8	9	1	0	2	0	1	1	3	0	1	6	2.0	
4.11.05	Clinical Genetic Services are available during the first trimester for women with asthma/pulmonary disease.	1	2	3	4	5	6	7	8	9	2	3	1	0	1	0	0	1	1	2	2.1	
4.11.06	Clinical Genetic Services are available prior to conception for women with asthma/pulmonary disease.	1	2	3	4	5	6	7	8	9	2	3	1	0	1	0	0	1	1	2	2.1	
4.12.01	MFM is available for initial consultation for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	0	1	2	6	9	0.4
4.12.01a	An initial consultation with an MFM is necessary for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	1	1	1	3	3	8	1.0	
4.12.02	MFM is available for follow-up of initial consultation for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	0	1	1	7	9	0.3

	1	2	3	4	5	6	7	8	9		
4.12.02a A follow-up visit with an MFM is necessary for women with preexisting diabetes.	0	0	0	0	0	2	2	2	3	8	1.0
4.12.03 MFM is available to participate in obstetrical co-management for women with preexisting diabetes.	0	0	0	0	0	1	1	2	5	9	0.8
4.12.03a MFM participation in obstetrical co-management is necessary for women with preexisting diabetes.	0	0	0	1	1	2	2	1	2	7	1.3
4.12.04 MFM is available to accept referral to take over primary obstetrical management for women with preexisting diabetes.	0	0	0	1	0	1	1	1	5	9	1.2
4.12.04a Availability of MFM to accept referral to take over primary obstetrical management is necessary for women with preexisting diabetes.	0	0	0	1	2	2	0	1	3	6	1.7
4.12.05 Clinical Genetic Services are available during the first trimester for women with preexisting diabetes.	2	1	0	0	2	1	0	1	2	5	2.6
4.12.05a Clinical Genetic Services during the first trimester are necessary for women with preexisting diabetes.	2	1	0	1	1	1	0	2	1	5	2.6
4.12.06 Clinical Genetic Services are available prior to conception for women with preexisting diabetes.	2	1	0	0	2	0	1	1	2	5	2.7
4.12.06a Clinical Genetic Services prior to conception are necessary for women with preexisting diabetes.	2	1	0	1	1	1	0	1	2	5	2.7
4.13.01 MFM is available for initial consultation with gestational diabetes.	0	0	0	0	0	3	1	2	3	8	1.1



		1	2	3	4	5	6	7	8	9		
4.13.01a	An initial consultation with an MFM is necessary for women with gestational diabetes.	1	0	2	2	1	0	2	0	1	4	1.9
4.13.02	MFM is available for follow-up of initial consultation with gestational diabetes.	0	0	0	1	3	2	0	1	2	6	1.4
4.13.03	MFM is available to participate in obstetrical co-management with gestational diabetes.	0	0	0	1	3	1	1	2	1	6	1.4
4.13.04	MFM is available to accept referral to take over primary obstetrical management with gestational diabetes.	0	0	0	2	2	0	3	1	1	7	1.4
4.13.05	Clinical Genetic Services are available during the first trimester with gestational diabetes.	4	1	1	0	1	1	0	0	1	2	2.1
4.13.06	Clinical Genetic Services are available prior to conception with gestational diabetes.	4	1	2	0	1	0	0	0	1	2	1.8
4.14.01	MFM is available for initial consultation for obese women.	0	0	2	0	2	0	1	2	2	7	2.0
4.14.02	MFM is available for follow-up of initial consultation for obese women.	0	0	2	0	2	3	0	1	1	6	1.4
4.14.03	MFM is available to participate in obstetrical co-management for obese women.	0	0	2	0	2	2	1	1	1	6	1.6
4.14.04	MFM is available to accept referral to take over primary obstetrical management for obese women.	1	0	2	1	3	0	1	0	1	5	1.7
4.14.05	Clinical Genetic Services are available during the first trimester for obese women.	3	2	1	0	2	0	0	0	1	2	1.9

		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.14.06	Clinical Genetic Services are available prior to conception for obese women.	3	2	1	0	2	0	0	0	1	2	1.9
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.15.01	MFM is available for initial consultation for women with previous preterm delivery.	0	0	0	0	0	0	3	1	5	9	0.8
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.15.02	MFM is available for follow-up of initial consultation with previous preterm delivery.	0	0	0	0	1	1	2	3	2	8	1.0
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.15.03	MFM is available to participate in obstetrical co-management with previous preterm delivery.	1	0	0	0	1	2	1	3	1	7	1.7
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.15.04	MFM is available to accept referral to take over primary obstetrical management with previous preterm delivery.	1	0	0	0	1	2	1	3	1	7	1.7
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.15.05	Clinical Genetic Services are available during the first trimester with previous preterm delivery.	4	2	0	0	2	0	0	0	1	2	1.9
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.15.06	Clinical Genetic Services are available prior to conception with previous preterm delivery.	4	2	1	0	1	0	0	0	1	2	1.7
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.16.01	MFM is available for initial consultation with a history of a previous C section.	3	0	1	1	1	0	3	0	0	4	2.2
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.16.02	MFM is available for follow-up of initial consultation with a history of a previous C section.	3	1	0	1	2	1	1	0	0	4	2.0
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.16.03	MFM is available to participate in obstetrical co-management with a history of a previous C section.	3	1	0	1	1	1	2	0	0	4	2.2
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
4.16.04	MFM is available to accept referral to take over primary obstetrical management with a history of a previous C section.	3	0	0	1	3	0	2	0	0	5	1.9

		1	2	3	4	5	6	7	8	9		
4.16.05	Clinical Genetic Services are available during the first trimester with a history of a previous C section with a history of a previous C section.	7	0	1	0	0	0	0	0	1	1	1.1
4.16.06	Clinical Genetic Services are available prior to conception with a history of a previous C section.	7	0	1	0	0	0	0	0	1	1	1.1
4.17.01	MFM is available for initial consultation for women with abnormal placentation.	0	0	0	0	0	0	4	2	3	8	0.8
4.17.01a	An initial consultation with an MFM is necessary for women with abnormal placentation.	0	0	0	0	2	1	2	2	2	7	1.2
4.17.02	MFM is available for follow-up of initial consultation for women with abnormal placentation.	0	0	0	0	1	1	2	1	4	8	1.2
4.17.02a	A follow-up visit with an MFM is necessary for women with abnormal placentation.	0	0	0	0	2	3	1	1	2	6	1.2
4.17.03	MFM is available to participate in obstetrical co-management for women with abnormal placentation.	0	0	0	0	1	1	2	1	4	8	1.2
4.17.03a	MFM participation in obstetrical co-management is necessary for women with abnormal placentation.	0	0	1	0	2	1	2	1	2	7	1.6
4.17.04	MFM is available to accept referral to take over primary obstetrical management for women with abnormal placentation.	0	0	1	0	1	1	1	1	4	8	1.7
4.17.04a	Availability of MFM to accept referral to take over primary obstetrical management is necessary for women with abnormal placentation.	0	0	1	1	2	1	0	1	3	6	2.0

		1	2	3	4	5	6	7	8	9		
4.17.05	Clinical Genetic Services are available during the first trimester for women with abnormal placentation.	7	0	1	0	0	0	0	0	1	1	1.1
		1	2	3	4	5	6	7	8	9		
4.17.06	Clinical Genetic Services are available prior to conception for women with abnormal placentation.	7	0	1	0	0	0	0	0	1	1	1.1
		1	2	3	4	5	6	7	8	9		
4.18.01	MFM is available for initial consultation for women with BMI > 50.	0	0	0	0	2	0	2	0	5	9	1.3
		1	2	3	4	5	6	7	8	9		
4.18.02	MFM is available for follow-up of initial consultation for women with BMI > 50.	0	0	1	0	1	1	2	2	2	7	1.4
		1	2	3	4	5	6	7	8	9		
4.18.03	MFM is available to participate in obstetrical co-management for women with BMI > 50.	0	0	0	0	2	1	4	0	2	7	1.0
		1	2	3	4	5	6	7	8	9		
4.18.04	MFM is available to accept referral to take over primary obstetrical management for women with BMI > 50.	1	0	0	0	3	1	2	1	1	6	1.7
		1	2	3	4	5	6	7	8	9		
4.18.05	Clinical Genetic Services are available during the first trimester for women with BMI > 50.	3	1	1	1	1	0	0	1	1	3	2.3
		1	2	3	4	5	6	7	8	9		
4.18.06	Clinical Genetic Services are available prior to conception for women with BMI > 50.	3	1	1	1	1	0	0	1	1	3	2.3

## Chapter 5

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
5.01.01	Subspecialist is available for initial consultation for women with pre-existing hypertension.	1	0	0	1	1	0	5	0	1	7	1.4
5.01.02	Subspecialist is available for follow-up of initial consultation for women with pre-existing hypertension.	1	1	0	0	1	0	5	0	1	7	1.7
5.01.03	Subspecialist is available to participate in co-management of obstetrical care for women with pre-existing hypertension.	1	0	1	1	1	0	3	1	1	7	2.0
5.01.03a	Subspecialist participation in co-management of obstetrical care is necessary for women with pre-existing hypertension.	3	0	1	1	0	0	3	0	1	4	2.7
5.01.04	Subspecialist is available during delivery for women with pre-existing hypertension.	2	2	4	0	0	0	1	0	0	3	1.1
5.01.05	Multi-disciplinary care is available during antenatal care for women with pre-existing hypertension.	1	0	0	1	0	0	5	1	1	7	1.3
5.01.06	Multi-disciplinary care is available during delivery for women with pre-existing hypertension.	1	2	2	0	0	1	1	1	1	3	2.4
5.02.01	Subspecialist is available for initial consultation for women with pregnancy induced hypertension.	3	1	1	0	2	0	1	0	1	3	2.3
5.02.02	Subspecialist is available for follow-up of initial consultation for women with pregnancy induced hypertension.	3	1	0	0	2	0	2	0	1	5	2.6

		1	2	3	4	5	6	7	8	9		
5.02.03	Subspecialist is available to participate in co-management of obstetrical care for women with pregnancy induced hypertension.	3	1	2	0	1	0	1	0	1	3	2.1
		1	2	3	4	5	6	7	8	9		
5.02.04	Subspecialist is available during delivery for women with pregnancy induced hypertension.	3	2	1	0	1	0	1	1	0	2	2.0
		1	2	3	4	5	6	7	8	9		
5.02.05	Multi-disciplinary care is available during antenatal care for women with pregnancy induced hypertension.	2	1	1	0	1	0	2	0	2	5	2.8
		1	2	3	4	5	6	7	8	9		
5.02.06	Multi-disciplinary care is available during delivery for women with pregnancy induced hypertension.	3	1	1	0	1	0	2	0	1	3	2.6
		1	2	3	4	5	6	7	8	9		
5.03.01	Subspecialist is available for initial consultation for women with preeclampsia.	3	2	1	0	1	0	0	0	2	2	2.3
		1	2	3	4	5	6	7	8	9		
5.03.02	Subspecialist is available for follow-up of initial consultation for women with preeclampsia.	3	2	0	0	1	0	1	0	2	2	2.8
		1	2	3	4	5	6	7	8	9		
5.03.03	Subspecialist is available to participate in co-management of obstetrical care for women with preeclampsia.	3	2	1	0	1	0	0	0	2	2	2.3
		1	2	3	4	5	6	7	8	9		
5.03.04	Subspecialist is available during delivery for women with preeclampsia.	3	2	1	0	1	1	0	0	1	2	2.0
		1	2	3	4	5	6	7	8	9		
5.03.05	Multi-disciplinary care is available during antenatal care for women with preeclampsia.	2	2	1	0	0	1	1	0	2	3	2.8
		1	2	3	4	5	6	7	8	9		
5.03.06	Multi-disciplinary care is available during delivery for women with preeclampsia.	2	2	1	0	1	0	1	1	1	3	2.6

		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.01	Subspecialist is available for initial consultation for women with eclampsia.	3	0	1	0	2	0	1	1	1	5	2.6
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.01a	An initial consultation with a subspecialist is necessary for women with eclampsia.	3	0	1	0	2	0	2	1	0	5	2.3
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.02	Subspecialist is available for follow-up of initial consultation for women with eclampsia.	3	0	0	0	1	0	3	1	1	7	2.6
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.02a	A follow-up visit with a subspecialist is necessary for women with eclampsia.	3	0	0	0	2	0	3	1	0	5	2.3
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.03	Subspecialist is available to participate in co-management of obstetrical care for women with eclampsia.	3	0	1	0	1	0	2	0	2	5	2.9
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.03a	Subspecialist participation in co-management of obstetrical care is necessary for women with eclampsia.	3	0	1	0	2	0	1	0	2	5	2.7
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.04	Subspecialist is available during delivery for women with eclampsia.	4	0	0	0	3	1	0	0	1	5	2.3
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.05	Multi-disciplinary care is available during antenatal care for women with eclampsia.	4	0	0	0	1	0	2	0	2	5	3.1
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.04.06	Multi-disciplinary care is available during delivery for women with eclampsia.	4	0	0	0	2	0	2	0	1	5	2.7
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.05.01	Subspecialist is available for initial consultation for women with preexisting cardiac disease.	0	0	0	0	0	0	0	3	6	9	0.3
		<a href="#">1</a>	<a href="#">2</a>	<a href="#">3</a>	<a href="#">4</a>	<a href="#">5</a>	<a href="#">6</a>	<a href="#">7</a>	<a href="#">8</a>	<a href="#">9</a>		
5.05.01a	An initial consultation with a subspecialist is necessary for women with preexisting cardiac disease.	0	0	0	0	0	1	0	3	5	9	0.7

	1	2	3	4	5	6	7	8	9		
5.05.02 Subspecialist is available for follow-up of initial consultation for women with preexisting cardiac disease.	0	0	0	0	0	0	1	2	6	9	0.4
5.05.02a A follow-up visit with a subspecialist is necessary for women with preexisting cardiac disease.	0	0	0	0	1	1	2	2	3	8	1.1
5.05.03 Subspecialist is available to participate in co-management of obstetrical care for women with preexisting cardiac disease.	0	0	0	0	0	1	0	3	5	9	0.7
5.05.03a Subspecialist participation in co-management of obstetrical care is necessary for women with preexisting cardiac disease.	0	0	0	0	0	1	3	2	3	8	0.9
5.05.04 Subspecialist is available during delivery for women with preexisting cardiac disease.	0	0	1	0	2	1	0	1	4	8	1.9
5.05.04a A subspecialist during delivery is necessary for women with preexisting cardiac disease.	0	0	1	1	2	1	1	1	2	6	1.8
5.05.05 Multi-disciplinary care is available during antenatal care for women with preexisting cardiac disease.	0	0	0	0	1	0	1	0	7	9	0.7
5.05.05a Multi-disciplinary care during antenatal care is necessary for women with preexisting cardiac disease.	0	0	0	0	0	1	0	1	7	9	0.4
5.05.06 Multi-disciplinary care is available during delivery for women with preexisting cardiac disease.	0	0	0	0	3	1	0	0	5	9	1.7
5.05.06a Multi-disciplinary care during delivery is necessary for women with preexisting cardiac disease.	0	0	0	0	4	1	1	0	3	6	1.6



5.06.01	Subspecialist is available for initial consultation for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	1	1	7	9	0.3
5.06.01a	An initial consultation with a subspecialist is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	1	0	1	7	9	0.4
5.06.02	Subspecialist is available for follow-up of initial consultation for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	1	1	7	9	0.3
5.06.02a	A follow-up visit with a subspecialist is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	1	1	1	6	9	0.7
5.06.03	Subspecialist is available to participate in co-management of obstetrical care for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	1	1	7	9	0.3
5.06.03a	Subspecialist participation in co-management of obstetrical care is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	1	1	1	6	9	0.7
5.06.04	Subspecialist is available during delivery for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	1	2	0	2	4	8	1.2
5.06.04a	A subspecialist during delivery is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	3	1	2	1	2	7	1.3
5.06.05	Multi-disciplinary care is available during antenatal care for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	1	0	1	7	9	0.4
5.06.05a	Multi-disciplinary care during antenatal care is necessary for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	1	0	0	1	7	9	0.6
5.06.06	Multi-disciplinary care is available during delivery for women with cardiomyopathy.	1	2	3	4	5	6	7	8	9	0	0	0	0	1	2	0	1	5	9	1.2

		1	2	3	4	5	6	7	8	9		
5.06.06a	Multi-disciplinary care during delivery is necessary for women with cardiomyopathy.	0	0	0	0	2	1	2	1	3	7	1.3
		1	2	3	4	5	6	7	8	9		
5.07.01	Subspecialist is available for initial consultation for women with HIV.	0	0	0	0	0	0	0	3	6	9	0.3
		1	2	3	4	5	6	7	8	9		
5.07.01a	An initial consultation with a subspecialist is necessary for women with HIV.	0	0	0	0	0	1	0	3	5	9	0.7
		1	2	3	4	5	6	7	8	9		
5.07.02	Subspecialist is available for follow-up of initial consultation for women with HIV.	0	0	0	0	0	0	2	1	6	9	0.6
		1	2	3	4	5	6	7	8	9		
5.07.02a	A follow-up visit with a subspecialist is necessary for women with HIV.	0	0	0	0	1	0	2	2	4	8	1.0
		1	2	3	4	5	6	7	8	9		
5.07.03	Subspecialist is available to participate in co-management of obstetrical care for women with HIV.	0	0	0	0	0	0	1	4	4	8	0.6
		1	2	3	4	5	6	7	8	9		
5.07.03a	Subspecialist participation in co-management of obstetrical care is necessary for women with HIV.	0	0	0	0	0	1	1	2	5	9	0.8
		1	2	3	4	5	6	7	8	9		
5.07.04	Subspecialist is available during delivery for women with HIV.	0	0	3	1	2	1	1	0	1	5	1.6
		1	2	3	4	5	6	7	8	9		
5.07.05	Multi-disciplinary care is available during antenatal care for women with HIV.	0	0	0	0	0	0	2	1	6	9	0.6
		1	2	3	4	5	6	7	8	9		
5.07.05a	Multi-disciplinary care during antenatal care is necessary for women with HIV.	0	0	0	0	0	0	2	2	5	9	0.7
		1	2	3	4	5	6	7	8	9		
5.07.06	Multi-disciplinary care is available during delivery for women with HIV.	0	1	1	0	2	2	0	1	2	6	1.9
		1	2	3	4	5	6	7	8	9		
5.07.06a	Multi-disciplinary care during delivery is necessary for women with HIV.	1	1	0	0	3	1	0	1	2	5	2.1

5.08.01	Subspecialist is available for initial consultation for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	8	0.7
5.08.01a	An initial consultation with a subspecialist is necessary for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	7	1.2
5.08.02	Subspecialist is available for follow-up of initial consultation for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	7	1.0
5.08.03	Subspecialist is available to participate in co-management of obstetrical care for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	7	1.2
5.08.04	Subspecialist is available during delivery for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	4	1.3
5.08.05	Multi-disciplinary care is available during antenatal care for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	7	1.9
5.08.06	Multi-disciplinary care is available during delivery for women with other infectious diseases.	1	2	3	4	5	6	7	8	9	4	1.6
5.09.01	Subspecialist is available for initial consultation for women with psychiatry/mental health illness.	1	2	3	4	5	6	7	8	9	9	0.4
5.09.01a	An initial consultation with a subspecialist is necessary for women with psychiatry/mental health illness.	1	2	3	4	5	6	7	8	9	7	1.1
5.09.02	Subspecialist is available for follow-up of initial consultation for women with psychiatry/mental health illness.	1	2	3	4	5	6	7	8	9	8	0.9

		1	2	3	4	5	6	7	8	9		
5.09.02a	A follow-up visit with a subspecialist is necessary for women with psychiatry/mental health illness.	0	0	0	0	3	0	4	1	1	7	1.0
5.09.03	Subspecialist is available to participate in co-management of obstetrical care for women with psychiatry/mental health illness.	0	0	1	0	1	2	1	3	1	7	1.4
5.09.03a	Subspecialist participation in co-management of obstetrical care is necessary for women with psychiatry/mental health illness.	1	0	0	0	4	1	1	1	1	5	1.6
5.09.04	Subspecialist is available during delivery for women with psychiatry/mental health illness	1	1	1	1	4	1	0	0	0	5	1.2
5.09.05	Multi-disciplinary care is available during antenatal care for women with psychiatry/mental health illness	0	1	0	0	2	0	1	4	1	8	1.6
5.09.05a	Multi-disciplinary care during antenatal care is necessary for women with psychiatry/mental health illness.	0	0	0	0	0	1	6	1	1	7	0.4
5.09.06	Multi-disciplinary care is available during delivery for women with psychiatry/mental health illness.	1	1	0	0	3	2	0	2	0	5	1.7
5.10.01	Subspecialist is available for initial consultation for women with substance abuse.	0	0	0	0	1	0	3	1	4	8	1.1
5.10.01a	An initial consultation with a subspecialist is necessary for women with substance abuse.	0	0	0	0	3	0	4	0	2	7	1.1
5.10.02	Subspecialist is available for follow-up of initial consultation for women with substance abuse.	0	0	0	1	2	0	4	0	2	7	1.2

		1	2	3	4	5	6	7	8	9		
5.10.03	Subspecialist is available to participate in co-management of obstetrical care for women with substance abuse.	0	0	0	1	3	0	3	0	2	7	1.4
5.10.04	Subspecialist is available during delivery for women with substance abuse.	0	0	3	1	3	1	1	0	0	5	1.1
5.10.05	Multi-disciplinary care is available during antenatal care for women with substance abuse.	0	0	0	0	1	1	2	3	2	8	1.0
5.10.05a	Multi-disciplinary care during antenatal care is necessary for women with substance abuse.	0	0	0	0	1	1	3	3	1	7	0.9
5.10.06	Multi-disciplinary care is available during delivery for women with substance abuse.	1	0	0	0	5	0	1	2	0	5	1.3
5.11.01	Subspecialist is available for initial consultation for women with asthma/pulmonary disease.	0	0	0	1	2	0	2	3	1	7	1.3
5.11.02	Subspecialist is available for follow-up of initial consultation for women with asthma/pulmonary disease.	0	0	0	1	3	1	2	2	0	6	1.2
5.11.03	Subspecialist is available to participate in co-management of obstetrical care for women with asthma/pulmonary disease.	0	1	0	1	2	1	2	2	0	6	1.6
5.11.04	Subspecialist is available during delivery for women with asthma/pulmonary disease.	0	2	0	1	3	1	1	1	0	5	1.4
5.11.05	Multi-disciplinary care is available during antenatal care for women with asthma/pulmonary disease.	0	0	0	1	3	0	3	2	0	7	1.2
5.11.06	Multi-disciplinary care is available during delivery for women with asthma/pulmonary disease.	0	2	1	0	3	0	2	1	0	5	1.7

5.12.01	Subspecialist is available for initial consultation for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	1	0	3	1	4	8	1.1
5.12.01a	An initial consultation with a subspecialist is necessary for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	1	0	0	1	1	1	5	9	1.3
5.12.02	Subspecialist is available for follow-up of initial consultation for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	4	1	4	8	0.9
5.12.02a	A follow-up visit with a subspecialist is necessary for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	1	1	4	0	3	7	1.0
5.12.03	Subspecialist is available to participate in co-management of obstetrical care for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	1	0	0	6	0	2	7	0.8
5.12.03a	Subspecialist participation in co-management of obstetrical care is necessary for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	1	0	0	0	2	1	3	1	1	7	1.6
5.12.04	Subspecialist is available during delivery for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	1	4	1	2	0	1	5	1.1
5.12.05	Multi-disciplinary care is available during antenatal care for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	0	0	4	5	9	0.4
5.12.05a	Multi-disciplinary care during antenatal care is necessary for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	0	1	1	2	5	9	0.8
5.12.06	Multi-disciplinary care is available during delivery for women with preexisting diabetes.	1	2	3	4	5	6	7	8	9	0	0	0	0	2	3	2	0	2	6	1.1
5.13.01	Subspecialist is available for initial consultation for women with gestational diabetes.	1	2	3	4	5	6	7	8	9	0	2	2	0	0	1	0	1	3	6	2.8

	1	2	3	4	5	6	7	8	9		
5.13.01a An initial consultation with a subspecialist is necessary for women with gestational diabetes.	1	2	2	0	0	1	3	0	0	3	2.1
5.13.02 Subspecialist is available for follow-up of initial consultation for women with gestational diabetes.	0	2	1	0	2	0	1	1	2	5	2.3
5.13.03 Subspecialist is available to participate in co-management of obstetrical care for women with gestational diabetes.	0	2	1	1	2	0	1	1	1	5	2.0
5.13.03a Subspecialist participation in co-management of obstetrical care is necessary for women with gestational diabetes.	1	1	3	0	1	1	2	0	0	3	1.8
5.13.04 Subspecialist is available during delivery for women with gestational diabetes	0	2	4	0	2	1	0	0	0	3	1.0
5.13.05 Multi-disciplinary care is available during antenatal care for women with gestational diabetes	0	0	1	0	0	0	3	4	1	8	1.0
5.13.05a Multi-disciplinary care during antenatal care is necessary for women with gestational diabetes.	1	0	1	0	0	1	4	1	1	7	1.6
5.13.06 Multi-disciplinary care is available during delivery for women with gestational diabetes.	0	2	2	0	1	2	1	0	1	5	2.0
5.14.01 Subspecialist is available for initial consultation for obese women.	0	3	3	0	1	1	0	0	1	3	1.6
5.14.02 Subspecialist is available for follow-up of initial consultation for obese women.	0	3	3	0	1	1	0	0	1	3	1.6
5.14.03 Subspecialist is available to participate in co-management of obstetrical care for obese women.	0	3	3	0	1	1	0	0	1	3	1.6

		1	2	3	4	5	6	7	8	9		
5.14.04	Subspecialist is available during delivery for obese women.	1	3	2	0	1	1	0	1	0	3	1.7
5.14.05	Multi-disciplinary care is available during antenatal care for obese women.	0	0	1	0	1	1	0	3	3	8	1.4
5.14.05a	Multi-disciplinary care during antenatal care is necessary for obese women.	1	1	0	0	2	0	1	2	2	7	2.3
5.14.06	Multi-disciplinary care is available during delivery for obese women	1	2	1	0	1	1	1	1	1	5	2.4
5.15.01	Availability of anesthesiologist consultation at entry to Labor and delivery is an essential component of HROB services.	0	0	0	0	0	0	0	2	7	9	0.2
5.15.02	Availability of anesthesiologist consultation at entry to Labor and delivery is an essential component of HROB services.	0	0	0	0	0	0	0	2	7	9	0.2



## Chapter 6

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
6.00.01	Cardiomyopathy that is diagnosed postpartum is an indicator of failure of availability of high risk obstetric care.	4	4	1	0	0	0	0	0	0	2	0.6
6.00.02	At a population level higher rates of hypertensive stroke indicate worse availability to high risk obstetric care.	0	0	0	0	0	1	2	6	0	8	0.4
6.00.03	At a population level higher rates of postpartum suicide indicate worse availability of high risk obstetric care.	0	1	0	1	0	3	2	2	0	6	1.3
6.00.04	At a population level morality rates from amniotic fluid embolus is an indicator of failure of availability of high risk obstetric care.	0	2	3	0	0	1	2	1	0	3	2.0
6.00.05	At a population level a higher rate of maternal death from hemorrhage suggests insufficient availability of high risk obstetric care.	0	0	0	0	0	0	0	6	3	8	0.3
6.00.06	At a population level, rates of perinatal transmission of HIV is an indicator of failure of availability of high risk obstetric care.	0	0	0	0	0	0	0	4	5	9	0.4
6.00.07	Delivery of a VLBW infant at a Level I or Level II nursery is an indicator of failure of availability of high risk obstetric care.	0	0	0	0	0	0	2	3	4	8	0.7
6.00.08	At a population level, higher eclampsia rates suggest a failure of availability of high risk obstetric care.	0	0	1	1	1	1	2	3	0	7	1.4
6.00.09	At a population level, a higher incidence rate of DIC is an indicator of poorer availability of high risk obstetric care.	0	1	0	0	3	0	2	3	0	7	1.6

		1	2	3	4	5	6	7	8	9		
6.00.10	At a population level, more use of general anesthesia for cesarean delivery is an indicator of less availability of high risk obstetric care.	1	0	0	0	1	2	1	3	1	7	1.7
		1	2	3	4	5	6	7	8	9		
6.00.11	At a population level, a higher incidence rate of VTE following cesarian section is an indicator of less availability of high risk obstetric care.	0	0	1	0	0	1	3	3	1	7	1.1
		1	2	3	4	5	6	7	8	9		
6.00.12	At a population level, a higher mortality rate from acute fatty liver is an indicator of lesser availability of high risk obstetric care.	0	0	2	0	3	1	3	0	0	5	1.2
		1	2	3	4	5	6	7	8	9		
6.00.13	At a population level, a higher incidence of neonatal abstinence withdrawal syndrome is an indicator of worse availability of high risk obstetric care.	1	1	2	1	2	1	0	1	0	4	1.7
		1	2	3	4	5	6	7	8	9		
6.00.14	Pregnant women not offered serum marker screening for neural tube defects and trisomies 21 and 18 during their pregnancy represent an insufficient availability of high risk obstetric care.	0	1	1	0	0	1	1	1	4	8	2.0
		1	2	3	4	5	6	7	8	9		
6.00.15	Women with history of genetic disorder who are not offered genetic counseling during pregnancy represent insufficient availability of high risk obstetric care.	0	0	0	0	0	0	1	4	4	8	0.6
		1	2	3	4	5	6	7	8	9		
6.00.16	Women with history of birth defect who are not offered genetic counseling during pregnancy represent insufficient availability of high risk obstetric care.	0	0	0	0	0	0	1	4	4	8	0.6

		1	2	3	4	5	6	7	8	9		
6.00.17	Women with history of exposure to teratogens who are not offered genetic counseling during pregnancy represent insufficient availability of high risk obstetric care.	0	0	0	0	0	0	1	4	4	8	0.6
6.00.18	Women of specific ancestries (Eastern European, African, Cajun, Southeast Asian, etc.) who are not offered genetic counseling during pregnancy represent insufficient availability of high risk obstetric care.	1	0	0	0	3	1	2	0	2	6	1.8
6.00.19	At a population level, a higher incidence of in-hospital eclampsia rates is an indicator of worse availability to high risk obstetric care.	0	0	0	0	1	0	0	7	1	8	0.4
6.00.20	At a population level, a higher incidence of post-discharge eclampsia rates is an indicator of worse availability of high risk obstetric care.	0	2	2	0	2	1	1	1	0	5	1.8

## Chapter 7

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
7.01.01	Preconception care represents high risk care for women with Preexisting Hypertension.	0	0	0	0	0	0	2	4	3	8	0.6
7.01.02	Women with Preexisting Hypertension should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	0	1	4	4	8	0.6
7.02.01	Preconception care represents high risk care for women with a history of pregnancy induced hypertension.	0	0	0	1	1	0	3	3	1	7	1.1
7.02.02	Women with a history of pregnancy induced hypertension condition should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	1	0	0	2	4	2	8	0.9
7.03.01	Preconception care represents high risk care for women with a history of preeclampsia.	0	0	0	0	1	0	2	3	3	8	0.9
7.03.02	Women with a history of preeclampsia should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	0	3	3	3	8	0.7
7.04.01	Preconception care represents high risk care for women with a history of eclampsia.	0	0	0	0	0	0	1	4	4	8	0.6
7.04.02	Women with a history of eclampsia should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	0	2	3	4	8	0.7

		1	2	3	4	5	6	7	8	9		
7.05.01	Preconception care represents high risk care for women with Preexisting Cardiac Disease (exclude simple mitral valve prolapse).	0	0	0	0	0	0	0	2	7	9	0.2
		1	2	3	4	5	6	7	8	9		
7.05.02	Women with Preexisting Cardiac Disease (exclude simple mitral valve prolapse) should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	0	0	2	7	9	0.2
		1	2	3	4	5	6	7	8	9		
7.06.01	Preconception care represents high risk care for women with a history of pregnancy-related cardiomyopathy.	0	0	0	0	0	0	0	2	7	9	0.2
		1	2	3	4	5	6	7	8	9		
7.06.02	Women with history of pregnancy-related cardiomyopathy should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	0	0	2	7	9	0.2
		1	2	3	4	5	6	7	8	9		
7.07.01	Preconception care represents high risk care for women with HIV Disease.	0	0	0	0	0	0	0	3	6	9	0.3
		1	2	3	4	5	6	7	8	9		
7.07.02	Women with HIV Disease should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	0	0	3	6	9	0.3
		1	2	3	4	5	6	7	8	9		
7.08.01	Preconception care represents high risk care for women with other infectious diseases.	0	0	0	0	0	1	4	2	2	7	0.8
		1	2	3	4	5	6	7	8	9		
7.08.02	Women with other infectious diseases should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	1	4	2	2	7	0.8
		1	2	3	4	5	6	7	8	9		
7.09.01	Preconception care represents high risk care for women who have a psychiatric/mental health illness.	0	0	0	1	0	1	1	3	3	8	1.1

		1	2	3	4	5	6	7	8	9		
7.09.02	Women who have a psychiatric/mental health illness should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	2	1	3	3	8	0.9
7.10.01	Preconception care represents high risk care for women with other Substance Abuse.	0	0	1	1	1	0	2	1	3	7	1.8
7.10.02	Women with other Substance Abuse should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	1	1	1	1	0	2	1	2	7	2.1
7.11.01	Preconception care represents high risk care for women with Asthma/Pulmonary Disease.	0	0	0	1	2	1	2	1	2	7	1.4
7.11.02	Women with Asthma/Pulmonary Disease should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	1	2	2	1	1	2	6	1.4
7.12.01	Preconception care represents high risk care for women with Preexisting Diabetes Mellitus.	0	0	0	0	0	0	0	1	8	9	0.1
7.12.02	Women with Preexisting Diabetes Mellitus should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	0	0	0	0	0	2	7	9	0.2
7.13.01	Preconception care represents high risk care for women with a history of Gestational Diabetes.	0	1	0	0	1	1	2	3	1	7	1.4
7.13.02	Women with a history of Gestational Diabetes should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	1	0	0	1	2	2	2	1	7	1.4
7.14.01	Preconception care represents high risk care for Obese women.	0	0	1	0	2	0	2	3	1	7	1.4

7.14.02	Obese women should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	1	2	3	4	5	6	7	8	9	7	1.4
7.15.01	Preconception care represents high risk care for women with Previous Preterm Delivery.	1	2	3	4	5	6	7	8	9	9	0.6
7.15.02	Women with Previous Preterm Delivery should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	1	2	3	4	5	6	7	8	9	8	0.8
7.16.01	Preconception care represents high risk care for women with a history of a previous C Section.	1	2	3	4	5	6	7	8	9	5	1.3
7.16.02	Women with a history of a previous C section should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	1	2	3	4	5	6	7	8	9	5	1.6
7.17.01	Preconception care represents high risk care for women with a history of a Abnormal Placentation.	1	2	3	4	5	6	7	8	9	6	1.8
7.17.02	Women with a history of Abnormal Placentation should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	1	2	3	4	5	6	7	8	9	6	2.1
7.18.01	Preconception care represents high risk care for women on any teratogenic medication.	1	2	3	4	5	6	7	8	9	9	0.2
7.18.02	Women on teratogenic medications should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	1	2	3	4	5	6	7	8	9	9	0.4
7.19.01	Preconception care represents high risk care for women on psychotropic medications.	1	2	3	4	5	6	7	8	9	9	1.0

		1	2	3	4	5	6	7	8	9		
7.19.02	Women on psychotropic medications should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	1	0	0	1	1	0	6	9	1.2
7.20.01	Preconception care represents high risk care for women with Chronic Illness.	0	0	1	0	0	1	0	3	4	8	1.2
7.20.02	Women with Chronic Illness should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	1	0	0	1	0	3	4	8	1.2
7.21.01	Preconception care represents high risk care for women with Prescription Medication Abuse.	0	0	1	0	1	0	1	3	3	8	1.3
7.21.02	Women with Prescription Medication Abuse should have a documented visit with an appropriate clinician 9 to 21 months prior to their delivery.	0	0	1	0	1	0	1	3	3	8	1.3
7.22.01	Women with an identifiable high risk condition and who are of reproductive age should receive preconception counseling by an appropriate clinician yearly as part of HROB services.	0	0	0	0	0	0	2	3	4	8	0.7



## Chapter 8

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
8.01.01	A woman who gets pregnant while taking FDA Category A medication is evidence of insufficient availability of preconception high risk obstetric care.	8	1	0	0	0	0	0	0	0	1	0.1
8.01.02	A woman who completes her first trimester while still on FDA Category A medication is evidence of a insufficient availability of high risk obstetric care.	8	1	0	0	0	0	0	0	0	1	0.1
8.01.03	A pregnant woman who fills a prescription for FDA Category A medication is evidence of insufficient availability of high risk obstetric care.	8	1	0	0	0	0	0	0	0	1	0.1
8.02.01	A woman who gets pregnant while taking FDA Category B medication is evidence of insufficient availability of preconception high risk obstetric care.	7	2	0	0	0	0	0	0	0	1	0.2
8.02.02	A woman who completes her first trimester while still on FDA Category B medication is evidence of a insufficient availability of high risk obstetric care.	7	2	0	0	0	0	0	0	0	1	0.2
8.02.03	A pregnant woman who fills a prescription for FDA Category B medication is evidence of insufficient availability of high risk obstetric care.	7	2	0	0	0	0	0	0	0	1	0.2
8.03.01	A woman who gets pregnant while taking FDA Category C medication is evidence of insufficient availability of preconception high risk obstetric care.	6	1	2	0	0	0	0	0	0	1	0.6

		1	2	3	4	5	6	7	8	9		
8.03.02	A woman who completes her first trimester while still on FDA Category C medication is evidence of a insufficient availability of high risk obstetric care.	6	1	2	0	0	0	0	0	0	1	0.6
		1	2	3	4	5	6	7	8	9		
8.03.03	A pregnant woman who fills a prescription for FDA Category C medication is evidence of insufficient availability of high risk obstetric care.	6	1	2	0	0	0	0	0	0	1	0.6
		1	2	3	4	5	6	7	8	9		
8.04.01	A woman who gets pregnant while taking FDA Category D medication is evidence of insufficient availability of preconception high risk obstetric care.	5	1	0	1	1	0	0	0	1	1	1.8
		1	2	3	4	5	6	7	8	9		
8.04.02	A woman who completes her first trimester while still on FDA Category D medication is evidence of a insufficient availability of high risk obstetric care.	4	1	0	1	1	0	1	0	1	2	2.3
		1	2	3	4	5	6	7	8	9		
8.04.03	A pregnant woman who fills a prescription for FDA Category D medication is evidence of insufficient availability of high risk obstetric care.	4	1	0	1	1	0	1	0	1	2	2.3
		1	2	3	4	5	6	7	8	9		
8.05.01	A woman who gets pregnant while taking FDA Category X medication is evidence of insufficient availability of preconception high risk obstetric care.	1	0	0	0	1	1	1	0	5	9	1.9
		1	2	3	4	5	6	7	8	9		
8.05.02	A woman who completes her first trimester while still on FDA Category X medication is evidence of a insufficient availability of high risk obstetric care.	0	0	0	0	0	0	1	3	5	9	0.6

		1	2	3	4	5	6	7	8	9		
8.05.03	A pregnant woman who fills a prescription for FDA Category X medication is evidence of insufficient availability of high risk obstetric care.	0	0	0	0	0	0	1	2	6	9	0.4
		1	2	3	4	5	6	7	8	9		
8.06.01	A woman who gets pregnant while using tobacco is evidence of insufficient availability of preconception high risk obstetric care.	5	2	0	0	1	1	0	0	0	1	1.2
		1	2	3	4	5	6	7	8	9		
8.06.02	A woman who completes her first trimester while still using tobacco is evidence of a insufficient availability of high risk obstetric care.	4	2	0	0	2	1	0	0	0	2	1.6
		1	2	3	4	5	6	7	8	9		
8.07.01	A woman who gets pregnant while drinking alcohol is evidence of insufficient availability of preconception high risk obstetric care.	6	1	0	0	1	1	0	0	0	1	1.1
		1	2	3	4	5	6	7	8	9		
8.07.02	A woman who completes her first trimester while still drinking alcohol is evidence of a insufficient availability of high risk obstetric care.	4	2	0	0	2	1	0	0	0	2	1.6
		1	2	3	4	5	6	7	8	9		
8.08.01	A woman who gets pregnant while using cocaine is evidence of insufficient availability of preconception high risk obstetric care.	5	2	0	0	1	1	0	0	0	1	1.2
		1	2	3	4	5	6	7	8	9		
8.08.02	A woman who completes her first trimester while still using cocaine is evidence of a insufficient availability of high risk obstetric care.	4	2	0	0	2	1	0	0	0	2	1.6

		1	2	3	4	5	6	7	8	9		
8.09.01	A woman who gets pregnant while taking taking opioids [i.e. hydrocodone (Vicodin), oxycodone (OxyContin), Oxymorphone (Opana), Propoxyphene (Darvon), Hydromorphone (Dilaudid), Meperidine (Demerol), Diphenoxylate (Lotomil)] is evidence of insufficient availability of preconception high risk obstetric care.	5	1	0	0	1	2	0	0	0	1	1.7
		1	2	3	4	5	6	7	8	9		
8.09.02	A woman who completes her first trimester while still taking opioids is evidence of a insufficient availability of high risk obstetric care.	5	1	0	0	1	2	0	0	0	1	1.7
		1	2	3	4	5	6	7	8	9		
8.09.03	A pregnant woman who fills a prescription for opioids is evidence of insufficient availability of high risk obstetric care.	5	1	0	0	1	2	0	0	0	1	1.7
		1	2	3	4	5	6	7	8	9		
8.10.01	A woman who gets pregnant while taking Central Nervous System Depressants [i.e. Pentobarbital sodium (Nembutal), Diazepam (Valium), Alprazolam (Xanax)] is evidence of insufficient availability of preconception high risk obstetric care.	5	1	0	0	1	1	1	0	0	1	1.8
		1	2	3	4	5	6	7	8	9		
8.10.02	A woman who completes her first trimester while still taking Central Nervous System Depressants is evidence of a insufficient availability of high risk obstetric care.	5	0	0	0	2	1	1	0	0	1	2.1
		1	2	3	4	5	6	7	8	9		
8.10.03	A pregnant woman who fills a prescription for Central Nervous System Depressants is evidence of insufficient availability of high risk obstetric care.	4	0	0	1	1	1	1	1	0	4	2.4

		1	2	3	4	5	6	7	8	9		
8.11.01	A woman who gets pregnant while taking stimulants [i.e. Dextroamphetamine (Dexedrine), Methylphenidate (Ritalin and Concerta), Amphetamines (Adderall)] is evidence of insufficient availability of preconception high risk obstetric care.	5	0	0	0	2	1	1	0	0	1	2.1
		1	2	3	4	5	6	7	8	9		
8.11.02	A woman who completes her first trimester while still taking stimulants is evidence of a insufficient availability of high risk obstetric care.	4	1	0	0	1	1	1	1	0	2	2.4
		1	2	3	4	5	6	7	8	9		
8.11.03	A pregnant woman who fills a prescription for stimulants is evidence of insufficient availability of high risk obstetric care.	4	0	0	1	1	1	1	0	1	4	2.6
		1	2	3	4	5	6	7	8	9		
8.12.01	A woman who gets pregnant while taking warfarin (excluding mechanical valves) is evidence of insufficient availability of preconception high risk obstetric care.	2	0	0	0	1	1	1	3	1	7	2.2
		1	2	3	4	5	6	7	8	9		
8.12.02	A woman who completes her first trimester while still taking warfarin (excluding mechanical valves) is evidence of a insufficient availability of high risk obstetric care.	1	0	0	0	0	2	1	2	3	8	1.7
		1	2	3	4	5	6	7	8	9		
8.12.03	A pregnant woman who fills a prescription for warfarin (excluding mechanical valves) is evidence of insufficient availability of high risk obstetric care.	0	0	0	0	1	1	2	2	3	8	1.1
		1	2	3	4	5	6	7	8	9		
8.13.01	A woman who gets pregnant while taking valproic acid is evidence of insufficient availability of preconception high risk obstetric care.	1	0	2	0	0	1	3	1	1	7	2.0

		1	2	3	4	5	6	7	8	9		
8.13.02	A woman who completes her first trimester while still taking valproic acid is evidence of a insufficient availability of high risk obstetric care.	1	0	1	1	0	0	3	2	1	7	1.9
		1	2	3	4	5	6	7	8	9		
8.13.03	A pregnant woman who fills a prescription for valproic acid is evidence of insufficient availability of high risk obstetric care.	1	0	1	0	1	0	2	2	2	7	2.0
		1	2	3	4	5	6	7	8	9		
8.14.01	A woman who gets pregnant while taking lithium is evidence of insufficient availability of preconception high risk obstetric care.	1	1	0	0	1	1	4	1	0	7	1.7
		1	2	3	4	5	6	7	8	9		
8.14.02	A woman who completes her first trimester while still taking lithium is evidence of a insufficient availability of high risk obstetric care.	1	0	0	0	1	1	4	2	0	7	1.2
		1	2	3	4	5	6	7	8	9		
8.14.03	A pregnant woman who fills a prescription for lithium is evidence of insufficient availability of high risk obstetric care.	1	0	0	0	1	1	4	2	0	7	1.2
		1	2	3	4	5	6	7	8	9		
8.15.01	A woman who gets pregnant while taking phenytoin is evidence of insufficient availability of preconception high risk obstetric care.	2	2	0	0	0	2	2	0	1	6	2.6
		1	2	3	4	5	6	7	8	9		
8.15.02	A woman who completes her first trimester while still on phenytoin is evidence of a insufficient availability of high risk obstetric care.	1	1	0	0	2	1	2	1	1	6	2.0
		1	2	3	4	5	6	7	8	9		
8.15.03	A pregnant woman who fills a prescription for phenytoin is evidence of insufficient availability of high risk obstetric care.	1	1	0	0	1	1	3	1	1	7	1.9

		1	2	3	4	5	6	7	8	9		
8.16.01	A woman who gets pregnant while taking tretinoin is evidence of insufficient availability of preconception high risk obstetric care.	0	1	0	0	0	1	1	2	4	8	1.4
		1	2	3	4	5	6	7	8	9		
8.16.02	A woman who completes her first trimester while still on tretinoin is evidence of a insufficient availability of high risk obstetric care.	0	1	0	0	0	0	2	2	4	8	1.3
		1	2	3	4	5	6	7	8	9		
8.16.03	A pregnant woman who fills a prescription for tretinoin is evidence of insufficient availability of high risk obstetric care.	0	0	0	0	0	0	1	4	4	8	0.6
		1	2	3	4	5	6	7	8	9		
8.17.01	A woman who gets pregnant while using marijuana is evidence of insufficient availability of preconception high risk obstetric care.	5	1	1	0	1	1	0	0	0	1	1.3
		1	2	3	4	5	6	7	8	9		
8.17.02	A woman who completes her first trimester while still using marijuana is evidence of a insufficient availability of high risk obstetric care.	4	2	1	0	1	1	0	0	0	2	1.3
		1	2	3	4	5	6	7	8	9		
8.17.03	A pregnant woman who fills a prescription for marijuana is evidence of insufficient availability of high risk obstetric care.	3	2	1	0	2	1	0	0	0	2	1.6
		1	2	3	4	5	6	7	8	9		
8.18.01	A woman who gets pregnant while taking methadone is evidence of insufficient availability of preconception high risk obstetric care.	4	1	0	1	0	1	2	0	0	2	2.2
		1	2	3	4	5	6	7	8	9		
8.18.02	A woman who completes her first trimester while still on methadone is evidence of a insufficient availability of high risk obstetric care.	4	1	0	1	0	0	2	1	0	2	2.4

		1	2	3	4	5	6	7	8	9		
8.18.03	A pregnant woman who fills a prescription for methadone is evidence of insufficient availability of high risk obstetric care.	4	1	0	1	0	0	2	1	0	2	2.4
		1	2	3	4	5	6	7	8	9		
8.19.01	A woman who gets pregnant while using heroin is evidence of insufficient availability of preconception high risk obstetric care.	5	1	0	0	0	2	1	0	0	1	1.9
		1	2	3	4	5	6	7	8	9		
8.19.02	A woman who completes her first trimester while still on heroin is evidence of a insufficient availability of high risk obstetric care.	4	2	0	0	0	2	1	0	0	2	1.9
		1	2	3	4	5	6	7	8	9		
8.20.01	A woman who gets pregnant while taking thalidomide is evidence of insufficient availability of preconception high risk obstetric care.	0	1	0	0	0	1	1	2	4	8	1.4
		1	2	3	4	5	6	7	8	9		
8.20.02	A woman who completes her first trimester while still on thalidomide is evidence of a insufficient availability of high risk obstetric care.	0	0	0	0	1	0	2	1	5	9	1.0
		1	2	3	4	5	6	7	8	9		
8.20.03	A pregnant woman who fills a prescription for thalidomide is evidence of insufficient availability of high risk obstetric care.	0	0	0	0	0	0	1	3	5	9	0.6
		1	2	3	4	5	6	7	8	9		
8.20.04	HROB services represent a continuum of services that may be offered by a variety of clinicians including: primary care clinicians, obstetrical clinicians, high risk obstetrical clinicians, internists, anesthesiologists and others as required by the clinical circumstances.	0	0	0	0	0	0	0	0	9	9	0.0



		1	2	3	4	5	6	7	8	9		
8.20.05	HROB services represent a continuum of services that includes preconception care, antenatal care, labor and delivery, and post partum care.	0	0	0	0	0	0	0	0	9	9	0.0
8.20.06	HROB services represent a continuum of services that includes preventive, diagnostic and therapeutic care.	0	0	0	0	0	0	0	0	9	9	0.0
8.20.07	Preconception counseling is an essential component of HROB services for women with identifiable risk.	0	0	0	0	0	0	0	0	9	9	0.0

## Chapter 9

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
9.00.01	A second delivery within 9 months of a previous delivery suggests insufficient availability of high risk obstetric care.	2	0	1	0	2	1	3	0	0	5	1.9
9.00.02	A second delivery within 12 months of a previous delivery suggests insufficient availability of high risk obstetric care.	3	0	2	0	1	0	3	0	0	3	2.2
9.00.03	A second delivery within 15 months of a previous delivery suggests insufficient availability of high risk obstetric care.	5	0	1	0	1	1	1	0	0	1	1.9
9.00.04	A second delivery within 18 months of a previous delivery suggests insufficient availability of high risk obstetric care.	6	1	1	0	1	0	0	0	0	1	0.8
9.00.05	A second delivery within 21 months of a previous delivery suggests insufficient availability of high risk obstetric care.	7	0	1	0	1	0	0	0	0	1	0.7
9.00.06	A hemoglobin A1c greater than 12% in the first trimester indicates insufficient availability of high risk preconception obstetric care.	0	0	0	0	0	1	1	5	2	8	0.6
9.00.07	A hemoglobin A1c greater than 11% in the first trimester indicates insufficient availability of high risk preconception obstetric care.	0	0	0	0	0	1	1	6	1	8	0.4
9.00.08	A hemoglobin A1c greater than 10% in the first trimester indicates insufficient availability of high risk preconception obstetric care.	0	0	0	0	0	1	1	6	1	8	0.4

		1	2	3	4	5	6	7	8	9		
9.00.09	A hemoglobin A1c greater than 9% in the first trimester indicates insufficient availability of high risk preconception obstetric care.	0	0	0	0	0	1	1	6	1	8	0.4
9.00.10	A hemoglobin A1c greater than 8.5% in the first trimester indicates insufficient availability of high risk preconception obstetric care.	0	0	0	0	0	3	2	3	1	7	0.9
9.00.11	A hemoglobin A1c greater than 8% in the first trimester indicates insufficient availability of high risk preconception obstetric care.	0	0	0	0	2	2	2	2	1	7	1.1
9.00.12	A hemoglobin A1c greater than 7.5% in the first trimester indicates insufficient availability of high risk preconception obstetric care.	0	0	1	1	5	1	0	0	1	5	0.9

## Chapter 10A

#	Scenario		Frequency									Median	Variation
			1	2	3	4	5	6	7	8	9		
10.00.01	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available immediately	Phone	0	0	0	0	0	1	0	3	5	9	0.7
10.00.01	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available immediately	E-mail	4	0	2	1	0	0	0	0	2	3	2.3
10.00.01	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available immediately	Telemed	1	0	1	0	0	0	3	2	2	7	1.8
10.00.01	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available immediately	In Person	1	0	0	0	0	1	4	0	3	7	1.4
10.00.02	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 2 hours	Telemed	0	0	1	0	0	0	2	3	3	8	1.1
10.00.02	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 2 hours	Phone	0	0	0	0	0	1	0	2	6	9	0.6
10.00.02	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 2 hours	E-mail	3	0	2	1	0	0	0	1	2	3	2.7
10.00.02	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 2 hours	In Person	1	0	0	0	0	0	2	2	4	8	1.4

			1	2	3	4	5	6	7	8	9		
10.00.03	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 24 hours	E-mail	2	0	2	1	0	1	0	0	3	4	2.8
10.00.03	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 24 hours	In Person	1	0	0	0	0	0	2	0	6	9	1.3
10.00.03	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 24 hours	Telemed	0	0	1	0	0	0	1	2	5	9	1.1
10.00.03	When a primary OB provider perceives a need for an urgent inpatient MFM consult, it should be available within 24 hours	Phone	0	0	0	0	0	1	0	1	7	9	0.4
10.00.04	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available immediately	E-mail	3	0	2	1	1	2	0	0	0	3	1.7
10.00.04	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available immediately	Phone	1	0	1	1	0	1	0	0	5	9	2.4
10.00.04	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available immediately	In Person	2	0	1	1	0	2	3	0	0	6	2.0
10.00.04	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available immediately	Telemed	2	0	1	1	1	2	2	0	0	5	1.9
10.00.05	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 hours	In Person	1	0	1	0	0	1	5	1	0	7	1.3

			1	2	3	4	5	6	7	8	9		
10.00.05	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 hours	Telemed	1	0	1	0	1	1	4	1	0	7	1.6
			1	2	3	4	5	6	7	8	9		
10.00.05	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 hours	Phone	0	0	1	0	0	1	3	0	4	7	1.4
			1	2	3	4	5	6	7	8	9		
10.00.05	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 hours	E-mail	2	0	3	0	2	0	2	0	0	3	1.8
			1	2	3	4	5	6	7	8	9		
10.00.06	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 24 hours	E-mail	1	0	2	1	0	1	3	0	1	6	2.1
			1	2	3	4	5	6	7	8	9		
10.00.06	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 24 hours	In Person	0	0	0	0	0	2	2	2	3	8	1.0
			1	2	3	4	5	6	7	8	9		
10.00.06	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 24 hours	Telemed	0	0	1	0	0	1	3	1	3	7	1.3
			1	2	3	4	5	6	7	8	9		
10.00.06	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 24 hours	Phone	1	0	0	0	0	2	1	0	5	9	1.8
			1	2	3	4	5	6	7	8	9		
10.00.07	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 48 hours	E-mail	1	0	1	1	0	1	1	1	3	7	2.3
			1	2	3	4	5	6	7	8	9		
10.00.07	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 48 hours	Phone	1	0	0	1	0	0	1	1	5	9	1.8

			1	2	3	4	5	6	7	8	9		
10.00.07	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 48 hours	In Person	0	0	0	1	0	0	1	3	4	8	1.0
			1	2	3	4	5	6	7	8	9		
10.00.07	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 48 hours	Telemed	0	0	1	1	0	0	1	2	4	8	1.6
			1	2	3	4	5	6	7	8	9		
10.00.08	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 1 week	E-mail	1	0	1	1	0	0	1	0	5	9	2.3
			1	2	3	4	5	6	7	8	9		
10.00.08	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 1 week	In Person	0	0	0	1	0	0	1	1	6	9	0.9
			1	2	3	4	5	6	7	8	9		
10.00.08	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 1 week	Telemed	0	0	1	1	0	0	1	1	5	9	1.6
			1	2	3	4	5	6	7	8	9		
10.00.08	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 1 week	Phone	1	0	0	1	0	0	1	0	6	9	1.7
			1	2	3	4	5	6	7	8	9		
10.00.09	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 weeks	E-mail	1	0	1	1	0	0	1	0	5	9	2.3
			1	2	3	4	5	6	7	8	9		
10.00.09	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 weeks	Phone	1	0	0	1	0	0	1	0	6	9	1.7
			1	2	3	4	5	6	7	8	9		
10.00.09	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 weeks	Telemed	0	0	1	1	0	0	1	1	5	9	1.6

		1	2	3	4	5	6	7	8	9			
10.00.09	When a primary OB provider perceives a need for an urgent outpatient MFM consult, it should be available within 2 weeks	In Person	0	0	0	1	0	0	1	1	6	9	0.9



## Chapter 10B

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
10.00.10	When a primary OB provider perceives a need for a non urgent outpatient MFM consult, it should be available immediately.	1	2	3	0	2	0	0	0	1	3	1.6
10.00.11	When a primary OB provider perceives a need for a non urgent outpatient MFM consult, it should be available within 2 hrs	1	2	1	2	3	0	0	0	0	4	1.2
10.00.12	When a primary OB provider perceives a need for a non urgent outpatient MFM consult, it should be available within 24 hrs	0	1	1	2	3	1	0	1	0	5	1.2
10.00.13	When a primary OB provider perceives a need for a non urgent outpatient MFM consult, it should be available within 48 hrs	0	0	0	1	4	1	1	2	0	5	1.1
10.00.14	When a primary OB provider perceives a need for a non urgent outpatient MFM consult, it should be available within 1 week	0	0	0	0	0	1	3	3	2	8	0.8
10.00.15	When a primary OB provider perceives a need for a non urgent outpatient MFM consult, it should be available within 2 weeks	0	0	0	0	0	0	0	4	5	9	0.4

## Chapter 11

#	Scenario	Frequency									Median	Variation
		1	2	3	4	5	6	7	8	9		
11.00.01	Availability may appropriately be described by time to new appointment	0	0	0	0	0	0	2	3	4	8	0.7
11.00.02	Availability may appropriately be described by time for follow up appointment	0	1	0	2	0	0	3	2	1	7	1.7
11.00.03	Availability may appropriately be described by distance/time to travel to see an MFM	0	0	1	0	1	0	2	4	1	8	1.2
11.00.04	Availability may appropriately be described by distance/time to see a medical/surgical specialist	0	0	1	0	1	0	2	4	1	8	1.2
11.00.05	Availability may appropriately be described by local transportation systems	0	0	0	1	2	1	2	3	0	7	1.2
11.00.06	Availability may appropriately be described by sufficiency of transportation from one community to another with more dense medical resources	0	0	0	0	1	1	3	4	0	7	0.8
11.00.07	Availability may appropriately be described by sufficiency of transportation from their home community to a regional perinatal center	0	0	0	0	0	2	3	3	1	7	0.8
11.00.08	Availability may appropriately be described by sufficiency of support for residential stay when travel is required	0	0	1	0	1	0	4	1	2	7	1.2

	1	2	3	4	5	6	7	8	9		
11.00.09 When providing HROB services from a distance, coordination of scheduling between consultants (e.g. such as MFM and Med specialist) is an essential component of available HROB services.	0	0	0	0	0	1	1	1	6	9	0.7

## ***Appendix E***

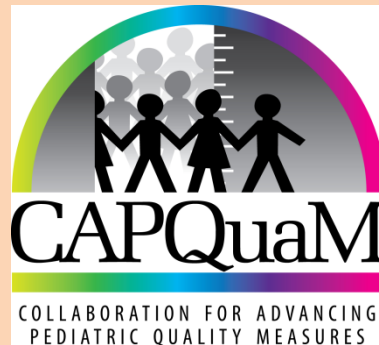
*Pediatric Academic Society*

*State of the Science Presentation*

May 2012 (given by Dr. Larry Kleinman)

# Applying Evidence Standards in an Uncertain World

Considering uncertainty when  
developing measures in the PQMP



Lawrence C. Kleinman, MD, MPH, FAAP  
PI, Mount Sinai CAPQuaM  
PAS State of the Science  
May, 2012

# Rock n Roll

[http://www.youtube.com/watch?feature=player\\_detailpage&v=QXgMhnl3QOI#t=71s](http://www.youtube.com/watch?feature=player_detailpage&v=QXgMhnl3QOI#t=71s)

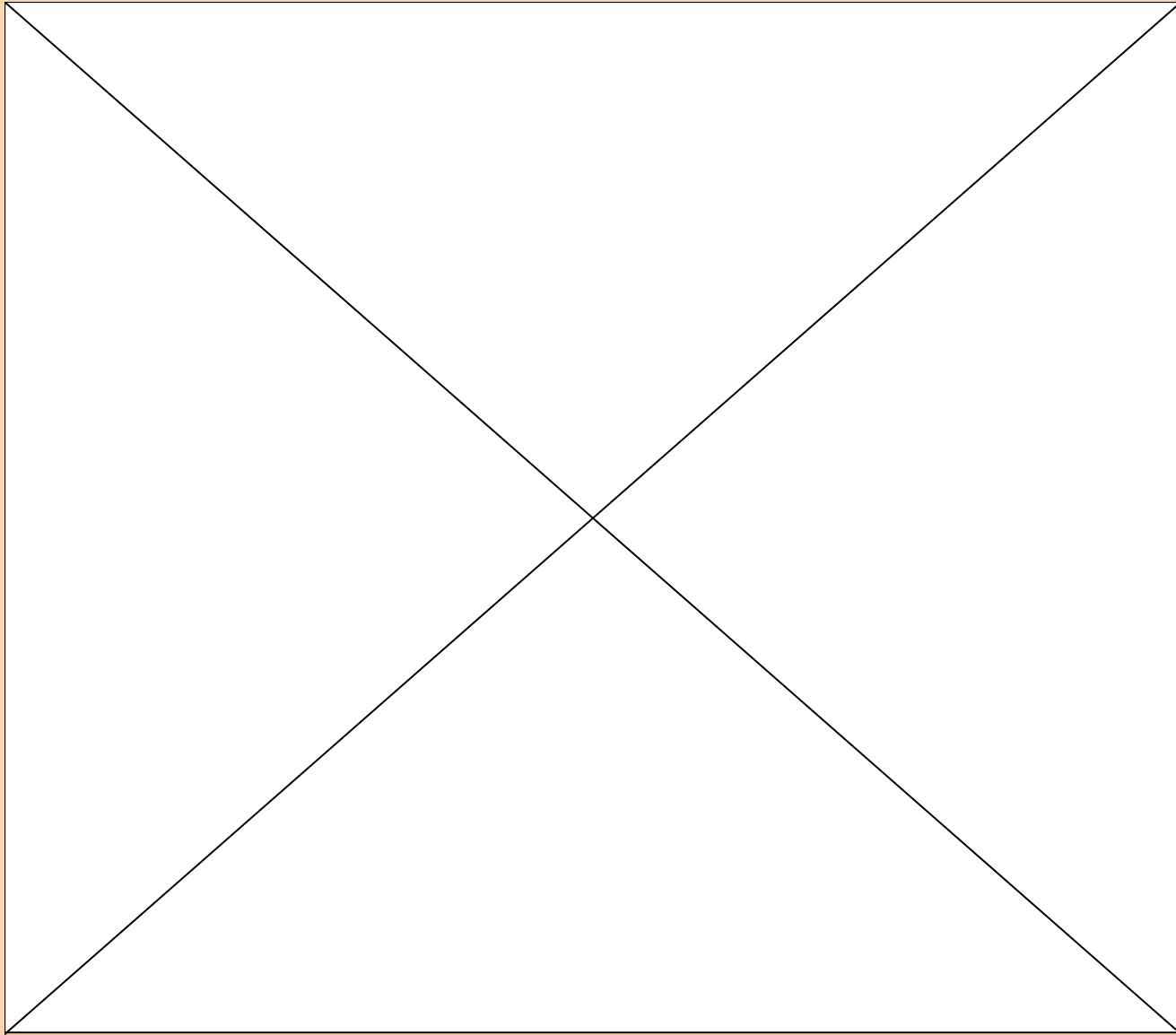
This ain't no Party, this ain't no Disco,  
This ain't no fooling around;  
No time for Dancing, or Lovey Dovey,  
I ain't got time for that now  
Transmit the message to the receiver;  
Hope for an answer some day...

# Sources of uncertainty abound...

- The science is constantly evolving;
- Evidence in the literature is challenging to apply to a specific patient:
  - e.g., Inclusion and exclusion criteria limit generalizability of trials
- Real world outcomes vary from research trial outcomes.
- Science reduces uncertainty, doesn't eliminate it

# The Challenge of Evidence

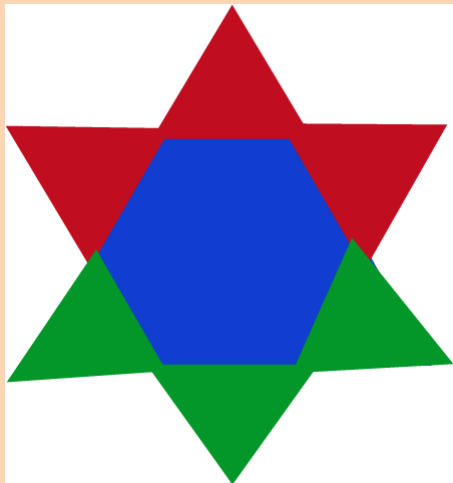
[http://www.youtube.com/watch?v=Dn1eT55sD6o&feature=player\\_embedded](http://www.youtube.com/watch?v=Dn1eT55sD6o&feature=player_embedded)



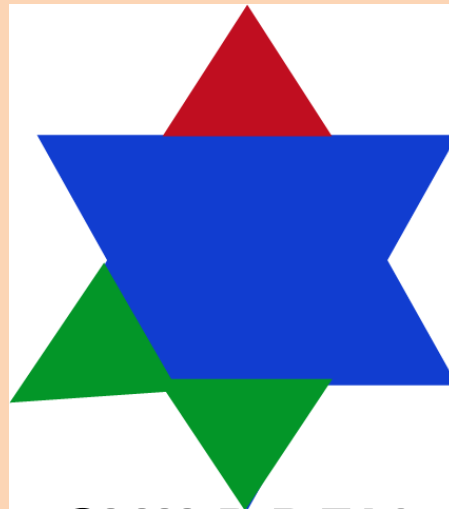


# Uncertainty Index (UNI)

- Proportion of **care** that has not been shown to be **ineffective** and that we aren't sure is **effective**
- Children's health care is under researched compared to adults and thus  $\uparrow$  UNI
  - In general  $\downarrow$  Research  $\rightarrow$   $\uparrow$  UNI



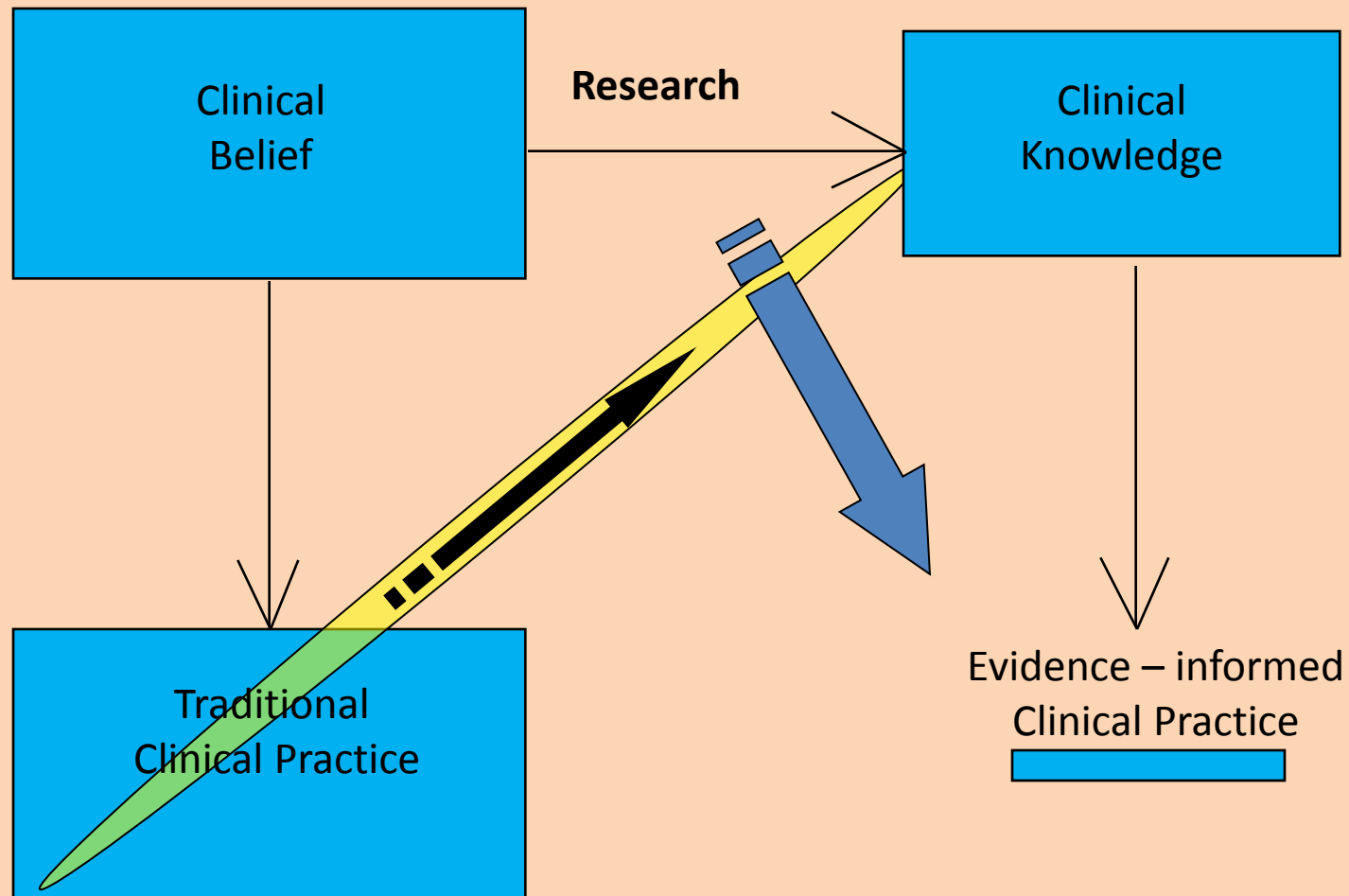
**ADULTS**



**CHILDREN**

$$\text{UNI} = \frac{\text{Blue}}{\text{Blue} + \text{Green}}$$

# Evidence is particularly limited when it comes to pediatric care



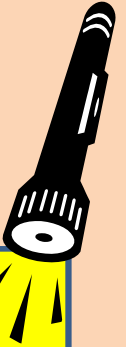
We are looking for measures that represent the keys to high quality care



# One need for PQMP Innovation

- Develop and enhance methods that can produce meaningful measures even when the science does not reduce uncertainty enough to eliminate all important disagreements

# Spectrum of Clinical Practice



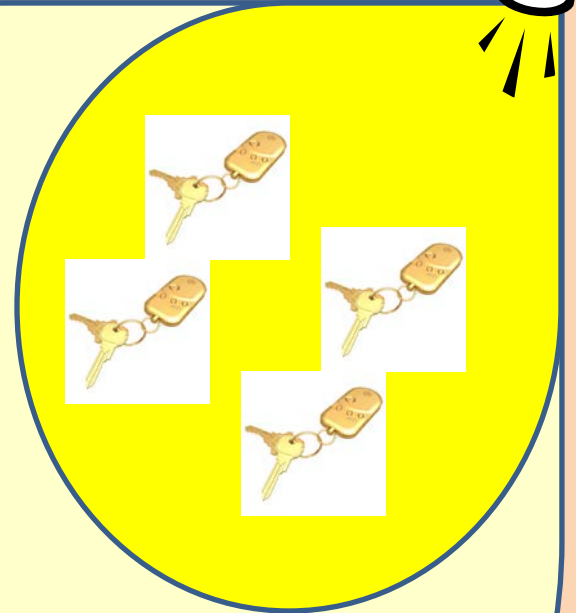
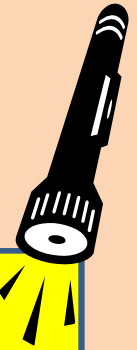
Very Limited or  
No Evidence

Some evidence

Strong  
Evidence



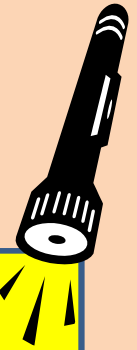
# Current State of QM



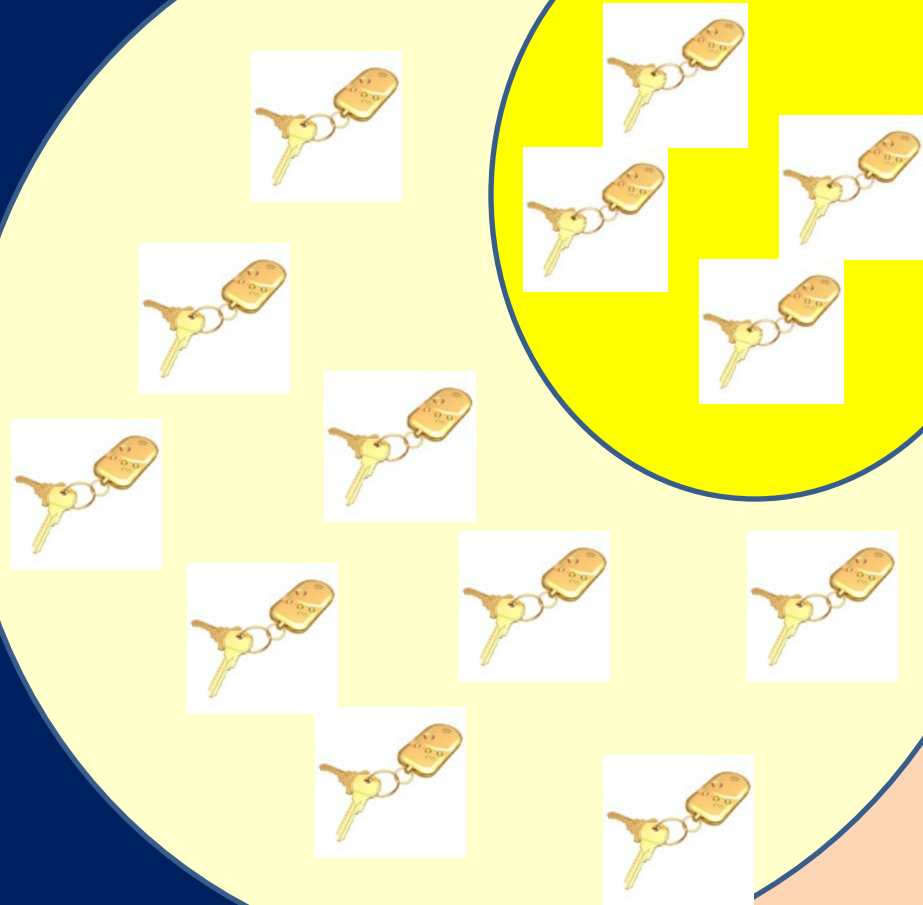
Very Limited or  
No Evidence

Some evidence

# CAPQuaM Vision



Very Limited or  
No Evidence



# Definition: High Risk Obstetrical Services

How do we identify the target population?

- By conditions present in the woman?
- By clinical services required?
- By the clinicians providing the services?



# Definition: Availability\*

- Geographic: Density and Distance
  - Accepts Medicaid?
- Timeliness:
  - Delays for appointments?
- Process availability
  - Barriers to care?

\*(AHRQ commissioned paper: Kuhlthau; 2010)

# Construct of Availability

- Derived from Aday, Andersen, et al, 1974
- Availability necessary for accessibility
- Often necessary to measure availability indirectly by measuring access

# CHIPRA Availability Measure

- Measure should capture impact of health care system on availability
- Differences in access reflect both system and individual contributions
- CHIPRA measure should capture differences across health care systems that reflect system contributions/differences

# What is Availability

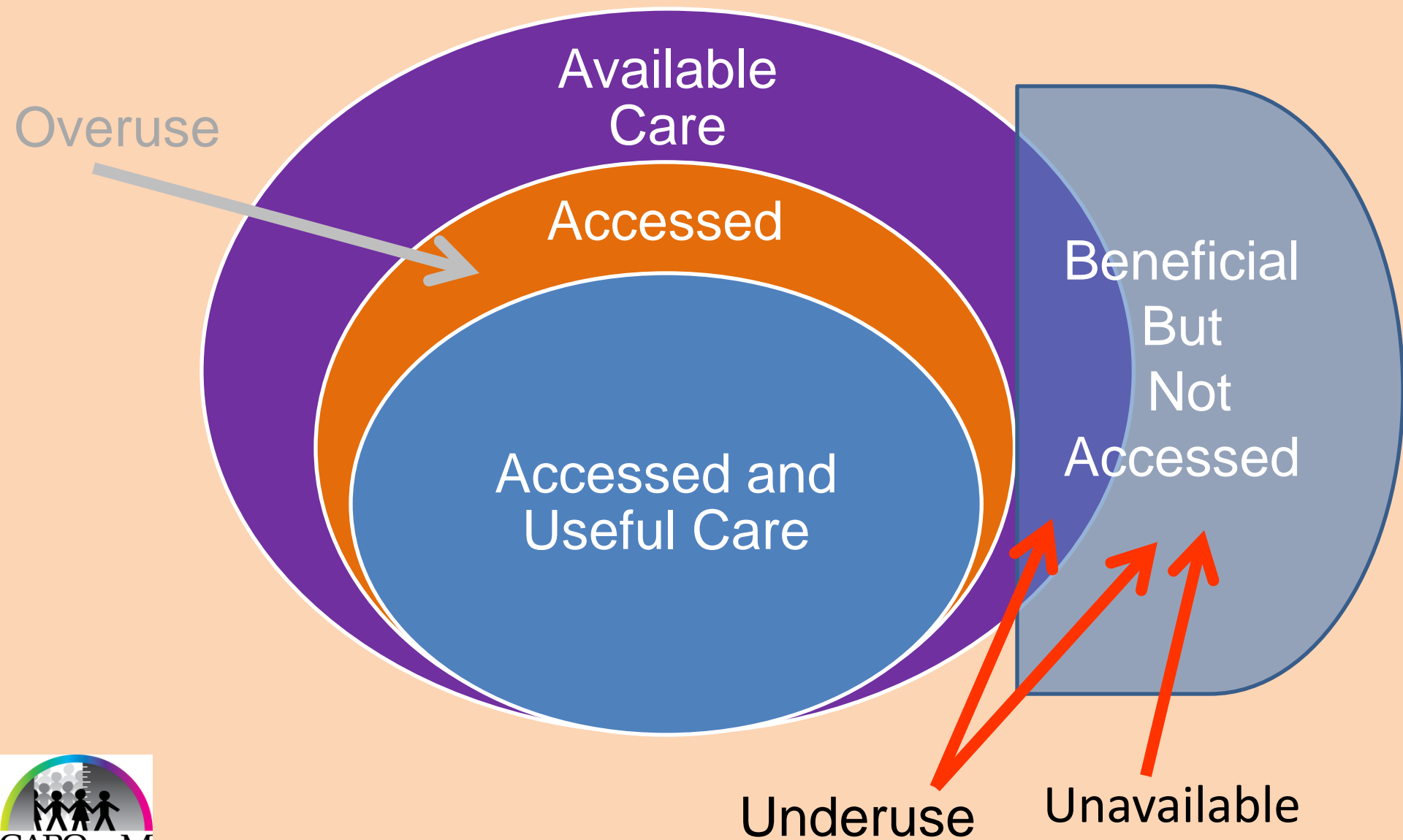
- System's contribution to *potential* access\*
- Contrast to utilization, which is a measure of *realized* access
  - Both system and individual contributions
- High levels of utilization are evidence of availability
- Underutilization (or over-utilization of rescue services) may indicate care not available

\*Andersen RM, et al 1974  
Aday & Andersen, 1983

# Measuring Availability

- Lack of availability may be measured directly or indirectly
- Sufficient availability typically measured indirectly through access/utilization measures

# Measure: Availability of HROB Care



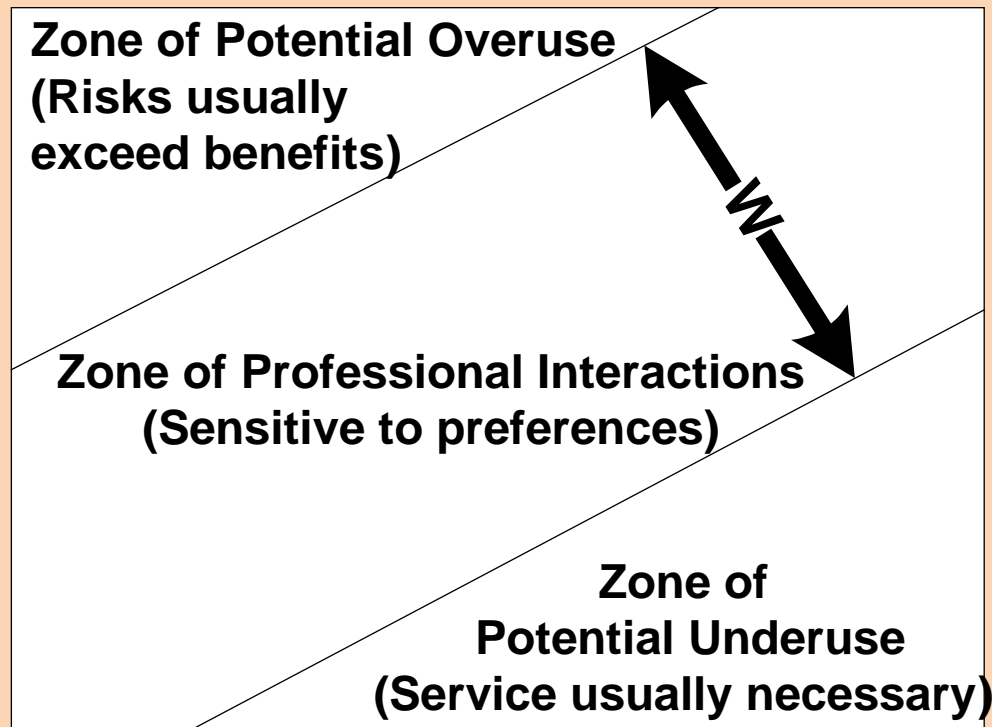
# Our Approach

- Build Coalition of Strong Institutional Partners
  - Accreditors (TJC, NCQA)
  - Clinicians (AAP, AAFP, ACOG)
  - Consumers (Consumer Reports, IPFCC, NAMI)
  - Insurers
- Offered things of opposing value(s)
  - Overuse on the one hand
  - Validation of clinical process on the other

# Explicitly incorporate uncertainty

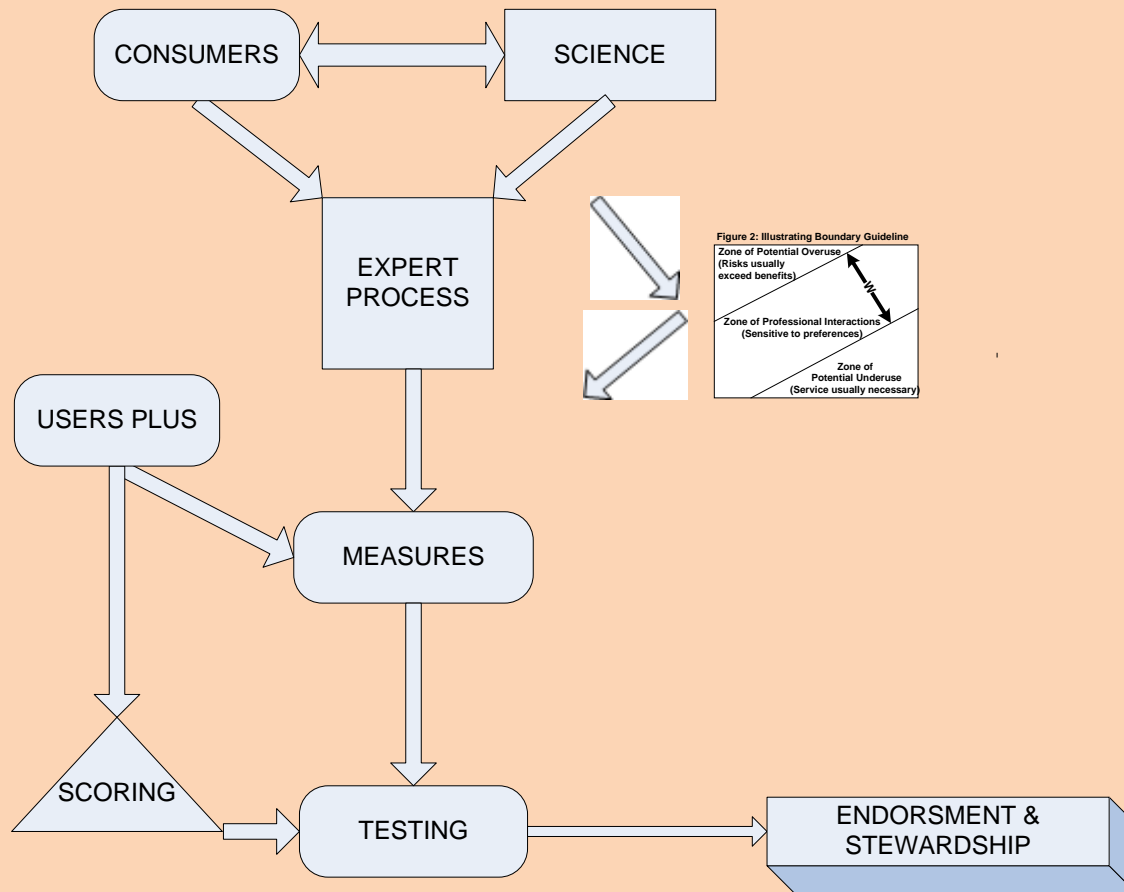
- Example: CAPQuaM's Boundary Guideline
- Incorporates evidence and uncertainty

Figure 2: Illustrating Boundary Guideline





# Develop Consensus around the Process, not the Measure



# Engagement

- Consumer Stakeholders
  - Share their beliefs, priorities, values based upon relevant experiences (CFLR is novel)
- Clinician Stakeholders
  - Share their beliefs priorities, values and relevant experiences
  - Staff expert panels to develop criteria to support boundary guideline
- Organizational Stakeholders
  - Assist with specification of measures
  - Plan for interpretation of measures

# Assigned Measures, Phase 1

- Availability of High Risk Ob Care
- Inpatient Perinatal
  - Temperature on admission to NICU
- ER Visits for Asthma
  - As an indicator of chronic asthma care
  - As an indicator of adequacy of primary care

# Highly engaged and engineered approach

- Expert process, informed by science and stakeholders
- Anticipate that structured integration of literature, judgment, and engagement will be sufficient to meet evidence standards for federal endorsement

Evidence: What do you see?



## *Appendix F*

### *HROB Questionnaire*



COLLABORATION FOR ADVANCING  
PEDIATRIC QUALITY MEASURES

**CAPQuaM Demonstration Survey**  
**Structural Attributes Important for**  
**High Risk Obstetrical Services**

**Please answer each of the following questions regarding your health care facility. If your institution has more than one campus, please answer a separate questionnaire for each site at which deliveries of newborns occur.**

**Your name** \_\_\_\_\_

**Title** \_\_\_\_\_

**Contact Information (phone, email):**

**Hospital, Health System, or Facility Name** \_\_\_\_\_

**Address** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Chief Medical Officer (or equivalent) Name** \_\_\_\_\_

**Contact Information (phone, email):**



Please answer the following four questions for your facility.

**1. Does this facility always have 24/7 in-house dedicated coverage of the obstetrical service by a physician capable of safely managing labor and delivery and performing a cesarean section, including an emergent cesarean section?**

- a) Yes
- b) No
- c) Unsure
- d) Refuse

**2. Does this facility always have 24/7 in-house coverage dedicated to the obstetrical service by an anesthesiologist who is qualified to provide obstetrical anesthesia?**

- a) Yes
- b) No
- c) Unsure
- d) Refuse

**3. Does this facility provide 24/7 on-site blood banking services/transfusions services that are always available for obstetrical patients? By 24/7 blood banking/transfusion services we mean that the following are always available to obstetrical patients: testing of blood group and Rh Type; cross-matching; antibody testing; transfusion with on site and available blood, either ABO specific or 0-Rh-negative; transfusion with fresh frozen plasma; and transfusion with cryoprecipitate.**

- a) Yes
- b) No
- c) Unsure or unable to answer
- d) Refuse

**4. Does your hospital offer level 3 or higher NICU services according to either American Academy of Pediatrics (AAP) criteria or other explicit criteria recognized by your state Department of Health? In general, a unit is not Level 3 unless there is 24/7 coverage by a neonatologist and the unit routinely cares for infants sustained on ventilators for days or longer. For your reference, detailed specifications of the AAP criteria for levels of neonatal care are shown below.**

- a) Yes
- b) No
- c) Unsure or unable to answer
- d) Refuse

**TABLE 1** Definitions, Capabilities, and Provider Types: Neonatal Levels of Care

Level of Care	Capabilities	Provider Types <sup>a</sup>
<b>Level I</b> Well newborn nursery	<ul style="list-style-type: none"> <li>• Provide neonatal resuscitation at every delivery</li> <li>• Evaluate and provide postnatal care to stable term newborn infants</li> <li>• Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable</li> <li>• Stabilize newborn infants who are ill and those born at &lt;35 wk gestation until transfer to a higher level of care</li> </ul>	Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses
<b>Level II</b> Special care nursery	Level I capabilities plus: <ul style="list-style-type: none"> <li>• Provide care for infants born ≥32 wk gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis</li> <li>• Provide care for infants convalescing after intensive care</li> <li>• Provide mechanical ventilation for brief duration (&lt;24 h) or continuous positive airway pressure or both</li> <li>• Stabilize infants born before 32 wk gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility</li> </ul>	Level I health care providers plus: Pediatric hospitalists, neonatologist, and neonatal nurse practitioners.
<b>Level III</b> NICU	Level II capabilities plus: <ul style="list-style-type: none"> <li>• Provide sustained life support</li> <li>• Provide comprehensive care for infants born &lt;32 wks gestation and weighing &lt;1500 g and infants born at all gestational ages and birth weights with critical illness</li> <li>• Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists</li> <li>• Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide</li> <li>• Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography</li> </ul>	Level II health care providers plus: Pediatric medical subspecialists <sup>b</sup> , pediatric anesthesiologists <sup>b</sup> , pediatric surgeons, and pediatric ophthalmologists <sup>b</sup> .
<b>Level IV</b> Regional NICU	Level III capabilities plus: <ul style="list-style-type: none"> <li>• Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions</li> <li>• Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site</li> <li>• Facilitate transport and provide outreach education</li> </ul>	Level III health care providers plus: Pediatric surgical subspecialists

<sup>a</sup> Includes all providers with relevant experience, training, and demonstrated competence.

<sup>b</sup> At the site or at a closely related institution by prearranged consultative agreement.

**Table is from the AAP Policy Statement, Levels of Neonatal Care, published in *Pediatrics*, 2012. 130:587-597.**

## ***Appendix G***

### ***New York State Perinatal Designation Matrix***

# Attachment 4 NYS Perinatal Designation Matrix

3/21/07

**Service/Capacity Issue Codes:**  
 N = Neonatal Criteria  
 M= Maternal Criteria  
 P= Perinatal Criteria (both N & P)

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
1. (N) Minimum NICU bed capacity	Does not apply.	Minimum of 10 NICU beds.	Minimum of 15 NICU beds.	Minimum of 25 NICU beds.	Standard in original designation survey.
2. (N) Minimum NICU volumes	None specified	Greater than 70 NICU discharges per year	Greater than 120 NICU discharges per year	Greater than 200 NICU discharges per year	Current NYS regs. 721.3
3. (N) Number of high-risk newborn patient days annually	Does not apply.	No fewer than 1,200 high-risk newborn patient days annually.	No fewer than 2,000 high-risk newborn patient days annually.	No fewer than 4,000 high-risk newborn patient days annually.	Current NYS regs. 721.3
4. (N) Case mix index for high-risk neonatal patients	Does not apply.	Greater than 1,5000	Greater than 2,0000	Greater than 4,3000	Standard in original designation survey. Data-driven based on 2005 CMI data. Reflects practice of hospitals within each level. Includes all but extreme outliers.
5. (N) Chief of Normal Nursery/NICU	None specified.	Full-time board-certified pediatrician with subspecialty certification in Neonatal Medicine or minimum-completed fellowship in neonatal medicine.	Full-time board-certified pediatrician with subspecialty certification in Neonatal Medicine.		Current NYS regs. 721.5

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
6. (N) Availability of neonatologists	Not required.	A neonatologist available on-site within 20 minutes, 24 hours a day.	Neonatologists with qualifications similar to those of the chief of their service readily available (within 20 minutes and in-house) for consultation 24 hours a day. Personnel in-house qualified to manage obstetric and neonatal emergencies.		Current NYS regs. 721.6
7. (N) Pediatric cardiac surgery	Does not apply.	Does not apply.	Pediatric cardiac surgery available in less than 4 hours after birth and 365 days/year.		Current NYS regs. 721.6
8. (M) Number of high-risk maternal patient days annually	Does not apply.	No fewer than 150 high-risk maternal patient days annually.	No fewer than 250 high-risk maternal patient days annually.	No fewer than 400 high-risk maternal patient days annually.	Current NYS regs. 721.3
9. (M) Case mix index for high risk maternal patients	Does not apply	Greater than 1.05	Greater than 1.10	Greater than 1.15	Standard in original designation survey. Data-driven based on 2005 CMI data. Reflects practice of hospitals within each level. Includes all but extreme outliers
10. (M) Chief of Obstetrics	None specified.	Board-certified obstetrician with special interest, experience, and expertise in maternal-fetal medicine.	Full-time board-certified obstetrician. Subspecialty maternal-fetal medicine certification recommended.	Full-time board-certified obstetrician with subspecialty certification in maternal-fetal medicine.	Current NYS regs. 721.5
11. (P) Chief of Obstetric Anesthesia Services	None specified.	Board-certified in anesthesia and have training and experience in obstetric anesthesia.	Board-certified in anesthesia with special training and experience in maternal-fetal anesthesia.		Current NYS regs. 721.6

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
12. (P) Number of births in the perinatal network	Does not apply.	Does not apply.	Does not apply.	At least 8,000 births.	Current NYS regs. 721.3
13. (P) Transfers and transport	A basic care hospital may receive back-transfers of high-risk newborns for continuing care after the problems that required neonatal intensive care have resolved.	A specialty care hospital may receive back-transfers of high-risk newborns for continuing care after the problems that required neonatal intensive care have resolved.	A subspecialty care hospital may receive high-risk maternal and newborn transfers from basic or specialty care hospitals or other subspecialty care hospitals.	<b>Demonstrates that they are receiving transports from affiliates of mothers/babies needing a higher level of care.</b>  <b>Coordinates, if not performs, all inter-hospital transports for high-risk mothers and newborns among its affiliates. Has the ability to initiate a transport within 30 minutes of receiving a call. Average transport time to each affiliate does not exceed 2 hours.</b>	Current NYS regs. 721.4
14. (P) Availability of laboratory facilities	The maternity and newborn service have immediate access to the hospital's laboratory services including a 24-hour capability to provide blood group, Rh type, cross-matching, antibody testing and basic emergency laboratory evaluations.  Either ABO Rh-specific or O-Rh-negative blood and fresh frozen plasma and cryoprecipitate available at the facility at all times. Such other procedures required by the maternity and newborn service are performed on a timely basis.				Current NYS regs. 721.8 AAP/ACOG Guidelines for Perinatal Care 5th Edition
			Micro-techniques available	Micro-techniques available	Standard in original designation survey.

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
15. (P) Availability and qualifications of other obstetricians and pediatricians	A physician or licensed midwife with appropriate training and expertise to attend all deliveries.	A physician or licensed midwife with appropriate training and expertise to attend all deliveries.  Care for high-risk pregnant women and neonates provided by appropriately qualified physicians. General pediatricians or obstetricians with expertise to assume responsibility for acute care for infants and women available within 20 minutes, 24 hours a day.	A physician or licensed midwife with appropriate training and expertise to attend all deliveries.  Other maternal-fetal medicine specialists and neonatologists with qualifications equivalent to those of the chief of their service or minimally will have successfully completed a fellowship in maternal fetal or neonatal medicine, whatever is appropriate. Maternal-fetal medicine specialist and neonatologist available on-site within 20 minutes 24 hours a day. Personnel in-house qualified to manage obstetric and neonatal emergencies.		Current NYS regs. 721.6
16. (P) Availability and qualifications of personnel for perinatal emergencies	The maternity and newborn service have available services for the identification of high-risk mothers and fetuses, anesthesia services available on a 24-hour basis, radiology and ultrasound examination.  An organized plan of action that includes personnel and equipment for identification and immediate resuscitation of newborns and mothers requiring cardiorespiratory assistance.	A physician or licensed midwife with appropriate training and expertise to attend all deliveries. At least one person capable of initiating neonatal resuscitation should be present at every delivery.			Current NYS regs. 405.21 c. General requirements 11 (ii)  405.21 e. Intrapartum services 4(v)  405.21 e. Intrapartum services 4 (v) a (4) / 721.6
	Personnel with credentials to administer obstetric anesthesia available on a 24-hour basis. 405.21 c.	Personnel with credentials to administer obstetric anesthesia shall be available for all deliveries.			Current NYS regs.
	None specified.	None specified.	Personnel with credentials in administration of neonatal and pediatric anesthesia available as needed.		721.6

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
	<p>Ultrasound machine available to labor and delivery. Radiologist or obstetrician skilled in interpretation of ultrasound scans available within a timeframe to meet the patient's needs.</p>	<p>Ultrasound machine available to labor and delivery. Radiologist, or obstetrician skilled in interpretation of ultrasound scans 24 hours a day within a timeframe to meet the patient's needs.</p>	<p>Ultrasound machine available to labor and delivery. Radiologist, obstetrician or maternal-fetal medicine specialist skilled in interpretation of ultrasound scans in-house 24 hours a day.</p>		Current NYS regs. 721.6
	None specified.	<p>Portable, neonatal-appropriate equipment available within a timeframe appropriate to meet the patient's needs as well as appropriately trained personnel to administer needed services.</p>			
	None specified.	None specified.		<p>Obstetric and neonatal diagnostic imaging, provided by radiologists with special interest and competence in maternal and neonatal disease and its complications, available 24 hours a day.</p>	Current NYS regs 721.6
	None specified.	None specified.		<p>Radiologist on staff with expertise in pediatric radiology.</p>	
	<p>Ability to provide basic antepartum, intrapartum and neonatal care.</p>	<p>Fetal evaluation/ antepartum consultation within a timeframe to best meet the needs of patients.</p>		<p>Fetal evaluation/antepartum unit in-house, staffed by maternal-fetal medicine specialists, obstetricians, registered nurses, available 24 hours a day.</p>	AAP/ACOG Guidelines for Perinatal Care 5th Edition
<p>17. (P) Availability of consultant and surgical services</p>	<p>Radiologist or obstetrician skilled in interpretation of ultrasound available in a time frame to meet the patient's needs.</p>	<p>Hospital staff shall include a radiologist skilled in interpretation of ultrasound scans, clinical pathologist, a designated, in-house credentialed person for neonatal resuscitation, all available 24 hours a day.  Specialized adult and pediatric medical and surgical consultation readily available</p>	<p>Adult and pediatric subspecialists in cardiology, neurology, hematology, genetics, nephrology, metabolism, endocrinology, gastroenterology, nutrition, radiology, infectious diseases, pulmonology, immunology, and pharmacology shall be available for consultation.  Adult and pediatric surgeons and pediatric surgical subspecialists (e.g. cardiovascular; neurologic; orthopedic, ophthalmologic, urologic, and ENT surgeons) available for consultation and care. General surgeons readily available.</p>		Current NYS regs. 721.6



Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
18. (P) Affiliation agreements	Executed and current affiliation agreement(s) with higher level hospital(s) for transfers and consultation, and with a single RPC for quality of care oversight.			Executed and current affiliation agreement with all hospitals in network.	Current NYS regs. 721.10
19. (P) Teaching status	Does not apply.	Does not apply.	<b>Must be a teaching hospital.</b>	<b>Must be a teaching hospital or an academic medical center.</b>	Standard in original designation survey.
20. (P) Quality of Care	Quality improvement committee and plan for perinatal services.	Quality improvement committee and plan for perinatal services.	Quality improvement committee and plan for perinatal services.	Quality improvement committee and plan for RPC perinatal services.  <b>Also a comprehensive program of quality improvement activities among affiliate hospitals, including review of:</b> <ul style="list-style-type: none"> <li>• Statistical data from the SPDS or equivalent data source;</li> <li>• Affiliate's QI program, policies and procedures;</li> <li>• Care provided by medical, nursing, and other health care practitioners associated with the perinatal services;</li> <li>• Appropriateness and timeliness of maternal and newborn referrals and transfers, and of patients retained at the affiliate who should have been transferred;</li> <li>• Maternal and newborn serious adverse events or occurrences.</li> </ul>	Current NYS regs. 721.9

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
21. (P) Regional Perinatal Services to Affiliates	Does not apply.	Does not apply.	Does not apply.	<p>An RPC provides the following services to affiliate hospitals:</p> <ul style="list-style-type: none"> <li>• Education and training to update and enhance staff knowledge and familiarity with relevant procedures and technological advances;</li> <li>• Reviews, in conjunction with its perinatal affiliates, all cases of patients transferred to a higher level of care to determine whether such transfers were appropriate and accomplished according to established transfer agreements;</li> <li>• Participates in case conferences with its perinatal affiliates and associated birth centers to determine whether any non-transferred high-risk cases were handled appropriately and whether the transfer guidelines were adequate to address such circumstances.</li> <li>• Provides all aspects of comprehensive maternal and neonatal care, and its functions and responsibilities also include efforts to coordinate and improve quality of perinatal care among its affiliates, attending level consultation regarding patient transfer and clinical management, transport of high-risk patients, outreach to affiliates to determine</li> </ul>	Current NYS regs. 405.21 d. (v)

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
22. (P) Availability of specialty services	Does not apply.	<u>Pharmacy Services:</u> Specialized pharmaceutical services for newborns including antibiotics, caffeine, theophylline and diuretics.	<u>Pharmacy Services:</u> <b>Personnel qualified to prepare, dispense and administer specialized pharmaceutical services to newborns shall be available 24 hours a day.</b>  Specialized pharmaceutical services for newborns must include antibiotics, caffeine, theophylline, diuretics, amino acid solutions and TPN.	educational needs, education and training of affiliate hospitals, data collection, evaluation and analysis within that region	Current NYS regs. 721.6, standard in original designation survey.
23. (P) Bioethical Committee	Does not apply.	Does not apply.	Does not apply.  Bioethical review committee to assist the perinatal service and provide guidance to staff and families in the resolution of issues affecting care, support and treatment of severely ill, injured or handicapped infants with life threatening conditions.	Pathologists with special competence in placental, fetal, and neonatal disease on hospital staff.  Does not apply.  Involved in one or more of the following: perinatal research, evaluation of high-risk technologies, provision of highly specialized services, e.g., ECMO, fetal surgery.  Agreements with at least one other RPC for clinical services not offered.	Current NYS regs, 405.21 h. NICU services 3 (ii)

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source	
24. (P) Nursing Care	<p>Maternal and newborn nursing care must be provided under the direct supervision of a Registered Nurse.</p> <p>All obstetric personnel shall be qualified in interpretation of fetal heart rate monitoring and understand the physiology of labor.</p> <p>All newborn personnel shall be qualified in assessment of the newborn and all aspects of routine monitoring and care, including education and support related to breastfeeding.</p>	<p>Does not apply.</p>	<p>Direct patient care shall be provided by registered nurses who have education and experience in the care of moderately high-risk women and/or newborns and demonstrate competence in the observation and treatment of such patients, including cardiorespiratory monitoring. Registered nurses shall be able to monitor and support the stability of cardiopulmonary, neurologic, metabolic, and thermal functions; assist with special procedures such as lumbar puncture, endotracheal intubation, umbilical catheterization and perform emergency resuscitation.</p> <p>Appropriate and adequate numbers of the nursing staff who are trained in breastfeeding support for mothers and infants with special needs.</p>	<p>Registered nurses shall have specialty certification or advanced training and experience in the nursing management of high-risk, unstable women, high risk neonates with multi-organ system problems and in specialized care technology.</p> <p>An advanced practice nurse is available for consultation and support on nursing care issues. Assessment and monitoring activities remain the responsibility a registered nurse or an advanced practice nurse in obstetric-neonatal nursing.</p> <p>Registered nurses with specialized training participate in regional perinatal center responsibilities such as outreach, training, education and support.</p>	<p>Current NYS regs, 721.7</p> <p>Current NYS regs, 721.7</p>	
25. (P) Ancillary Personnel	<p>Infection control personnel responsible for surveillance of infections in women and neonates, as well as for the development of an appropriate environmental control program.</p> <p>At least one staff member with expertise in bereavement responsible for the hospital's bereavement activities, including a systemic approach to ensuring that individuals in need receive the services.</p>					<p>Current NYS regs, 721.8</p>

Service/ Capacity Issue	Basic Care (Level I)	Specialty Care (Level II)	Subspecialty Care (Level III)	RPC	Source
	At least one qualified social worker available with expertise in the socioeconomic and psychosocial problems of pregnant women, ill neonates, and their families assigned to the perinatal service. Additional qualified social workers must be available when there is a high volume of activity.				
	Licensed practical nurses and other licensed patient care staff with demonstrated knowledge and clinical competence in the nursing care of women, fetuses, and newborns during labor, delivery, and the postpartum and neonatal periods.				
	Does not apply.	At least one occupational or physical therapist with neonatal expertise available.			
	Does not apply.	At least one registered dietician/nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk women and neonates is available.			
	Does not apply.	Respiratory therapists or nurses with special training who can manage the mechanical ventilation of neonates with cardiopulmonary disease.			