QUALIFYING STATEMENTS

The Department of Veterans Affairs (VA) and The Department of Defense (DoD) guidelines are based on the best information available at the time of publication. They are designed to provide information and assist decision-making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

Variations in practice will inevitably and appropriately occur when providers take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.
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I-53. Routine Cervical Examination: Not Recommended
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APPENDIX G Acronym List
APPENDIX H Participant List
APPENDIX I Bibliography

The Recommendations are new in Version 2.0 (2009)
Updated Recommendation was included in Version 1.0 (2003) and was modified in version 2.0 (2009)
INTRODUCTION

The Clinical Practice Guideline for Pregnancy Management (GPM) was developed under the auspices of the Veterans Health Administration (VHA) and the Department of Defense (DoD) pursuant to directives from the Department of Veterans Affairs (VA). VHA and DoD define clinical practice guidelines as:

“Recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach that includes:

- Determination of appropriate criteria such as effectiveness, efficacy, population benefit, or patient satisfaction; and
- Literature review to determine the strength of the evidence in relation to these criteria.”

The intent of the guideline is to:

- Reduce current practice variation and provide facilities with a structured framework to help improve patient outcomes
- Provide evidence-based recommendations to assist providers and their patients in the decision-making process concerning pregnancy
- Identify outcome measures to support the development of practice-based evidence that can ultimately be used to improve clinical guidelines.

2009 UPDATE VERSION OF THE GUIDELINE

In 2003, the first DoD/VA Clinical Practice Guideline for the Management of Uncomplicated Pregnancy was implemented. One of the key components of this CPG was changing from the traditional interval-based visit template (every four weeks in the first and second trimesters) towards a system in which an antenatal visit is planned for a specific gestational age, with each visit having specific well-defined goals and objectives.

The first version of the VA/DoD pregnancy guideline limited its scope of care to women with uncomplicated pregnancies. No recommendations or guidance were given for providers caring for women with common or minor complications of pregnancy. Thus, the guideline was named as the VA/DoD Clinical Practice Guideline for the Management of Uncomplicated Pregnancy (UCP). Women who initially received care according to the guideline simply “exited the guideline” when complications arose. No guidance for even the basic care of these women was provided and the tools, including the medical record materials (flow sheets, mother’s handbook, etc.), were deemed non-applicable. However, the UCP guideline materials continued to be used in most institutions and care has been supplemented as needed.

The goal-oriented prenatal care system, first outlined in the 2003 version of the guideline, should be applied to all pregnant women regardless of their risk factors. As such, this guideline encompasses the basic components of prenatal care that will be provided to all pregnant women by low-risk providers (such as Certified Nurse-Midwives, Nurse Practitioners, or Family Practice Care Providers) as well as evidence-based recommendations for advanced prenatal care that should be applied when complications emerge during pregnancy or an increased risk for complications is identified.

However, rather than discard the recommendations for the basic components of prenatal care in women who have been identified with some risk, this version of the guideline includes evidence-based recommendations for routine prenatal care. It also includes additional recommendations suggesting specific and general actions to initiate the appropriate advanced prenatal care for many women with identified risks or complications. Women with specific risk factors, or who develop high-risk conditions complicating the pregnancy, may require additional surveillance (i.e., additional ultrasounds, lab studies, etc.) and/or consultation with advanced prenatal care providers such as Obstetrician/Gynecologists (OB/GYN) specialists or Maternal-Fetal Medicine (MFM) subspecialists.
The recommendations in this guideline may be modified according to local practice conditions and updated scientific evidence. Except in very unusual circumstances, the recommendations outlined in this guideline should serve as a backbone to the supplemental prenatal care that is provided or recommended by advanced prenatal care providers.

The guideline and algorithms are designed to be adapted by individual facilities, considering needs and resources. The algorithm will serve as a guide that providers can use to determine best interventions and timing of care to optimize quality of care and clinical outcomes for their patients. This should not prevent providers from using their own clinical expertise in the care of an individual patient. Guideline recommendations are intended to support clinical decision-making but should never replace sound clinical judgment.

**BACKGROUND**

**Goals of the Guideline**

- The primary goal of the Pregnancy Guideline is to improve pregnant woman and provider satisfaction with antenatal care (also referred to in the literature as “prenatal” or “antepartum” care). Approaches include:
  - Outlining antenatal visits for specific gestational ages, with each visit having specific well-defined goals and objectives.
  - Helping ensure both pregnant women and providers are aware of the specific expectations for each visit, thus promoting a partnership with the common goal of a healthy infant and mother. Enhanced patient education will be a hallmark of this healthcare partnership and the goal-oriented prenatal care system.
  - Presenting a standardized care plan in the Pregnancy Guideline that is expected to improve overall patient satisfaction and lessen inter-provider variability, which is often perceived by pregnant women in a negative manner and as a sign of clinical naiveté and uncertainty.
  - Providing a scientific evidence-base for practice interventions and evaluations.

**Target population**

- The guideline offers best practice advice for antenatal care of pregnant women.
- The guideline will not address specific intra-partum or post-partum needs.

**Audiences**

The guideline is relevant to primary and secondary healthcare professionals who have direct contact with pregnant women, and make decisions concerning antenatal care.
Development Process
The development process of this guideline follows a systematic approach described in “Guideline-for-Guidelines,” an internal working document of VHA’s National Clinical Practice Guideline Counsel. Appendix A clearly describes the guideline development process.

The literature was critically analyzed and evidence was graded using a standardized format. The evidence rating system for this document is based on the system used by the U.S. Preventative Services Task Force. (See Appendix A – Development Process.)

Evidence Rating System

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>A strong recommendation that the clinicians provide the intervention to eligible patients. Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.</td>
</tr>
<tr>
<td>B</td>
<td>A recommendation that clinicians provide (the service) to eligible patients. At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.</td>
</tr>
<tr>
<td>C</td>
<td>No recommendation for or against the routine provision of the intervention is made. At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.</td>
</tr>
<tr>
<td>D</td>
<td>Recommendation is made against routinely providing the intervention to asymptomatic patients. At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.</td>
</tr>
<tr>
<td>I</td>
<td>The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined.</td>
</tr>
</tbody>
</table>

Lack of Evidence – Consensus of Experts
Where existing literature was ambiguous or conflicting, or where scientific data were lacking on an issue, recommendations were based on the clinical experience of the Working Group. These recommendations are indicated in the evidence tables as based on “Working Group Consensus.”

This Guideline is the product of many months of diligent effort and consensus-building among knowledgeable individuals from the VA, DoD, and academia, and a guideline facilitator from the private sector. An experienced moderator facilitated the multidisciplinary Working Group. The draft document was discussed in two face-to-face group meetings. The content and validity of each section was thoroughly reviewed in a series of conference calls. The final document is the product of those discussions and has been approved by all members of the Working Group.

The list of participants is included in Appendix H to the guideline.
Implementation

The guideline and algorithms are designed to be adapted to individual facility needs and resources. The algorithm will serve as a guide that providers can use to determine best interventions and timing of care for their patients to optimize quality of care and clinical outcomes. This should not prevent providers from using their own clinical expertise in the care of an individual patient. Guideline recommendations are intended to support clinical decision-making but should never replace sound clinical judgment.

Although this guideline represents the state-of-the-art practice at the time of its publication, medical practice is evolving and this evolution will require continuous updating of published information. New technology and more research will improve patient care in the future. The clinical practice guideline can assist in identifying priority areas for research and optimal allocation of resources. Future studies examining the impact of this clinical practice guideline may lead to the development of new practice-based evidence.

Outcomes

1. Complete initial screening and intake by the nurse or provider during the first trimester.
2. Timely comprehensive screening for risk factors as outlined in the guideline.
3. Timely prenatal counseling and education as outlined in the guideline.

Content of the Guideline

The guideline consists of an algorithm that describes the step-by-step process of the clinical decision-making and intervention that should occur, and a summary chart that describes the interventions that should take place throughout the goal-oriented prenatal visits during pregnancy. General and specific recommendations for each visit are included in an annotation section. The links to these recommendations are embedded in the relevant specific steps in the algorithm and the chart describing the overall visits throughout pregnancy.

Each annotation includes a brief discussion of the research supporting the recommendations and the rationale behind the grading of the evidence as well as the determination of the strength of the recommendations (SR). A complete bibliography of the references found in this guideline can be found in Appendix I.
### Guideline Update Working Group*

<table>
<thead>
<tr>
<th>VA</th>
<th>DoD</th>
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<tbody>
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* Bolded names are Co-Chair of the Guideline Working Group.  
Additional contributor contact information is available in Appendix H.

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*VA/DoD Clinical Practice Guideline  
For Pregnancy Management*
A-0. Organization of Prenatal Care

BACKGROUND

Goal-oriented visits can be provided during individual encounters with OB providers, or can be accomplished in a group setting. Recommendations for reduced visit prenatal care have been instituted at some healthcare facilities. This first DoD/VA Clinical Practice Guideline for the Management of Uncomplicated Pregnancy was implemented in 2003. One of the key components of the clinical practice guideline was changing from the traditional interval-based visit template (every four weeks in the first and second trimesters) towards a system in which an antenatal visit is planned for a specific gestational age, with each visit having specific well-defined goals and objectives.

Group prenatal care has been implemented in many clinical practices in the United States and abroad. Centering Pregnancy® is a group model of prenatal care which provides care in a group setting, integrating assessment support and education at each visit. Studies have shown group prenatal care results in equal or improved perinatal outcomes with no added cost.

Level of care settings:

Throughout this guideline, the term Routine Prenatal Care refers to prenatal care generally provided to pregnant women by Family Medicine Physicians, Women’s Health Nurse Practitioners, Certified Nurse-Midwives or Obstetrician/Gynecologists. The term Advanced Prenatal Care generally refers to care provided to women with complicated pregnancies provided by Obstetrician/Gynecologists and/or Maternal-Fetal Medicine specialists.

Routine Prenatal Care Providers

Individuals qualified to provide routine obstetric care include Family Practice Physicians, Certified Nurse-Midwives, Women’s Health Nurse Practitioners, and Obstetrician/Gynecologists. These providers may have varied experience in providing more advanced prenatal care.

Advanced Prenatal Care Providers

Obstetrician-Gynecologist: physician qualified by training and experience to manage complicated pregnancies by virtue of having completed four years of Obstetrics and Gynecology residency training and maintaining currency in the profession.

Maternal-Fetal Medicine (MFM) Specialist: physician who has completed two to three years of Maternal-Fetal Medicine fellowship after completing four years of Obstetrics and Gynecology residency training. Fellowship training provides additional education and practical experience to gain special competence in managing various obstetrical, medical, and surgical complications of pregnancy.

MFM specialists function in collaboration with Family Medicine physicians, Women’s Health Nurse Practitioners, Certified Nurse-Midwives and Obstetricians. The relationship and referral patterns between Obstetrician-Gynecologists and MFM specialists will depend on the acuity of the patient’s condition and local circumstances.

RECOMMENDATIONS

1. Goal-oriented prenatal care system can be delivered to all pregnant women. [B]
2. Education should be a central component of prenatal care for all pregnant women. [B]
3. Group model of prenatal care, such as the Centering Pregnancy® model, is an acceptable alternative to individual provider appointments. [A]

DISCUSSION

A systematic review published in the Cochrane database concluded that a reduction in the number of antenatal visits with an increased emphasis on the content with regard to services offered at each of the visits could be implemented without an increase in adverse perinatal outcomes (Villar et al., 2001). Partridge & Holman (2005) conducted a study to determine the effects of a reduced number of antepartum visits (as recommended by the 2003 VA/DoD
C PG) on maternal and neonatal outcomes at a military community hospital. The study found that there was no change in perinatal outcomes or patient satisfaction. Application of the prenatal care guideline was associated with a reduction in prenatal visits but a small increase in labor and delivery visits that did not persist after the initial year. No adverse perinatal or patient satisfaction outcomes were noted.

The Centering Pregnancy® Program is a model for delivering prenatal care in a group setting (Rising et al., 2004; Walker et al., 2004). Groups form between 12 to 16 weeks of pregnancy, and continue through the prenatal and postpartum period. Groups are facilitated by the provider or a professional skilled in group leadership. Each group session includes an individual assessment by the provider, as well as education on various pregnancy topics, preparation for childbirth, and early parenting. Women participate in self-care activities such as taking their own blood pressures and weight, and recording them in the chart. The opportunity to meet together for nine or 10 sessions of 90 to 120 minutes each with the same group of expectant parents allows for continued sharing and development of a support network which often extends in to the childrearing period.

A randomized controlled trial was conducted at two university-affiliated hospital prenatal clinics involving 1,047 pregnant women (Ickovics et al., 2007). The results revealed that women assigned to group care were significantly less likely to experience preterm delivery compared with those who received standard individual prenatal care. Women in group sessions were less likely to have suboptimal prenatal care, had significantly better prenatal knowledge, felt more prepared for labor and delivery, and had greater satisfaction with care.

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Effect of reduced number of visits</td>
<td>Villar et al., 2001 Partridge, 2005</td>
<td>I II</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 Group prenatal care is an acceptable alternative to individual appointments and can result in equal or improved perinatal outcomes</td>
<td>Ickovics et al., 2007 Baldwin et al., 2006</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

A-1. Confirmed Pregnancy

Confirmation of pregnancy is established by a confirmed positive urine or serum pregnancy test.

A-2. First Visit with Nurse: Complete Self-Questionnaire; Assess for Risk Factors

Weeks 6 to 8

BACKGROUND

After confirmation of the pregnancy, the goal of the first prenatal contact is to exchange information and identify existing risk factors that may impact the pregnancy. This initial contact may be accomplished in a group setting or during a one-on-one visit. This encounter provides an opportunity early in the pregnancy to obtain general short-term risk stratification. In this visit, the nurse should identify women who: (1) Need immediate referral to an advanced prenatal care provider (e.g., high risk for ectopic pregnancy); (2) Need to see an advanced prenatal care provider at the first provider visit; or (3) Can have the first provider visit with a low-risk prenatal care provider. Table 1 contains a checklist of the data collected during the first visit with the nurse and/or obstetric healthcare provider. These data are required to appropriately triage women into one of the three categories noted above. In addition, all active duty pregnant women are required to have an occupational health screening. This referral/consultation with occupational health should be done at this initial encounter.
RECOMMENDATIONS

1. Initial assessment by nurse may include the following actions:
   a. Assure the patient completes the Self-Questionnaire (see Appendix B - Screening Items for Self-Administered Questionnaire – First Visit)
   b. Review the patient’s completed Self-Questionnaire for issues requiring immediate evaluation or intervention (see Appendix B - Screening Items for Self-Administered Questionnaire – First Visit)
   c. Obtain initial prenatal lab tests to be reviewed and documented at the following visit
   d. Consult with an advanced prenatal care provider regarding advice or instruction to the patient if there are immediate needs (see Table-1)
   e. Arrange immediate referral to advanced prenatal care for follow-up in cases needing short-term assessment or intervention (see Table-1)
   f. Provide brief information about options for screening for fetal chromosomal abnormalities and arrange for counseling (See I-36)
   g. Arrange follow-up with the appropriate provider at 10-12 weeks.

Table 1. Prenatal Risk Assessment by Nurse - Checklist

<table>
<thead>
<tr>
<th>Risk Assessed by Nurse</th>
<th>Nurse assessment and Questionnaire (see Appendix B)</th>
<th>Laboratory tests</th>
<th>Immediate referral to advanced prenatal care provider</th>
<th>Consult with advanced prenatal care provider</th>
<th>Follow-up with advanced prenatal care: Weeks 10-12</th>
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<tbody>
<tr>
<td>Uncertain dating criteria</td>
<td>√</td>
<td>Ultrasound</td>
<td></td>
<td>√</td>
<td></td>
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<tr>
<td>Late presentation</td>
<td>√</td>
<td>Ultrasound</td>
<td></td>
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</tbody>
</table>

**Past OB history:**

| Recurrent pregnancy loss | √ | | |
| Ectopic pregnancy risk (prior hx of ectopic, prior tubal surgery, current IUD, hx of tubal infertility, hx PID) | √ | Quantitative HCG/US | √ |
| Prior macrosomia or prior gestational diabetes mellitus (GDM) | √ | Glucola for GDM | |
| Preterm birth | √ | | | √ |
| Second-trimester pregnancy loss | √ | Ultrasound | | √ |
| Cervical surgery (LEEP, cone biopsy) | √ | | | √ |
| Bariatric surgery (less than 18 months) | √ | | | √ |

**Current Problems:**

| Vaginal bleeding (current) | √ | | |
| Significant abdominal pain/cramping (current) | √ | | √ |
| Prescription, over-the-counter, and herbal medications | √ | | | √ |
| Drug/alcohol use | √ | | | √ |
| Smoking | √ | | | √ |

**Medical Conditions:**

| Cardiovascular diseases | √ | | | √ |
| Cardiac abnormality | √ | | | √ |
| Diabetes mellitus (DM) – Type 1 or 2 | √ | Hgb A1c | √ | | √ |
| Renal disorder (includes pyelonephritis) | √ | | | | √ |
| Hypertension | √ | If not controlled | | | √ |
| Thyroid disorders | √ | Thyroid function | | | √ |
### Risk Assessed by Nurse

<table>
<thead>
<tr>
<th>Risk Assessed by Nurse</th>
<th>Nurse assessment and Questionnaire (see Appendix B)</th>
<th>Laboratory tests</th>
<th>Immediate referral to advanced prenatal care provider</th>
<th>Consult with advanced prenatal care provider</th>
<th>Follow-up with advanced prenatal care: Weeks 10-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders on medications</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Family history of DM in first relative</td>
<td>✓</td>
<td>Glucola for GDM</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Neurological disorder</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Autoimmune disorder/Lupus</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Major mental illness</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Blood disorders</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Hepatitis</td>
<td>✓</td>
<td>Hepatitis panel</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Sexually transmitted disease (STD)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Human immunodeficiency virus (HIV)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Rash or viral illness</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Radiation/toxic chemical exposure since becoming pregnant</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Transplant</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hx of genetic disease or family history of genetic disease</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Dental complaint</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>To Dentistry</td>
</tr>
<tr>
<td>Screen for MDD</td>
<td>✓</td>
<td></td>
<td></td>
<td>To Behavior Health if suicidal or moderate or severe MDD</td>
<td></td>
</tr>
<tr>
<td>Occupational hazards</td>
<td>✓</td>
<td></td>
<td></td>
<td>To Public Health</td>
<td></td>
</tr>
<tr>
<td>Homeless</td>
<td>✓</td>
<td></td>
<td></td>
<td>To Social Services</td>
<td></td>
</tr>
<tr>
<td>Domestic violence</td>
<td>✓</td>
<td></td>
<td></td>
<td>To Social Work if unsafe</td>
<td></td>
</tr>
<tr>
<td>Hx of infertility</td>
<td>✓</td>
<td>Transvaginal US</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hx of mental illness on medications</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet restriction</td>
<td>✓</td>
<td></td>
<td></td>
<td>To Nutrition Counseling</td>
<td>✓</td>
</tr>
<tr>
<td>Eating disorder</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body mass index (BMI) &gt; 29 kg/m²</td>
<td>✓</td>
<td>Glucola for GDM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI &lt; 20 kg/m²</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (&lt;16 or &gt;35)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Routine Lab Tests:
- Human immunodeficiency virus (HIV) ✓
- Complete blood count (CBC) ✓
- (ABO Rh) blood typing ✓
- Antibody screen ✓
- Rapid plasma reagent (RPR) ✓
- Hepatitis B surface antigen test ✓
- Rubella test ✓
- Urinalysis and culture ✓
### A-3. The First Provider Visit:  
**Weeks 10-12**

#### BACKGROUND

The first provider visit offers an opportunity for the provider to review the information obtained through the Self-Questionnaire and the results of the initial laboratory studies and to note any salient issues previously identified at the initial 6-8 week nurse’s visit. The provider also has an opportunity to further investigate notable issues, complete a physical examination, address/document fetal viability, confirm the gestational age and address any complications that may have arisen in the interval since the initial nurse’s visit.

The provider will outline the plan of care based on the information gathered from this and the initial nurses’ visit. The plan for the ongoing prenatal care should be based on the backbone of routine prenatal care outlined in this guideline and then individualized by addressing any currently identifiable risks/complications and outlining any indicated supplemental prenatal interventions. The outline of care may involve referring the patient to, or consulting with, an advanced prenatal care provider. (See Annotation A-0 for Level of Care Settings)

#### RECOMMENDATIONS

1. At the first provider visit, a complete medical history and physical examination (including thyroid, breast and pelvic examination) should be obtained. Information from the previous visit(s) and laboratory studies should be reviewed and significant problems/risks should be assessed.

2. At the first provider visit, the provider should outline an individualized plan of prenatal care that includes guideline-based routine prenatal care and consultation with advanced prenatal care providers or other medical specialty care services if needed.

3. The following are conditions not addressed by this guideline that will require supplemental care that might be best provided by routine or advanced obstetric care providers and/or behavioral health providers depending on the individual circumstances and local conditions:
   - Current mental illness requiring medical therapy
   - Substance use disorders
   - Eating disorders.

4. The following are among conditions that require supplemental prenatal care or consultation with or referral to an advanced prenatal care provider (Table 2):
   a. General
      - Body mass index (BMI) <16.5 or >30
      - Age (<16 or > 34 years at delivery)
- At risk for diabetes

b. Infections:
   - Hepatitis B or C (see I-11)
   - Human Immunodeficiency virus (HIV)
   - Syphilis (positive RPR)
   - Cytomegalovirus (CMV)
   - Toxoplasmosis
   - Primary Herpes
   - Rubella
   - Parvovirus
   - Positive gonorrhea (see I-29)
   - Positive Chlamydia (see I-30)
   - Genital herpes (see I-32)
   - Recurrent urinary tract infections/stones

c. Pre-existing medical conditions:
   - Abnormal pap smear (see I-31)
   - Controlled hypothyroidism
   - Previous gastric bypass/bariatric surgery (see I-28)
   - Mild depression (I- 21 & 34)
   - Cardiovascular disease
   - High blood pressure
   - Familial hyperlipidemia
   - Pregestational diabetes
   - Kidney disease (including pyelonephritis)
   - Inflammatory bowel disease
   - Bronchio pulmonary disease including asthma
   - Autoimmune diseases including Anticardiolipin Antibody Syndrome, and Systemic Lupus Erythematosus
   - Thromboembolic disease, current or historical
   - Cancer
   - Seizure disorders
   - Hematologic disorders (including anemia, thrombocytopenia)
   - Genetic disease with known effect on pregnancy

d. Obstetric conditions:
   - Vaginal bleeding
   - Isoimmunization
   - Placenta previa—symptomatic or present beyond 28 weeks
- Placental abruption
- At risk for preterm birth (see A-4)
- Prior cesarean section (see I-39)
- Previous uterine or cervical surgery
- Intrauterine fetal demise
- Preterm labor
- Preterm ruptured membranes
- Recurrent pregnancy loss
- Suspected or documented fetal growth abnormalities (intrauterine growth restriction [IUGR] or macrosomia)
- Abnormalities of amniotic fluid including oligohydramnios, polyhydramnios
- Fetal anomaly(s)
- Multiple gestation
- Surgical condition during pregnancy (e.g., appendectomy, ovarian cystectomy, cerclage)
Table 2. Conditions Requiring Supplemental Care

<table>
<thead>
<tr>
<th>Risk Assessed by Routine Prenatal Care Provider</th>
<th>Referral/Consult with Advanced Prenatal Care Provider</th>
<th>Consider Referral/Consult with Advanced Prenatal Care Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GENERAL CONDITIONS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genetic condition potentially affecting fetus</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Body Mass Index (BMI &lt; 16.5 or &gt;30)</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Age &lt; 16 or &gt; 34</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Genetic condition affecting patient or spouse</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td><strong>OBSTETRIC CONDITIONS</strong> (current or historical)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrent pregnancy loss</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Ectopic pregnancy</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Significant abdominal pain/cramping</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Vaginal bleeding</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Second-trimester pregnancy loss</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Preterm labor (current) or birth (history)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Cervical surgery (LEEP, cone biopsy)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Uterine abnormality</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Short (&lt;2.5 cm) cervix (&lt; 36 weeks)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Pregnancy induced hypertensive disorders</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Gestational diabetes mellitus (GDM)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Malpresentation (&gt; 36 weeks)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Placenta Previa (symptomatic or beyond 28 weeks)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Abnormal amniotic fluid: oligo/poly hydramnios</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Preterm ruptured membranes</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Fetal growth abnormality (&lt;10, &gt;90 %tile)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Known or suspected fetal anomaly</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Multiple gestation</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Isoimmunization</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Abnormal prenatal screening result (aneuploidy risk)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Abnormal prenatal screening result (ONTD risk)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Intrauterine fetal demise</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Teratogenic exposure including drugs or radiation</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Placental abruption</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Prior cesarean section</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Intrapartum complications</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td><strong>GYNECOLOGIC, MEDICAL, SURGICAL CONDITIONS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current need for surgery</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Bariatric surgery (&lt; 18, &gt; 36 months ago)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus (DM) – Type 1 or 2</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Hematalogic disorders (except mild anemia)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal disorders on medication</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Chronic hypertension</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Pulmonary disease including asthma</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Cancer (current or recent)</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Neurological disorders including epilepsy</td>
<td>√</td>
<td></td>
</tr>
</tbody>
</table>
A-4. Assessment of Risk Factors for Preterm Birth

**BACKGROUND**

Preterm birth is the second leading cause of neonatal mortality in the United States. Although many preterm births are due to the development of obstetric complications, over 70 percent result from spontaneous preterm birth which includes deliveries related to idiopathic preterm labor, preterm rupture of membranes, and cervical insufficiency. Demographic or historical risk factors for spontaneous preterm birth delivery may be discovered at the initial nursing intake or provider visit. Other risk factors develop as a woman’s pregnancy progresses and include certain symptoms or physical examination and imaging findings. Although the prediction and prevention of spontaneous preterm birth remain challenging, continual surveillance for these risk factors may be beneficial as effective therapeutic options are developed. Some risk factors only require annotation in the obstetric record and routine surveillance as indicated in this pregnancy guideline. The identification of other risk factors should prompt increased surveillance in the form of consultation with an advanced prenatal care provider or ancillary testing and imaging studies.

To date, no single test or sequence of tests has an optimal sensitivity or predictive value for preterm birth. Fetal fibronectin testing and cervical length measurement by transvaginal ultrasound appear to be useful in the management of some women meeting the criteria for increased surveillance. Most studies have shown that these tests have limited utility when used in the asymptomatic woman at low risk for preterm delivery. Importantly,
modalities such as salivary estriol levels, bacterial vaginosis screening and home uterine activity monitoring are generally not effective at predicting preterm birth regardless of risk status.

Recent data suggest that the administration of progesterone intramuscularly or intravaginally beginning early in pregnancy in women at high risk for preterm birth significantly reduces the rate of preterm delivery. Specifically, women with a prior spontaneous birth at less than 37 weeks’ of gestation and asymptomatic women with a shortened cervical length in the 2nd trimester appear to benefit from the administration of progesterone beginning early in pregnancy. Progesterone therapy is typically begun early in the 2nd trimester and continued until approximately 36 weeks. Both intramuscular 17 alpha hydroxyprogesterone caproate (250 mg, administered weekly) and vaginal progesterone suppositories (100 to 200mg, administered once daily) have been described in the literature.

Despite the apparent benefits of progesterone in high-risk populations and its growing use, the ideal progesterone formulation and long-term safety of the drug must be confirmed by additional studies. Progesterone supplementation for the prevention of preterm birth should still be considered investigational.

The identification of women at risk for preterm birth now increases in importance in light of the expanded availability of and indications for progesterone therapy for the prevention of preterm birth.

RECOMMENDATIONS

Assessment of preterm birth

1. Women should be assessed for preterm birth risk as early as possible in the pregnancy in order to optimize maternal and newborn outcomes.

2. Screening for preterm birth risk factors should continue up to 37 weeks estimated gestational age.

3. Women at increased risk but meeting the criteria for normal surveillance should have the risk factor(s) documented in the medical record to increase awareness of the risk but may continue to be followed in accordance with the routine management of the pregnancy guideline.

4. Routine care providers should consult with an advanced prenatal care provider whenever a woman meets the criteria for increased surveillance for preterm birth.

5. Women requiring increased surveillance should be considered for ancillary studies and other additional intervention. Progesterone supplementation should be considered in these women (see A-4).

6. Routine screening of fetal fibronectin (fFN) in asymptomatic or low-risk women is not recommended (see I-52). fFN testing in symptomatic or high-risk women between 24 and 34 6/7 weeks’ gestation may be useful in guiding management.

7. The measurement of cervical length by transvaginal ultrasound may be useful in some patients requiring increased surveillance for preterm labor. Sonographic cervical length measurement is not recommended as a routine screening or prediction tool in women only requiring normal surveillance.

8. The determination of salivary estriol levels, bacterial vaginosis screening and home uterine activity monitoring are not recommended as a means to predict preterm birth.

Progesterone therapy

9. It is reasonable to offer antenatal progesterone therapy to women at high-risk for preterm delivery and who meet the generally accepted inclusion criteria. [B]

10. Progesterone may be administered intramuscularly on a weekly basis or intravaginally on a daily basis. [B]

11. Progesterone therapy should only be initiated after consultation with an advanced prenatal care provider (obstetrician or maternal-fetal medicine specialist). [C]
Table 3. Risk Factors for Preterm Birth Stratified by Those Requiring either Normal or Increased Surveillance *

<table>
<thead>
<tr>
<th>Normal Surveillance</th>
<th>Increased Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Nonwhite race</td>
<td>Risk factors known from prior history:</td>
</tr>
<tr>
<td>• Age younger than 17 years or older than 35 years</td>
<td>• Prior cervical surgery</td>
</tr>
<tr>
<td>• Low socioeconomic status</td>
<td>• History of preterm delivery (less than 34 weeks)</td>
</tr>
<tr>
<td>• Single parent</td>
<td></td>
</tr>
<tr>
<td>• Smoking</td>
<td>Findings that may be identified during the pregnancy:</td>
</tr>
<tr>
<td>• History multiple first trimester spontaneous abortions</td>
<td>• Antepartum vaginal bleeding or persistent placenta previa</td>
</tr>
<tr>
<td>• History of lower genital tract infection</td>
<td>• Uterine over-distension due to any cause (e.g., multiple gestation, polyhydramnios)</td>
</tr>
<tr>
<td>• Low pre-pregnancy weight/body mass index</td>
<td>• Abnormality of uterine cavity or architecture (e.g., septic uterus, uterine fibroids)</td>
</tr>
<tr>
<td>• Occupational stress or prolonged standing (greater than 3 hours)</td>
<td>• Uterine contractions, back ache, or pelvic pressure</td>
</tr>
<tr>
<td>• Periodontal disease</td>
<td>• Shortened cervical length</td>
</tr>
<tr>
<td></td>
<td>• Rupture of membranes</td>
</tr>
<tr>
<td></td>
<td>• Cervical dilation greater than or equal to 2 cm in 2nd trimester in symptomatic women</td>
</tr>
<tr>
<td></td>
<td>• Soft cervical consistency in 2nd trimester in symptomatic women (nulliparous women)</td>
</tr>
<tr>
<td></td>
<td>• Abdominal surgery during current pregnancy</td>
</tr>
<tr>
<td></td>
<td>• Illicit drug use (e.g., methamphetamine, cocaine)</td>
</tr>
<tr>
<td></td>
<td>• Use of assisted reproductive technology</td>
</tr>
</tbody>
</table>

*Women with multiple risk factors in the Normal Surveillance category may require individualized assessment and warrant consultation with an advanced prenatal care provider.

DISCUSSION

Several methods of identifying women at high risk for preterm delivery have been evaluated in recent years. Numerical scoring systems using historical risk factors have generally failed to identify most women who deliver preterm. Vaginal probe ultrasonographic cervical assessment (I-63) appears to increase the ability to predict spontaneous preterm birth in high-risk women, but currently has a limited role in the screening of normal-risk women. The fetal fibronectin immunoassay (see I-52) performed on cervical secretions obtained from the posterior fornix has a high negative predictive value for delivery within seven days of testing in women presenting with signs and symptoms of preterm labor. Other methods for identifying women at high risk for preterm labor include: home uterine activity monitoring, salivary estriol, screening for periodontal disease, and bacterial vaginosis (I-60) testing. However, the efficacy of these modalities has not been clearly demonstrated and their use remains controversial.

Historically, the lack of an effective treatment to prevent preterm birth has rendered any prediction scheme impotent. The ability of cervical cerclage to prevent preterm birth or lengthen gestation likewise remains questionable with conflicting reports of efficacy in the obstetric literature. Antimicrobial therapy, including treatment of bacterial vaginosis, does not appear to meaningfully reduce the preterm birth rate. Tocolysis of preterm labor with various agents remains unproven in the prevention of preterm delivery but is often used to prolong latency to allow the administration of antenatal corticosteroids.

In contrast to these controversial or minimally effective treatments, recent data suggest that the administration of progesterone (see A-4) intramuscularly or intravaginally beginning early in pregnancy in women at high risk for preterm birth significantly reduces the rate of preterm delivery. The possibility of preventing preterm birth, as the availability of progesterone treatment expands, raises the importance of identification of women at high risk for preterm delivery.

The identification of any of the risk factors for preterm birth should be documented clearly in the obstetric record to facilitate potential intervention. Generally, any such intervention should be logically based upon the plausible
strength of association between the risk factors for preterm birth and the ability of the intervention to mitigate such risks. For instance, a history of prior preterm birth places a woman at higher risk for preterm delivery than simply a maternal age younger than 17 years, though both are known risk factors.

The use of predictors of spontaneous preterm birth permits identification of a group of women for whom increased surveillance and possible intervention may be tested. By stratifying women at low risk for preterm birth to normal surveillance, unnecessary, costly, and potentially hazardous intervention might be avoided. As various combinations of risk factors may be present in any one woman, the Working Group recommends a simple approach by which women are stratified according to the normal or increased requirements of surveillance as early as possible in the pregnancy. The appropriate intervention or referral may then be made based on these categorizations.

For discussion and summary of risk factors see Appendix D.

**EVIDENCE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Offer progesterone therapy to women at risk for recurrent preterm birth</td>
<td>Da Fonseca et al., 2003 Fonseca et al., 2007 Meis et al., 2003</td>
<td>I</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 Progesterone may be administered intramuscularly or intravaginally</td>
<td>ACOG, 2003 Da Fonseca et al., 2003 Fonseca et al., 2007 Meis et al., 2003</td>
<td>III</td>
<td>Poor</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Fair</td>
<td>Good</td>
</tr>
<tr>
<td>3 Progesterone should be initiated after consultation with obstetrician or MFM specialist</td>
<td>ACOG, 2003 Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
</tr>
<tr>
<td>1 Surveillance and intervention based on risk stratification for preterm birth</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

**A-5. Routine Visits:**

Visits during this period should include the following:

- Auscultation of fetal heart tones - if negative, elevate care
- Screening fundal height
- Screening for hypertensive disorders
- Assessing weight gain
- Education about symptoms of preterm labor (week 20)

For specific interventions see Prenatal Care Interventions – Weeks 16-27.
A-6. Routine Visits:  Weeks 28-41

Visits during this period should include the following:
- Auscultation of fetal heart tones - if negative, elevate care
- Screening fundal height
- Screening for hypertensive disorders
- Assessing weight gain
- Assessing for symptoms of preterm labor (week 28, 32)
- Assessing fetal kick counts

For specific interventions see Prenatal Care Interventions – Weeks 28-41.

A-7. Postpartum Visit

BACKGROUND

The postpartum visit provides the opportunity for providers to interact with the new mother and her infant through interview, exam, and testing. The timing and the content of the postpartum visit have often been topics for debate. Recent literature helps the provider to answer these questions based on the evidence. The maternal postpartum visit should occur approximately eight weeks after delivery. Eight weeks is the optimal time to decrease the rate of false positive cervical smears.

RECOMMENDATIONS

1. The following should be included in the postpartum visit:
   - Pelvic and breast examinations. [B]
   - Cervical smear should be completed as indicated by cervical cancer screening guidelines (see I-31). [A]
   - Initiate or continue the HPV vaccine series for women age < 26 years (see I-50). [C]
   - Screening for postpartum depression (see I-21). [B]
   - Screening for domestic violence (see I-20). [B]
   - Diabetes testing for patients with pregnancies complicated by gestational diabetes. The two-hour 75g oral glucose tolerance test (GTT) is recommended but a fasting glucose can also be done. [B]
   - Education about contraception, infant feeding method, sexual activity, weight, exercise and the woman’s assessment of her adaptation to motherhood. Pre-existing or chronic medical conditions should be addressed with referral for appropriate follow-up as indicated. [I]

DISCUSSION

The optimal timing of the postpartum visit is approximately eight weeks after delivery. This time is chosen primarily due to the decreased rate of abnormal cervical smears observed at eight weeks (28 percent) versus the rate at six (32 percent) or four (59 percent) weeks. There were no differences in the distribution of abnormal Pap smears at the repeat smear done three months after the postpartum examination (Rarick & Tchabo, 1994) though this data does not take into account the use of liquid-based cytology and the most current recommendations for frequency of Pap smears. Some providers may choose to perform the visit at six weeks for convenience of the woman who is returning to work before the eight-week time frame. As facilities switch to liquid-based cytology, new studies will be needed to evaluate the number of false positives at six versus eight weeks postpartum to optimize visit timing.
The postpartum Pap smear is of value in identifying a significant yield of dysplasia. The sensitivity of the prenatal Pap test may be less than desired. The rate of abnormal postpartum smears in pregnant women with normal prenatal smears ranges from 2.8 (Londo et al., 1994) to over 5 percent (Weiss et al., 1989). These studies are challenged by a smaller study by Jazayeri and colleagues, who found that in patients without risk factors for cervical intraepithelial neoplasia and a normal Pap smear during pregnancy, there was no significant difference between their prenatal and postpartum smears (Jazayeri et al., 1999).

Women with a history of GDM are at increased risk of developing diabetes. Some women will be diagnosed shortly after pregnancy, suggesting they had pre-existing diabetes. Although the ADA advocates use of fasting blood glucose determination, the oral GTT will more accurately identify those women with impaired glucose tolerance. Unfortunately, the incidence of postpartum screening in women with GDM is poor.

There is no evidence to recommend for or against discussion of specific topics at the postpartum visit. Topics to be addressed at this visit are ultimately based on the discretion of the provider and the needs of the woman.

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Postpartum visit at eight weeks</td>
<td>Rarick &amp; Tchabo, 1994</td>
<td>I</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>2 Tests traditionally performed at this visit include the cervical smear, pelvic exam, and breast exam. The Pap smear may be deferred in women without a history of abnormal Pap smears and whose Pap smear remains current</td>
<td>Jazaveri et al., 1999 Londo et al., 1994 Weiss et al., 1989</td>
<td>II</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>3 Diabetes screening in women whose pregnancies were complicated by GDM</td>
<td>ACOG, 2001 Conway, 1999</td>
<td>II</td>
<td>Fair</td>
<td>B</td>
</tr>
</tbody>
</table>

**LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)**
**INTERVENTIONS**

Prenatal care for all pregnant women should include the interventions listed in the following Summary Table. Each intervention should be completed by the indicated week (NOTE: Between weeks 38-41, weekly visits may be needed). Intervention marked with * only apply if the risk/condition has been identified/diagnosed.

**Summary Table: Prenatal Care Interventions**

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>Trimester</th>
<th>Week:</th>
<th>6-8</th>
<th>10-12</th>
<th>16-20</th>
<th>24</th>
<th>28</th>
<th>32</th>
<th>36</th>
<th>38-41</th>
<th>Post Date</th>
<th>Post-partum</th>
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<tbody>
<tr>
<td>I-1 Screening for hypertensive disorders</td>
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<td>I-2 Breastfeeding education</td>
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<td>I-3 Exercise during pregnancy</td>
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<td>I-4 Influenza vaccine (season-related)</td>
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<td>I-5 Screening for tobacco use - offer cessation</td>
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<td>I-6 Screening for alcohol use - offer cessation</td>
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<td>I-7 Screening for drug abuse - offer cessation</td>
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<td>I-8 Screening for Rh status</td>
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<td>I-9 Screening for rubella</td>
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<td>I-12 Treatment for hepatitis B *</td>
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<td>I-13 Screening for syphilis (Rapid Plasma Reagin)</td>
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<td>I-14 Screening for asymptomatic bacteriuria</td>
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<td>I-15 Screening for tuberculosis</td>
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<td>I-16 Screening for HIV – counsel</td>
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<td>I-17 Immunization – Td booster (first trimester)</td>
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<td>I-19 Screening for hemoglobinopathies *</td>
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<td>I-20 Screening for domestic abuse</td>
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<td>I-21 Screening for depression</td>
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<td>I-23 Auscultation fetal heart tones</td>
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<td>I-24 Screening fundal height</td>
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<td>I-25 Assessing weight gain (inappropriate)</td>
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<td>Management of obesity *</td>
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<td>Gastric bypass consideration *</td>
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<td>Screening for gonorrhea</td>
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<td>I-30</td>
<td>Screening for Chlamydia</td>
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<td>Screening for cervical cancer</td>
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<td>Screening for HSV and prophylaxis</td>
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<td>Management of depression *</td>
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<td>I-35</td>
<td>Assessment of periodontal disease</td>
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<td>I-36</td>
<td>Education about Prenatal Screening</td>
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<td>- Screening test 1st trimester</td>
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<td>I-37</td>
<td>Obstetric ultrasound</td>
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<td>I-38</td>
<td>Education about preterm labor</td>
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<td>I-39</td>
<td>Counseling for trial of labor *</td>
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<td>I-40</td>
<td>Screening for gestational diabetes</td>
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<td>I-41</td>
<td>Iron supplementation *</td>
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<td>I-42</td>
<td>Anti-D prophylaxis for Rh-negative women *</td>
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<td>I-43</td>
<td>Assess for preterm labor</td>
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<td>I-44</td>
<td>Daily fetal movement counts</td>
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<td>Screening for Group B Streptococcal (GBS)</td>
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<td>I-48</td>
<td>Consider Weekly cervical check/stripping</td>
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<td>I-50</td>
<td>Immunization HPV vaccine *</td>
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<td>I-51</td>
<td>Education on Shaken Baby Syndrome</td>
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### Interventions Not Recommended In Routine Prenatal Care (All Weeks)

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<th>Intervention</th>
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<tbody>
<tr>
<td>I-52</td>
<td>Screening with fetal fibronectin</td>
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<td>I-53</td>
<td>Cervical examination</td>
</tr>
<tr>
<td>I-54</td>
<td>Antenatal pelvimetry</td>
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<tr>
<td>I-55</td>
<td>Urine dipstick test</td>
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<td>I-56</td>
<td>Edema evaluation</td>
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<tr>
<td>I-57</td>
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<td>I-58</td>
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<td>I-59</td>
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<tr>
<td>I-64</td>
<td>Repeat screening for anemia, syphilis, and isoimmunization</td>
</tr>
<tr>
<td>I-65</td>
<td>Screening for hypothyroidism</td>
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</tbody>
</table>
Interventions at All Visits

I- 1. Screening for Hypertensive Disorders of Pregnancy: [Update] Weeks (All)

BACKGROUND

Hypertension in pregnancy can be defined as either a diastolic pressure greater than 90 mmHg or systolic pressure greater than 140 mmHg recorded on two separate occasions more than six hours apart, at any time during the gestation. Hypertension detected before the 20th week of gestation in the absence of gestational trophoblastic disease or high-order multiple gestation is generally considered indicative of chronic hypertension. Gestational hypertension is defined as isolated hypertension in the absence of proteinuria occurring after 20 weeks’ gestation. Hypertension occurring in conjunction with proteinuria beyond 20 weeks’ gestation is classified as preeclampsia. Proteinuria is defined as >300 mg in a 24-hour urine collection in the absence of evidence of a urinary tract infection. Regardless of the etiology or specific diagnosis, all hypertensive disorders of pregnancy are associated with an increased risk for adverse perinatal outcome and require supplemental monitoring and care beyond the routine care outlined in this guideline.

RECOMMENDATIONS

1. Recommend measuring blood pressure of all pregnant women at each prenatal visit, following the guidelines of the National High Blood Pressure Education Program and the VA/DoD Clinical Practice Guidelines for Hypertension. [B]

2. Women diagnosed with hypertension during pregnancy should be managed by, or in consultation with, an advanced prenatal care provider. [C]

3. Korotkoff 5 sound (disappearance of sound) will be used to determine the diastolic pressure. [C]

DISCUSSION

The risks of untreated preeclampsia and chronic hypertension in pregnancy are many. Potential maternal complications include placental abruption, renal failure, cerebral hemorrhage, disseminated intravascular coagulation, pulmonary edema, circulatory collapse, eclampsia, and death. Fetal complications may include hypoxia, low birth weight, premature delivery, or perinatal death (Chesley, 1984; Cunningham & Lindheimer, 1992; National Institutes of Health [NIH] Working Group on High Blood Pressure in Pregnancy, 2000). There are no clinical tests or signs that remotely and accurately predict outcomes of the various hypertensive disorders of pregnancy; thus, any woman demonstrating persistent hypertension during pregnancy should be considered at increased risk for adverse perinatal outcomes and monitored appropriately.

The best screening strategy for hypertension in pregnancy appears to be early detection of hypertension through routine screening at each prenatal encounter. Although there is no direct proof that regular blood pressure screening reduces maternal or perinatal morbidity or mortality, it is unlikely that ethical concerns will allow a study to withhold blood pressure screening or treatment from a control group. Since the screening test is simple, inexpensive, and acceptable to women, screening is indicated on an empirical basis (United States Preventive Services Task Force [USPSTF], 1996; NIH Working Group on High Blood Pressure in Pregnancy, 2000). There are no updated consensus reports from either the USPSTF or NIH.

The collection of meaningful blood pressure data requires consistent use of correct technique and a cuff of appropriate size. The woman should be in the sitting position and the blood pressure should be measured after the woman has rested for five minutes. The blood pressure cuff should be appropriately sized for the woman’s arm and placed at the level of the heart (National High Blood Pressure Education Program, 1990). Korotkoff 5 sound (disappearance of sound) will be used for determining the diastolic pressure (NIH Working Group on High Blood Pressure in Pregnancy, 2000).
While the overall recommendations contained in this section are graded as Level III quality of evidence, it is important to recognize that these expert consensus recommendations are actually based on evidence-based information spanning the spectrum of scientific validity from level I through III. Providers are referred to the appropriate most current documents for further descriptions and discussion (USPSTF, 1996; ACOG, 2001; NIH Working Group on High Blood Pressure in Pregnancy, 2000). Also, see VA/DoD guidelines for Hypertension in Primary Care.

It should be noted here that there is emerging, albeit controversial, data regarding antiplatelet therapy in patients with hypertensive disorders of pregnancy. There are ongoing studies investigating the positive role of low-dose aspirin administration in patients at risk for developing preeclampsia. While the current body of literature, including a Cochrane review, provides evidence of no increased risk of perinatal complications with the use of low-dose aspirin in the second and third trimester, there is a paucity of information regarding which women are most likely to benefit, when treatment is best started and at what dose (Askie et al., 2007; Duley et al., 2007; Kozer et al., 2003).

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine blood pressure screening at each prenatal visit</td>
<td>ACOG, 2001NIH Working Group on High Blood Pressure in Pregnancy, 2000USPSTF, 1996</td>
<td>III</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>2 Women diagnosed with hypertension may require a higher level of care</td>
<td>ACOG, 2001Cunningham &amp; Lindheimer, 1992NIH Working Group on High Blood Pressure in Pregnancy, 2000</td>
<td>III</td>
<td>Poor</td>
<td>B</td>
</tr>
</tbody>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

### I- 2. Breastfeeding Education: Weeks (All)

**BACKGROUND**

Between 50 and 90 percent of expectant mothers decide how they will feed their babies either before conceiving or very early in pregnancy (Bailey & Sheriff, 1992; Dix, 1991). Prenatal breastfeeding education is a key opportunity to educate expectant mothers on the benefits and methods associated with successful breastfeeding during the time they are making their decision on choice of infant feeding method.

**RECOMMENDATIONS**

1. Recommend offering breastfeeding education to all pregnant women during the first visit with the provider. [B]
2. Recommend asking pregnant women, “What do you know about breastfeeding?” rather than, “Do you plan on breast or bottle feeding?” to provide an open opportunity for education. [B]
3. Recommend continuing education throughout pregnancy for those pregnant women who express a desire to breastfeed or for those who are still undecided on feeding method. [C]
4. Recommend including family/significant others in breastfeeding education. [B]

**DISCUSSION**

Breastfeeding is the most nutritious form of feeding the human infant, offering such immunologic benefits as lowering the incidence of otitis media (Duncan et al., 1993) and gastrointestinal tract disease (Howie et al., 1990). Breastfeeding mothers also benefit with less postpartum blood loss, faster return to prepartum weight (Dewey et al., 1993) and decreased incidence of both ovarian (Gwinn et al., 1990) and breast cancers (Layde et al., 1989). Providers caring for pregnant women are ideally positioned to educate these women about the multiple benefits of
breastfeeding. Care should be taken to approach the topic with sensitivity to engender a supportive environment for questioning. The BEST Start Program is one that focuses on asking the woman for information regarding her beliefs about breastfeeding, rather than focusing just on her infant feeding method of choice (Bryant & Roy, 1990). Use of this method has been associated with a 50 percent increase in breastfeeding in the general population, with more marked effects in teenagers. At the first prenatal visit, a woman is asked, “What do you know about breastfeeding?” instead of “Are you going to breastfeed or bottle feed this baby?” The program elicits and acknowledges the mother’s concerns and then educates her about the benefits of breastfeeding. This is repeated at each prenatal visit. Appropriate prenatal breastfeeding education is instrumental in helping the mother to establish realistic expectations, which, in turn, will prevent premature weaning. Use of anticipatory guidance has been shown to positively influence the breastfeeding process. Including the mother’s significant other is helpful, since positive, knowledgeable support promotes increased breastfeeding satisfaction and duration. Education provided over the course of the pregnancy should be personalized for each woman with particular attention being paid to those women who have had prior breast surgery or who have noticed no change in breast size over the course of the pregnancy. These women should be provided additional information by a provider well acquainted with breastfeeding education or by a lactation consultant.

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<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
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</thead>
<tbody>
<tr>
<td>1 Breastfeeding inquiry</td>
<td>Hartley &amp; O’Connor, 1996</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 Breastfeeding education</td>
<td>Hill &amp; Humenick, 1993</td>
<td>III</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Hill, 1991</td>
<td>II-3</td>
<td></td>
<td></td>
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<tr>
<td>3 Longitudinal breastfeeding education</td>
<td>Berens, 2001</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>4 Family/significant other participation in breastfeeding education</td>
<td>Berens, 2001</td>
<td></td>
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<td></td>
<td>Humenick et al., 1997</td>
<td>III</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 3. Exercise During Pregnancy: Update

BACKGROUND

Attitudes toward exercise during pregnancy have changed markedly in recent decades. The underlying concern has revolved around fears that the exercise-induced increases in maternal body temperature, circulating stress hormones, and biomechanical stress, coupled with the decreased visceral blood flow, could have adverse effects on multiple aspects of the course and outcome of pregnancy. Only recently has a substantial amount of research been completed to support the idea that it is both safe and beneficial to exercise during pregnancy. Currently, there is no evidence to suggest that regular maternal exercise is associated with fetal compromise or unexplained fetal death. Furthermore, regular exercise improves maternal fitness, reduces the usual musculoskeletal complaints associated with pregnancy, enhances feelings of well being, improves body image, and decreases maternal weight gain and fat deposition in late pregnancy.

RECOMMENDATIONS

1. Strongly recommend all healthy, pregnant women perform regular mild to moderate exercise sessions, three or more times per week. [A]
2. Recommend individualized exercise programs for all pregnant women, based on their pre-pregnancy activity level. [I]
3. Recommend against high-altitude (>10,000 feet) activities, scuba diving, and contact sports during pregnancy. [I]
DISCUSSION

A meta-analysis by Kramer and McDonald (2006) combined results from 11 studies and found that regular exercise in pregnancy improves or maintains physical fitness without negative effects on the mother or fetus. Hatch et al. (1993) and Clapp et al. (2000) found that for low-risk women, maternal exercise enhanced feto-placental growth and was not associated with adverse maternal or fetal outcomes. Cycling and swimming are currently considered the safest form of exercise during pregnancy, but walking seems to be the most frequent form of exercise (43 percent) actually chosen by pregnant women. At present, there is no published literature on the effect of weight training on the course and outcome of pregnancy (Clapp, 2001). Several randomized controlled trials (RCTs) and numerous prospective observational studies by Clapp have looked at the effects of exercise on low-risk women. Some of these women led sedentary lifestyles prior to pregnancy and began a formal exercise program during the first trimester, and others were trained athletes who continued to exercise at training levels throughout the duration of their pregnancies. Neither group of women demonstrated associated adverse maternal, fetal, or neonatal effects and there were varying degrees of benefit.

On the other hand, pregnancy complications are much higher and birth weights significantly lower at altitudes above 10,000 feet, which suggests that exposure to the additional physiologic stress produced by exercising at high altitudes may not be wise (Alderman et al., 1995). Similarly, pregnant women who dive recreationally to levels requiring decompression on a regular basis, demonstrate a three- to six-fold increase in the incidence of spontaneous abortion, congenital malformation, intrauterine growth restriction, and preterm labor (Camporsei, 1996). Common sense dictates that contact sports or any activity where there is a reasonable risk of abdominal trauma (e.g., kickboxing, hockey, football, skydiving, soccer, and horseback riding) should be avoided during pregnancy (Hammer et al., 2000).

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<th>Recommendations</th>
<th>Sources of Evidence</th>
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<th>QE</th>
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<tbody>
<tr>
<td>2 Individualized exercise programs, based on the woman’s pre-pregnancy activity level</td>
<td>ACOG, 1994 Clapp et al., 1999 Sternfeld et al., 1995</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>3 High altitude, contact sports and scuba diving (not recommended)</td>
<td>Alderman et al., 1995 Camporsei, 1996 Hammer et al., 2000</td>
<td>II-2</td>
<td>Good</td>
<td>D</td>
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</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 4. Influenza Vaccine (Season-Related): Weeks (Any Week)

BACKGROUND

Women who acquire influenza during pregnancy may experience an increase in morbidity and mortality during an epidemic, with a possible increased abortion rate. Most recent CDC guidelines suggest that immunization of pregnant women for influenza has been found to be safe for both the mother and the fetus regardless of gestational age.
RECOMMENDATIONS

1. Recommend immunizing all pregnant women for influenza during the epidemic season. [B]

DISCUSSION

Maternal immunization can enhance passive immunity of infants to pathogens that cause life-threatening illnesses. In most instances, immunization during pregnancy will provide important protection for the woman, as well as for her infant (Englund et al., 1998).

Influenza vaccination may be offered to anyone who wishes to reduce the chance of becoming ill with influenza, to include pregnant women who will be in the second or third trimester during epidemic season. Pregnant women with medical problems should be offered the influenza vaccination before the influenza season regardless of stage of pregnancy (ACOG #305, 2004).

EVIDENCE TABLE

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<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
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</thead>
<tbody>
<tr>
<td>1. Influenza immunization</td>
<td>ACOG, 2004</td>
<td>II</td>
<td>Fair</td>
<td>B</td>
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<td></td>
<td>Englund et al., 1998</td>
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*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

First Visit with Nurse (6-8 Weeks)

**1- 5. Screening for Tobacco Use – Offer Cessation:**

**BACKGROUND**

Tobacco use in pregnancy is associated with decreased birth weight, as well as risk for spontaneous abortion and preterm labor. Newborns exposed to environmental tobacco smoke experience an increased incidence of upper respiratory infections and deaths from Sudden Infant Death Syndrome (SIDS). Behavioral and pharmacologic methods for smoking cessation are both safe and effective in pregnancy.

**RECOMMENDATIONS**

1. Strongly recommend routine screening for tobacco use in pregnancy at the initial prenatal visit. For patients who smoke, recommend assessment of smoking status at each subsequent prenatal visit. [A]
2. If the screening is positive, cessation should be strongly recommended. [A]
3. There is insufficient data to recommend for or against pharmacologic therapy for tobacco cessation in pregnancy. [I]

**DISCUSSION**

A Cochrane review (Lumley et al., 2004) found that all nicotine replacement therapy (NRT) products are Category D and not recommended for use by pregnant women. Despite the absence of data on safety, efficacy, and effectiveness, the use of pharmacologic agents in pregnancy is becoming increasingly considered, given the increased awareness of the harm from smoking in pregnancy and the benefits of pharmacotherapy (Benowitz et al., 2000). Dempsey et al. (2001) recommend that doses of prescribed nicotine in pregnancy should be similar to a smoking dose, and that intermittent forms of NRT (gum, spray, inhaler) are preferred to continuous use formulations as the total dose of nicotine will be less. All NRT trials in pregnancy to date are of nicotine patches (continuous use formulations). As there are still too few trials to assure safe use in pregnancy, and animal studies suggest nicotine...
may be toxic to the developing central nervous system, Dempsey et al. (2001) recommend registries of women using NRT be established to gather more outcome data. Certainly, if nicotine replacement therapy results in smoking cessation and subsequent cessation of the nicotine replacement therapy, the overall dose of nicotine to the fetus would be less than if the woman continues to smoke.

Bupropion is Category C, but no trials for smoking cessation in pregnancy have been reported (Oncken, 2003). Chantix (varenicline) is Category C, but has not been studied in pregnant women. Animal studies reported low fetal weights and fertility problems in offspring (package insert).

### EVIDENCE TABLE

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<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
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<tbody>
<tr>
<td>1 Screening for tobacco use</td>
<td>Dolan-Mullen et al., 1991</td>
<td>I</td>
<td>Good</td>
<td>A</td>
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<tr>
<td></td>
<td>Lumley et al., 2004</td>
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<tr>
<td>2 Cessation of tobacco use</td>
<td>Dolan-Mullen et al., 1994</td>
<td>I</td>
<td>Good</td>
<td>A</td>
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<td></td>
<td>Panjari et al., 1999</td>
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<td></td>
<td>Wisborg et al., 2000</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

### I-6. Screening for Alcohol Use – Offer Cessation: Weeks 6 - 8

#### BACKGROUND

Alcohol is a known teratogen with adverse effects on fetal facial and central nervous system development. Maternal alcohol consumption is a leading preventable cause of birth defects and childhood disabilities in the United States (Centers for Disease Control [CDC], 1995). While there is a clear dose-dependent effect, numerous observational studies have failed to delineate a threshold level for safe alcohol consumption during pregnancy.

#### RECOMMENDATIONS

1. Recommend routine screening for alcohol consumption using a standardized tool (refer to the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders). [B]
2. If the screening is positive, cessation should be strongly recommended. [B]
3. There is insufficient evidence regarding which cessation intervention tool is the most effective. [I]

#### DISCUSSION

One screening and treatment study showed good identification of pregnant drinkers with the T-ACE tools, but no difference with a brief counseling intervention (i.e., one-hour session with a trained counselor) (Chang et al., 1999). Two smaller RCTs of brief interventions showed modest reductions in alcohol use (Handmaker et al., 1999; Reynolds et al., 1995). No evidence was found showing the effect of any interventions on maternal or neonatal morbidity or mortality.

There are several brief alcohol screening questionnaires available for routine office use. The T-ACE questionnaire with a cut-off of tolerance of >2 drinks/day and the TWEAK questionnaire with a cut-off of >1 drink/day seem to have the highest sensitivities for alcohol use (Chang et al., 1998; Bradley et al., 1998). The standard ACOG antepartum record questions are not useful for detecting alcohol consumption in pregnant women (Budd et al., 2000).
EVIDENCE TABLE

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<th>Recommendations</th>
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<th>QE</th>
<th>SR</th>
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</table>
| 1. Screening for evidence of problem drinking, using a standardized tool | Chang et al., 1999  
Handmaker et al., 1999  
Reynolds et al., 1995 | I  | Fair | B  |
| 2. If the screening is positive, recommend cessation | Chang et al., 1999  
Handmaker et al., 1999  
Reynolds et al., 1995 | I  | Fair | B  |

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 7. Screening for Drug Use – Offer Treatment: Weeks 6 - 8

BACKGROUND

Up to one in ten babies may be exposed to illegal drugs during pregnancy. Use of these drugs may be harmful to the health and growth of the fetus, particularly early in pregnancy. Drug use later in pregnancy increases the risk for preterm delivery and fetal growth restriction. Risks to the mother include HIV, hepatitis, and addiction.

RECOMMENDATIONS

1. Recommend routine screening for illicit drug use using a self-report method. [C]
2. Recommend pregnant women identified as abusing drugs be offered treatment and receive care in consultation with or referral to an advanced prenatal care provider. (See also VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.) [C]

DISCUSSION

One systematic review and two cohort studies were identified. One study recommended screening for drug use by using a self-report method (Howell et al., 1999). Ask the question: “Are you currently using or have you used recreational/illicit drugs during this pregnancy?” (Horrigan et al., 1996). No systematic reviews or trials evaluating a screen-and-treat strategy for substance abuse were found.

A low-quality but inclusive qualitative systematic review of variable quality trials revealed benefits to different drug abuse treatment programs for pregnant women. Benefits included improved treatment retention rates, increased birth weights, decreased drug use, and increased knowledge of issues surrounding drug abuse (Howell et al., 1999).

The diagnosis of substance abuse is hampered by the potential for adverse socio-economic consequences pertaining to discovery of the abuse.

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<th>QE</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. Routine screening for illicit drug use</td>
<td>Horrigan et al., 1996</td>
<td>II-2</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>2. If the screening is positive, offer treatment</td>
<td>Howell et al., 1999</td>
<td>II-3</td>
<td>Fair</td>
<td>C</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)
I- 8. Screening for Blood Type (ABO,Rh) and Antibody Status: Weeks 6 to 8

BACKGROUND

Since the introduction of anti-D (Rhogam) immune globulin injections during and after pregnancy in women who are D antigen negative, the incidence of isoimmunization has fallen from 10 cases to 1.3 cases/1,000 live births. Testing and identification of pregnant women with non-anti-D antibodies allows for early treatment of infants, which may improve fetal outcomes.

RECOMMENDATIONS

1. Recommend evaluation of maternal ABO and Rh blood type and blood antibody status at the initial prenatal visit. [B]
2. Pregnant women with positive antibody screens should be referred for consultation to assist with further management. [C] (see I-42)
3. There is insufficient evidence to recommend for or against routine repeat testing at 28 weeks' gestation. [I]

DISCUSSION

No systematic reviews or prospective studies were found comparing a regimen of “expanded” antibody testing to ABO and Rh testing only. Descriptive studies of isoimmunization and complication rates for non-Rh (D) antibodies show that there are increasingly comparable rates of morbidity and mortality associated with non-D as well as with D isoimmunization. Conventional Indirect Antiglobulin (Coombs') Testing appears to detect the majority of these cases. The overall burden of disease is low, but is similar to anti-D isoimmunization (Bowell et al., 1986; Howard et al., 1998).

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<th>Recommendations</th>
<th>Sources of Evidence</th>
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<tbody>
<tr>
<td>1 Antibody screening</td>
<td>Bowell et al.,</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>2 Rh status screening</td>
<td>Howard et al., 1998</td>
<td>II-2</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>3 Repeat screening at 28 weeks</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
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</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 9. Screening for Rubella: Weeks 6 - 8

BACKGROUND

Congenital Rubella Syndrome (CRS) is a constellation of findings in newborns exposed to the rubella virus prior to 16 weeks' gestation. The syndrome includes hearing loss, developmental delay, and ocular and cardiac defects. The incidence of CRS has declined dramatically since the advent of rubella vaccination in 1969. Identification of women lacking rubella immunity during the preconception period allows for immunization before pregnancy. Identification of non-immune women during pregnancy allows for risk counseling and immunization postpartum.

RECOMMENDATIONS

1. Recommend all pregnant women have a serum screen for rubella status at the initial prenatal visit. [B]
2. Recommend seronegative pregnant women be counseled to avoid exposure. [B]
3. Recommend seronegative pregnant women be vaccinated in the immediate postpartum period. [B]
DISCUSSION

Rubella in the first 16 weeks of pregnancy causes miscarriage, abortion, stillbirth, and CRS. The most common manifestations of CRS are hearing loss, developmental delay, growth retardation, and cardiac and ocular defects. Approximately 20 percent of infants born to mothers infected with rubella during the first three months of pregnancy have signs of CRS at birth, most commonly cataracts and congenital heart disease (McElhaney et al., 1999). No treatment for rubella is mentioned in the literature. Vaccination prior to pregnancy shows that greater than 90 percent have protection against clinical rubella illness, and seropositivity is long lasting. Due to concerns about possible teratogenicity, a measles/mumps/rubella (MMR) or measles vaccination is not recommended during pregnancy (Chang et al., 1970; Horstmann et al., 1985). Hemagglutination-Inhibition tests, associated with both false positive and false negative results, have been replaced by enzyme immunoassay and latex agglutination with sensitivities of 92 to 100 percent and specificities of 71 to 100 percent (Steece et al., 1985).

Postpartum vaccination demonstrates >90 percent protection against clinical rubella infection and seropositivity is long lasting. Vaccinating healthy women of childbearing age provides protection for the women from adult onset rubella and for their future children from Congenital Rubella Syndrome (CRS).

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<th>Sources of Evidence</th>
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<tr>
<td>1 Serum screening for rubella status at the initial prenatal visit</td>
<td>McElhaney et al., 1999</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 Counseling seronegative pregnant women to avoid exposure</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>B</td>
</tr>
<tr>
<td>3 Vaccinating seronegative pregnant women in the immediate postpartum period</td>
<td>Horstman et al., 1985</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 10. Screening for Varicella: Weeks 6 to 8

BACKGROUND

Varicella infection during pregnancy may lead to poor outcomes for both mother and fetus. The incidence of varicella in pregnancy is less than one in 1,000. Most adults are immune to varicella due to previous exposure. In women who report no history of infection, 85 percent are found to have positive antibody titers. Identification of non-immune persons through screening with subsequent immunization may decrease the incidence of varicella.

RECOMMENDATIONS

1. Recommend routine screening for varicella through history. [B]
2. If negative/unsure history, obtain a varicella titer. [B]
3. Recommend offering vaccination postpartum, if varicella is non-immune. [B]

DISCUSSION

A single systematic review was identified. The CDC (2007) recommends that all adults be immunized, if seronegative. Among U.S. women of childbearing age, the mean incidence of varicella is 2.16/1,000 per year. Maternal infection in the first half of the pregnancy has been associated with congenital varicella syndrome. In addition, varicella infections during pregnancy may result in higher rates of complications from the infection, such as varicella pneumonia and death (Smith et al., 1998). Varicella disease during the first two trimesters of pregnancy might infect the fetus and result in congenital varicella syndrome. Therefore, routine antenatal screening for
evidence of immunity and postpartum vaccination for those without evidence of immunity is now recommended (CDC, ACIP 2007).

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine varicella screening</td>
<td>Smith et al., 1998</td>
<td>I</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>2 Postpartum varicella immunization in seronegative pregnant women</td>
<td>CDC, 2007</td>
<td>I</td>
<td>Good</td>
<td>B</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

I- 11. Screening for Hepatitis B Virus (HBV): [Update]  

**BACKGROUND**

Each year in the United States an estimated 22,000 infants are born to women with chronic hepatitis B virus (HBV). The incidence of acute hepatitis B in pregnancy is 1 to 2/1,000 and the prevalence of chronic hepatitis B is 5-15/1,000. Certain groups including Southeast Asians, Pacific Islanders, Alaskan Native Americans, drug addicts, transfusion recipients, women on dialysis and those with tattoos have an increased prevalence of infection (Duff, 1998).

However, these risk factors will only identify 60 percent of women with HBV infection. Perinatal transmission of hepatitis B virus occurs if the mother has an acute infection, particularly during late pregnancy or the early postpartum period, or if the mother is a chronic hepatitis B antigen carrier.

The risk of vertical transmission (mother to infant) can be greatly reduced (>90 percent) if the infectious status of the mother is known and therapy is given to the baby shortly after delivery. The risk of vertical transmission may also be reduced by maternal therapy during the last month of pregnancy.

**RECOMMENDATIONS**

1. Recommend routine laboratory screening for hepatitis B surface antigen at the initial prenatal visit.  [A]
2. Repeat laboratory screening of pregnant women with identification of hepatitis risk factors during the pregnancy (e.g., healthcare worker, intravenous (IV) drug use, exposure to hepatitis, visit for evaluation or therapy for sexually transmitted infections, and new tattoos and blood transfusions).  [C]
3. Vaccinate pregnant women with hepatitis risk factors who have not been previously vaccinated.  [B]
4. Women at risk for HBV infection in pregnancy should be counseled concerning additional methods to prevent HBV infection.  [C]

**DISCUSSION**

Universal laboratory screening of all pregnant women for hepatitis B is recommended in early in pregnancy (ACOG, 2007). Screening strategies using only risk factors would fail to identify 40 percent of infected women (Mast et al., 2005). The mortality risk for adults contracting HBV is one percent. Most (85 to 90 percent) women infected with HBV will clear the infection completely and the remainder will be chronic carriers. In those 10 to 15 percent who become chronic carriers, 15 to 30 percent will have persistent hepatitis and cirrhosis with associated sequelae.

In contrast to adults, 85 to 95 percent of neonates who contract HBV will become chronic carriers and 25 to 30 percent will suffer serious complications or die from the disease. The vertical transmission rate is lowest with maternal disease in the first trimester (10 percent) and highest in the third trimester (90 percent).
Vaccination is effective in preventing maternal infection. Prenatal therapy for mothers and postnatal therapy for infants reduces the vertical transmission rate by more than 90 percent. Thus, prevention and therapeutic strategies can have a large impact in preventing neonatal infection in at-risk pregnancies.

Two single antigen vaccines for HBV are currently available and are 95 percent effective in producing seroconversion in recipients. An effective hepatitis A and B vaccine is also available and highly effective.

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Screen for hepatitis B at first prenatal visit</td>
<td>ACOG, 2007</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2. Rescreen pregnant women with risk factors for hepatitis</td>
<td>Duff, 1998</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>3. Vaccinate pregnant women with hepatitis risk factors who have not been previously vaccinated</td>
<td>Mast et al., 2005</td>
<td>II</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>4. Pregnant women at risk for HBV infection during pregnancy should be counseled concerning other methods of preventing HBV infection</td>
<td>Mast et al., 2005</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

**I- 12. Treatment for Hepatitis B Infection:**

**BACKGROUND**

Perinatal transmission of hepatitis B virus occurs if the mother has an acute infection, particularly during late pregnancy or the early postpartum period, or if the mother is a chronic hepatitis B antigen carrier.

Vertical transmission of infection occurs in 90 percent of pregnancies where the mother is hepatitis B e antigen positive and in about 10 percent of surface antigen positive, e antigen negative mothers. Most (85 to 95 percent) of infected infants become chronic carriers. Infants born to infectious mothers treated by both hepatitis vaccination and hepatitis B-specific immunoglobulin are 90 percent less likely to become infected than untreated infants.

There is also evidence that treating the mother in the last month of pregnancy with lamivudine or hepatitis B immunoglobulin may further reduce the transmission rate if she is highly infectious (HBV-DNA >1.2x10⁹ geq/mL).

**RECOMMENDATIONS**

1. Treat all infants born to hepatitis B positive mothers with Hepatitis B immunoglobulin and initiate hepatitis B vaccination within 12 hours of birth. [A]

2. Strongly consider treating infants born to women at high risk for hepatitis B who have not been vaccinated or whose infectious status is unknown. [B]

3. Consider treating women who have high copy numbers of HBV-DNA with lamivudine during the last month of pregnancy. [B]

4. Women with HBV infection should be taught, and encouraged to implement, strategies to decrease transmission to non-infected intimate contacts. [B]
DISCUSSION

Universal laboratory screening of all pregnant women for hepatitis B is recommended early in pregnancy (ACOG, 2007). Repeat screenings are also recommended for women who are, or become, high risk for acquiring hepatitis B infection during pregnancy. Such a strategy will identify approximately one percent of the overall population as being HBV positive during pregnancy.

The likelihood of vertical transmission is highest in the third trimester and around the time of birth. A combination of passive and active immunization of infants born to hepatitis B surface antigen-positive mothers affords very good protection to the infected infants (Sangfelt et al., 1995; Michielsen & Van Damme, 1999).

Randomized trials have demonstrated a reduction in late pregnancy vertical transmission by maternal therapy with lamivudine and with hepatitis B immune globulin (HBIG).

However, follow-on studies leave some uncertainty regarding the cost effectiveness of using HBIG alone to prevent vertical transmission (Yuan et al., 2006).

EVIDENCE TABLE

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<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Active and passive immunization of neonates born to HBV-positive mothers within 12 hours of birth</td>
<td>Sangfelt et al., 1995; Michielsen &amp; Van Damme, 1999 ACOG, 2007 #86</td>
<td>I</td>
<td>Good</td>
</tr>
<tr>
<td>2.</td>
<td>Strongly consider treating infants born to women at high risk for hepatitis B who have not been vaccinated or whose infectious status is unknown</td>
<td>ACOG, 2007 #86</td>
<td>II</td>
<td>Good</td>
</tr>
<tr>
<td>3.</td>
<td>Consider treating women who have high copy numbers of HBV-DNA lamivudine during the last month of pregnancy</td>
<td>Ahu et al., 2003 Li et al., 2004 Van Zonneveld et al., 2003 Xu et al., 2004</td>
<td>I</td>
<td>Good</td>
</tr>
<tr>
<td>4.</td>
<td>Teach and encourage women with HBV to implement strategies to decrease transmission to non-infected intimate contacts</td>
<td>ACOG, 2007 #86 Mast et al., 2005</td>
<td>II</td>
<td>Fair</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)


BACKGROUND

Syphilis is a sexually transmitted disease that can cause significant mortality and morbidity in both the mother and fetus. The disease is acquired through either sexual or congenital transmission and can be effectively treated using broad-spectrum antibiotics. Screening for maternal syphilis, treating, and tracking all confirmed cases, can prevent congenital syphilis.

RECOMMENDATIONS

1. Recommend routine screening for syphilis using serologic testing (i.e., RPR or Venereal Disease Research Laboratory [VDRL]) at the initial prenatal visit. [B]
2. Recommend a confirmatory test using a more specific treponemal assay (FTA-ABS, MHA-TP, HATTS) for pregnant women who test positive. [B]
3. Strongly recommend therapy with penicillin G antibiotic for pregnant women who have confirmed syphilis, as recommended by other sexually transmitted disease (STD) guidelines. [A] 

4. Recommend appropriate medical and legal mandates follow-up and state/service branch reporting requirements for pregnant women screening positive. [I]

**DISCUSSION**

Three cohort studies identified strong association between untreated maternal syphilis and premature birth as well as a wide variety of severe abnormalities (Donders et al., 1993; Dorfman & Glaser, 1990). A number of variables are associated with asymptomatic syphilis: large urban areas or southern states, a history of STDs, low socioeconomic status, black race or Hispanic heritage, and a history of prostitution or IV drug use (CDC, 1998). Serologic tests have a sensitivity of 62 to 76 percent in primary syphilis and near 100 percent in secondary syphilis. Treponemal tests should not be used as initial screening tests (Hart, 1986). Maternal antibiotic therapy prevents nearly all congenital syphilis.

**EVIDENCE TABLE**

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<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
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<th>SR</th>
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</thead>
<tbody>
<tr>
<td>1 Routine syphilis screening</td>
<td>Donders et al., 1993, Dorfman &amp; Glaser, 1990</td>
<td>II-3</td>
<td>Fair</td>
<td>A</td>
</tr>
<tr>
<td>2 Confirmatory syphilis testing in pregnant women with positive screens</td>
<td>Hart, 1986</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>3 Treatment of confirmed positive</td>
<td>CDC, 1998</td>
<td>II-2</td>
<td>Fair</td>
<td>A</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

#### I- 14. Screening for Asymptomatic Bacteriuria:

**Weeks 6 - 8**

**BACKGROUND**

Bacteriuria occurs in two to seven percent of pregnant women. Asymptomatic bacteriuria (ASB) in pregnant women is an established risk factor for serious complications including pyelonephritis, preterm delivery, and low birth weight.

**RECOMMENDATIONS**

1. Strongly recommend screening for ASB at initial obstetrical visit via urine culture and sensitivity. [A]

2. There is insufficient evidence to recommend for or against repeat screening throughout the remainder of pregnancy. [I]

3. Strongly recommend a three to seven-day course of appropriate antibiotics based on positive culture and sensitivity, and woman's history of medication allergies. [A]

4. There is insufficient evidence to recommend for or against a test of cure (TOC) after completion of antibiotic therapy, except in pregnant women with ASB-Group B Strep. [I]

**DISCUSSION**

The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit (Grade A) on the basis of good evidence that treatment for asymptomatic bacteriuria reduces the incidence of symptomatic urinary tract infections, low-birth-weight children, and preterm delivery (USPSTF, 2008).
Pregnant women with ASB have a 13 to 27 percent chance of developing pyelonephritis. They also have a 1.5 to 2-fold increased risk of preterm delivery or delivery of a low-birth-weight infant compared to women without ASB (Smaill, 2001).

Treatment of ASB in pregnancy reduces the risk of maternal pyelonephritis (numbers-needed-to-test [NNT]=7) and the risk of preterm delivery and/or low birth weight infants (NNT=21) compared to no treatment or placebo (Smaill, 2001).

The risks of pyelonephritis and preterm delivery/low-birth-weight infants are reduced by similar degrees with either short-term treatment (three to seven days) or continuous treatment until delivery. There are no differences in cure rates for bacteriuria or rates of recurrent ASB between single-dose and short-course therapy, but the data for this outcome are heterogeneous; the data regarding pyelonephritis and preterm delivery are too limited to be definitive (Smaill, 2001).

Dipstick urine tests, microscopic examination for pyuria and bacteriuria, and rapid enzymatic screening tests do not accurately detect ASB in pregnancy (Millar et al., 2000).

### EVIDENCE TABLE

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<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Screen ASB at the initial prenatal visit by urine culture</td>
<td>Romero et al., 1989 Smaill, 2001 USPSTF, 2008</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2 Repeat screening throughout pregnancy</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
<tr>
<td>3 A three- to seven-day course of appropriate antibiotics based on positive culture and sensitivity, and woman's history of medication allergies</td>
<td>Smaill, 2001</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>4 TOC after completion of antibiotic therapy</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

### BACKGROUND

The incidence of tuberculosis has increased in the United States. Most new cases occur in cities with at least 500,000 people and in women in higher risk groups. High-risk groups for tuberculosis include individuals who:

- Have HIV infection
- Live in close contact with individuals known or suspected to have tuberculosis
- Have medical risk factors known to increase risk of disease if infected
- Are born in a country with high tuberculosis prevalence
- Are medically underserved
- Have a low income
- Are alcoholics
- Are intravenous drug users
- Are residents of long-term care facilities (e.g., correctional institutions, mental institutions, nursing homes and facilities)
- Are healthcare professionals working in high-risk healthcare facilities.
RECOMMENDATIONS

1. All pregnant women from one or more high-risk groups should be screened for tuberculosis with a Mantoux test with purified protein derivative (PPD) soon after the pregnancy is diagnosed. [C]

2. Pregnant women with a positive PPD with known conversion in the last two years and no clinical or X-ray evidence of disease should be treated with isoniazid (300 mg per day) starting after the first trimester and continuing for nine months. [C]

3. For pregnant women with a positive PPD whose time of conversion is unknown and who have no clinical or X-ray evidence of disease present, consider delaying therapy until after the pregnancy. [C]

4. Pregnant women with active tuberculosis should be treated with multi-drug therapy including isoniazid and rifampin, supplemented by ethambutol if isoniazid drug resistance is suspected. [C]

EVIDENCE TABLE

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<tr>
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<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. All pregnant women from one or more high-risk groups should be screened for</td>
<td>ACOG Guidelines for Perinatal Care, 1998</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
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<tr>
<td>tuberculosis with a Mantoux test with purified protein derivative (PPD) soon</td>
<td>ATS/CDC, 2000</td>
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<td>after the pregnancy is diagnosed</td>
<td>ACOG, 2006</td>
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<tr>
<td>2. Pregnant women with a positive PPD with known conversion in the last two</td>
<td>ACOG Guidelines for Perinatal Care, 1998</td>
<td>II,</td>
<td>III</td>
<td></td>
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<tr>
<td>years and no clinical or X-ray evidence of disease should be treated with</td>
<td>ATS/CDC, 2000</td>
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<tr>
<td>isoniazid (300 mg per day) starting after the first trimester and continuing</td>
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<td>for nine months</td>
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<tr>
<td>3. For pregnant women with a positive PPD whose time of conversion is unknown</td>
<td>ACOG Guidelines for Perinatal Care, 1998</td>
<td>II</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>and who have no clinical or X-ray evidence of disease present, consider</td>
<td>ATS/CDC, 2000</td>
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<tr>
<td>delaying therapy until after the pregnancy</td>
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<tr>
<td>4. Pregnant women with active tuberculosis should be treated with multi-drug</td>
<td>ACOG Guidelines for Perinatal Care, 1998</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>therapy including isoniazid and rifampin, supplemented by ethambutol if</td>
<td>ATS/CDC, 2000</td>
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<td></td>
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<tr>
<td>isoniazid drug resistance is suspected</td>
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</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 16. Screening for HIV – Counsel:  

BACKGROUND

During the past decade, HIV infection became a leading cause of morbidity and mortality among women. As the incidence of HIV infection has increased among women of childbearing age, increasing numbers of children have become infected through perinatal transmission.
**RECOMMENDATIONS**

1. Strongly recommend routine testing for HIV infection at the initial prenatal visit. [A]
2. Pregnant women who test positive for HIV should be referred for treatment and counseling. [I]
3. Recommend retesting all high-risk pregnant women during the early third trimester and offer repeat testing for patients who refused the first test. [B]

**DISCUSSION**

Several studies have indicated that counseling and testing strategies that offer testing only to those women who report risk, fail to identify up to 50 to 70 percent of HIV-infected women (CDC, 1995). A policy of routine screening for all pregnant women with their consent is recommended on the grounds of easier implementation and greater sensitivity than risk profile screening (AAP/ACOG, 1995).

A randomized placebo controlled trial demonstrated that a regimen of zidovudine started by 14 to 34 weeks' gestation and continued through six weeks postpartum reduced vertical transmission of HIV from 25 to 8.3 percent. Zidovudine has had a low incidence of severe side effects in the mother and infants studied, but long-term effects are unknown (Connor et al., 1994).

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine HIV screening</td>
<td>AAP/ACOG, 1995 CDC, 1995</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2 Retest high-risk women</td>
<td>Higgins et al., 1991 Tookey et al., 1998</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

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**I- 17. Screening for Td and Tdap Booster:**

**Weeks 6 - 8**

**BACKGROUND**

Tetanus and diphtheria were serious causes of infectious morbidity and mortality of people of all ages prior to the advent of widespread effective active immunization programs. The majority of cases of diphtheria and tetanus occur in adults who have not received adequate vaccination, and fatality rates for diphtheria are approximately 10 percent and 25 percent for tetanus. The tetanus-diphtheria (Td) vaccine is made up of bacterial toxins that cause the production of antibodies against the live bacterium when administered to an individual. Unfortunately, the immune response is not lifelong, thus periodic revaccination is required to ensure immunity. Since the vaccine is made up of inactive bacterial particles and not live bacteria, pregnancy is not a contraindication to providing indicated preventive services such as tetanus booster vaccination.

**RECOMMENDATIONS**

1. Strongly recommend routine screening for Tdap booster status at the initial prenatal visit. [A]
2. If there is no documentation of Td booster within the last 10 years: [A]
   a. Provide Tdap in the immediate postpartum period before discharge from the hospital or birthing center
   b. May provide Tdap at an interval as short as two years since the most recent Td vaccine
   c. Provide Td during pregnancy for tetanus and diphtheria protection when indicated, or defer the Td vaccine indicated during pregnancy to substitute Tdap vaccine in the immediate postpartum period if the woman is likely to have sufficient protection against tetanus and diphtheria.
3. Td booster should be provided if indicated. There are no contraindications other than a previous severe reaction to Td vaccination, such as anaphylaxis, generalized urticaria, or angioedema. [A]

4. If the pregnant woman is an immigrant and it is unclear that she ever received the primary vaccination series, she should be given a primary series with an initial dose, a second dose a month later, and a third dose 12 months later. [B]

**DISCUSSION**

Effective antibody response is 95 to 100 percent in healthy adults after primary vaccination series. Immunity wanes over the years and the precise duration of immunity is unknown for specific individuals, but generally lasts at least a decade for small inoculum of tetanus encountered in a small or minor wound. For any other wound, it is recommended that a tetanus booster be administered unless the patient has received a Td booster within the previous five years. Neonates receive passive immunization from maternal antibodies until their immune system is adequate to provide an antibody response to neonatal vaccinations.

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Screening for Td booster status at the first prenatal visit</td>
<td>USPSTF, 1996</td>
<td>II-1</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2 If no documentation of Td booster within the last 10 years, provide Td booster; there are no contraindications other than documented allergies to administration of Td during pregnancy</td>
<td>Fingar et al., 1998 ICSI, 2001 USPSTF, 1996</td>
<td>II-1</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>3 Pregnant women deemed unlikely to have received initial three-dose vaccination (immigrants from underdeveloped countries) should receive an initial three dose series</td>
<td>Fingar et al., 1998 ICSI, 2001 USPSTF, 1996</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

**I- 18. Screening for Anemia:** New

**BACKGROUND**

Anemia occurs in two to four percent of pregnant women. It is defined as a hemoglobin or hematocrit concentration less than the fifth percentile of a healthy pregnant population and varies during the trimesters of pregnancy and in African versus non-African populations. Non-African women with a hematocrit less than 33, 32 and 33 percent in the first, second and third trimesters, respectively, are anemic. The threshold for anemia in the African-American population is two percent lower. Severe anemia, defined as a hemoglobin < 6 gm/dL is associated with adverse pregnancy outcomes due to inadequate fetal oxygenation. Iron deficiency and acute blood loss are the most common causes of anemia. Anemia can be categorized by the size of the red blood cell (microcytic, normocytic and macrocytic), the mechanism of the anemia, or by whether the anemia is acquired or inherited. Certain ethnic groups are at increased risk for inheritable causes of anemia and should be screened for such (see Appendix C - Screening for Hemoglobinopathies). Iron deficiency anemia is usually microcytic (Mean Corpuscular Volume <80 fl), can be confirmed by laboratory findings of diminished stores, and responds to iron supplementation. Iron deficiency anemia during pregnancy has been associated with an increased risk of low birth weight, preterm delivery, and perinatal mortality. There is also an association between maternal iron deficiency anemia and postpartum depression and poor results in mental and psychomotor performance testing in offspring.
**RECOMMENDATIONS**

1. All pregnant women should be screened for anemia during pregnancy with a hematocrit or hemoglobin measurement during the first visit. [C]

2. Pregnant women with anemia should be further evaluated to define the cause of the anemia and given nutrient supplementation if deficient (e.g. iron, B12 or Folate). [C]

3. Red blood cell transfusion should be considered for pregnant women with severe anemia. [C]

4. Iron sucrose transfusion should be considered for pregnant women with iron deficiency anemia who fail to respond to oral iron supplementation after eliminating modifiable causes of malabsorption. [C]

**EVIDENCE TABLE**

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<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
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<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. All pregnant women should be screened for anemia during pregnancy with a</td>
<td>ACOG, 2008 #95 CDC, 1998</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>hematocrit or hemoglobin measurement in the first and third trimester</td>
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<tr>
<td>2. Pregnant women with anemia should be further evaluated to define the cause</td>
<td>ACOG, 2008 #95 Institute of Medicine, 1993 Reveiz et al.,</td>
<td>II,</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>of the anemia and given nutrient supplementation if deficient (e.g. iron,</td>
<td>2007</td>
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<td>B12 or Folate)</td>
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<tr>
<td>3. Red blood cell transfusion should be considered for pregnant women with</td>
<td>ACOG, 2008 #95</td>
<td>II</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>severe anemia</td>
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<tr>
<td>4. Iron sucrose transfusion should be considered for pregnant women with</td>
<td>ACOG, 2008 #95 Faich &amp; Strobos, 1999 Bhandal &amp; Russell,</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
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<tr>
<td>iron deficiency anemia who fail to respond to oral iron supplementation after</td>
<td>2006</td>
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<td>eliminating modifiable causes of malabsorption</td>
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</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

**I- 19. Screening for Hemoglobinopathies:**

**Weeks 6-8**

**BACKGROUND**

The hemoglobinopathies are a heterogeneous group of single-gene disorders that includes the structural hemoglobin variants such as sickle cell disease and thalassemia. More than 270 million people worldwide are heterozygous carriers of hereditary disorders of hemoglobin, and at least 300,000 affected homozygotes or compound heterozygotes are born each year. Sickle cell disease and the thalassemias are discussed below.

**RECOMMENDATIONS**

1. Carrier screening should be offered to individuals of African, Southeast Asian, and Mediterranean descent. [A]

2. A complete blood count and hemoglobin electrophoresis are the recommended tests to screen for hemoglobinopathies. [B]
DISCUSSION

Genetic screening can identify couples at risk for offspring with hemoglobinopathies and allow them to make informed decisions regarding reproduction and prenatal diagnosis. Individuals of African, Southeast Asian, and Mediterranean ancestry are at a higher risk for being carriers of hemoglobinopathies and should be offered carrier screening. Ethnic groups considered to be at low risk for hemoglobinopathies include northern Europeans, Japanese, Native Americans, Inuit (Eskimo), and Koreans. If both parents are determined to be carriers, genetic counseling is recommended. It should be noted that ethnicity is not always a good predictor of risk because individuals from at-risk groups may marry outside their ethnic group. A CBC and hemoglobin electrophoresis should be performed for screening patients at risk. Solubility tests alone are inadequate for screening because they fail to identify important transmissible hemoglobin gene abnormalities affecting fetal outcome. Couples at risk for having a child with sickle cell disease, thalassemia or sickle-thalassemia disease should be offered genetic counseling to review prenatal testing and reproduction options. Prenatal diagnosis of hemoglobinopathies is best accomplished by DNA analysis of cultured amniocytes or chorionic villi.

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Offer carrier screening to individuals of African, Southeast Asian, and Mediterranean descent</td>
<td>ACOG, 2007 Angastiniotis et al., 1998 Davies et al., 2000</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2 A complete blood count and hemoglobin electrophoresis are the recommended tests to screen for hemoglobinopathies</td>
<td>ACOG, 2007</td>
<td>III</td>
<td>Good</td>
<td>B</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 20. Screening for Domestic Abuse: Weeks 6 - 8

BACKGROUND

Domestic violence is an epidemic problem that may be first identified during pregnancy. Unfortunately, high-quality evidence-based documentation does not exist regarding the benefits of specific interventions to decrease domestic violence. Healthcare providers need to be aware that a woman's decision to leave an abusive relationship may result in an escalation of violence.

RECOMMENDATIONS

1. Recommend routine screening for domestic abuse at the first visit, week 28, and the post partum visit, using the following three simple/direct questions: [B]
   - Within the last year, have you been hit, slapped, kicked, or otherwise physically hurt by someone?
   - Since you've been pregnant, have you been hit, slapped, kicked, or otherwise physically hurt by someone?
   - Within the last year, has anyone forced you to engage in sexual activities?

2. There is insufficient evidence to recommend for or against specific interventions for identified domestic abuse in pregnancy. [I]

3. If the screening is positive, follow appropriate medical/legal mandates for reporting requirements for state/branch of service. [C]
DISCUSSION

Domestic violence is a common problem, estimated to occur in up to 20 percent of pregnancies (Gazmararian et al., 1996). The few observational studies that have assessed the relationship between abuse during pregnancy and maternal or fetal outcomes have not found consistent associations.

One poor-quality non-randomized trial found a decreased frequency and severity of violence at six and 12 months postpartum for women offered three one-on-one 30-minute counseling sessions with a trained nurse, as part of their prenatal care. The intervention and control groups were not comparable prior to intervention, making the results difficult to interpret (Parker et al., 1999).

A second non-randomized trial of poor quality found no difference when abused women were given simple written information or offered unlimited access to a professional counselor during prenatal care, with or without additional support from a “mentor mother.” Because the study had significant methodological flaws, it is possible that a clinically significant benefit from the intervention could have been missed (McFarlane et al., 2000).

There are several studies validating multiple screening tools for the occurrence of domestic violence (McFarlane et al., 1995; Norton et al., 1995). The recommendation for the utilization of three simple/direct questions is based on the only study that addressed domestic violence and the pregnant population (McFarlane et al., 1992).

Renker (2007) conducted a survey of 519 women postpartum who had been screened with a computer-based program for domestic abuse. The computer-based interviews offer an alternative approach to screening and women who are hesitant to disclose domestic violence to a provider may be more likely to report it on the computer survey.

Three simple questions by a primary provider during a prenatal visit will detect abuse approximately as effectively as a well-validated research instrument (McFarlane et al., 1992).

Higher rates of detection are achieved if providers ask about abuse at several prenatal visits, rather than asking a single time (Covington et al., 1997).

A systematic review evaluating the available evidence on interventions aimed at preventing abuse or reabuse of women found that no study has examined, in a comparative design, the effectiveness of screening when the end point is improved outcomes for women (as opposed to identification of abuse). No high-quality evidence exists to evaluate the effectiveness of shelter stays to reduce violence. Among women who have spent at least one night in a shelter, there is fair evidence that those who received a specific program of advocacy and counseling services reported a decreased rate of reabuse and an improved quality of life. The benefits of several other intervention strategies in treating both women and men are unclear, primarily because of a lack of suitably designed research measuring appropriate outcomes (Wathen & Macmillan., 2003).

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine screening during pregnancy for domestic abuse</td>
<td>Gazmararian et al., 1996</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 Routine screening for domestic abuse with three simple/direct questions at weeks 8, 24, and 32, possibly using a computerized interview</td>
<td>McFarlane et al., 1992 Renker et al., 2007</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>3 Specific interventions after identifying domestic abuse in pregnancy</td>
<td>McFarlane et al., 2000 Parker et al., 1999 Wathen &amp; Macmillan, 2003</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)
I-21. Screening for Depression: Weeks 6-8, 28, Postpartum visit

BACKGROUND
Depression in pregnancy in general, and in the peripartum period in particular, is a well-recognized problem. Although estimates vary, in the first three months after childbirth, 14.5 percent of women have a new episode of major or minor depression, and 10 percent to 20 percent of mothers are believed to suffer with depression sometime during their postpartum course, making postpartum depression the most common serious postpartum disorder. In addition, it is an under-recognized entity, with 50 percent of cases undetected. This rate of under-detection can be reduced by the use of a screening instrument, administered during the course of pre- and postnatal visits. This detection can lead to further diagnostic interviews and to appropriate treatment, lessening the deleterious effects of depression on both the mother and child. When a woman is diagnosed with depression, treatment should follow (see I-34).

RECOMMENDATIONS
1. Women should be screened for depression during their first contact with obstetric healthcare services, at week 28 and at the postpartum visit. [B]
2. Depression screening should be performed using a standardized screening tool such as the Edinburgh Postnatal Depression Scale (EDPS) or the PHQ-2. [B]
3. Women should be asked early in pregnancy if they have had any previous psychiatric illnesses, and if they had a past history of serious psychiatric disorder they should be referred for a psychiatric assessment during the antenatal period. [B]

RATIONALE
Early detection of depression during pregnancy is critical because depression can adversely affect birth outcomes and neonatal health and, if left untreated, can persist after the birth. Untreated postpartum depression can impair mother-infant attachments and have cognitive, emotional, and behavioral consequences for children. The best studied of these screening instruments is the Edinburgh Postnatal Depression Scale (EDPS).

EVIDENCE STATEMENTS
- Women are at elevated risk for depression during the antenatal and post-partum periods. The point prevalence of depression is seven to 15 percent during pregnancy and five to greater than 31 percent in the post-partum period (AHRQ, 2005; Bennett et al., 2004; Gaynes et al., 2005).
- In addition to adverse effects on the mother, depression has adverse effects on the fetus and infants (Epperson et al., 1999). The presence of maternal depressive symptoms at a critical time for infant and family has additional adverse effects, such as marital distress (Beck, 2001), problems with mother-infant interaction and attachment (Righetti-Veltema et al., 2003) and adverse behavioral and cognitive effects in the child (Grace et al., 2003).
- In a systematic review of the evidence for depression screening during pregnancy, only one study reported on screening accuracy in a population, with six patients with major depression and 14 patients with either major or minor depression. For major depression, sensitivities for the Edinburgh Postnatal Depression Scale (EPDS) at all thresholds evaluated (12, 13, 14, 15) were 1.0, underscoring the markedly small number of depressed patients involved; specificities ranged from 0.79 (at EPDS >12) to 0.96 (at EPDS >15). For major or minor depression, sensitivity was much poorer (0.57 to 0.71), and specificity remained fairly high (0.72 to 0.95) (Gaynes et al., 2005).
- For postpartum depression screening, a systematic review reported that the small number of depressed patients involved in the studies precluded identifying an optimal screener or an optimal threshold for screening. “Our ability to combine the results of different studies in a meta-analysis was limited by the use of multiple cut-offs and other differences in the studies that would have made the pooled estimate hard to interpret. Where we were able to combine the results through meta-analysis, the pooled analysis did not add to what one could conclude from individual studies.” (Gaynes et al., 2005.)
• Three systematic reviews evaluated screening tools for postpartum depression, used either in the prenatal or postpartum period.
  - The first review (Austin & Lumley, 2003) included 16 studies evaluating screening tools prenatally. Outcome assessments used the Edinburgh Postnatal Depression Scale (EPDS) or standardized diagnostic psychiatric interviews, or both. However, most of the studies were small – only four studies had adequate sample sizes to assess the sensitivity and specificity of postpartum depression screens. In the two largest population-based studies the positive predictive value was low. The authors concluded that no screening instruments were appropriate for prenatal prediction of postpartum depression.
  - A second review (Boyd et al., 2005) included 36 studies of self-reported scales for postpartum depression screens two weeks after labor. Out of eight tools that have been evaluated, the results suggested that the EPDS is the most extensively studied postpartum measure with moderate psychometric soundness. However, as in the other reviews, most of the studies included had small sample sizes.
  - The evidence report/technology assessment (Gaynes et al., 2005) also looked at the predictive value of different screening tools for detecting depression during the perinatal period. Although the EPDS and the PDSS seemed to have higher sensitivities than the BDI (with estimates ranging from 0.75 to 1.0 at different thresholds), the author questioned the external validity of the studies and the accuracy given the small sample sizes in several studies.

• A review of the literature (Gjerdingen et al., 2007) concluded that postpartum depression screening improves recognition of the disorder but that additional studies with large, representative samples are needed to help identify the ideal postpartum depression screening tool.

• Although there are no published reports on the validity of the PHQ-9 in screening for postpartum depression it has been used as a screen in obstetrics/gynecology practices that include both women of childbearing age and older women. The PHQ-2 was studied in eight primary care clinics and seven obstetrical/gynecology clinics, where construct and criterion validity were found to be very good, and sensitivity and specificity high (83 and 92 percent, respectively) (Kronke et al., 2003). A single study (done in Europe and with no control group) showed that a two-item questionnaire, substantially the same as the PHQ-2, performs comparably to longer instruments (Jesse et al., 2005).

• Administering the EPDS by phone at six to eight weeks postpartum is an efficient and accurate way to identify women at high-risk for postpartum depression within the first six months after delivery (Hanusa, 2008).

• Studies that have addressed postpartum depression screening demonstrate that screening is feasible in the outpatient setting and can improve the rates of detection and treatment (Georgiopoulos et al., 2001; NICE, 2007).
EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Women are at increased risk for depressive disorders during pregnancy and postpartum periods</td>
<td>Gaynes et al., 2005</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2 Depression screening improves detection during pregnancy and in postpartum</td>
<td>Georgiopoulos et al., 1999</td>
<td></td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Gjerdingen et al., 2007</td>
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<td></td>
<td>NICE, 2007</td>
<td></td>
<td></td>
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<tr>
<td>3 PHQ-2 is a sensitive screen for depression in postpartum women</td>
<td>Kronke et al., 2003</td>
<td>II</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>4 EDPS is a sensitive and valid screen for depression in the antepartum and postpartum period</td>
<td>Adouard et al., 2005</td>
<td>II</td>
<td>Good</td>
<td>B</td>
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<td></td>
<td>Boyd et al., 2005</td>
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<td>Evins et al., 2000</td>
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<td></td>
<td>Peindl et al., 2004</td>
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<td></td>
<td>Hanusa et al., 2008</td>
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</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

First Visit With Provider (10-12 Weeks)

I- 22. Establishing the Gestational Age: New

Weeks 10-12

BACKGROUND

Establishing accurate pregnancy dating impacts the management of normal and abnormal pregnancies and thus is one of the most important responsibilities of prenatal care providers. Accurate dating is essential for timing tests such as prenatal screening tests for aneuploidy, assessment of proper fetal growth and maturity and management of the pregnancy past the due date. Common usage of the term gestational age refers to menstrual age that equals conceptional age plus 14 days.

Currently, the gestational age is assessed by menstrual history, clinical examination, ultrasound or by a known conceptional date. Gestational age is most accurately established by a certain conception date as occurs with reproductive technologies, single intercourse associated conceptions and basal body temperature records, each of which is highly predictive of conceptional age. The next most accurate assessment of menstrual age is by a six to eleven-week crown-rump length measurement by ultrasound followed by a certain last menstrual period in women with regular cycles, then by early second-trimester sonographic examinations and then first trimester followed by second-trimester physical examination. Dating the pregnancy by menstrual history or clinical examination is subject to considerable error. The mother’s initial detection of fetal movements and late pregnancy ultrasound are too unreliable to be useful for accurate assessment of the gestational age.

RECOMMENDATIONS

1. Establish the gestational age-based estimated delivery date (EDD) prior to 20 weeks’ gestational age. [B]

2. Various information and methods for dating a pregnancy may be available for consideration. EDD should be based on the most accurate information/method available for the individual pregnancy (see Table 4. Accuracy of Pregnancy Dating Information/Modalities (Prioritized List). [B]

3. Gestational age permitting, first-trimester ultrasound should be used to establish the gestational age and EDD if there is any uncertainty regarding the EDD due to: a pelvic examination discrepancy (≥ +/− two weeks), an unknown or uncertain last menstrual period (LMP), or irregular menstrual cycles. [B]
4. When a first-trimester dating ultrasound has not been previously performed a dating ultrasound at 16 to 22 weeks should be obtained. This examination can be combined with a basic screening anatomy ultrasound. [B]

5. Situations with abnormal fetal biometric ratios (e.g., head / abdominal circumference [HC/AC], biparietal diameter /femur length [BPD/FL]) limit the accuracy of biometric measurements for pregnancy dating and may signal fetal anomalies or karyotype abnormalities. Such circumstances require individualized assessment by an advanced prenatal care provider to establish dating and recommend ongoing assessment(s) and management. [C]

6. When clinical decisions late in pregnancy necessitate gestational age information and the dates have not been established prior to the 29th week, fetal maturity may be assumed when one of the following criteria are met:

   a. 20 weeks of audible fetal heart tones by a non-electronic method
   b. 30 weeks of audible fetal heart tones by an electronic method
   c. 36 weeks from a positive pregnancy test in a reliable laboratory.

Table 4. Accuracy of Pregnancy Dating Information/Modalities (Prioritized List)

<table>
<thead>
<tr>
<th>No.</th>
<th>Information/Modalities</th>
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<tbody>
<tr>
<td>1.</td>
<td>In vitro fertilization (+/- 1 day)</td>
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<tr>
<td>2.</td>
<td>Ovulation induction, artificial insemination, a single intercourse record, ovulation predictor assay or basal body temperature measurement (+/- 3 days).</td>
</tr>
<tr>
<td>3.</td>
<td>First-trimester sonographic assessment (6-11 weeks) (+/- 8%).</td>
</tr>
<tr>
<td>4.</td>
<td>Reported LMP, if reliable.</td>
</tr>
<tr>
<td>5.</td>
<td>Twelve to 22-week second-trimester sonographic examination (CRL or BPD, HC, AC and FL) if the LMP is unknown or uncertain or if the LMP is more than 8 percent discordant from the sonographic examination.</td>
</tr>
<tr>
<td>6.</td>
<td>Twenty-three to 28-week second-trimester sonographic examination (BPD, HC, AC, FL) confirmed by a second examination 3-6 weeks later demonstrating normal interval growth (+/- 8%).</td>
</tr>
<tr>
<td>7.</td>
<td>Third-trimester sonographic evaluation (+/-8%).</td>
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</table>
**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Establish the gestational age-based due date (EDD) prior to 20 weeks’ gestational age</td>
<td>Mongelli et al., 1996 Wilcox et al., 1993</td>
<td>II</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>2. Base the due date on the most accurate data available</td>
<td>Mongelli et al., 1996, 2005 Peek et al., 1994</td>
<td>II</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>3. Gestational age permitting, first-trimester ultrasound should be used to establish the gestational age if there is any uncertainty in the EDD</td>
<td>Mongelli et al., 1996 Peek et al., 1994 Sladkevicius et al., 2005</td>
<td>II</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>4. When a first-trimester dating ultrasound has not been previously performed a dating ultrasound combined with an anatomy ultrasound at 16 to 22 weeks should be obtained</td>
<td>Geirsson et al., 1993 Gardosi et al., 1997 Mul et al., 1996</td>
<td>II</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>5. The presence of abnormal fetal biometric ratios limit the accuracy of biometric measurements for dating, may signal fetal anomalies, and require individualized assessment by an advanced prenatal care provider</td>
<td>Watson et al., 2007 ACOG, Practice Bulletin #98, 2008</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>6. When clinical decisions late in pregnancy necessitate gestational age information and the dates have not been established, fetal maturity may be assumed based on well-established clinical grounds</td>
<td>ACOG, 1999</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

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**I. 23. Auscultation Fetal Heart Tones:** Weeks 10-12, All following visits

**BACKGROUND**

No studies show improved perinatal outcome from identifying fetal heart tones, but expert opinion concurs that an occasional fetal demise may be found (with no other signs or symptoms) or an occasional cardiac anomaly might be detected. The primary indication for identifying fetal heart tones is the enormous psychological benefit to parents.

**RECOMMENDATIONS**

1. Recommend assessing fetal heart tones at each prenatal visit, starting at 10 to 12 weeks. [C]

**DISCUSSION**

This intervention has not been specifically researched, though studies can be found that correlate fetal heart tones with confirmation of fetal viability. Auscultation of fetal heart tones is an easy and inexpensive way to document fetal health. It has no known risk and offers significant psychological benefit and reassurance to both expectant parents and healthcare providers alike. Additionally, routine auscultation of fetal heart tones assists in early
identification of fetal demise which may otherwise be asymptomatic, and affords the opportunity to initiate appropriate counseling and treatment.

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Auscultation of fetal heart tones</td>
<td>Engstrom, 1985</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
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<tr>
<td></td>
<td>Jimenez et al., 1983</td>
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<td></td>
<td>Working Group Consensus</td>
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</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 24. Screening Fundal Height:  

Weeks 10-12; All following visits

BACKGROUND

Fundal height is commonly used as an indicator of fetal growth. A discrepancy between fundal height and gestational age in weeks, particularly between weeks 20 and 36, may indicate abnormal growth and/or abnormalities in amniotic fluid volume. Timely detection and treatment of these abnormalities may improve fetal outcomes.

RECOMMENDATIONS

1. Recommend measuring fundal height in all pregnant women at each visit during the second and third trimesters. [B]
2. There is insufficient evidence to recommend for or against measuring fundal height after 36 weeks’ gestation. [I]

DISCUSSION

Fundal height measurement is inexact and subject to inter- and intra-observer errors. However, the screening maneuver is simple, inexpensive, and widely used during prenatal care. Women should always be placed in the same position for the measurement, lying supine with the legs extended. All studies of the reliability and validity of fundal height measurements have used this position (Engstrom & Work, 1992). The measurement, taken between the symphysis pubis and the fundus, should approximate the gestational age in weeks within three centimeters; any difference greater than three centimeters may warrant further investigation, particularly between weeks 20 and 36. Several studies have shown good sensitivity and specificity for predicting low birth weight for gestational age (Mathai et al., 1987; Pearce & Campbell, 1987; Wise & Engstrom, 1985). Fundal height measurements after 36 weeks’ gestation continue to be of benefit despite lower yield in accuracy, especially among multiparous women.

EVIDENCE TABLE

<table>
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<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Fundal height measurement after 36 weeks</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)
I- 25. Assessing (Inappropriate) Weight Gain:  Weeks 10-12; All following visits

BACKGROUND

Pregnant women who experience inappropriate weight gain may be at risk for a number of complications. Excessive weight gain may increase the risk for macrosomic infants, shoulder dystocia, operative delivery and postpartum obesity. Inadequate weight gain is associated with preterm delivery, intrauterine growth restriction, and low birth weight. Screening for inappropriate weight gain allows for early intervention to prevent these complications.

Obesity is defined as a BMI of 30 kg/m² or greater and affects approximately one-third of adult women. Obese women are at increased risk for several pregnancy complications (see I-27).

RECOMMENDATIONS

1. Recommend assessing and documenting body mass index (BMI) of all pregnant women at the initial visit. [B]
2. Pregnant women found to have a BMI <20 kg/m² should be referred for nutrition counseling and considered at increased risk for fetal growth restriction. [B]
3. Recommend screening for inappropriate weight gain for all women at every visit during pregnancy. [C]
4. Pregnant women with inadequate weight gain at 28 weeks who are unresponsive to nutritional treatment need additional surveillance. Consider consultation/referral to advanced prenatal care provider. [C]

DISCUSSION

No systematic reviews or controlled trials of screening for inappropriate weight gain during pregnancy were identified. Recommendations endorsed by the Institute of Medicine (IOM), AAP and ACOG (1995) have been based on the pre-pregnancy BMI. Women with a BMI below 19.8 kg/m² are recommended to gain 12.7 to 18.2 kg (28 to 40 lb), women with a BMI of 19.8 to 26.0 kg/m² are advised to gain between 11.4 and 16.0 kg (25 to 35 lb), and women with a high BMI (26.0 to 29.0 kg/m²) are recommended to gain between 6.8 and 9.1 kg (15 to 20 lb). Women who have a very high BMI (i.e., above 29 kg/m²) are advised to gain at least 6.8 kg (15 lb) (IOM, 1990).

Maternal BMI of less than 20 kg/m² at the start of pregnancy is associated with increased prevalence of preterm delivery and low-birth-weight infants (Sebire et al., 2001). This retrospective analysis did not look at weight gain over the course of pregnancy on these outcomes.

For inadequate weight gain, only balanced protein-energy supplementation may be safe and effective. High-protein and isocaloric protein-energy supplementation may be associated with untoward fetal effects. For excessive weight gain, protein-energy restriction is not significantly effective and may adversely impact birth weight (Kramer, 2000).

Excessive weight gain may be associated with adverse changes in fetal or neonatal weight and minor maternal morbidity, but these data are difficult to separate from data concerning baseline obesity (Kelly et al., 1997). Maternal overweight condition increases the risk of antepartum stillbirth, especially term antepartum stillbirth, whereas weight gain during pregnancy was not associated with risk (Stephansson et al., 2001).
EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine assessment of BMI at first visit</td>
<td>Sebire et al., 2001</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 Nutrition counseling for inadequate weight gain or initial BMI &lt;20 kg/m²</td>
<td>Kramer, 2000, Sebire et al., 2001</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>3 Routine screening for inappropriate weight gain at each visit</td>
<td>Kelly et al., 1997</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>4 The practical evaluation of weight gain at 24 to 28 weeks</td>
<td>Kelly et al., 1997</td>
<td>II-2</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>5 Individualized weight gain based on pre-pregnancy weight</td>
<td>IOM, 1990</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)


BACKGROUND

Women in the United States commonly (expect to) practice multivitamin supplementation throughout pregnancy. This tradition is based on the assumption that women have increased nutritional requirements during pregnancy that cannot be met by diet alone.

RECOMMENDATIONS

Multivitamins

1. Multivitamin supplements should be taken one month preconceptually and should be continued through the first trimester. [C]
2. Pregnant women taking nutritional supplements for a medical condition should continue that supplementation throughout pregnancy (e.g., B-12 with pernicious anemia and folate with seizure disorders). [I]
3. Pregnant women on restrictive diets (vegetarians, bariatric surgery) should have nutrition consultation to customize vitamin supplementation regimen. [I]

Folate

4. Folate supplements (400 mcg daily) should be taken one month preconceptually, continued through the first trimester and should be administered as part of the multivitamin supplementation. [A]
5. Women who have delivered a child with an open neural tube defect (NTD) should supplement their diets with 4 mg folate daily for at least one month prior to conception and through the first trimester to reduce the risk of recurrence. [A]

Calcium

6. Calcium supplementation may be considered to reduce the risk of preeclampsia in high-risk women and those with low baseline calcium intake. [A]

Omega3
7. There is insufficient evidence to support the use of Omega 3 supplements in the prevention of preterm birth, preeclampsia, and low birth weight. [I]

8. Other dietary supplements should be used with caution and only after discussion with provider. [I]

**DISCUSSION**

Nutrition has long been hypothesized to have a role in the etiology of preeclampsia. It is now well understood that, while preeclampsia is clinically evident late in pregnancy, the casual exposure(s) and many of the pathophysiologic changes are present months earlier. Periconceptional exposures may be particularly relevant, as they may affect implantation and/or decidual vascular remodeling (Bodnar et al., 2006). After adjusting for covariates, Bodnar and colleagues showed that regular use of multivitamins in the periconceptional period was associated with a 45 percent reduction in preeclampsia (n=1835) risk compared with nonuse. The analysis in this study showed a lack of a protective effect from multivitamins among overweight women. This prospective cohort study from 1997-2001 included pregnant women aged 14 to 44 years who were carrying singleton infants. Taking multivitamins or prenatal vitamins regularly was defined as at least once per week, not to include supplements that subjects began using during pregnancy.

Three systematic reviews were identified that addressed supplementation during pregnancy with individual vitamins. Individual folate supplementation in pregnancy (approximately 500 micrograms) resulted in increased or maintained serum folate levels and red cell folate levels, and increased hemoglobin levels late in pregnancy (Mahomed, 2001). Periconceptual folate supplementation has a strong protective effect against NTD (odds ratio=0.28). Preconceptual folate has been shown to decrease the incidence of neural tube defects. It did not, however, have any measurable effect on any other pregnancy outcome. There was no impact on any other maternal or infant outcome. Adequate folate supplementation can be provided through the use of multivitamins containing 400 mcg of folic acid. Individual pyridoxine (vitamin B-6) supplementation was associated with decreased dental decay in pregnant women (Mahomed & Gulmezoglu, 2001a). Supplementation with vitamin D during pregnancy may lead to a small reduction in birth weight and a higher daily mean maternal weight gain (Mahomed & Gulmezoglu, 2001b). These data support the hypothesis that periconceptional vitamin supplementation may extend benefits beyond a reduction in NTD risk.

**Multivitamins**

Goh and colleagues’ meta analysis of seven case control analytic studies states that there is a protective effect of taking prenatal multivitamin supplementation against three of the most prevalent forms of childhood cancers. There is an 18 percent protective decrease risk for pediatric brain tumors, 47 percent for neuroblastomas, and 36 percent protective effect for leukemia (Goh et al., 2007).

**Calcium**

A Cochrane review (Hofineyr, et al, 2006) found that calcium supplementation during pregnancy is a safe and relatively inexpensive means of reducing the risk of preeclampsia in women at increased risk, and women from communities with low dietary calcium. Calcium supplementation appears to almost halve the risk of preeclampsia, and to reduce the rare occurrence of the composite outcome ‘death or serious morbidity’.

**LC-PUFA**

The overall meta-analysis on the intake of long-chain polyunsaturated fatty acids found no evidence that supplementation influenced the percentage of preterm deliveries, the rate of low-birth-weight infants, or the rate of preeclampsia or eclampsia.

Dietary ingredients used in dietary supplements are not subject to the pre-market safety evaluations required of new food ingredients, new uses of old food ingredients, or medications. Although the Dietary Supplement Health and Education Act (DSHEA) does give the FDA the right to ban harmful dietary supplements, the burden of proof is on the FDA. No mandatory system exists for reporting the harmful effects of dietary supplements or the production and packaging of products. That means the concentration or dosage of ingredients in different products, and what contaminants are in the product, are unknown.
EVIDENCE TABLE

<table>
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<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
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</thead>
<tbody>
<tr>
<td>1. Routine vitamin supplementation during pregnancy</td>
<td>Goh et al., 2007 Mahomed, 2001</td>
<td>I</td>
<td>III</td>
<td>B</td>
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<td></td>
<td>Mahomed &amp; Gulmezoglu, 2001a, b</td>
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<tr>
<td>2. Regular periconceptional multivitamin use</td>
<td>Bodnar et al., 2006</td>
<td>II-2</td>
<td>Fair</td>
<td>C</td>
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<td>3. Routine calcium supplementation for high-risk and low dietary intake</td>
<td>Hofmeyr et al., 2006</td>
<td>I</td>
<td>Good</td>
<td>A</td>
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<td>4. Continuation of preconceptual vitamin supplements until the end of first trimester</td>
<td>Werler et al., 1999</td>
<td>II-3</td>
<td>Good</td>
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<td>5. Continuation of preconceptual folate until the end of the first trimester</td>
<td>Lumley et al., 2001</td>
<td>I</td>
<td>Good</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 27. Obesity: New

Weeks 10-12

BACKGROUND

Obesity is defined as a BMI of 30 kg/m² or greater and affects approximately one-third of adult women. Obese women are at increased risk for several pregnancy complications.

RECOMMENDATIONS

1. Recommend the following for obese pregnant women: [I]
   a. Provision of specific information concerning maternal and fetal risks of obesity
   b. Consideration of screening for gestational diabetes mellitus (GDM) on presentation or in the first trimester and repeated screening later in pregnancy if results are initially negative
   c. Assessment and possible supplementation of vitamin B12, folate, iron, and calcium for women who have undergone bariatric surgery
   d. Anesthesia consultation before labor
   e. Possible use of graduated compression stockings, hydration, and early mobilization during and after cesarean section
   f. Continuation of nutrition counseling and exercise program after delivery, and consultation with weight loss specialists before attempting another pregnancy.

DISCUSSION

Obesity was associated with an increased risk of gestational hypertension, preeclampsia, gestational diabetes, and fetal macrosomia as well as increased cesarean delivery rate. Operative and postoperative complications include increased rates of excessive blood loss, operative time greater than two hours, wound infection, endometritis and anesthetic challenges. Potential intrapartum complications include difficulty estimating fetal weight, inability to obtain interpretable external fetal heart rate and uterine contraction patterns, and difficulty performing emergent cesarean delivery (ACOG Committee Opinion #315, 2005).
EVIDENCE TABLE

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<tr>
<td>1 Recommendations for obese pregnant women</td>
<td>ACOG, 2005</td>
<td>III</td>
<td>Fair</td>
<td>I</td>
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</table>

**LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)**

I- 28. History of Gastric Bypass/Bariatric Surgery: New  Weeks 10-12

BACKGROUND
The number of obese women of childbearing age undergoing bariatric surgery is increasing, resulting in questions regarding appropriate management of subsequent pregnancies. Pregnancy outcomes after bariatric surgery are consistent with general community outcomes. Nutritional and vitamin deficiencies, specifically iron, vitamin B12, folate and calcium are the most common complications.

RECOMMENDATIONS

1. Women with a gastric band should be monitored by their general surgeons during pregnancy because adjustment of the band may be necessary. [C]

2. Women who have undergone bariatric surgery should be evaluated for nutritional deficiencies and need for nutritional supplementation where indicated (e.g., Vitamin B12, folate, iron, and calcium). [C]

3. Women who experience dumping syndrome should NOT be screened for gestational diabetes with a glucose load but rather with fasting and two-hour postprandial glucose values. [C]

DISCUSSION

Obesity occurs in one in three adult women. A large percentage of bariatric procedures are performed on women of reproductive age (Wax et al., 2007). There are limited data and no randomized studies concerning pregnancy after bariatric surgery. Patients who undergo bariatric surgery are at risk of becoming pregnant unexpectedly after weight loss following surgery. All patients are advised to delay pregnancy for 12 to 18 months after surgery to avoid pregnancy during the rapid weight loss phase.

Pregnancies after bariatric surgery are less likely to be complicated by gestational hypertension, diabetes, macrosomia, and cesarean delivery when compared to pregnancies of obese women (Gurewitsch et al., 1996; Wax et al., 2007). Two prospective studies involving approximately 70 patients after laparoscopic adjustable gastric banding showed it was safe for both mother and newborn (Bar-Zohar et al., 2006) and the outcomes were similar to the general community rather than those of severely obese women (Dixon et al., 2005).

There are three main types of bariatric surgery including malabsorptive procedures (i.e., jejunoileal bypass), restrictive procedures (i.e., gastric banding), and combined procedures. While more common with malabsorptive procedures, nutritional and vitamin deficiencies can occur after bariatric surgery. Bypassing the pyloric portion of the stomach decreases stomach acidity as well as secretion of intrinsic factor. This leads to impaired absorption of vitamin B-12 and iron as well as impaired release of nutrients from food (Gurewitsch et al., 1996).

Dumping syndrome can occur after gastric bypass. These women may not tolerate a glucose load and should be screened for gestational diabetes with fasting and two-hour postprandial glucose values for one week at 24 to 28 weeks gestation (Wax et al., 2007).
EVIDENCE TABLE

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<tr>
<td>1 Women who have undergone bariatric surgery should be evaluated for nutritional deficiencies and may need vitamin supplementation</td>
<td>Gurewitsch et al., 1996 Wax et al., 2007</td>
<td>II</td>
<td>Poor</td>
<td>C</td>
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<tr>
<td>2 Women with adjustable gastric bands should be monitored by their general surgeons during pregnancy</td>
<td>ACOG, 2005 #315</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
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<tr>
<td>3 Women with dumping syndrome should not undergo diabetes screening with a glucose load</td>
<td>Wax et al., 2007</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
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</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 29. Screening for Gonorrhea: Weeks 10-12

BACKGROUND

The CDC (1998) reports that there are approximately one million new cases of gonorrhea each year, and up to 80 percent of women infected with gonorrhea are asymptomatic. The reported prevalence among pregnant women varies from 0.4 to 7.5 percent. In pregnancy, infection with this organism can be asymptomatic or cause cervicitis, endometritis, or systemic illness. It has also been associated with septic abortion, neonatal ophthalmic infections, and abscesses of Bartholin’s or Skene’s glands. Maternal infection with gonorrhea has been associated with adverse pregnancy outcomes such as preterm labor, premature rupture of membranes (PROM), and preterm delivery (McGregor et al., 1990).

RECOMMENDATIONS

1. Recommend screening for gonorrhea in all pregnant women. [B]
2. Pregnant women with positive cultures should be treated with ceftriaxone, per the CDC guidelines. [B]
3. Pregnant women with positive screens for gonorrhea should be screened for other sexually transmitted diseases (STDs) and follow local mandatory reporting requirements. [I]
4. Recommend performing a test of cure (TOC) during pregnancy after completing antibiotic therapy. TOC in pregnant women, unlike non-pregnant women, is recommended due to risk of complications resulting from persistent or recurrent infections. [I]
5. Recommend counseling to decrease rate of reinfection. [C]
6. Recommend referring the partner for testing and treatment, as appropriate. [C]
7. Infected pregnant women must abstain from intercourse pending TOC. [C]

DISCUSSION

Pelvic inflammatory disease (PID) occurs in 10 to 20 percent of untreated gonococcal infections in women. PID is an important cause of chronic pelvic pain, ectopic pregnancy, and infertility. Early detection and treatment of gonococcal infection in asymptomatic pregnant women offers the potential benefits of preventing future complications of infection. Similarly, early detection and treatment during pregnancy has the potential to reduce morbidity from obstetric complications. Antibiotic treatment effectively reduces the morbidity of untreated gonococcal infections. However, high rates of reinfection emphasize the need for measures to prevent future infection (Vuylsteke et al., 1993).
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<th>Sources of Evidence</th>
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<tbody>
<tr>
<td>1 Routine gonorrheal screening during pregnancy</td>
<td>CDC, 1998</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

**I-30. Screening for Chlamydia:**

**BACKGROUND**

Chlamydia trachomatis is one of the most common STDs in the United States. It is a leading cause of urethritis, cervicitis, PID, infertility, chronic pelvic pain, and ectopic pregnancy. In pregnancy, it can lead to preterm labor and delivery with resultant complications. Infection rates for neonatal conjunctivitis range between 15 and 25 percent and for neonatal pneumonitis between five and 15 percent. The morbidity and mortality rates for pregnant and nonpregnant women are equal.

**RECOMMENDATIONS**

1. Recommend screening all pregnant women for Chlamydia trachomatis at the initial physical examination. [B]
2. Pregnant women with positive cultures should be treated with azithromycin or erythromycin, per the CDC guidelines. [A]
3. Pregnant women with positive screens for Chlamydia should be screened for other sexually transmitted diseases (STDs). [I]
4. Recommend performing a test of cure (TOC) during pregnancy after completing antibiotic therapy. TOC in pregnant women, unlike nonpregnant women, is recommended due to risk of complications resulting from persistent or recurrent infections. [C]
5. Recommend counseling to decrease rate of re-infection. [C]
6. Recommend referring partner for testing and treatment, as appropriate. [C]
7. Infected pregnant women must abstain from intercourse pending TOC. [C]

**DISCUSSION**

The CDC reports that there are about four million new cases of Chlamydia each year, and up to 75 percent of women infected with Chlamydia are asymptomatic. The reported prevalence among pregnant women varies from two to 37 percent (Hammerschlag et al., 1979; Leu, 1991).

Chlamydia is the presumed cause of 25 to 50 percent of the 2.5 million pelvic inflammatory disease (PID) cases each year. PID is an important cause of infertility and ectopic pregnancy in American women (Rolfs et al., 1992). Infection during pregnancy increases the risk of postpartum and postabortion endometritis. Each year more than 155,000 infants are born to Chlamydia-infected mothers, with a vertical transmission rate greater than 50 percent (CDC, 1998). Neonatal infection can result in ophthalmic neonatorum and pneumonia (Blackwell et al., 1993). Acute Chlamydia infection has also been implicated as a factor in stillbirth and preterm delivery (Gencay et al., 2000).

Early detection and treatment of Chlamydia infection in asymptomatic pregnant women offers the potential benefits of preventing future complications of infection, as noted above. Early detection and treatment during pregnancy has the potential to reduce morbidity from obstetric complications. Due to ethical considerations about withholding treatment for Chlamydia, the evidence to support such treatment is indirect; antibiotic treatment effectively reduces the morbidity of untreated Chlamydia infections. High rates of reinfection emphasize the need for measures to prevent future infection (Vuylsteke et al., 1993).
High-risk profiles for asymptomatic Chlamydia infection can be devised. A large majority of cases occur in persons under age 25 (CDC, 1998). Demographic and behavioral variables have been associated with higher rates of infection: unmarried, history of STDs, new or multiple sexual partners, early sexual activity, low socio-economic status, and black race. Evidence of cervical ectopy, friability, or erythema as well as mucopurulent discharge on pelvic exam is suggestive of Chlamydia infection (Stergachis et al., 1993).

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<tr>
<td>1. Routine screening for Chlamydia trachomatis at initial physical examination</td>
<td>Hammerschlag et al., 1979</td>
<td>II-2</td>
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<tr>
<td>2. Treatment per CDC guidelines for positive cultures</td>
<td>Blackwell et al., 1993</td>
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<tr>
<td>3. Screening for other STDs, if Chlamydia screen is positive</td>
<td>Vuylsteke et al., 1993</td>
<td>II-2</td>
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<tr>
<td>4. TOC after completion of antibiotic therapy</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
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<tr>
<td>5. Counseling to prevent reinfection</td>
<td>Vuylsteke et al., 1993</td>
<td>II-2</td>
<td>Fair</td>
<td>C</td>
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**LE** = Level of Evidence; **QE** = Quality of Evidence; **SR** = Strength of Recommendation (See Appendix A)

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### I- 31. Screening for and Prevention of Cervical Cancer: Update Weeks 10-12

**BACKGROUND**

Pregnant women who are exposed to oncogenic human papilloma virus are at risk for cervical cancer. Screening for cervical cancer usually begins within three years of a woman becoming sexually active or by age 21, whichever comes first. The screening is performed annually with conventional cervical cytology smears or every two years using liquid-based cytology in women with no history of dysplasia. Pregnancy presents an opportunity to detect disease in those women not previously screened, and to initiate preventative measures in those who fit criteria for human papilloma virus (HPV) immunization.

**RECOMMENDATIONS**

1. Women current with routine screening for cervical cancer do not need to undergo additional testing. If the woman will come due for routine screening before the eight week postpartum visit, a screening test should be performed at the first prenatal visit. [B]

2. For women who do not receive cervical cancer screening antenatally, screening should be considered at the eight-week postpartum visit to ensure compliance with routine cervical cancer screening guidelines. [B]

3. Recommend performing cervical screening in pregnancy with a brush sampler and spatula. [A]

4. Recommend women with abnormal cervical cytology during pregnancy be managed based on local algorithms, which may include repeat testing, observation, or colposcopy. [C]

**DISCUSSION**

Once the number one cancer killer of women, cervical cancer mortality has decreased by over 70 percent since the 1950s, now ranking the 13th most frequently diagnosed cancer among American women (Saslow et al., 2002). This decrease is largely attributed to implementation and widespread use of cervical cytology testing, which can identify dysplasia in the premalignant stage, along with treatment of these early lesions.
The American Cancer Society (ACS) (Saslow, 2002) recommends routine cervical screening for sexually active women between the ages of 21 and 70. Furthermore, ACS recommends cervical screening be performed annually with conventional cervical cytology smears or every two years using liquid-based cytology. Women over age 30 who have had three consecutive, technically satisfactory normal/negative cytology results may be screened every two to three years (unless they have a history of in utero diethylstilbestrol (DES) exposure, are HIV positive, or are immunocompromised by organ transplantation, chemotherapy, or chronic corticosteroid treatment) (Saslow et al., 2002).

The United States Preventative Services Task Force (USPSTF) strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix. Indirect evidence suggests most of the benefit can be obtained by beginning screening within three years of onset of sexual activity or age 21 (whichever comes first) and screening at least every three years (USPSTF, 2003). All pregnant women are included in this population, and recommendations for screening apply during this time in their lives. There is no evidence of an increased incidence of cervical dysplasia during pregnancy that would necessitate more frequent testing (Lurain & Gallop, 1979). This fact, combined with increased rates of false positive cervical cytology in pregnancy, challenges the common practice of uniformly performing cervical smears at the first antenatal visit.

The goal in evaluating abnormal cervical cytology is to rule out the presence of invasive cervical cancer (LaPolla et al., 1988). Colposcopy is safe during pregnancy, but should be performed only by colposcopists experienced in pregnancy exams (Wright et al., 2007).

The use of cytobrush and spatula may cause minimal spotting in pregnancy, but is not associated with any adverse outcomes (Hoffman et al., 1991; Koonings et al., 1992). The endocervical swab is less sensitive than a brush for endocervical sampling and should therefore not be used (Martin-Hirsch et al., 1999).

### EVIDENCE TABLE

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<tbody>
<tr>
<td>1    Screening cervical smear in pregnancy</td>
<td>Lurain &amp; Galop, 1979</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
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<td>2    Method of cervical smears</td>
<td>Hoffman et al., 1991 Koonings et al., 1992</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>3    Management of abnormal cervical smears</td>
<td>Wright et al., 2007</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

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### I- 32. Screening for HSV: New Weeks 10-12 or onset of symptoms

**BACKGROUND**

Herpes Simplex Virus (HSV) is one of the most common sexually transmitted infections but it is not a reportable disease so the true incidence is not known. It is estimated that approximately 45 million adolescent and adult Americans are infected with HSV-2 (Fleming et al., 1997). However, HSV-1 can also cause genital disease.

Approximately 10 percent of women who are HSV-2 seronegative have partners who are seropositive and are at risk of transmission during pregnancy (Gardella et al., 2005). Most new infections in pregnancy are asymptomatic (Brown et al., 1997). Approximately 80 percent of infected infants are born to mothers with no reported history of HSV infection (Whitley et al., 1988).

**RECOMMENDATIONS**

1. Routine HSV culture-based screening of pregnant patients is not recommended. [I]
2. Symptomatic patients, those who are seropositive, or seronegative patients who have infected partners require further testing and counseling. [B]

---

*Interventions*
DISCUSSION

Maternal HSV screening has been proposed as a means to decrease neonatal transmission in pregnant patients by identifying asymptomatic patients who are seropositive or seronegative patients who have infected partners. These patients could then be offered suppressive therapy or be counseled regarding ways to decrease transmission during pregnancy.

Several cost effective analyses have been done with variable results. The estimated cost to prevent one case of neonatal herpes ranges from $200,000 to $4,000,000 (ACOG, 2007). No evidence of cost effectiveness of screening exists from either clinical trials or cohort studies in pregnancy (ACOG, 2007). Although screening may be beneficial in select couples or populations, ACOG currently does not recommend routine screening for HSV in pregnant women.

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<tr>
<td>1 Routine HSV screening of pregnant patients is not recommended</td>
<td>ACOG, 2007</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
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</table>

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I- 33. Counseling for Cystic Fibrosis Screening: Update

BACKGROUND

Cystic fibrosis (CF) is an autosomal recessive genetic condition. More than 1,300 mutations have been identified in the gene for cystic fibrosis, but the severity of disease (the phenotype) resulting from some of these mutations is not well characterized. Screening tests for common mutations are available and can reduce a couple’s risk for having a child with cystic fibrosis. The risk of being a carrier depends on an individual’s ethnicity and family history.

RECOMMENDATIONS

1. Information about cystic fibrosis (CF) should be provided to all couples. [I]
2. For couples who desire screening at <18 weeks’ gestation, only one partner should initially be screened; if the screening is positive then the other partner should be screened. [I]
3. Cystic fibrosis carrier screening should be offered to all couples who desire it. Informed consent should be obtained prior to testing. [I]
4. Either sequential (testing one partner first) or concurrent (testing both partners simultaneously) carrier screening for cystic fibrosis is appropriate. The latter option may be preferred if there are time constraints for decisions regarding prenatal diagnostic testing or termination of the affected pregnancy. [I]
5. Recommend genetic counseling for individuals with a family history of cystic fibrosis, or for individuals found to be carriers of two cystic fibrosis mutations who have not previously received a diagnosis of cystic fibrosis. [I]

DISCUSSION

The current recommendations regarding counseling and the option of subsequent screening for CF are based on the expert opinions of the American College of Medical Geneticists, ACOG, and the National Institutes of Health (NIH). The sensitivity of the screening test and the carrier risk vary among different ethnic groups. The results often are reported with a table of the residual carrier risk for each ethnic group, and it is the provider’s responsibility to interpret the results based on the patient’s ethnicity. A negative carrier screening test result can reduce but not eliminate the risk of being a cystic fibrosis carrier. ACOG educational materials explain the relative risks for carrying CF, screening options, and subsequent options, should a couple learn that they carry the CF gene (ACOG, 2005).
I-34. Management of Depression during Pregnancy: New When diagnosed

BACKGROUND

Untreated maternal depression is associated with various adverse pregnancy outcomes to include premature birth, fetal growth restriction, low-birth-weight infants, increased life stress, decreased social support, poor maternal weight gain, alcohol and drug use, and smoking. Treatment options for pregnant patients with depression may involve pharmacological and/or nonpharmacological options.

RECOMMENDATIONS

1. When antenatal depression symptoms are mild to moderate, consider referring patients for non-pharmacological treatment, such as Interpersonal Therapy (IPT). [A]

2. When pharmacological treatment of depression is necessary during pregnancy, the potential risks of SSRI exposure during pregnancy should be balanced with the potential risks of untreated depression on the mother and fetus. [B]

3. Avoid paroxetine use during pregnancy when possible. Consider fetal echocardiography for women exposed to paroxetine during early pregnancy. [B]

4. Choice of medications should be based on the well-characterized reproductive safety profiles of the medication, while also considering the severity of the depressive disorder and the wishes of the pregnant patient. [C]

5. Multidisciplinary management of the pregnant patient with depression is recommended to the extent that it is possible. This may involve the patient’s obstetrician, behavioral healthcare provider, primary care physician, and pediatrician. [C]

RATIONALE

There are various nonpharmacological treatments for depression during pregnancy, which do not present the same risks as antidepressant medication. Two systematic reviews (Misri & Kendrick, 2007; Bledsoe & Grote 2006) identified several efficacious psychotherapeutic and biologic treatments for major depression. Regarding psychotherapy, Interpersonal Psychotherapy (IPT) has the most empirical support at this time (Adouard et al., 2005; Grote et al., 2004; Spinelli and Endicott, 2003; Spinelli, 1997) and is ideal for patients who are dealing with role transitions into motherhood. Although Cognitive Behavioral Therapy (CBT) has not been researched specifically related to depression during pregnancy, there is a plethora of empirical evidence behind its utility as an efficacious nonpharmacological treatment for Major Depressive Disorder and postpartum depression (Misri et al., 2004). Additional research is needed to further validate CBT as an efficacious treatment for depression during pregnancy. Due to the potential risks associated with pharmacological treatment, and the empirical support behind CBT in general, it may also be considered an appropriate first-line treatment option.

Promising biologic treatments include light therapy (Epperson et al., 2004; Oren et al., 2002), which has been noted as especially useful for women who note depressive symptoms in relationship to seasonal changes. Ryan, Mills & Misri (2005) also cited electroconvulsive therapy (ECT) to be “relatively safe and effective” for treating depression during pregnancy, although research indicates it is most appropriate for treating severe psychosis or suicidality. ECT should not be considered until all other treatment options have been attempted.

The teratogenic effect of SSRI use during pregnancy was most recently examined in two large case-controlled studies, the National Birth Defects Prevention Study and the Slone Epidemiology Center Birth Defects Study. The
The National Birth Defects Prevention Study found no significant associations between SSRI use overall and congenital heart defects, but did find an association between SSRI use, particularly paroxetine, during early pregnancy and anencephaly, craniosynostosis, and omphalocele. The absolute risks remained small and associations were found after more than 40 statistical tests were performed. In the Sone Epidemiology Center for Birth Defects Study, SSRI use overall was not associated with craniosynostosis, omphalocele, or heart defects. However, the study found associations between paroxetine and right ventricular outflow defects and between sertraline and omphalocele and atrial and ventricular septum defects. The authors conducted 42 comparisons in their analyses (Louik et al., 2007).

In another comparison from the National Birth Defects Prevention Study the authors found no association between the use of SSRIs during early pregnancy and significantly increased risks of congenital heart defects or of most other categories of birth defects (Alwan et al., 2007). GlaxoSmithKline raised concerns about a 1.5 to two-fold increased risk of congenital cardiac malformations, namely atrial and ventricular septal defects, associated with first-trimester paroxetine exposure. This resulted in the manufacturer changing paroxetine’s pregnancy FDA category from C to D. Given that the absolute risk of associated malformations remains small, SSRIs in general are not considered to be major teratogens. It is important to note that current literature on the risk of general and specific malformations associated with SSRI exposure during pregnancy is limited and often conflicting. As such, it is strongly recommended that pharmacological treatment of depression during pregnancy be individualized and that providers balance potential risks of SSRI exposure during pregnancy with potential risks of untreated depression on the mother and fetus.

As the only FDA Pregnancy Category D agent with a higher risk of cardiovascular malformation, paroxetine should be avoided in pregnant women. All other SSRIs are FDA Pregnancy Category C agents and generally considered safe in pregnancy. However, SSRIs as a class have been associated with risk of miscarriage, preterm labor, and an increase in persistent pulmonary hypertension in the newborn. The SADHEART (Glassman et al., 2002), ENRICHED, and CREATE (Lespérance et al., 2007) studies indicate that SSRIs are safe medications in cardiac patients.

### EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Interpersonal Psychotherapy (IPT) is an efficacious treatment for depression during pregnancy</td>
<td>Adouard et al., 2005</td>
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<td>Bledsoe &amp; Grote, 2006</td>
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<td>Grote et al., 2004</td>
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<td>Spinelli &amp; Endicott, 2003</td>
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<td></td>
<td></td>
<td>Spinelli, 1997</td>
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<td>2</td>
<td>Light therapy is promising for treating depression during pregnancy, especially when affected by seasonal change</td>
<td>Epperson et al., 2004</td>
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<td>Fair</td>
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<td>Oren et al., 2002</td>
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<td>3</td>
<td>SSRI use prior to 20 weeks’ gestation, with the exception of paroxetine, has not been shown to increase congenital malformations</td>
<td>Einarson &amp; Einarson, 2005</td>
<td>II-2</td>
<td>Fair</td>
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<td>4</td>
<td>SSRI use is associated with a neonatal withdrawal syndrome</td>
<td>Levinson-Castiel, 2006</td>
<td>II-2</td>
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<td>5</td>
<td>SSRI use is associated with an increased rate of persistent pulmonary hypertension</td>
<td>Chambers, 2006</td>
<td>II-2</td>
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<tr>
<td>7</td>
<td>Behavioral therapy has benefit in postpartum depression</td>
<td>AHRQ, 2005</td>
<td>II-2</td>
<td>Fair</td>
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</tbody>
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*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*
I- 35. Periodontal Disease and Dental Care:  

**BACKGROUND**

Prenatal care providers have a significant role in educating women concerning the importance of good oral health during pregnancy. Periodontal disease prevalence among women of reproductive age is estimated at 37 percent to 46 percent and can be as high as 30 percent among pregnant women. In addition, fewer than half of women receive dental care during pregnancy. The prenatal care team can encourage women to maintain a high level of oral hygiene, to visit an oral health professional, and promote the completion of all needed treatment during pregnancy. Instruction on oral health for pregnant women should include expected physiologic changes in the mouth and interventions to prevent threats to their oral health.

Periodontal disease is a bacterial infection characterized by gingivitis (gum inflammation, bleeding, redness, tenderness and sensitivity) and periodontitis. If left untreated, periodontal disease can result in the formation of pockets around teeth caused by the destruction of the attachment of gums to teeth and teeth to the alveolar bone. Eventually it may lead to tooth loss. Periodontal disease is both preventable and curable. Treatment of periodontal disease in pregnant women is safe, and improves periodontal health.

Treatment of periodontal disease during pregnancy and the risk of adverse outcomes to the fetus have been debated in the literature. The most recent research completed does not support a direct relationship between provision of periodontal treatment in pregnancy to reduce adverse outcomes in pregnancy.

**RECOMMENDATIONS**

1. Assessment of oral health and instruction on maintaining a high level of oral hygiene should be offered to all pregnant women during their initial prenatal assessment to promote oral health and the general health of the woman. [C]

2. Preventative dental treatment is safe and should be provided as early in pregnancy as possible. [B]

3. Routine dental care, including x-rays and periodontal therapy, are effective and safe during pregnancy, and should be recommended. [B]

4. There is insufficient evidence to recommend the routine treatment of periodontal disease in order to alter the rates of preterm delivery (PTD), low birth weight (LBW) or fetal growth restriction. [I]

**DISCUSSION**

A systematic review of 29 studies suggests a correlation between periodontal disease and preterm birth (Xiong et al., 2006). The meta-analysis focused on preterm low birth weight, low birth weight, preterm birth, birth weight by gestational age, miscarriage or pregnancy loss, preeclampsia, and gestational diabetes mellitus. Of the chosen studies, 29 suggested an association between periodontal disease and increased risk of adverse pregnancy outcome (odds ratios [ORs] ranging from 1.10 to 20.0) and 15 found no evidence of an association (ORs ranging from 0.78 to 2.54). A meta-analysis of the clinical trials suggested that oral prophylaxis and periodontal treatment may reduce the rate of preterm LBW (pooled risk ratio (RR): 0.53, 95 percent confidence interval [CI]: 0.30-0.95, \( P < 0.05 \)), but did not significantly reduce the rates of preterm birth (pooled RR: 0.79, 95 percent CI: 0.55-1.11, \( P > 0.05 \)) or LBW (pooled RR: 0.86, 95 percent CI: 0.58-1.29, \( P > 0.05 \)).

The New York State Department of Health (2006) published practice guidelines on oral health during pregnancy. This guideline stated that at the first prenatal visit, the prenatal care provider should conduct an assessment to identify women who require immediate oral healthcare and make appropriate referrals. This assessment should include interviewing the patient for problems in the mouth, previous dental visits and access to a dental provider. The American Academy of Periodontology (2004) endorsed preventative oral care services in pregnant women in their policy statement based on scientific literature that has indicated women with periodontal disease may be at risk of delivering preterm, LBW babies.

Periodontal disease is both preventable and curable. Dental services have been found to be safe and effective and improve periodontal disease during pregnancy (Michalowicz et al., 2006). Diagnostic X-rays have been found to be safe during pregnancy when a protective apron with a thyroid collar is used (American Dental Association, 2006).
A large multicenter randomized control trial (Michalowicz et al., 2006) demonstrated that treatment of periodontitis during pregnancy is safe but such treatment does not significantly alter the rates of PTD, LBW or fetal growth restriction. However, birth outcome findings from this study must be interpreted cautiously, in light of the fact that some control subjects who developed severe periodontal disease received periodontal therapy, but were not removed from the control group. Xiong and colleagues (2006) conducted a comparative review of pregnant women and adverse fetal outcomes in pregnant women. They found great variation in periodontal disease definitions, as well as no universally accepted standard for periodontal disease diagnosis among the studies reviewed. They did find a large body of evidence pointing to inconsistent conclusions on the relationship between periodontal disease and pregnancy outcomes, especially in economically disadvantaged women.

Additional multicenter intervention studies are needed to increase the understanding of the relationship between periodontal treatment and pregnancy outcomes.

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Provide dental screening and patient teaching on oral health during pregnancy at the first visit</td>
<td>III</td>
<td>II-2</td>
<td>C</td>
</tr>
<tr>
<td>2</td>
<td>Preventive dental services are safe in pregnant women and should be provided early in pregnancy to prevent oral disease</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>3</td>
<td>Routine dental care, including X-rays and periodontal therapy, are effective and safe during pregnancy, and should be recommended</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>4</td>
<td>Routine treatment of periodontal disease has not been proven to decrease rates of preterm birth, low birth weight or fetal growth restriction</td>
<td>I</td>
<td>II-2</td>
<td>I</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

**I- 36. Prenatal Screening for Fetal Chromosomal Abnormalities: New Weeks 10-12; 16-20**

**BACKGROUND**

There is a three to five percent chance for a pregnancy to be complicated by a fetal structural or karyotype abnormality. Many of these abnormalities are detectable prior to delivery. Prenatal detection of fetal abnormalities provides an opportunity for preparation and/or intervention that may optimize the desired pregnancy outcome. Normal findings on prenatal tests may also decrease parental anxiety and stress.

Methods of prenatal evaluation broadly fall into screening and diagnostic categories. While screening modalities gather information used to calculate an individualized risk for the pregnancy, the results are not definite. These risks are usually reported both as a ratio of the likelihood that the baby(s) will be abnormal (e.g., 1:300) and more generally as “high risk” or “low risk”. High risk is usually defined as being a ratio of more than 1:100 to 1:270.
where the cutoff value depends on the specific test selected. Diagnostic testing provides yes or no (i.e., affected or not affected) results.

Screening modalities include measurement of maternal serum analytes, ultrasound evaluation, or a combination of maternal serum analyte and ultrasound evaluation. These modalities can variably be applied in each of the three trimesters of pregnancy but are typically performed in the first and second trimesters. The information obtained from these modalities can be combined to yield a complex array of screening strategies, each with its own inherent strengths and weaknesses including varied accuracy rates.

Multiple screening and testing modalities are now defined and offered but the individual tests/strategies are not uniformly available. Due to the complex nature of the testing strategies, the potential harm of both screening and diagnostic testing, their varied local availability, and their inherent elective nature, it is imperative that detailed counseling be provided to the prospective mother prior to electing or declining a specific testing strategy.

Ultrasound can be diagnostic of certain fetal anomalies but a fetal tissue sample is necessary to diagnose or exclude fetal karyotype abnormalities. Fetal tissue samples are usually obtained by chorionic villus sampling (CVS), amniocentesis, or fetal cord blood sampling (cordocentesis). Each of these methods has limitations and inherent risks of provoking a pregnancy loss. Some large studies have shown amniocentesis to be significantly less likely to cause pregnancy loss than cordocentesis or CVS but the risk of CVS in experienced hands has been reported to be very low in other studies. Amniocentesis is also the most widely available of the diagnostic methods. Chorionic villus sampling provides an earlier result than either amniocentesis or cordocentesis.

RECOMMENDATIONS

1. All pregnant women, regardless of age, should be offered a prenatal screening test for the most common clinically significant fetal anomalies as a routine part of prenatal care. [B]

2. Women presenting for care at appropriate gestational ages should have aneuploidy screening and diagnostic options available to them that provide first-trimester results as well as strategies that provide second-trimester results. The specific first-trimester screening strategy made available by or in the institution must be decided prior to embarking upon that strategy. [B]

3. Initial limited and comprehensive prescreen/pretest counseling methods may include written or multimedia communication, one-on-one, or group counseling formats. Posttest and late entry counseling should be provided in an individualized one-on-one format. [B]

4. Screening programs should show respect for the needs and quality of life of the woman and her family. Counseling should be nondirective and should respect a woman’s choice to accept or to refuse any or all of the testing or options offered at any point in the process. [I]

5. The following modes of prenatal screening/diagnostic testing should be available for women receiving prenatal care in the DoD/VA: [B] (see Appendix E)
   a. No test at all
   b. Screening with results in first trimester
   c. Screening with results in second trimester
   d. Diagnostic/invasive test in first and second trimester.

6. In order to make these screening and diagnostic options available, each institution providing prenatal care should provide locally or arrange for access to: genetic counseling, first- and second-trimester serum marker assessment, first-trimester nuchal translucency (NT) measurement, basic and comprehensive second-trimester ultrasound assessment, first-trimester chorionic villus sampling and second-trimester amniocentesis. [I]

7. All women considered high-risk, due to maternal age, personal or family history, or the result of a previous test, should be offered the choice of a first- or second-trimester screening strategy and the choice of first- or second-trimester diagnostic testing including appropriate comprehensive pre- and post-test genetic counseling. [I]

8. A comprehensive ultrasound may be offered as a primary or follow-on screening test. [B]
9. First-trimester NT should be interpreted for risk assessment only when performed by a trained sonographer who is accredited to provide this service [B] and when offered together with biochemical markers. [A]

10. For women who undertake first-trimester screening (FTS), second-trimester serum alpha fetoprotein (AFP) screening and/or ultrasound examination should be offered to screen for open neural tube defects (ONTD). [B]

11. Pregnant women with persistent unexplained elevations of maternal serum alphafetoprotein (MSAFP) are at increased risk for adverse perinatal outcome and should receive specialized prenatal care. [B]

12. The Quad Marker Screen should be used rather than the Triple Marker Screen when second-trimester serum screening is undertaken. [B]

DISCUSSION

Common Chromosome Conditions

The most common chromosome conditions associated with advanced maternal age involve the presence of an additional chromosome (21, 18, 13, or X). Of these, trisomy 21, 18, and 13 are associated with congenital anomalies and mental handicap.

Most families who have a child with an open neural tube defect (ONTD), Down syndrome (DS) or trisomy 18 (T18) have no prior family history of the same. The incidence of ONTD varies with racial background and geographical location. While maternal age is the key risk factor for trisomy 21, 18 and 13, more than half of children born with DS are born to women less than 35 years old. Using a maternal age of 35 as a cutoff for offering diagnostic testing will only identify about 40 percent of affected pregnancies (Summers et al., 2003). The incidence of DS approximates one in 700 births regardless of race or geographical location.

Prenatal Screening

Maternal serum analyte screening with multiple serum markers (e.g., alphafetoprotein, human chorionic gonadotropin [HCG], unconjugated estriol and inhibin) has been demonstrated to be a cost-effective means of antenatal screening for several categories of serious fetal structural abnormalities, fetal aneuploidy, and placental abnormalities. Specific structural fetal abnormalities include open neural tube defects (ONTD) (e.g., anencephaly and open spinal defects), ventral wall defects (e.g., omphalocele and gastroschisis), as well as other rare conditions (e.g., skin disorders and congenital nephrosis).

The specific fetal aneuploid conditions commonly detected through maternal serum analyte screening include Down syndrome (trisomy 21) and Edward’s Syndrome (trisomy 18). Sex chromosome abnormalities or other aneuploid conditions are less reliably detected.

ONTDs occur in one to two/1,000 live births; 90 to 95 percent of ONTD cases occur in mothers without risk factors such as a positive family history, medical therapy for maternal seizure disorder, or pregestational diabetes mellitus. ONTDs are associated with high rates of perinatal mortality, morbidity, and long-term developmental disability.

Ventral wall defects occur in 0.5 to one infant/1,000 live births and are associated with an increased incidence of associated serious fetal anomalies and aneuploidy, omphalocele, or fetal growth restriction. Both require immediate postnatal surgical treatment for optimal outcome.

The practice of using solely the cut-off of maternal age of 35 or over to identify at-risk pregnancies is inferior to screening tests that consist of maternal serum markers and ultrasound assessment of nuchal translucency (Resta et al., 2005).

Several large, multicenter trials have shown that in the first trimester, a combination of nuchal translucency measurement, serum markers, and maternal age is a very effective screening test for Down syndrome (Malone et al., 2003; Wald et al., 2003; Wapner et al., 2003). First-trimester screening can lead to a diagnosis of fetal aneuploidy much earlier in the pregnancy than second-trimester screening/diagnostic methods. Earlier detection allows the woman and her family to make decisions about continuing the pregnancy in a more private manner (diagnosis can be made before it is evident that the patient is pregnant) (ACOG, 2007; Malone et al., 2005).

Ultrasound has become a valid method to screen for ONTD (Lennon et al., 1999).
The decision whether or not to undergo a screening strategy or diagnostic test should be greatly influenced by whether or not the woman would consider pregnancy termination for an anomalous fetus (ACOG, 2007). Thus, this issue should be addressed when counseling women about screening and diagnostic testing.

Women who would continue a pregnancy regardless of the result of screening or diagnostic testing should be less inclined to undergo screening or diagnostic testing because the results are not likely to provide her with useful information, except the reassurance that comes with a low-risk screening test. Accordingly, the women who would most benefit from a normal/low-risk result are women who started out high-risk e.g. women > 35 years of age (ACOG, 2007; Berkowitz et al., 2006).

Women who would consider pregnancy termination should be more likely to undergo screening testing because they would be more likely to undergo diagnostic testing in the event of an abnormal test (Berkowitz et al., 2006).

Women who want diagnostic testing regardless of the result of screening testing would reasonably skip screening tests and move directly to diagnostic testing. For a priori low-risk women, an amniocentesis by an experienced provider would be appropriate (Eddleman et al., 2006). For a priori high-risk women, either a CVS or an amniocentesis would be appropriate (Wapner et al., 2003).

**Benefit and Harm**

To date, there is no clear evidence that data obtained from prenatal aneuploidy screening or testing provides any utility in terms of improving outcome for the fetus. Ultimately, the potential benefit of screening and diagnostic testing is to provide information to the pregnant women and her involved partner/family. Whether or not the test is useful for the pregnant women and her partner/family depends on their perceived benefits of the testing.

Potential benefits of prenatal screening/testing include:

- Peace of mind that comes with a normal test
- The screening test provides more individualized risk numbers that might assist the pregnant woman in deciding whether or not she would choose to undergo diagnostic testing
- A diagnostic test provides a definitive answer regarding the fetal karyotype
- A definitive answer could facilitate decision-making about whether to continue or terminate the pregnancy.

There is potential harm in the screening and diagnostic testing (ACOG, 2007):

- The prevalence in the population for fetal aneuploidy in the second trimester is small, resulting in relatively high false positive screening test results
- The great majority of women who have abnormal screening tests will ultimately deliver normal babies (>95%)
- False positive tests occur in five percent of the overall population and in 20 percent or more of women over 35 years old. False positive tests cause maternal/familial anxiety and unnecessary procedures. The likelihood of having a normal baby when the screening tests are abnormal is approximately 95 percent
- Unnecessary diagnostic tests, in the case of false positive screening testing, can result in complications leading to the delivery of a previable fetus or fetuses resulting in fetal wastage/pregnancy loss (Biggio et al., 2004)
- Ongoing maternal/family anxiety in the case of an abnormal screening test, particularly when the woman declines to undergo diagnostic testing, can have a significant negative impact for the duration of the pregnancy and beyond.

**Screening Protocols**

Many studies have been published that address screening for fetal chromosomal abnormalities (ACOG, 2007; SOGC, 2007). Studies also suggest that diagnostic testing via karyotype analysis on tissue obtained at the time of chorionic villus sampling (CVS) (Caughey et al., 2006) or amniocentesis is less risky than previously thought when these procedures are performed by experienced providers (Eddleman et al., 2006).
Multiple algorithms have been proposed to standardize screening protocols. These algorithms are exceedingly complex and are not suitable for use by the patient (ACOG, 2007). They include calculations based on variations of first- and second-trimester maternal serum markers and first- and second-trimester fetal ultrasound findings. Each of these screening markers, whether used independently or in combination with other markers, alter the sensitivity and specificity, and hence the overall performance of the tests (see Appendix E: Table E5).

**Validity of Tests**

Recent data overwhelmingly support the use of the Quad Screen compared to the Triple Screen (ACOG 2007; Wald et al., 1997). The second-trimester Triple Screen should no longer be considered standard of care.

While the Quad Screen is available throughout most of the military and civilian community, newer methods of testing involving the first trimester are less widely available, particularly for those algorithms involving ultrasound (ACOG, 2007). First-trimester screening methods have benefits compared to second-trimester testing, including potentially earlier diagnosis (in those algorithms that disclose to the patient the calculated first-trimester risk), greater sensitivity for the same screen positive rate and greater privacy (diagnosis can be made before it is evident that the patient is pregnant).

A potential increased risk of first-trimester screening is that the diagnostic test (CVS) is less widely available and may pose higher risk of loss than second-trimester testing particularly when performed by less experienced physicians. The attributable risk of CVS overall appears to be controversial but true if comparing standard quoted CVS risk (0.5 to two percent) compared to the recently identified second-trimester amniocentesis risk (0.15 percent) (Alfirevic et al., 2003).

**Conclusion**

Maternal serum analyte screening should be considered a pure screening modality as there is a relatively high false-positive rate (i.e., five to seven percent of all screened women will have a positive test while more than 95 percent of screen-positive women will have a fetus without a structural abnormality or aneuploidy). However, given the relative low cost and non-invasive nature of maternal serum screening and the serious nature of the fetal abnormalities potentially detected, the current standard of care and respect for patient autonomy results in the recommendation that maternal serum analyte screening should be offered to all pregnant women. Pre-test counseling should emphasize that the decision to undergo screening must be made by the woman after she has considered a number of factors, including personal attitudes and beliefs concerning miscarriage, elective pregnancy termination, birth of a child with a major birth defect or aneuploidy, and the potential anxiety associated with false-positive screening results.

Maternal serum analyte screening should be offered to all pregnant women, but should not be considered a routine, mandatory laboratory test. Pre-test counseling and patient education are required to ensure that women understand the limitations and high false-positive rate, as well as the need for subsequent non-invasive (targeted sonography) and invasive (amniocentesis) testing often used in women with positive screening test results. Routine sonographic examination of low-risk pregnant women improves the accuracy of maternal serum analyte screening as risk estimation is highly dependent upon accurate gestational dating. Women under age 35 at estimated date of confinement (EDC) should be offered invasive testing, generally by amniocentesis, if their screening results yield a risk estimate similar to the mid-gestation risk of a 35-year-old woman (1/270). For women age 35 or older at EDC, maternal serum analyte screening can be chosen instead of direct diagnostic testing by amniocentesis or chorionic villus sampling. Such screening will detect approximately 89 percent of fetuses with Down syndrome in this population with only 25 percent of pregnant women requiring amniocentesis (Haddow et al., 1994).

Elevated MSAFP is predictive for ONTD as well as a variety of other fetal anomalies, including abdominal wall defects and central nervous system malformations. The benefit of detection of ONTD by amniocentesis should be weighed against the risk of fetal loss from the procedure (0.2 to 1.3 percent).

Pregnant women who have persistent serum elevations of alpha-fetoprotein (AFP) in the absence of evidence of fetal abnormalities have been shown to have a two- to three-fold increase in their relative risk for preterm delivery, preterm premature rupture of membranes (PROM), preeclampsia, fetal growth restriction, and intrauterine fetal death. Relative to women with normal AFP levels, unexplained persistent elevations of maternal serum AFP may be indicative of a mild chronic fetomaternal hemorrhage or abnormal decidual-chorionic interface. Thus, women with
at least two values of MSAFP exceeding 2.5 MOM, when corrected for gestational age, should be referred to advanced prenatal care follow-up.

Down syndrome (trisomy 21) occurs in 1/800 births, increasing in risk with advancing maternal age. Eighty percent of babies with Down syndrome are born to women under 35 with no risk factors. Low MSAFP is associated with increased risk for Down syndrome (Haddow et al., 1992). If risk for Down syndrome is calculated solely on age versus AFP, detection increases from 25 to 37 percent. Pregnant women with fetuses affected by trisomy 21 tend to have lower than average levels of MSAFP and unconjugated estriol with elevated levels of serum HCG, when compared to women carrying euploid fetuses. Adding serum HCG and unconjugated estriol (“triple screen”) increases detection to 56 to 75 percent without increasing false positivity (Smith-Bindman et al., 2001). Triple screen also increases the antenatal detection rate for a variety of chromosome disorders, particularly sex chromosome abnormalities (Kellner et al., 1995). Ultrasound to assess fetal age is indicated for all women with low MSAFP or abnormal triple screen. It should be followed by amniocentesis for gestational age-adjusted persistent abnormal values. The benefit of increased detection of chromosome abnormalities should be weighed against the risk of fetal loss from amniocentesis.

Edward’s Syndrome (trisomy 18) occurs in approximately one in 5,000 live births and is associated with a high rate of fetal death or early neonatal demise. Affected individuals surviving the neonatal period typically have profound neurodevelopmental delay and are unlikely to survive beyond five years of age. Pregnant women with fetuses affected by trisomy 18 tend to have lower than average levels of MSAFP, HCG, and unconjugated estriol. Approximately 50 percent of fetuses with trisomy 18 can be detected with maternal serum analyte screening and follow-up fetal karyotype analysis of screen-positive women.

Customary practice is to offer amniocentesis or chorionic villus sampling to all women age 35 or older at the time of birth, and to women whose risk of Down syndrome by maternal serum analyte screening is equivalent to that of a 35-year-old woman. Data from randomized trials suggest the attributable risk of pregnancy loss due to amniocentesis is less than 1:1500 when performed by experienced clinicians. Accordingly, ACOG has recommended amniocentesis be available to women of all ages regardless of their a priori risk for carrying a fetus with aneuploidy (ACOG, 2007).

For gravidas over 35, maternal serum analyte screening with subsequent confirmatory fetal karyotype analysis of screen-positive women identify up to 89 percent of fetuses with Down syndrome, with a false positive rate of 25 percent. For pregnant women over 35 who are willing to accept a potentially false-negative screen, the quad screen is a cost effective alternative to routine amniocentesis. This alternative practice could make more than 75 percent of amniocenteses unnecessary, thereby also reducing amniocentesis-associated fetal losses (Haddow et al., 1994). The complexity of the pre-screening and pre-testing counseling requires referral of high-risk women to a qualified healthcare provider for counseling. Any pregnant women determined to have a fetus with a serious structural abnormality or fetal aneuploidy should receive advanced prenatal care.

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Offer multiple marker maternal serum analyte screening to all pregnant women at gestational ages between 15 and 20 weeks</td>
<td>ACOG, 2007  Haddow et al., 1992  Malone et al., 2005</td>
<td>II-1</td>
<td>Good</td>
</tr>
<tr>
<td>2</td>
<td>Provide pre-test patient education and counseling</td>
<td>Nadel et al., 1990  Dahl et al., 2006  Davey et al., 2005</td>
<td>II-2</td>
<td>Good</td>
</tr>
<tr>
<td>3</td>
<td>Women at high-risk for fetal aneuploidy (age ≥35 at delivery or prior first child or fetus with aneuploidy) require genetic counseling</td>
<td>Haddow et al.,1994</td>
<td>II-1</td>
<td>Good</td>
</tr>
<tr>
<td>4</td>
<td>Screen-positive women require targeted ultrasound examination for</td>
<td>Smith-Bindman et al., 2001  ACOG, 2007</td>
<td>II-1</td>
<td>Good</td>
</tr>
<tr>
<td>Risk Modification and Counseling Prior to Decision for Invasive Testing</td>
<td>( LE = \text{Level of Evidence};\ \QE = \text{Quality of Evidence};\ \SR = \text{Strength of Recommendation (See Appendix A)} )</td>
<td></td>
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<td></td>
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<tr>
<td>5</td>
<td>Women with persistent unexplained elevations of maternal serum AFP are at increased risk for adverse prenatal outcome</td>
<td>ACOG, 2007 [394x748]  SOGC, 2008 [394x748]  Dugoff et al., 2005</td>
<td>I</td>
<td>Good</td>
</tr>
</tbody>
</table>

Ultrasound

Ultrasound is commonly used in pregnancy for other indications (see I-37). These ultrasounds are performed for a host of reasons to include earlier detection of severe anomalies, confirmation of dating, general assessment of fetal well-being, and maternal reassurance. It is not possible to completely separate aneuploidy screening from the above when ultrasounds are performed.

Counseling

Multiple factors may influence a woman’s decision regarding which, if any, tests to choose. These factors may include: local availability of the testing, cost of the testing, the position of the woman/family regarding whether or not she would continue a pregnancy given an adverse fetal condition and whether or not she would consider the risk of diagnostic testing to be worth gaining this information. In order for a woman to come to an informed decision about which method of testing, if any, to undergo, she must be carefully counseled. Because of the complexity and changing nature of the currently available testing, extensive counseling is required to clarify the nature of the testing and allow appropriate informed consent. Unfortunately, many patients perceive the counseling they were provided as inadequate (Dahl et al., 2005).

Few studies evaluated the relative efficacy of various approaches to genetic counseling. Methods limited to brief counseling alone lead to higher rates of dissatisfaction with care and with testing, and are inadequate for women making decisions about such testing (Dahl et al., 2006; Davey et al., 2005).

Audio-visual counseling was found to be an effective means to educate patients about genetic screening and does not require a trained genetics professional to administer (Fries et al., 2005). In another randomized trial (Hunter et al., 2005) assessing changes in knowledge, decisional conflict, state anxiety, satisfaction, and pregnancy outcomes, all participants showed a significant increase in knowledge and a decrease in decisional conflict post-intervention. While all reported high levels of satisfaction, those in individual counseling were significantly more satisfied than those receiving group counseling or the decision aid. This study has shown unique benefits with each type of intervention such that women and their partners preferred individual genetic counseling, while they learned best in group counseling sessions, and experienced the least decisional conflict regarding genetic testing with a decision aid.

Comprehensive Counseling should include:

- **Initial brief counseling/information** This counseling/information, ideally provided in the first trimester, seeks to provide summary information and identify women who desire to forgo any screening or diagnostic testing for fetal aneuploidy/anomalies and to provide an opportunity for women to begin to consider screening/testing options.

- **Comprehensive prescreen/pretest counseling.** This counseling should be comprehensive in nature and should be provided to all women who are considering undertaking a screening strategy or diagnostic testing for fetal aneuploidy/anomalies. Comprehensive counseling should include information regarding the elective nature of the testing, the various available screening strategies, the potential benefits and limitations of screening tests, the potential risks and benefits of diagnostic testing, the locally available diagnostic testing strategies, and the financial and institutional limitations of pregnancy termination in the DoD/VA.

- **Posttest counseling.** This counseling should be provided to all women who have undergone screening or diagnostic testing when the result of the testing is abnormal or “high risk.” This posttest counseling should include a discussion of the significance of the result, including its limitations such as the false positive rate and an outline of further options and management strategies for the woman and her family.
• **Late entry counseling.** This counseling should be provided to women presenting for prenatal care when the gestational age of her pregnancy limits options for screening strategies or diagnostic testing. The counseling should be based on the individual circumstances including the gestational age and patient desires.

### EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 All women, regardless of age, should be offered aneuploidy screening</td>
<td>ACOG, 2007</td>
<td>III</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 When discussing options with patients, providers should furnish information on detection and false positive rates, advantages and disadvantages of each testing method</td>
<td>ACOG, 2007</td>
<td>III</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>3 Unique benefits with each type of intervention: individual counseling, group counseling sessions, and use of decision aids and audiovisual presentation</td>
<td>Hunter et al., 2005 Fries et al., 2005</td>
<td>I</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>5 First-trimester screening can lead to a diagnosis of fetal aneuploidy much earlier</td>
<td>ACOG, 2007 Malone et al., 2003, 2005 Wapner et al., 2003 Wald et al., 2003</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>6 Measurement of nuchal translucency alone is less effective for first-trimester screening than is the combined test (nuchal translucency measurement and biochemical markers)</td>
<td>Nicolaides et al., 2004 Snijders et al., 2002</td>
<td>IIb</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>7 Patients undergoing first-trimester screening for aneuploidy should be offered maternal serum alpha fetoprotein (MSAFP) in the second trimester to screen for open neural tube defects</td>
<td>Lennon et al., 1999 Nicolaides et al., 1992</td>
<td>II</td>
<td>Fair</td>
<td>B</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*
Visits During Weeks: 16-27

I- 37. Obstetric Ultrasound: Update  Week 16-20

BACKGROUND

Ultrasound is commonly performed for a host of reasons to include earlier detection of severe anomalies, confirmation of dating, general assessment of fetal well-being, and maternal reassurance. It is not possible to completely separate aneuploidy screening from the above when ultrasounds are performed.

Fetal assessment by a comprehensive sonographic survey has been proven to be a useful means of ascertaining fetal health and establishing an accurate gestational age in, pregnant women.

Women with specific risk factors, or who develop high-risk conditions that may complicate the pregnancy, require additional surveillance including ultrasound(s) to assist in decision making.

None-the-less, the routine use of screening ultrasound in low risk women has not been conclusively demonstrated to improve long-term outcome in the offspring of these women. Thus, from a cost effectiveness standpoint, the routine use of screening ultrasound in well-dated pregnancies remains controversial.

A single screening ultrasound examination at 18-20 weeks for all pregnant women who desire the examination after having been counseled regarding the limitations and safety of the exam is supported by ACOG.

ACTION ITEM

Second trimester scanning should be recommended and available to women considering an invasive test on the basis of age, or other risk factors, when the absence of soft markers may lower the estimated risk and assist decision-making.

RECOMMENDATIONS

1. Recommend counseling and educating all pregnant women prior to scheduling sonographic studies about the potential benefits, limitations, and safety of prenatal ultrasound. Documentation of education and counseling is recommended; however, written informed consent is not deemed necessary. [C]

2. A complete obstetric sonographic examination should be recommended and available to women considering an invasive test on the basis of age, or other risk factors, when a more accurate gestational age is required for decision-making regarding medical or antenatal routine care interventions, or for predicting actual date of delivery [A]

3. A complete obstetric sonographic examination should be recommended and available to women or who are at increased risk for a sonographically detectable maternal or fetal abnormality where an intervention may improve the outcome (See table for list of indications) [A].

4. There is insufficient evidence to recommend for or against complete obstetric sonographic examination in the second trimester to all low-risk asymptomatic consenting pregnant women [I]

5. All complete obstetric sonographic studies should be performed and interpreted by qualified healthcare providers. [A]

Table 5. Indications for Ultrasonography During Pregnancy

A. Evaluation Of Known Or Suspected Complications Of Pregnancy:
- confirm intrauterine pregnancy
- suspected ectopic pregnancy
- vaginal bleeding
- abdominal and pelvic pain
- maternal pelvic or adnexal masses
- uterine abnormalities
- cervical insufficiency
- suspected amniotic fluid abnormalities
- suspected placental abruption
- premature rupture of membranes
- premature labor
- suspected placenta previa
- suspected hydatidiform mole
- evaluate abdominal / pelvic pain or mass

B. Pregnancy Dating:
- uncertain gestational age
- assigned gestational age and clinical size discrepancy
- evaluation of suspected multiples

C. As Component of Screening For Fetal Aneuploidy:
- abnormal biochemical markers
- history of previous congenital anomaly
- to assess findings that may increase or decrease the risk of aneuploidy
- family, environmental or maternal history increasing the risk for fetal anomalies
- to screen for fetal anomalies

D. Evaluation of Fetal Growth and Well Being:
- confirm cardiac activity
- suspected fetal death
- determine fetal presentation
- fetal condition in late registrants for prenatal care
- medical conditions posing high risk of fetal growth abnormalities
- signs of fetal growth abnormality
- follow up of known fetal anomaly

E. As adjunct For Procedures:
- amniocentesis, chorionic villus sampling or fetal surgery
- external cephalic version
- cervical cerclage placement/evaluation
- embryo transfer, or localization and removal of an intrauterine device

RATIONALE

Neither early, late, nor serial ultrasound examination in low risk pregnancy has been proven to improve perinatal morbidity or mortality. Clinical trials show that a single mid-trimester ultrasound examination detects multiple gestations and congenital malformations earlier in pregnancy, but there is currently insufficient evidence that early detection results in improved short term perinatal outcomes.

Routine second-trimester ultrasound can lower the rate of induction for presumed post-term pregnancy, a benefit likely to accrue primarily to women with unreliable dates, among whom ultrasound is more accurate than the unreliable dates for predicting actual date of delivery. It is also unclear whether the likeliest potential benefits of routine second-trimester ultrasound (reduced induction of labor for postterm pregnancy and increased induced abortions for fetal anomalies) would justify widespread testing from a cost effectiveness standpoint.

No benefits of routine ultrasound examination of the fetus in the third trimester have been demonstrated despite multiple randomized controlled trials. Additional trials of third-trimester placental grading are needed to adequately evaluate the potential benefits of screening for placental appearance.

DISCUSSION

One meta-analysis of controlled trials of routine versus selective ultrasound evaluation before 24 weeks’ gestation found that routine screening provided better gestational age assessment (with subsequent lower incidence of induction for post-term pregnancy), earlier detection of multiple gestations, and greater detection of unsuspected
fetal abnormalities (with subsequent increased terminations). There were, however, no significant overall differences regarding perinatal morbidity or mortality (LeFevre et al., 1993; Nielson, 2001).

One descriptive systematic review examining women’s views about antenatal ultrasound showed that most women were satisfied with ultrasound examinations, but did not include any controlled trials comparing satisfaction in women undergoing routine screening versus no screening (Bricker et al., 2000).

The RADIUS Trial, the largest randomized-controlled trial performed in the United States (Ewigman et al., 1993), showed no benefit to routine ultrasound (a mid-trimester study and a second study in the mid-third trimester) in low-risk pregnant women; however, this trial has been extensively criticized for methodologic problems and the selection of inappropriate outcome variables (Copel et al., 1994). Additionally, there was a high rate of exclusion of eligible participants and a relatively high rate of ultrasound use for “indicated” reasons in the control and excluded patients. Most importantly, the detection rate for serious fetal anomalies in the sonographic studies performed <24 weeks’ gestation was only 17 percent, considerably lower than three other large trials which reported detection rates of 51 to 74 percent (ACOG, 1997). Further evaluation of the data (Crane et al., 1994) demonstrated a statistically significant difference in the detection rate of serious anomalies prior to 24 weeks’ gestation in women who had their early sonographic study performed in a tertiary care center, compared to those whose studies were performed in a non-tertiary care or private office setting. This suggests that the sensitivity of routine ultrasound to detect fetal anomalies may vary greatly among facilities and providers, but that all efforts should be made to have obstetric sonographic studies performed by experienced and skilled obstetric sonographers and interpreting physicians.

The only large randomized controlled trial (RCT) demonstrating an improvement in perinatal outcome with routine mid-trimester ultrasound was the Helsinki Trial (Saari-Kemppainen et al., 1990), in which the perinatal mortality was 4.2/1,000 live births in the routine ultrasound group compared to 8.4/1,000 in the selective study group (P<.05). This decline in perinatal mortality was largely attributed to the early pregnancy termination of anomalous fetuses.

A Norwegian study demonstrated that routine obstetric sonograms performed between 16 and 20 weeks’ gestation reduced the median number of sonographic exams per patient compared to a group of patients receiving only indicated studies (Eik-Nes, 1993).

A follow-up study of children at ages eight to nine delivered to women participating in the Swedish RCT (Waldenstrom et al., 1988) demonstrated no adverse neurologic developmental effects from prenatal ultrasound exposure (Kieler et al., 1998).

There have been no RCTs of routine versus selective mid-trimester ultrasound conducted in a military population. Furthermore, previous RCTs in other populations may not be applicable to current practice patterns in terms of following standardized criteria for the images obtained during routine complete ultrasounds exams, the qualifications of clinicians and physicians interpreting the images, and the use of routine mid-trimester sonography in conjunction with maternal serum analyte screening (Ecker & Frigoletto, 1999).

The American College of Radiology and the American Institute of Ultrasound in Medicine (AIUM), in collaboration with ACOG published a Practice Bulletin on Ultrasound in Pregnancy (ACOG 2009). The following advantages support the ACOG/AIUM statement:

• Evidence that carefully conducted mid-trimester sonograms may decrease the incidence of labor induction and increase the detection of serious fetal anomalies, multiple gestations, and women at risk for placenta previa. The early detection of serious fetal anomalies could potentially improve perinatal outcome in our population, either through patient-based decisions to terminate fetuses with serious or lethal anomalies, or by allowing for appropriate evaluation/counseling/education and possible transfer to appropriate tertiary care of all women choosing to continue their pregnancy who are located in remote areas and receiving care at Level I/II treatment facilities (Bricker & Neilson, 2001).

• Precise gestational dating improves the accuracy of maternal serum analyte screening resulting in fewer false positive tests. Most women who have a positive screening test undergo further counseling and ultrasound assessment. Reducing the false positive risk of maternal serum analyte screening reduces the cost of the additional counseling, associated comprehensive/genetic ultrasound evaluation, and invasive diagnostic testing precipitated by the false positive testing. These false positive tests result in maternal and family member emotional distress. Further, the testing can result in diagnostic testing that can result in the unintended loss of a normal fetus.
• Potential improvement in the emotional/psychological state of the woman and her family.
• Respect for maternal autonomy in the decision-making process for perinatal screening tests.

### EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Counsel and educate prior to scheduling sonographic study</td>
<td>Chervanak &amp; McCullough, 1992 Working Group Consensus ACOG Feb, 2009</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>2 A complete obstetric sonographic examination should be recommended and available to women considering an invasive test on the basis of age, or other risk factors, when a more accurate gestational age is required for decision-making regarding medical or antenatal routine care interventions, or for predicting actual date of delivery</td>
<td>ACOG Feb, 2009 Watson et al., 2007 ACOG, Practice Bulletin #98, 2008 Mongelli et al., 1996 Wilcox et al., 1993</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>3 Use ultrasound to evaluate / diagnose women who are at increased risk of sonographically detectable maternal or fetal complications or uncertainty regarding gestational age or fetal health</td>
<td>ACOG 2009</td>
<td>III</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>4 Complete obstetric sonographic examination for all consenting low-risk women</td>
<td>Society of Obstetricians and Gynecologists of Canada (SOGC), 1999 ACOG Feb, 2009 Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
<tr>
<td>5 Complete obstetric sonographic studies performed and interpreted by qualified healthcare providers</td>
<td>ACOG Practice Patterns, 1997 Crane et al., 1994 AIUM Guidelines, 2007</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
</tbody>
</table>

**LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)**

### I- 38. Education about Symptoms of Preterm Labor: Week-24

#### BACKGROUND

The majority of women who are admitted for the treatment of preterm labor, often in the advanced stages of labor and delivering within 12 hours of admission, recognized that there was something “different” about their pregnancy for hours or even days prior to seeking medical attention.

True preterm labor is defined as progressive cervical effacement and dilation in the presence of regular uterine contractions at a gestational age of at least 20 weeks, but no more than 37 weeks. A growing body of evidence suggests that progesterone administered to women at high risk for preterm birth significantly prolongs gestation. Additionally, many experts assert that the tocolysis of acute preterm labor allows the administration of antenatal corticosteroids and optimizes neonatal outcome. Thus, in addition to early risk factor assessment for preterm birth (see A-4), comprehensive patient education regarding the symptoms of preterm labor may maximize the opportunity for early evaluation and intervention to prevent delivery.
RECOMMENDATIONS

1. Pregnant women should be educated about the most common symptoms of preterm labor:
   a. Low, dull backache
   b. Four or more uterine contractions per hour. Uterine contractions may be perceived by the patient as:
      - Menstrual-like cramps
      - Sensation of the “baby rolling up in a ball”
      - Increased uterine activity compared to previous patterns
      - Abdominal cramping (may be associated with diarrhea)
   c. Increased pelvic pressure (may be associated with thigh cramps)
   d. Change in vaginal discharge such as change in color of mucus, leaking of clear fluid, spotting or bleeding or discharge associated with itching or fish-like odor immediately after intercourse
   e. General sensation that “something feels different” (e.g., agitation, flu-like syndrome, and sensation that baby has “dropped”).

2. A pregnant woman who experiences any of the above symptoms or is unsure about the presence of any of the above, should lie down on her side with one of her hands on her lower abdomen to palpate for uterine contractions for an additional hour. If symptoms persist and/or she palpates four or more uterine contractions in the hour, she should seek immediate medical care. The exception to this is the pregnant woman who notes the presence of vaginal bleeding, leaking of clear fluid from the vagina, or a vaginal discharge with a fish-like odor immediately after intercourse, all of which should prompt immediate medical attention. [I]

3. Re-emphasize to the pregnant woman that she is the most important link in the early diagnosis of preterm labor, and that early diagnosis and treatment of preterm labor increases the chances for a healthy infant.

4. Educate the pregnant woman that she can safely continue moderate exercise and activity during her pregnancy so long as she does not notice any of the symptoms of preterm labor. The exception to this is that she may notice some increase in uterine cramping with moderate exercise or activity. This is of no consequence so long as the cramping ceases when she stops her activity. She should limit her activity to no more than two hours per session. [B]

5. Women with uncomplicated pregnancies may continue a standard work schedule throughout their pregnancy. If their work is strenuous or they spend long periods of time on their feet they should limit their work week to 40 hours and workday to eight hours during the last trimester (beginning at 28 weeks) or sooner if they frequently experience symptoms of preterm labor while at work. Pregnant women should attempt to limit periods of time on their feet to three hours. [B]

6. There is no evidence that sexual intercourse increases the probability of preterm labor in women with uncomplicated pregnancy. They may experience some uterine contractions following orgasm; however, this is a normal response and she only needs to seek medical attention if they persist at four or more per hour for at least three hours, or if vaginal bleeding or spotting is noted.

DISCUSSION

Providers and their patients should maintain an ongoing dialogue regarding the potential early symptoms of preterm labor as well as the ability of the woman to maintain a normal lifestyle so long as her pregnancy remains uncomplicated.
EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Educate about the common symptoms of preterm labor</td>
<td>Herron et al., 1982 Katz et al., 1990 Morrison, 1990 Ross et al., 1986</td>
<td>II-2</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2. Perform intensive self-assessment if unsure about the presence of preterm labors symptoms prior to self-referral</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
<tr>
<td>3. Educate the pregnant woman that she is a vital link in the early detection and treatment of preterm labor</td>
<td>Herron et al., 1982 Katz et al., 1990</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>4. A regular, moderate exercise program does not increase the risk for preterm labor</td>
<td>See I-3 “Exercise During Pregnancy”</td>
<td>II-1</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>6. Coitus is not associated with an increased risk for preterm labor</td>
<td>Read &amp; Klebanoff, 1993</td>
<td>II-2</td>
<td>Good</td>
<td>A</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)


BACKGROUND

A trial of labor after previous cesarean delivery has been accepted as a way to reduce the overall cesarean rate. Although vaginal birth after cesarean delivery (VBAC) is appropriate for many women with a prior low-transverse cesarean delivery, several factors increase the likelihood of a failed trial of labor which ultimately leads to increased maternal and perinatal morbidity and mortality. The rate of uterine rupture for women in spontaneous labor after one prior cesarean delivery is approximately 0.5 percent.

Cesarean delivery on maternal request is defined as a cesarean delivery for a singleton pregnancy on maternal request at term in the absence of any medical or obstetric indicators. The overall U.S. cesarean rate rose to 29.1 percent in 2004, and limited evidence suggests that cesarean delivery on maternal request is also increasing for unclear reasons. Cesarean delivery on maternal request should be guided by the best possible information regarding potential health outcomes for both mother and baby.

RECOMMENDATIONS

1. Appropriate candidates for a trial of labor include women with one prior low transverse cesarean and no other contraindications to labor or vaginal delivery. Women with two prior low transverse cesareans are candidates provided they have undergone a previous vaginal delivery. [B]

2. Women who meet the criteria for a possible trial of labor should be counseled regarding the risks and benefits of VBAC versus repeat low transverse cesarean delivery. Ideally, informed consent should be documented in the antepartum period after 24 weeks, and again at the time of admission for delivery.
3. There is insufficient evidence to recommend for or against cesarean delivery on maternal request. [I]

DISCUSSION

Induction of labor may be necessary for women who desire a trial of labor after cesarean (ACOG, 2006). However, the potentially increased risk of uterine rupture associated with any induction should be discussed with the patient and documented in the medical record (ACOG, 2006). Induction of labor in VBAC candidates should not be considered unless in consultation with an obstetrician/gynecologist (MEDCOM, 40-18). Misoprostol should not be used for induction of labor in women who have had a cesarean delivery or major uterine surgery (ACOG, 2004). There is insufficient data to make recommendations regarding the use or avoidance of misoprostol for pregnancy termination in the first and second trimester (e.g. 19 week intrauterine fetal death). A physician who is independently privileged to monitor and evaluate labor and perform urgent cesarean delivery should be immediately available in the hospital throughout active spontaneous/augmented labor or at the initiation of labor induction (ACOG, 2004). Anesthesia and personnel for urgent cesarean delivery should be available in the hospital throughout active spontaneous/augmented labor or at the initiation of labor induction (MEDCOM, 40-18). Potential facility constraints and other staffing requirements should be considered before proceeding with trials of labor (MEDCOM, 40-18).

There is currently insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to vaginal delivery. Until quality evidence becomes available, any decision to perform a cesarean delivery on maternal request should be carefully individualized and consistent with ethical principles. Given that the risks of abnormal placentation and associated morbidity rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children (NIH Consensus, 2006).

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
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<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Appropriate candidates for trial of labor</td>
<td>ACOG, 2004</td>
<td>III</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>2. Counseling for trial of labor should be performed twice during pregnancy</td>
<td>ACOG, 2004 Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
<tr>
<td>3. Perform cesarean delivery on maternal request (recommend neither for or against)</td>
<td>AHRQ Evidence Report, 2006 NIH Consensus, 2006</td>
<td>I</td>
<td>II</td>
<td>Poor</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)
Visits during Weeks: 28-37

I- 40. Screening for Gestational Diabetes: Week 28

BACKGROUND
Routine screening of all pregnant women for gestational diabetes mellitus (GDM) should be performed at 24 to 28 weeks’ gestation. GDM is defined as marked impairment of glucose metabolism initially identified during pregnancy, and has also been associated with childhood obesity. Pregnant women with GDM are at increased risk for developing fetal macrosomia and requiring operative delivery. Uncontrolled or poorly controlled gestational diabetes may also lead to neonatal morbidity, such as hypoglycemia, polycythemia, and hyperbilirubinemia. Treatment aimed at normalizing glucose metabolism has been shown to reduce these risks. Therefore, any pregnant woman with GDM should have additional surveillance and management beyond the scope outlined in this guideline.

RECOMMENDATIONS
1. Recommend screening all pregnant women for GDM at 24 to 28 weeks’ gestation. [B]
2. Screening for GDM should be performed by randomly administering a 50 gram oral glucose tolerance test (GTT) followed by a blood draw one hour later. Generally accepted threshold values of the 1-hour screen are between 130 mg/dL and 140 mg/dL. Pregnant women who are positive require the diagnostic three-hour GTT. [B]
3. In the three-hour GTT a 100-gram glucose load is administered to a woman who has fasted overnight (minimum eight hours). Blood draws are performed fasting and at one, two and three hours after the oral glucose load. No special diet is required before this test. [C]
4. Two acceptable sets of threshold values for the three-hour 100-gram GTT can be used to diagnose gestational diabetes: the National Diabetes Data Group (NDDG) criteria and the Carpenter/Coustan conversion criteria. Institutions should adopt one of these two criteria sets based upon their population demographics. There should NOT be variance within the facility itself, though variance may occur between facilities. [B]
5. For patients with only one abnormal value, consider one of the following: [C]
   a. Undergo a repeat three-hour 100-gram glucose challenge test approximately one month following the initial test
   b. Have dietary management and intermittent postprandial glucose testing performed in a manner similar to women with gestational diabetes.
6. Patients with a history of gastric bypass surgery may experience a “dumping” syndrome following ingestion of large quantities of simple sugar. An alternative to the 50-gram glucose tolerance test in these patients includes a fasting and two-hour postprandial finger sticks for one week. Target ranges are 90 mg/dL or lower fasting and 120 mg/dL or lower for postprandial. [C]

DISCUSSION
GDM is defined as marked impairment of glucose metabolism first identified in pregnancy. Incidence is usually quoted as two to three percent, with a range of 0.31 to 37.4 percent noted. There is a higher prevalence in American Indian and Hispanic populations and a very low incidence among Caucasian teens (Garner et al., 1997; Stephenson, 1993). Pregnant women initially presenting for prenatal care with preexisting risk factors may benefit from early screening (at the time of the initial laboratory panel) in addition to the routine 24- to 28-week screen, although the benefit of treating women with GDM identified early in pregnancy has not been scientifically demonstrated. In view of this, there are theoretical benefits to treatment aimed at normalizing glucose metabolism in early pregnancy. Commonly used risk factors prompting screening early in pregnancy are: history of GDM in prior pregnancy, previous delivery of a macrosomic infant (≥4,000g), body mass index >28, first degree relative with diabetes, and high-risk ethnic groups (i.e., Native Americans, Hispanics, and Pacific Islanders). Women with an abnormal one-hour screen, but a normal three-hour diagnostic test early in pregnancy, should undergo repeat testing with the three-
hour GTT at 24 to 28 weeks’ gestation. Additionally, women with a normal one-hour screen early in pregnancy should also undergo repeat screening with a one-hour 50-gram GTT at 24 to 28 weeks’ gestation.

Routine screening should be done with a randomly administered 50-gram oral GTT followed by a blood draw one hour later. Generally accepted threshold values of the one-hour screen used to select the subpopulation of women for the diagnostic three-hour GTT vary between 130 and 140 mg/dL. Using a 130 mg/dL threshold will result in an overall increase in sensitivity for the detection of gestational diabetes, but will result in approximately 25 percent of all screened women requiring a three-hour GTT, while a 140 mg/dL threshold will detect approximately 80 percent of women with GDM with 15 percent of screened women requiring a three-hour GTT. The threshold values for identifying women to undergo the three-hour diagnostic test should be decided after careful review of internal pregnancy outcome information, population demographics and clinic resources. Pregnant women who have a one-hour GTT result > 200mg/dL have sufficient glucose impairment to be considered indicative of gestational diabetes without further diagnostic testing by a three-hour GTT and should immediately begin appropriate treatment and monitoring, in lieu of undergoing diagnostic testing with the three-hour GTT.

The growing body of evidence shows that a high-carbohydrate diet before oral GTT is not necessary in normally nourished pregnant women. The preparatory diet has negligible effect on the performance of the GTT, and can potentially delay both the diagnosis and the management of gestational diabetes.

There are two acceptable sets of threshold values for the three-hour 100-gram glucose challenge that can be used to diagnose gestational diabetes. The older criteria defined by the NDDG (1979) defines gestational diabetes if at least two of the four values equal or exceed 105mg/dL for the initial fasting specimen, 190 mg/dL for the specimen obtained at one hour, 165 mg/dL at two hours and 145 mg/dL at three hours for specimens collected after the 100-gram glucose load, respectively. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus has proposed altered values, which are believed to more closely approximate the original Carpenter and Coustan criteria of 95 mg/dL, 180 mg/dL, 155 mg/dL and 140 mg/dL for the fasting, one-, two- and three-hour specimens, respectively (Carpenter & Couston, 1982; NDDG, 1979). There is currently insufficient evidence-based comparison data to recommend one specific criteria set over the other. The lower threshold set is estimated to increase the proportion of a pregnant population diagnosed with gestational diabetes by one to three percent.

Pregnant women with only one abnormal value have been demonstrated to manifest increased risk for macrosomic infants and other morbidities. However, because the relationship between carbohydrate metabolism and fetal macrosomia is a continuum, there is current controversy regarding the optimal management of these women. Reasonable management options include: repeating the three-hour GTT approximately one month later, or initiating dietary modification and glucose monitoring similar to women with established GDM.
EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Perform a routine screening for GDM at 24 to 28 weeks with a random one-hour 50-gram glucose challenge test</td>
<td>Danilenko-Dixon et al., 1999 Griffin et al., 2000 Williams et al., 1999</td>
<td>II-2</td>
<td>Fair</td>
</tr>
<tr>
<td>2</td>
<td>Early screening of selected pregnant women with risk factors for GDM</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
</tr>
<tr>
<td>3</td>
<td>Method of screening is a random one-hour 50-gram glucose challenge</td>
<td>ACOG, 2001 Naylor et al., 1997</td>
<td>II-1 II-3</td>
<td>Good</td>
</tr>
<tr>
<td>4</td>
<td>All pregnant women with a one-hour positive test require a three-hour GTT</td>
<td>ACOG, 2001</td>
<td>III</td>
<td>Fair</td>
</tr>
<tr>
<td>5</td>
<td>Acceptable sets of threshold values for the three-hour 100 gram glucose challenge</td>
<td>ACOG, 2001 ADA, 2002</td>
<td>II-3</td>
<td>Fair</td>
</tr>
<tr>
<td>6</td>
<td>One abnormal value for a three-hour GTT warrants consideration of dietary management and glucose monitoring, or a repeat three-hour GTT approximately one month after the initial test</td>
<td>ACOG, 2001 Langer et al., 1987 Lindsay et al., 1989</td>
<td>III II-2 II-2</td>
<td>Fair</td>
</tr>
<tr>
<td>7</td>
<td>A high-carbohydrate diet before oral GTT is not necessary in normally nourished pregnant women</td>
<td>Buhling et al., 2004 Crowe et al., 2000 Entrekin et al., 1998</td>
<td>II-1</td>
<td>Poor</td>
</tr>
<tr>
<td>8</td>
<td>Patients with history of gastric bypass may not tolerate the 50-gram GTT; alternative is a fasting and two-hour postprandial finger sticks</td>
<td>Burt, 2005</td>
<td>III</td>
<td>Poor</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 41. Iron Supplement: Update

BACKGROUND
Iron supplementation in pregnancy is commonly practiced and generally expected by women in the United States. This tradition is based on the assumption that women have increased nutritional requirements during pregnancy that cannot be met by diet alone.

RECOMMENDATIONS
1. There is insufficient evidence to recommend for or against routinely supplementing iron for all pregnant women. [I]
2. Women exhibiting signs or symptoms of anemia at any time during their pregnancy should be evaluated upon presentation. [I]
3. Obtain a serum ferritin if iron deficiency anemia is suspected. Recommend supplementing with at least 50 mg elemental iron (325 mg ferrous sulfate) twice a day (bid) in all pregnant women diagnosed with iron deficiency anemia (abnormal ferritin). [B]
DISCUSSION

Published trials confirmed the improvements in hematological status but did not evaluate other clinical outcomes (Milman et al., 1999; O’Brien et al., 1999; Pena-Rosas & Viteri, 2006).

A Cochrane systematic review (Mahomed, 2001) found no evidence to recommend for or against routine iron supplementation. There was a paucity of information related to clinically relevant maternal and infant outcomes (Pena-Rosas & Viteri, 2006).

Another Cochrane systematic review found insufficient data assessing clinical maternal and neonatal effects of iron administration in women with iron deficiency anemia (Reveiz et al., 2007). Again, of concern was a lack of trials with clinically relevant outcomes and paucity of data on adverse effects.

EVIDENCE TABLE

<table>
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<tr>
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<th>QE</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1 Routine iron supplementation</td>
<td>Pena-Rosas &amp; Viteri, 2006</td>
<td>II-3</td>
<td>Poor</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Ziaei et al., 2007</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Selective iron supplementation</td>
<td>Hemminki &amp; Rimpela, 1991</td>
<td>I</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Reveiz et al., 2007</td>
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</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 42. Anti-D Prophylaxis for Rh-Negative Pregnant Women: Update Week 28

BACKGROUND

The incidence of Rh incompatibility varies by race and ethnicity. Approximately 15 percent of whites are Rh negative, compared with five to eight percent of African Americans, and one to two percent of Asians and Native Americans. Among whites, an Rh negative woman has an approximate 85 percent chance of mating with an Rh positive man, 60 percent of whom are heterozygous and 40 percent of whom are homozygous at the D locus. Pregnant women who have had D antigen isoimmunization in a previous pregnancy have an increased risk for development of fetal anemia and hydrops in future pregnancies. Since the introduction of anti-D (Rhogam) immune globulin injections during and after pregnancy in women who are D-antigen negative, the incidence of isoimmunization has fallen from 10 cases to 1.3 cases/1,000 live births.

RECOMMENDATIONS

1. Recommend determination of paternal erythrocyte antigen status for screen-positive women. [I]
2. Recommend administering anti-D prophylaxis to all unsensitized D-negative pregnant women. [B]
3. Recommend using either 300 mcg of anti-D immunoglobulin at 28 weeks or 100 mcg of anti-D-immunoglobulin at 28 and 34 weeks’ gestation. [I]
4. Pregnant women who have had isoimmunization in a previous pregnancy or who are screened positive for antibody screen should be referred to a Maternal Fetal Medicine specialist for care. [A]

DISCUSSION

The term “isoimmunization” refers to the detection of maternal antibodies to red blood cell antigens.

All trials of antenatal anti-D prophylaxis included routine postpartum anti-D prophylaxis for women with Rh-positive infants when clinically indicated.

A Cochrane review of two fair-quality RCTs shows a decrease in isoimmunization rates of Rh-negative women after antenatal anti-D prophylaxis, though only at a dose of 100 mcg at 28 and 34 weeks’ gestational age (Crowther, 2001).
A qualitative systematic review of randomized and non-randomized studies supports antenatal anti-D prophylaxis with either single dose (300 mcg at 28 weeks) or two-dose (100 mcg at 28 and 34 weeks) regimens of antenatal anti-D prophylaxis to reduce isoimmunization rates (Urbaniak, 1998).

Only two dose regimens have been evaluated by RCTs, and the evidence supporting the two 100-mcg dose regimen is of similar magnitude to the non-randomized evidence supporting the single dose regimens (250 mcg to 300 mcg) (Crowther, 2001).

Administration of anti-D immunoglobulin is recommended for all Rh-negative mothers regardless of paternal blood type, due to the inaccuracy of genotyping individuals.

Recent advances in Doppler technology have led to the development of noninvasive methods to assess the degree of fetal anemia. Studies have reported a good correlation between the peak systolic velocity in the fetal middle cerebral artery and hemoglobin in fetuses that have undergone two previous transfusions, expanding the clinical use of this Doppler test. The recommendation for middle cerebral artery Doppler ultrasonography does have some limitations. There is a higher false-positive rate after 34-35 weeks’ gestation. In addition, the measurements must be done by a practitioner specifically trained to perform Doppler for measurement of peak systolic velocity in the fetal middle cerebral artery.

**EVIDENCE TABLE**

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</tr>
</thead>
<tbody>
<tr>
<td>1 Anti-D prophylaxis for unsensitized D-negative pregnant women</td>
<td>Crowther, 2001 Urbaniak, 1998</td>
<td>I</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 Middle cerebral artery Doppler ultrasonograph for women who demonstrate evidence of isoimmunization or with a history of a prior hydropic infant</td>
<td>ACOG Practice Bulletin #75, 2006</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

I-43. Assess for Preterm Labor: Update  [Updated]  

**Weeks 28, 32**

**BACKGROUND**

The assessment of risk for various adverse perinatal outcomes has become a routine component of prenatal care. One of the principal adverse outcomes that has been subjected to such risk assessment and profiling is preterm labor and subsequent preterm delivery. Preterm delivery, defined as delivery prior to 37 weeks’ gestation, occurs in approximately 11 percent of all pregnancies in the United States. Efforts to identify and prevent preterm delivery have been hampered by the lack of an effective preventive method and treatment modalities that are only effective in delaying preterm births for a few days. Early efforts at lowering the preterm delivery rate focused on the use of risk factor profiling. Unfortunately, subsequent analysis of such risk profiles demonstrated that only approximately 50 percent of women who delivered prematurely were identified by the risk profile system. Thus, all pregnant women must be considered at risk for preterm labor until they reach 37 weeks’ gestation. This risk spans a wide spectrum and the approach of the practice guideline will be as follows:

- Screen each pregnant woman for clinically substantive risk factors (see A-4)
- Provide patient education regarding early clinical signs and symptoms of preterm labor and appropriate responses (see I-38)
- Inquire about the presence of clinical signs or symptoms of preterm labor at each visit between 24 and 36 weeks’ gestation.
RECOMMENDATIONS

1. Pregnant women should be educated about the most common symptoms of preterm labor:
   a. Low, dull backache
   b. Four or more uterine contractions per hour. Uterine contractions may be perceived by the patient as:
      - Menstrual-like cramps
      - Sensation of the “baby rolling up in a ball”
      - Increased uterine activity compared to previous patterns
      - Abdominal cramping (may be associated with diarrhea)
   c. Increased pelvic pressure (may be associated with thigh cramps)
   d. Change in vaginal discharge such as change in color of mucus, leaking of clear fluid, spotting or bleeding or discharge associated with itching or fish-like odor immediately after intercourse.
   e. Sensation that “something feels different” (e.g., agitation, flu-like syndrome, and sensation that baby has “dropped”).

2. A pregnant woman who experiences any of the above symptoms or is unsure about the presence of any of the above, should lie down on her side with one of her hands on her lower abdomen to palpate for uterine contractions for an additional hour. If symptoms persist or she palpates four or more uterine contractions in the hour, she should seek immediate medical care. The exception to this is the pregnant woman who notes the presence of vaginal bleeding, leaking of clear fluid from the vagina or a vaginal discharge with a fish-like odor immediately after intercourse, all of which should prompt immediate medical attention.

3. If no diagnosis of preterm labor is established, continuation in the guideline is appropriate.

DISCUSSION

While multicomponent efforts aimed at reducing prematurity have had heterogeneous results in prospective trials, there are no obvious harmful effects and such efforts are anticipated to foster a provider-patient relationship and empower the pregnant woman with a positive sense of active promotion of her baby’s health.

EVIDENCE TABLE

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Educate the pregnant woman that she is a vital link in the early detection and treatment of preterm labor</td>
<td>Herron et al., 1982, Katz et al., 1990</td>
<td>II-2</td>
<td>Good</td>
</tr>
<tr>
<td>2</td>
<td>Perform intensive self-assessment if unsure about the presence of preterm labor symptoms prior to self-referral</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 44. Daily Fetal Movements Counts: Weeks 28; All following visits

BACKGROUND

Nearly one-half of all fetal deaths occur in pregnancies of low-risk women. Since fetal movement is a sign of fetal well-being, it may be beneficial for all women to learn to assess fetal movement during the third trimester. One hundred percent of fetuses between 30 to 39 weeks’ gestation and 98 percent of fetuses 24 to 27 weeks’ gestation, move by the 75th minute of observation, so maternal perception of movement should occur within 1½ hours (Patrick
et al., 1982). A decrease in fetal movement may indicate fetal jeopardy and should immediately prompt the pregnant woman to seek further evaluation of fetal well-being.

RECOMMENDATIONS

1. Recommend instructing all pregnant women about the importance of assessing fetal movement on a daily basis beginning in the third trimester. [B]

2. Recommend instructing all pregnant women as to the course of action they should take if they do not perceive the minimum fetal movement counts within the time frame specific to their healthcare facility. [B]

DISCUSSION

Fetal movement counting is by far the oldest and simplest of all fetal assessment techniques. In Moore and Piacquadio’s (1989) study of 2,519 pregnant women, the fetal mortality rate was 8.7/1,000 among women who had no instruction in formal daily fetal movement assessment, and fell to 2.1/1,000 when women: 1) kept a record of how long it took to feel 10 fetal movements, and 2) took prompt action to seek further evaluation of fetal well-being when they did not perceive 10 movements within a two-hour time frame. In contrast, Grant and Hepburn (1984) did not observe significant differences in unexplained fetal death between counting and non-counting groups of women, but did note that there seemed to be a time period of decreased fetal movement prior to actual fetal death. Most data suggest an improvement in perinatal outcomes with the early identification of decreased fetal activity (Moore & Piacquadio, 1989; Neldam, 1980; Pearson & Weaver, 1976; Sadofsky & Yaffe, 1973).

Many methods of counting fetal movements have been proposed. Most research supports the idea that compliance among low-risk pregnant women is highest when the monitoring method is minimally time-consuming and relatively simple (Davis, 1987). The number of fetal movements perceived is arbitrary, though some studies suggest that the perceived lack of fetal movement for two hours or more requires further evaluation (Connors et al., 1988; Moore & Piacquadio, 1989; Wilailak et al., 1992).

Most authorities agree that once a decrease in fetal movement is reported, further and prompt investigation is warranted, usually via external fetal monitoring. It is imperative then, that women are given relevant information to assist them in recognizing warning signs of potential fetal compromise.

EVIDENCE TABLE

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<tr>
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<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Instruct all pregnant women to assess fetal movement on a daily basis beginning in the third trimester</td>
<td>Moore &amp; Piacquadio, 1989 Neldam, 1980</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>2. Instruct all pregnant women as to the course of action they should take if they do not perceive the minimum fetal movement counts within the time frame specific to their healthcare facility</td>
<td>Moore &amp; Piacquadio, 1989 Neldam, 1980 Pearson &amp; Weaver, 1976 Sadofsky &amp; Yaffe, 1973</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 45. Counseling for Family Planning: Week 32

BACKGROUND

Antepartum counseling for family planning allows the pregnant woman and provider ample time for discussion and informed decision-making. The different options for birth control discussed during pregnancy, including permanent sterilization, may enable the woman to consider the pros and cons of each method and choose the one that best fits her lifestyle.
RECOMMENDATIONS

1. Recommend antepartum counseling and educating all pregnant women regarding family planning, to include various temporary contraceptive means and/or permanent sterilization. [C]

DISCUSSION

Family planning counseling and education provided early in pregnancy may allow the couple to discuss the various methods of birth control and make an informed decision. This is opposed to waiting until later in pregnancy when the discomforts of pregnancy may cloud judgment. Involving husbands in antenatal family planning counseling sessions has been shown to lead to joint decision-making and encourage women’s use of contraception during the postpartum period (Soliman, 2000). Counseling that accesses a woman’s expectations regarding birth control, followed by a careful explanation of the side effects of a contraception choice, may reduce the rate of unplanned pregnancy (Rosenfeld & Everett, 1996). There are many factors that influence the choice of contraception, some of which include maternal age, parity, and medical history.

Women desiring sterilization as their preferred form of birth control should be thoroughly counseled as to the intended permanent nature of this procedure. While sterilization reversal is possible in some cases, it is both a difficult and costly procedure that most insurance companies will not cover (Pati et al., 2000).

EVIDENCE TABLE

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<tr>
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<th>LE</th>
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<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Antepartum counseling for family planning</td>
<td>Pati &amp; Cullins, 2000</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 46. Screening for Group B Streptococcus (GBS): Update Week 36

BACKGROUND

Group B streptococcus (GBS) infections are the leading cause of serious neonatal infections (i.e., sepsis, meningitis, and pneumonia) within the first seven days of life (early-onset infection). A preventive strategy using intrapartum antibiotics for prophylaxis (IAP) in women who have been identified as GBS carriers has been proven to decrease the incidence of early-onset GBS infections of the newborn.

RECOMMENDATIONS

1. Recommend screening all pregnant women for Group B streptococcus (GBS) at 35 to 37 weeks’ gestation, using a rectovaginal culture and selective broth media to identify colonized women. [B]

2. Screening should be repeated every four weeks until delivery. [C]

3. Pregnant women with positive rectovaginal cultures should be treated with intrapartum IV chemoprophylaxis with either Penicillin or Ampicillin (if no contraindications) (a). [A]

4. Pregnant women who have had a previous child with early-onset GBS infection or have GBS bacteruria in the current pregnancy should receive intrapartum antibiotics, without screening cultures. [A]

(a) Management of the GBS-colonized parturient with a history of an allergic reaction to penicillin agents: due to emerging resistance to previous second-line antimicrobial agents, clindamycin and erythromycin (10 to 15 percent resistant strains in most centers), alternative second-line agents for women with a history of allergic reactions to penicillin or ampicillin are listed below:

   a. Administer cefazolin 2gm IV load, followed by 1 gm IV every eight hours, for allergic reaction other than immediate hypersensitivity
b. Administer vancomycin 1 gm IV load, followed by 1 gm IV every 12 hours, for immediate hypersensitivity reaction (anaphylaxis, dyspnea, rapid onset of urticarial rash).

**DISCUSSION**

Based on evidence from a large retrospective cohort study, the CDC released national prevention guidelines in 2002. The guidelines, developed in collaboration with ACOG and AAP, resulted from data showing that routine screening and prophylaxis for GBS carriers prevented more cases of early-onset disease than the obstetrical risk factor-based method.

The guidelines for treatment are listed below, but there is a significant degree of confusion among providers of obstetric care as to how to treat GBS bacteruria and clarification of the literature in this area may prove helpful. Any amount of GBS that shows up in a urine culture during pregnancy should alert the provider to the likelihood of heavy GBS colonization in the woman and warrant IAP without the need for an additional screening culture during the 35-37 week time frame. However, GBS in the urine should be evaluated for treatment at the time of discovery based on the same criteria used to evaluate and treat other cases of ASB or UTI in pregnancy (i.e., antibiotic therapy generally initiated only in the presence of > 100K colonies of a single offending organism or with fewer than 100k colonies in women symptomatic of UTI).

Additionally, there has been intense interest in tests for rapid identification of GBS. These include real-time polymerase chain reaction (PCR), optical immunoassay (OIA), DNA hybridization, colorimetric assay using starch serum media, latex agglutination and enzyme immunoassay. In a large, systematic review published in April 2006, “many of the GBS tests, with the exception of real-time PCR and OIA, took either too long or were not of sufficient accuracy to be feasible for maternal intrapartum testing to aid decision-making concerning antibiotic prophylaxis to prevent neonatal GBS disease” (Honest et al., 2006). They further concluded that “in light of the poor methodologic quality of the existing studies and the imprecision of the evidence for PCR, a robust technology assessment comparing the most promising tests (PCR and OIA) is needed before reaching recommendations for practice.” In the event that rapid test technology is eventually implemented, systems will need to be in place for women at high risk of penicillin anaphylaxis to continue to receive late antenatal testing, to allow for sufficient time for GBS susceptibility testing.
## EVIDENCE TABLE

<table>
<thead>
<tr>
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<th>Sources of Evidence</th>
<th>LE</th>
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<th>SR</th>
</tr>
</thead>
</table>
| 1  Pregnant women should be screened for GBS at 35 to 37 weeks’ gestation using a rectovaginal culture and selective broth media to identify colonized women | ACOG, 2002  
CDC, 2002  
Main, 2000  
Main & Slagle, 2000 | II-1 | Good | B   |
| 2  Treat positive rectovaginal cultures with intrapartum IV chemoprophylaxis with either Penicillin or Ampicillin | ACOG, 2002  
CDC, 2002  
Main, 2000  
Main & Slagle, 2000  
Smail, 2001 | I   | Good | A   |
| 3  Women who have had a previous child with early-onset GBS infection or GBS bacteruria in the current pregnancy should receive intrapartum antibiotics, without screening cultures | ACOG, 2002  
CDC, 2002 | II-1 | Good | A   |
| 4  Pregnant women presenting in labor <37 weeks’ gestation should receive intrapartum IV chemoprophylaxis | ACOG, 2002  
Boyer, 1986  
CDC, 2002 | II-1 | Good | A   |
| 5  For women in labor at term with unknown culture status, administer IAP if the duration of membrane rupture ≥18 hours or maternal temperature ≥100.4°F (38°C) | ACOG, 2002  
CDC, 2002 | II-1 | Fair | B   |
| 6  Prophylactic antibiotics should be administered at least two hours prior to delivery, when possible(a) | De Cueto et al., 1998  
Lin et al., 2001 | II-2 | Good | B   |
| 7  Women undergoing scheduled cesarean delivery prior to the onset of labor with intact membranes do not require prophylactic antibiotics, unless they have had a previous child with early-onset GBS infection | Hagar et al., 2000 | III  | Fair | C   |

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

(a) Management of the parturient anticipated to deliver imminently following admission: as it is difficult to anticipate accurately when a woman will deliver, women identified as candidates for IAP should receive prophylactic antibiotics regardless of the interval between admission and delivery as vertical transmission rates have been shown to have a clinically and statistically significant decrease within two hours of maternal administration. Thus, withholding of IAP from women solely on the basis of anticipated admission-delivery interval should be discouraged.
I- 47. Assessment of Fetal Presentation: Weeks 36, 38-41

BACKGROUND
Fetal non-cephalic presentation at term can result in cesarean section delivery. Examination at 36 weeks can identify non-cephalic presentation. External version of the fetus to the vertex position can allow a trial of labor for vaginal delivery. Vaginal delivery is associated with less morbidity and mortality than cesarean section delivery.

RECOMMENDATIONS
1. Recommend screening for non-cephalic presentation for all patients at 36 weeks’ gestation. [B]
2. There is insufficient evidence to recommend for or against Leopolds versus cervical exam as the best screening method to determine fetal presentation. [I]
3. Recommend ultrasound for confirmation, if non-cephalic presentation is suspected. [B]
4. If non-cephalic presentation is confirmed and there are no contraindications, recommend external cephalic version at 37 weeks or beyond and referral to an advanced prenatal care provider. [B]

DISCUSSION
No systematic reviews or RCTs comparing Leopold's maneuvers to other manipulations were found. Two nonrandomized trials were found that evaluated Leopold's maneuvers as a screening test for fetal malpresentation, but did not assess the effect on maternal morbidity/mortality or infant mortality. The studies were of fair quality and suggest that the specificity for Leopold's to predict fetal malposition is high, but its sensitivity is only modest (Lydon-Rochelle et al., 1993; Thorp et al., 1991).

External cephalic version for breech presentation at term is associated with a significant reduction in non-cephalic births and cesarean sections, without significant effects on perinatal mortality (Hofmeyr & Kulier, 2001b). External cephalic version for breech presentation prior to term does not reduce the number of non-cephalic births nor does it improve pregnancy outcomes (Hofmeyr, 2001). There is no evidence to support the use of postural management for breech presentation (Hofmeyr & Kulier, 2001c). If external cephalic version for breech presentation cannot be accomplished, planned cesarean delivery for term breech decreases perinatal and neonatal death and neonatal morbidity. There is a modest increase in maternal morbidity but no effect on maternal mortality (Hannah et al., 2000; Hofmeyer & Hannah, 2001).

EVIDENCE

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<tr>
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<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Screening for non-cephalic presentation at 36 weeks’ gestation</td>
<td>Hofmeyr, 2001a</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2. Leopolds versus cervical exam for determining fetal presentation</td>
<td>Lydon-Rochelle et al., 1993 Thorp et al., 1991</td>
<td>II-2</td>
<td>Fair</td>
<td>I</td>
</tr>
<tr>
<td>3. Ultrasound for presentation confirmation</td>
<td>Thorp et al., 1991</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
</tr>
<tr>
<td>4. External cephalic version at 37 weeks or beyond, if there are no contraindications</td>
<td>Hofmeyr &amp; Kulier, 2001a &amp; 2001b</td>
<td>I</td>
<td>Good</td>
<td>B</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)
Visits During Weeks: 38-41


BACKGROUND

Post-dates pregnancies (over 42 weeks) occur in 10 percent of uncomplicated pregnant women. Post-dates pregnancies have a higher incidence of induction of labor, operative delivery, post-partum hemorrhage and shoulder dystocia. Routine membrane stripping, in low-risk pregnant women with accurate dating criteria, has been proposed as a method of encouraging earlier delivery to prevent post-dates pregnancy.

RECOMMENDATIONS

1. Consider offering routine membrane sweeping to all pregnant women every visit beginning at 38 weeks. [C]

DISCUSSION

Membrane sweeping lessens the incidence of post-dates pregnancies and the need for medical inductions (NNT = 8) (Boulvain et al., 2005). A well-done meta-analysis of randomized trials found no harm regarding neonatal morbidity/mortality if women undergo routine weekly “membrane stripping” beginning at 38 weeks’ gestation (Boulvain et al., 1999 & 2001, 2005). No “serious maternal morbidity/mortality,” increased cesarean-sections, instrumental delivery rates, or maternal infection was found. ACOG (2002) states that the risks of membrane stripping in women colonized with GBS “have not been investigated in well-designed prospective studies. Therefore data are insufficient to encourage or discourage this practice in women known to be GBS-colonized.” Membrane sweeping in women who are positive GBS carriers may increase susceptibility to litigation in the event of a GBS-related adverse fetal/neonatal outcome despite the fact that randomized trials found no harm regarding increased neonatal or maternal morbidity/mortality (Cohen & Goldberg, 2006).

EVIDENCE TABLE

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<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
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</thead>
<tbody>
<tr>
<td>1 Membrane stripping at each visit beginning at 38 weeks</td>
<td>Boulvain et al., 2005</td>
<td>I</td>
<td>Fair</td>
<td>C</td>
</tr>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 49. Term Management: New Weeks 38-41

BACKGROUND

Intrapartum fetal distress, meconium staining, postmaturity syndrome and primary cesarean section rates all increase after the 40th week of gestation (Devoe, 1983). Pregnancies continuing past the 41st week carry additional risk of oligohydramnios, perinatal morbidity and mortality (Sims & Walther, 1989). The goal of antepartum fetal testing is to prevent adverse fetal and maternal outcomes, to include fetal death. The success of antenatal fetal testing at predicting these outcomes, as well as the appropriate time to initiate antenatal fetal testing, have both been topics of debate in the medical community.

RECOMMENDATIONS

1. In the absence of contraindications, labor induction should be offered to women who reach 41 and 0/7 weeks undelivered. [A]
2. In those patients with a favorable cervix (Bishop score > 6), induction after 39 weeks may be considered. [B]

3. When labor induction is offered or planned, women should be educated on the risks of induction, including length of induction, discomfort involved, and the process in determining appropriate timing of induction. [B]

4. Antepartum fetal testing should begin as soon as possible after 41 and 0/7 weeks if not scheduled for induction at this time. [C]

5. Testing should consist of weekly amniotic fluid assessment and twice weekly non-stress testing (NST). [C]

6. Inadequate amniotic fluid index should prompt further evaluation to determine the need for delivery. [B]

DISCUSSION

Much debate has arisen concerning the appropriate timing and appropriate use of induction at term. Induction at 41 weeks completed compared with expectant management showed no difference in neonatal outcome. The major studies showed an equal or lower rate of cesarean in those randomized to induction (Heimstad et al., 2008; Sanchez-Ramos et al., 2003).

Induction after 39 weeks in patients with documented favorable cervices has been shown to have increased length of time in Labor and Delivery, but neonatal outcome and mode of delivery showed no difference (Nielsen et al., 2005). In institutions where facilities are limited, the increased length of labor may make that prohibitive. Generally, women are less satisfied with induction over spontaneous labor, more so when inductions take longer than expected or are more uncomfortable than expected (Shetty et al., 2005). Given that inductions of women with favorable cervices take longer to deliver on average than spontaneous labor (Nielsen et al., 2005), involvement of the patient’s expectations and education on the process and risks is very important for patient satisfaction.

Additionally, the appropriate timing and usefulness of antenatal testing has been debated. No significant differences in perinatal outcomes or C-section rates were observed between a group who had testing initiated at 40 weeks and a control group with testing initiated at 41 weeks (Rosen et al., 1995). On the other hand, adverse perinatal outcomes have been observed among patients between 41 and 42 weeks’ gestation, similar to those seen in patients that are post-term (>42 weeks’ gestation) (Guidetti et al., 1989). Based on these data, initiation of antenatal testing is recommended at the beginning of the 41st week.

The majority of studies reviewed used a twice-weekly NST and once weekly amniotic fluid index (AFI) for antenatal surveillance, the regimen recommended by ACOG (1999). There is general agreement that an AFI >5 cm (Rutherford et al., 1987) or a single pocket measuring >2 cm (Chamberlain, 1984) represents adequate amniotic fluid volume. Placental dysfunction with resultant decreased renal perfusion may lead to oligohydramnios (Seeds, 1980), or low amniotic fluid volume. A correlation between fetal acidosis and a non-reactive NST has been observed (Manning et al., 1993), leading to the NSTs use in screening for fetal well-being.
## EVIDENCE TABLE

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<th>Recommendations</th>
<th>Sources of Evidence</th>
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<tbody>
<tr>
<td>1 Inducing at 41 weeks reduced C-section</td>
<td>Heimstad et al., 2007 Sanchez-Ramos et al., 2003</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>2 Induction after 39 weeks with favorable cervix</td>
<td>Nielsen et al., 2005</td>
<td>I</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>3 Unrealistic expectations regarding induction length and pain leads to decreased patient satisfaction</td>
<td>Shetty et al., 2005</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>4 Antepartum fetal testing beginning at 41 weeks</td>
<td>Guidetti et al., 1989 Rosen et al., 1995</td>
<td>I</td>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>5 Antepartum testing should consist of weekly AFI and biweekly NST</td>
<td>ACOG, 1999</td>
<td>III</td>
<td>Fair</td>
<td>C</td>
</tr>
<tr>
<td>6 Abnormal testing may indicate fetal compromise and should prompt further surveillance or delivery</td>
<td>Chamberlain, 1984 Manning et al., 1993 Rutherford et al., 1987</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
</tr>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

## I- 50. Immunization HPV Vaccine: Prior to discharge; Postpartum visit

### BACKGROUND

Cervical cancer is currently the 13th most frequently diagnosed cancer among American women (Saslow et al, 2002). Over 70 percent of cervical cancers result from infection with high-risk human papilloma virus (HPV) types 16 and 18 (Wright et al., 2007). The U.S. Food and Drug Administration has approved a quadrivalent HPV vaccine for use in women between nine and 26 years of age. This vaccine is given in a series of three injections: an initial injection followed by subsequent injections at two and six months from date of initial injection. Pregnant women are members of the population at risk for cervical cancer due to exposure to oncogenic human papilloma virus. Pregnancy presents an opportunity to initiate preventative measures in those who fit criteria for HPV immunization. For women who do not receive cervical cancer screening antenatally, screening should be considered at the eight-week postpartum visit to ensure compliance with routine cervical cancer screening guidelines.

### RECOMMENDATIONS

1. Offer vaccination before postpartum discharge to all women < 26 years of age who have not previously completed HPV vaccination series. [B]

2. Women who begin their HPV vaccination series in the immediate postpartum period should complete the series with subsequent vaccinations at two months and six months following the first injection in the series. The eight-week postpartum visit provides an opportunity for the second injection. [C]

3. Vaccination to protect against HPV in individuals with a history of dysplasia is controversial and the decision to proceed in this situation should be made between a patient and her provider. [I]

4. Women who have initiated the HPV vaccine series before becoming pregnant should halt the series during pregnancy, and resume after delivery. [I]

5. HPV vaccination may be given to lactating women. [I]
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<tr>
<td>1. HPV vaccine reduces the incidence of cervical intraepithelial neoplasia and cervical cancer</td>
<td>Brison et al., 2007</td>
<td>II-2</td>
<td>Good</td>
<td>B</td>
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</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

I- 51. Education - Shaken Baby Syndrome (SBS): New At discharge; Postpartum visit

BACKGROUND

Shaken Baby Syndrome (SBS) is a preventable cause of injury and death. Thousands of cases occur each year in the United States. Unfortunately, evidenced-based documentation does not exist regarding prevention strategies.

The SBS toolkits are derived from educational components of the National Center on SBS but are customized to military families. The kits were developed in consultation with a steering committee and were tested with several focus groups.

RECOMMENDATIONS

1. All pregnant women and fathers should receive education about Shaken Baby Syndrome prior to discharge from the hospital. [I]

DISCUSSION

Each year in the United States, an estimated 1,200 to 1,400 children are injured or killed by shaking. Approximately 25 percent of victims of shaking die from their injuries while 80 percent of those who survive are left with life-long brain injury. Medical costs for the care of these infants can surpass $1 million.

The Military Services’ reports of child abuse fatalities have demonstrated that of the small number of total fatalities, a majority were under the age of two and a substantial number involved SBS or inflicted traumatic brain injury. In most of the fatalities, the child’s father, stepfather, or father surrogate committed the abuse.

Caregivers may resort to shaking a baby out of frustration with the infant’s behavior (i.e., inconsolable crying); lack of parenting knowledge or skills and unrealistic expectations about infants’ behavior. A comprehensive regional program of parent education was instituted in an eight-county region of western New York and monitored for 5.5 years. The program was administered to parents prior to discharge from the hospital and included information on the dangers of violent shaking and alternative responses. Patients were also asked to sign a commitment statement. The incidence of abusive head injury decreased by 47 percent (Dias et al., 2005).

In April 2007, the DoD in conjunction with the National Center on Shaken Baby Syndrome, launched a Department-wide initiative to prevent SBS. This campaign consisted of three key components: (1) A service provider toolkit containing parenting education curriculum for military fathers, and brochures and other educational resources listing the toll-free Military OneSource phone number for 24-hour support; (2) DVDs with educational messages designed for use with new parents in a variety of settings; and (3) A public service announcements that aired DoD-wide.

A Child Development Educational Approach, “The Period of PURPLE Crying®” program, approaches SBS prevention by helping parents and caregivers understand the frustrating features of crying in normal infants that can lead to shaking or abuse. The program was developed by the National Center on Shaken Baby Syndrome, the Harborview Injury Prevention and Research Center of the University of Washington, and the University of British Columbia. With a grant received from the Doris Duke Charitable Foundation and the George S. and Delores Dore...
Eccles Foundation, empirical tests have been completed on a new SBS prevention program. The program was tested through four different types of delivery systems: maternity services, pediatric offices, prenatal classes and nurse home visitor programs. More than 4,800 parents participated in the research and 75 parents participated in focus groups to develop the 10-minute DVD and 11-page booklet. Testing spanned three years of randomized controlled trials and results are expected to be submitted for publication in the coming year.

Available Resources

- Education may be guided using the Shaken Baby Syndrome toolkits from the DoD Family Advocacy Program accessible at: [www.militaryhomefront.dod.mil/service/fap/sbs](http://www.militaryhomefront.dod.mil/service/fap/sbs).
- The SBS toolkit materials from the DoD Family Advocacy Program website may be printed and given to new parents ([www.militaryhomefront.dod.mil/service/fap/sbs](http://www.militaryhomefront.dod.mil/service/fap/sbs)), or the SBS Toolkits can be purchased from the National Center on Shaken Baby Syndrome ([www.dontshake.com](http://www.dontshake.com)).
- Consider showing one of the educational DVDs to new parents prior to discharge from the hospital, e.g. “Portrait of Promise,” available from Children’s Hospital of Minnesota ([http://xpedio02.childrensmn.org/stellent/groups/public/@xcp/@web/@forparents/documents/policyreferenceprocedure/web008431.asp](http://xpedio02.childrensmn.org/stellent/groups/public/@xcp/@web/@forparents/documents/policyreferenceprocedure/web008431.asp)) or “The Period of Purple Crying” from the National Center on Shaken Baby Syndrome ([www.dontshake.com](http://www.dontshake.com)).

**EVIDENCE TABLE**

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<th>Sources of Evidence</th>
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<tbody>
<tr>
<td>1 Use of comprehensive parent education program decreases incidence of abusive head injury</td>
<td>Dias et al., 2005</td>
<td>II</td>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>2 SBS prevention kits are customized and validated as tools for military families</td>
<td>DoD SBS Prevention Program National Center on Shaken Baby Syndrome</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
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*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*
Interventions Not Recommended in Prenatal Care (All Weeks)

I- 52. Routine Screening with Fetal Fibronectin: Not Recommended

BACKGROUND
Fetal fibronectin levels can identify pregnant women at risk for preterm delivery. Routine fetal fibronectin screening of cervical vaginal fluid has been suggested by some experts as a means of reducing preterm delivery among low-risk/asymptomatic pregnancies. However, there is insufficient data to support fetal fibronectin screening in all pregnant women.

RECOMMENDATIONS
1. Recommend against routine screening for preterm birth with fetal fibronectin (fFN) test. [D]
2. Utilization of fFN testing in symptomatic women between 24 and 34 6/7 weeks’ gestation may be useful in guiding management of women with signs and symptoms of preterm labor. [B]

DISCUSSION
In a large meta-analysis, the accuracy for predicting spontaneous preterm birth using the fFN test varied considerably with no significant differences in estimates of accuracy in studies with high/low quality (Honest et al, 2002). Several prospective cohort studies have shown no improvement in outcomes for either mother or baby (Leitech et al., 1999; Ramsey & Andrews, 2003). The routine use of this expensive technology is not justified in light of the low predictive value of either a positive or negative test, along with absence of an effective intervention.

The potential value of fFN testing in the setting of questionable preterm labor is to more precisely discriminate between the subset of women who have true preterm labor versus false labor. A negative test in women with preterm contractions may provide information sufficient to avoid the use of tocolytics and corticosteroids in an individual at low risk for preterm birth (Ramsey & Andrews, 2003).

The following was noted in a memorandum reporting the findings and recommendations of a multidisciplinary and multi-service national Department of Defense (DoD) committee regarding the use of fFN testing as an adjunct to the assessment of suspected preterm labor: the primary benefit [of using the fFN test] is in patients presenting with preterm contractions where [one is] clinically uncertain if the patient will be delivering within one to two weeks. The fFN specimen should only be sent if the result would potentially change the patient’s management. It should not be used if it will not alter care (DoD Committee Consensus on Fetal Fibronectin Testing in Pregnancy (2007).

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<tbody>
<tr>
<td>1. Routine fetal fibronectin screening at 24 weeks’ estimated gestational age (EGA) for prevention of preterm labor (not recommended)</td>
<td>Ramsey &amp; Andrews, 2003</td>
<td>I</td>
<td>Good</td>
<td>D</td>
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<td></td>
<td>Goldberg et al., 1996</td>
<td>USMedCare Evidence-Based Practice Center, 2005</td>
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<td></td>
<td>Honest, 2002</td>
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<td>Leitech et al., 1999</td>
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<td>Revah et al., 1998</td>
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<td></td>
<td>Tekeskin, 2005</td>
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<td>2. Utilization of the fFN test in symptomatic women between 24 and 34 weeks’ gestation may be useful in guiding management of women with preterm contractions</td>
<td>ACOG, 2003</td>
<td>II-2</td>
<td>Fair</td>
<td>B</td>
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<td></td>
<td>Honest, 2002</td>
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<td>Tekeskin, 2005</td>
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*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*
I- 53. Routine Cervical Examination:  Not Recommended

BACKGROUND
Digital cervical examination can identify pregnant women at risk for preterm delivery. Universal screening of cervical dilation and effacement has been suggested as a means of reducing preterm delivery among low-risk/asymptomatic pregnancies. However, there is insufficient data to justify routine digital cervical examination in all pregnant women.

RECOMMENDATIONS
1. Recommend against performing cervical examination to screen for preterm birth prevention in low-risk asymptomatic pregnant women. [D]

DISCUSSION
A large RCT of routine cervical examinations during pregnancy failed to show a statistically or clinically significant difference in rates of low birth weight, delivery at less than 37 weeks’ EGA, and preterm premature rupture of membranes between pregnant women randomized to routine cervical examinations versus avoidance of cervical examination (unless clinically indicated) (Buekens et al., 1994). The median number of cervical examinations in the control group was one versus six in the experimental arm of the study.

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<tbody>
<tr>
<td>Routine cervical examination at 28 weeks’ gestation for prevention of preterm labor (not recommended)</td>
<td>Buekens et al., 1994</td>
<td>I</td>
<td>Good</td>
<td>D</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 54. Routine Antenatal Pelvimetry:  Not Recommended

BACKGROUND
Traditionally, all pregnant women underwent clinical pelvimetry during the course of their pregnancy to detect pelvic diameters that would preclude a trial of labor or place a woman at increased risk of dystocia.

RECOMMENDATIONS
1. Recommend against the use of antenatal pelvimetry (clinical or radiographic) in routine prenatal care. [D]
2. There is fair evidence that clinical pelvimetry is not effective in predicting the actual occurrence of cephalopelvic disproportion (CPD), and its performance is associated with significant increase in cesarean section rates. [D]

DISCUSSION
Only two randomized trials have evaluated pelvimetry for pregnant women experiencing normal pregnancy. Two additional trials have involved pregnant women with a previous cesarean section. These four trials are summarized in a Cochrane review (Pattinson, 2001). The performance of X-ray pelvimetry may be harmful and is associated with a significant increase in cesarean section rate (odds ratio=2.17) and radiographic exposure to the fetus (Parsons & Spellacy, 1985).
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<tbody>
<tr>
<td>1. Routine clinical pelvimetry for estimation of adequacy for trial of labor</td>
<td>Pattinson, 2001</td>
<td>I</td>
<td>Fair</td>
<td>D</td>
</tr>
<tr>
<td>2. X-ray pelvimetry may be harmful</td>
<td>Pattinson, 2001</td>
<td>I</td>
<td>Fair</td>
<td>D</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I-55. Routine Urine Dipstick Test:  
Not Recommended

BACKGROUND
Random urine dipstick testing for protein and glucose has been traditionally done at each prenatal visit. Concerns have been raised about the efficacy of the urine dipstick in detecting protein elevation that may indicate preeclampsia.

RECOMMENDATIONS
1. Recommend against the use of urine dipstick testing for protein and glucose during prenatal visits (the appropriate screening test for gestational diabetes is the one-hour glucola). [D]
2. Recommend the use of selective laboratory urinalysis for pregnant women with signs or symptoms of preeclampsia. [B]

DISCUSSION
Glycosuria screening by urine dipstick has poor sensitivity for the detection of gestational diabetes mellitus. In the presence of a routine program of third-trimester one-hour post 50 gm glucose plasma screening for gestational diabetes, urine screening for glycosuria offers no additional benefit. Urine screening could be useful in a setting of no routine plasma screening, but this has not been evaluated (Gribble et al., 1995; Watson, 1990; Hooper, 1996).

Dipstick proteinuria screening is not useful for detecting preeclampsia. The accuracy of dipstick proteinuria assessment compared to 24-hour protein determination is generally poor (Bell et al., 1999; Hooper, 1996). Urine dipstick testing is unreliable in detecting protein elevations that may occur early in the course of preeclampsia (Kuo et al., 1992).

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<tbody>
<tr>
<td>1. Routine urine dipstick testing</td>
<td>Kuo et al., 1992</td>
<td>II-2</td>
<td>Fair</td>
<td>D</td>
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</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I-56. Routine Edema Evaluation:  
Not Recommended

BACKGROUND
Routine clinical evaluation of edema has been performed to screen for preeclampsia. Dependent edema (DE) is a common occurrence in normal pregnancies, thus limiting its usefulness as a screening tool for preeclampsia.
According to the NIH consensus, “Edema occurs in too many normal pregnant women to be discriminant and has been abandoned as a marker in this and other classification schemes (for preeclampsia)” (NIH, 2000).

RECOMMENDATIONS

1. Recommend against routine evaluation for edema in pregnancy. [D]

DISCUSSION

No articles were found detailing an RCT of evaluation for edema in pregnancy. Data from the collaborative perinatal project found no significant association between edema and preeclampsia (Friedman & Neff, 1977). No data were found on the effect of screening or treating edema on maternal or neonatal morbidity or mortality or patient satisfaction. There is no evidence that edema is linked to identification of preeclampsia. Edema is not mentioned as a diagnostic criterion for preeclampsia in ACOG Technical Bulletin 219 (1996).

A systematic review (Young & Jewell, 2000) of several interventions for edema showed that rutoside (a flavonoid) improves symptoms associated with edema, but the lack of safety data for this therapy prohibits its recommendation. In addition, intermittent compression and immersion in water both improve some surrogate markers for edema control, but there is no data on their effect in controlling symptoms. One additional RCT (Kent et al., 1999) showed that both static immersion and water aerobics led to a similar diuresis and did not result in as much leg swelling as standing on land. There were two low-quality studies of diuretic therapy for edema, both of which had sufficient methodological flaws as to render their conclusions unusable (Prema et al., 1982; Walker, 1966).

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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 57. Routine Screening for Cytomegalovirus (CMV): Not Recommended

BACKGROUND

Cytomegalovirus (CMV) is the most common congenitally acquired infection (0.2 to two percent of all infants) and may result in significant poor perinatal outcome. Some have suggested routine screening for CMV antibody status to identify women at risk for primary CMV infection during pregnancy.

RECOMMENDATIONS

1. The evidence is insufficient to recommend for or against routine screening for cytomegalovirus (CMV). [I]
2. Recommend counseling pregnant women about methods to prevent acquisition of CMV during pregnancy. [C]

DISCUSSION

Primary CMV infections during pregnancy comprise significant risks for developing fetuses. The principle means of contracting primary CMV is from exposure to young children with CMV infection. Routine serologic screening of pregnant women for CMV has not proven effective in reducing the acquisition of CMV or adverse outcomes. Primary preventive measures should include counseling of pregnant women regarding risk reduction and avoidance of exposure to individuals with active CMV infection. Preconceptual serologic screening for CMV is recommended for day care workers, healthcare providers, and women with multiple sexual partners. Good hand washing and wearing gloves when handling soiled diapers or undergarments would significantly reduce risk for this virus. The appropriate time for counseling and screening for CMV is in the pre-conception period. For background
information refer to the reviews by Henderson and Weiner (1995), Schoub and colleagues (1993), and Trincado and Rawlinson (2001).

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<tbody>
<tr>
<td>1 Routine testing of pregnant women for CMV (not recommended)</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
<tr>
<td>2 Counseling of day care workers on good hand washing</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
</tr>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

**I- 58. Routine Screening for Parvovirus:** Not Recommended

**BACKGROUND**

Acute parvovirus B19 infection in pregnancy has been rarely associated with the development of fetal anemia and hydrops. It has been suggested that early detection of this infection may improve fetal outcomes. There is no immunization or treatment for parvovirus B19.

**RECOMMENDATIONS**

1. Recommend against routine testing for parvovirus in pregnancy. [D]

**DISCUSSION**

The detection of acute parvovirus infection is based on history, examination, and serologic or DNA-based testing. Women who are identified as having acute parvovirus infection in pregnancy should be referred to a Maternal Fetal Medicine specialist for counseling and follow-up. Routine serologic screening has no role in the prevention of parvovirus and the associated adverse outcomes (Guidozzi et al., 1994).

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<tbody>
<tr>
<td>1 Routine testing for parvovirus (not recommended)</td>
<td>Guidozzi et al., 1994</td>
<td>II-3</td>
<td>Fair</td>
<td>D</td>
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LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

**I- 59. Routine Screening for Toxoplasmosis:** Not Recommended

**BACKGROUND**

Toxoplasmosis infection has been rarely associated with fetal morbidity and mortality. Common sources for infection include the handling of contaminated meats and cat feces. It has been suggested that early detection and subsequent treatment of this infection may improve fetal outcomes.

**RECOMMENDATIONS**

1. Recommend against routine testing for toxoplasmosis in pregnancy. [D]
2. Recommend counseling pregnant women about methods to prevent acquisition of toxoplasmosis during pregnancy. [C]

**DISCUSSION**

Based on the low prevalence of the disease during pregnancy, the uncertain and costly screening, and the possible teratogenicity of treatment, routine serologic screening for toxoplasmosis is not recommended (Frenkel, 1995; Wallon et al., 1999; Wong & Remington, 1994).

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine screening for toxoplasmosis</td>
<td>Frenkel, 1995</td>
<td>II-3</td>
<td>Fair</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Wallon et al., 1999</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wong &amp; Remington, 1994</td>
<td>I-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Educate about prevention</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

I- 60. Routine Screening for Bacterial Vaginosis: Not Recommended

**BACKGROUND**

Bacterial vaginosis is found in approximately 10 to 20 percent of normal pregnancies and is a common condition in pregnancy that has been associated with an increased risk for preterm delivery. It has been suggested that screening for bacterial vaginosis may improve fetal outcomes through reduction of preterm labor.

**RECOMMENDATIONS**

1. Recommend against routine screening for bacterial vaginosis in asymptomatic pregnant women. [D]

**DISCUSSION**

Three meta-analyses were among the articles reviewed. The meta-analysis by Varma and Gupta tried to obviate the effects of the statistical heterogeneity of prior meta-analyses by separating out low- and high-risk women (Varma & Gupta, 2006). Interestingly, they found that screening and treating bacterial vaginosis in low-risk pregnancies produced a statistically significant reduction in preterm deliveries. However, evidence from numerous other studies showed no improved pregnancy outcomes in asymptomatic, low-risk women screened for bacterial vaginosis. There is a growing amount of data to suggest that pregnant women who are symptomatic or who have a history of prior preterm birth should undergo testing for bacterial vaginosis, and those who test positive for bacterial vaginosis, regardless of gestational age, should be treated. The CDC continues to recommend against treating with clindamycin cream during pregnancy and instead recommends a seven-day course of oral metronidazole or oral clindamycin (CDC 2002). The treatment of asymptomatic bacterial vaginosis in pregnant women does not reduce the occurrence of preterm delivery or other adverse perinatal outcomes (McDonald et al., 2007).
I- 61. Immunization – MMR: (measles/mumps/rubella) Not Recommended

BACKGROUND
Rubella in the first 16 weeks of pregnancy causes miscarriage, abortion, stillbirth, and Congenital Rubella Syndrome (CRS). The most common manifestations of CRS are hearing loss, developmental delay, growth retardation, and cardiac and ocular defects. Since 1969, when the vaccine was made available in the United States and childhood immunization was initiated, no major periodic rubella epidemics have occurred. Adults accounted for 25 percent of the measles cases reported in 1994 (Baughman et al., 1994). Complications of measles, including pneumonia and encephalitis, are more common among adults than among school-aged children. In 1994, measles was reported in 232 American adults, age 20 or older (Centers for Disease Control, 1994).

RECOMMENDATIONS
1. Recommend against routine measles/mumps/rubella (MMR) immunization during pregnancy. [D]

DISCUSSION
Due to theoretical concerns about possible teratogenicity from administration of an attenuated, live virus vaccine, MMR or measles vaccination is not recommended during pregnancy. Inadvertent administration during pregnancy has never been shown to cause CRS (Krogh et al., 1989). There are no known adverse consequences to vaccination postpartum while breastfeeding.

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine screening for bacterial vaginosis (not recommended)</td>
<td>Leitich et al., 2003 McDonald et al., 2007 Riggs et al., 2004 Varma &amp; Gupta, 2006 USPSTF, 2008</td>
<td>I</td>
<td>Good</td>
<td>D</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 62. Routine Immunization – Varicella: Not Recommended

BACKGROUND
The CDC recommends that all adults be immunized for varicella, if seronegative. Immunization prevents over 90 percent of varicella infections. Congenital varicella syndrome, while rare, can cause significant neonatal morbidity and mortality. There are theoretical concerns regarding administration of an attenuated virus during pregnancy. These include potential alterations in fetal immunity and inducement of a congenital varicella-like syndrome in the fetus.
RECOMMENDATIONS

1. Recommend against routine varicella vaccination in pregnancy. [D]
2. Recommend serological testing early in pregnancy for all pregnant women with a negative or uncertain history. [B]
3. Recommend offering vaccination postpartum to pregnant women who are non-immune. [B]

DISCUSSION

Four cohort studies were identified. Among U.S. women of childbearing age, the mean incidence of varicella is 2.16/1,000/year. After household exposure, approximately 90 percent of susceptible contacts will develop varicella. Varicella is an uncommon infection during pregnancy; its incidence is estimated at 1/7,500 based on eight cases occurring in 60,000 pregnancies prospectively studied. Maternal infection in the first half of the pregnancy has been associated with congenital varicella syndrome. Varicella infections at any time during pregnancy may result in maternal pneumonia and, rarely, death (Enders et al., 1994; Jones et al., 1994; Pastuszak et al., 1994; Smith et al., 1998).

Among adults with a negative or uncertain history of varicella, approximately 85 to 90 percent will be immune. Generally it is felt that if a woman has a positive history of varicella infection, she should be considered immune. Women with a negative or uncertain history of varicella infection should have their titers checked before receiving the immunization because of the high rate of seropositivity in those individuals. One study demonstrates that this approach is cost-effective (Smith et al., 1998).

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine varicella vaccination in pregnancy (not recommended)</td>
<td>Smith et al., 1998</td>
<td>II-2</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>2 Serological testing early in pregnancy for pregnant women with a negative or uncertain history</td>
<td>Smith et al., 1998</td>
<td>II-2</td>
<td>Poor</td>
<td>B</td>
</tr>
<tr>
<td>3 Postpartum varicella immunization</td>
<td>ACOG Guideline for Perinatal Care, 1998</td>
<td>III</td>
<td>Fair</td>
<td>B</td>
</tr>
</tbody>
</table>

*LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)*

I- 63. Routine Ultrasound Evaluation of Cervical Length: Not Recommended

BACKGROUND

Preterm delivery remains one of the principal causes of adverse perinatal outcomes. Multiple interventions to identify pregnant women at risk for preterm delivery have been studied in the recent past. It has been determined that cervical length, as measured by transvaginal sonography, correlates with the incidence of preterm delivery. Observational studies have found a linear relationship between cervical length and the rate of preterm delivery as well as the gestational age of delivery. This finding has prompted questions regarding the usefulness of routine screening of cervical length in pregnant women.

RECOMMENDATIONS

1. Recommend against *routine* cervical length screening at 24 weeks’ gestation. [D]
DISCUSSION

Several studies have shown that pregnant women with short cervices detected via routine second-trimester transvaginal ultrasound screening have a greater risk of preterm delivery than do pregnant women without short cervices. The predictive value varies depending on the study population and cervical length cut-off, but in general, short cervical lengths are quite specific, but not sensitive, at predicting preterm delivery. Therefore, a negative finding does not substantially decrease a pregnant woman’s risk of preterm delivery, whereas a positive finding does increase the risk. In a routine, low-risk population, one-half of pregnant women with the shortest cervical lengths (<15mm) may deliver preterm. Less than two percent of pregnant women in a low-risk population will have cervical lengths of this size (Heath et al., 2000; Heath et al., 1998; Hibbard et al., 2000; Iams et al., 1996). At the time these studies were conducted, there was no established therapy to prevent preterm delivery in low- or high-risk women. (See prescription of progesterone A-4.)

EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine cervical length screening at 24 weeks’ gestation</td>
<td>Doyle &amp; Monga, 2004 Grimes-Dennis &amp; Berghella, 2007</td>
<td>II-2</td>
<td>Fair</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Heath et al., 2000 Hibbard et al., 1998 &amp; 2000</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Honest et al., 2003 Iams, 2001</td>
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<tr>
<td></td>
<td>Iams et al., 1996 Taipale &amp; Hiilesmaa, 1998</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Williams &amp; Iams, 2004</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)

I- 64. Repeat Screening for Anemia, Syphilis, and Isoimmunization: Not Recommended

BACKGROUND

Traditional maternal care often requires repeat testing of all women for anemia, syphilis, and anti-D and non-anti-D antigen antibody development in the mother at 24 to 28 weeks’ gestation. This testing was done to identify correctable causes of potential morbidity and mortality in the mother and fetus. Pregnant women with anemia may respond to vitamin and iron supplementation and those with syphilis can be treated with antibiotics. The unborn fetus with D isoimmunization may be helped by in utero transfusion or early delivery.

RECOMMENDATIONS

1. Recommend against routine repeat screening for blood group antibodies. [D]
2. Recommend against routine repeat screening for anemia and syphilis. [D]
3. Recommend providers consider repeat testing for anemia or syphilis at 24 to 28 weeks for women who are at higher risk for these conditions. [C]

DISCUSSION

Repeat screening for anemia, syphilis, and antibody development has been commonly practiced. Little evidence was found to support the routine use of these tests in low-risk pregnant women. One cohort study determined repeat testing of Rh-positive women for anti-D antibody was not necessary (Davis & Abbott, 1986).

Pregnant women who may be at risk for development of anemia secondary to restrictive diets (e.g., vegan diet) or those who had anemia (hematocrit less than 30) at their initial visit warrant retesting during their pregnancy. The
optimal timing or interval of this testing is not known, though this has traditionally been performed at 24 to 28 weeks.

Pregnant women at risk for sexually transmitted disease through high-risk sexual behavior may benefit from repeat testing. However, no data exists to support improved outcomes for mothers or infants in those who are screened.

**EVIDENCE TABLE**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat antibody screening (not recommended)</td>
<td>Davis &amp; Abbott, 1986</td>
<td>II-2</td>
<td>Fair</td>
<td>D</td>
</tr>
<tr>
<td>Repeat anemia and syphilis screening (not recommended)</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td>Repeat anemia and syphilis screening for high-risk pregnant women</td>
<td>Working Group Consensus</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
</tr>
</tbody>
</table>

**I- 65. Routine Screening for Hypothyroidism:** Not Recommended

**BACKGROUND**

Recent publications have drawn attention to the role of thyroid hormone status of the mother on the future neuropsychological development of the child. Screening all pregnant women for thyroid hormone status has been suggested. To date, however, there are no evidence-based studies to provide meaningful and clinically relevant data to guide the practitioner.

**RECOMMENDATIONS**

1. Recommend against routine screening for thyroid hormone status of the mother. [D]
2. Recommend ensuring adequate iodine intake during pregnancy for pregnant women in areas of the country with questionable levels of dietary iodine. [C]

**DISCUSSION**

First-trimester hypothyroxinemia (a low for gestational age circulating maternal free T4, whether or not thyroid stimulating hormone [TSH] is increased) may pose an increased risk for poor neuropsychological development of the fetus. This would be a consequence of decreased availability of maternal T4 to the developing brain, its only source of thyroid hormone during the first trimester. The mother is the sole source of thyroid hormones until about 12 weeks’ gestation, when the fetal gland becomes active. Also, in pregnancy normal TSH may occur when free T4 levels are low (normal maternal T3 concentrations may prevent an increase in TSH). Hypothyroidism or subclinical hypothyroidism during pregnancy often stems from autoimmune disease (Hashimoto’s) but may result from mild iodine deficiency. The presence of thyroid antibodies with a normal TSH may predict those pregnant women who are likely to progress to frank hypothyroidism, which may necessitate closer monitoring of the mother.

The question of relevance is whether low maternal free T4 levels, which are still within the range generally accepted as having no adverse effects for the mother, might interfere with normal neurodevelopment of the offspring. Additionally, when subclinical hypothyroidism or evidence of possible autoimmune thyroid disease (i.e., high anti–thyroid peroxidase antibodies) is present, the clinical relevance of this on maternal pregnancy and outcome is currently unclear.

There is insufficient evidence that screening and early treatment of pregnant women with subclinical hypothyroidism or maternal hypothyroxinemia improves subsequent neonatal outcome. Routine screening, therefore, cannot be recommended at this time.
EVIDENCE TABLE

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Sources of Evidence</th>
<th>LE</th>
<th>QE</th>
<th>SR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Routine Screening for thyroid deficiency (not recommended)</td>
<td>Escobar et al., 2000</td>
<td>III</td>
<td>Poor</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Haddow et al., 1999</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pop et al., 1995</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Adequacy of nutritional iodine</td>
<td>Utiger, 1999</td>
<td>III</td>
<td>Poor</td>
<td>C</td>
</tr>
</tbody>
</table>

LE = Level of Evidence; QE = Quality of Evidence; SR = Strength of Recommendation (See Appendix A)
APPENDICES

Appendix A: Guideline Development Process
Appendix B: Screening Items for Self-Administered Questionnaire – First Visit
Appendix C: Hemoglobinopathies
Appendix D: Risk Factors – Preterm Birth
Appendix E: Prenatal Screening for Fetal Chromosomal Abnormalities
Appendix F: Questions for Literature Search
Appendix G: Acronym List
Appendix H: Participant List
Appendix I: Bibliography
APPENDIX A
Guideline Development Process

The development update of the VA/DoD Clinical Practice Guideline for Pregnancy Management followed the steps described in “Guideline for Guidelines,” an internal working document of the VA/DoD Evidence-Based Practice Working Group that requires an ongoing review of the work in progress. The Working Group of the VA/DoD was charged with updating the evidence-based action recommendations whenever possible.

The Offices of Quality and Performance and Patient Care Services, in collaboration with the network Clinical Managers, the Deputy Assistant Under Secretary for Health, and the Medical Command of the DoD identified clinical leaders to champion the guideline development process. During a preplanning conference call, the clinical leaders defined the scope of the guideline and identified a group of clinical experts from the VA and DoD that formed the Pregnancy Management Working Group. Working Group members included representatives of the following specialties: family practice, OB/GYN (Prenatal Care), nursing, midwifery, genetic counseling, psychology/psychiatry (mental health), maternal fetal medicine specialist, and pharmacy.

The Working Group defined a set of clinical questions within the area of the guideline. This ensured that the guideline development work outside the meeting focused on issues that practitioners considered important and produced criteria for the search and the protocol for systematic review and, where appropriate, meta-analysis.

The Working Group participated in an initial face-to-face meeting to reach consensus about the guideline algorithm and recommendations, and to prepare a draft update document. The draft continued to be revised by the Working Group at-large through numerous conference calls and individual contributions to the document. Following the initial effort, an editorial panel of the Working Group convened to further edit the draft document. Recommendations for the performance or inclusion of specific procedures or services were derived through a rigorous methodological approach that included the following:

- Determining appropriate criteria, such as effectiveness, efficacy, population benefit, or patient satisfaction
- Reviewing literature to determine the strength of the evidence in relation to these criteria
- Formulating the recommendations and grading the level of evidence supporting the recommendation
- Integrating the feedback of the experts from the VA and DoD following their review of the final draft document.

This update of the UCP Guideline is the product of many months of diligent effort and consensus building among knowledgeable individuals from the VA, DoD, academia, as well as guideline facilitators from the private sector. An experienced moderator facilitated the multidisciplinary Working Group. The list of participants is included in Appendix H.

Formulation of Questions

The Working Group developed researchable questions and associated key terms after orientation to the scope of the guideline and to goals that had been identified by the Working Group. The questions specified (adapted from the Evidence-Based Medicine toolbox, Center for Evidence-Based Medicine, [http://www.cebm.net]):

- Population – Characteristics of the target patient population
- Intervention – Exposure, diagnostic, or prognosis
- Comparison – Intervention, exposure, or control used for comparison
- Outcome – Outcomes of interest.

These specifications served as the preliminary criteria for selecting studies. Literature searches were conducted on all topics identified in the algorithm or recommendations of the original guidelines. After reviewing the initial search for systematic reviews and meta-analyses, the Working Group decided to focus the search for individual randomized controlled trials (RCTs) on specific interventions specified in a list of questions. (for list of the questions see Appendix F).
Selection of Evidence

The evidence selection was designed to identify the best available evidence to address each key question and ensure maximum coverage of studies at the top of the hierarchy of study types. Published, peer-reviewed RCTs, as well as meta-analyses and systematic reviews that included randomized controlled studies were considered to constitute the strongest level of evidence in support of guideline recommendations. This decision was based on the judgment that RCTs provide the clearest, scientifically sound basis for judging comparative efficacy. The Working Group made this decision recognizing the limitations of RCTs, particularly considerations of generalizability with respect to patient selection and treatment quality. When available, the search sought out critical appraisals already performed by others that described explicit criteria for deciding what evidence was selected and how it was determined to be valid. The sources that have already undergone rigorous critical appraisal include Cochrane Reviews, Best Evidence, Technology Assessment, and AHRQ systematic evidence reports.

In addition to Medline/PubMed, the following databases were searched: Database of Abstracts of Reviews of Effectiveness (DARE) and Cochrane Central Register of Controlled Trials. For Medline/PubMed searches, limits were set for language (English), and type of research (RCT, systematic reviews and meta-analysis).

As a result of the literature reviews, articles were identified for possible inclusion. These articles formed the basis for formulating the guideline recommendations. The following inclusion criteria were used for studies:

• English language only of studies performed in United States, United Kingdom, Europe, Australia, Japan, New Zealand
• Full articles only
• Study populations limited to adults age 17 years or above; all races, ethnicities, cultural groups
• Randomized controlled trials or prospective studies
• Published from 2002 to December 2007.

Seed Guidelines

• Institute for Clinical Systems Improvement (ICSI) – Health Care Guideline: Routine Prenatal Care, July 2000.

Admissible evidence (study design and other criteria):

• Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results.
• Randomized controlled trials (RCTs); systematic reviews (including EPC and HTA reviews); and meta-analyses.
• Relevant outcomes must be able to be abstracted from data presented in the articles.
• Sample sizes must be appropriate for the study question addressed in the paper. RCTs were included if they were initiated with 30 or more participants.
Preparation of Evidence Tables (Reports) and Evidence Rating

The results of the search were organized and evidence reports as well as copies of the original studies were provided to the Working Group for further analysis. Each study was appraised by a group of research analysts for scientific merit, clinical relevance, and applicability to the populations served by the Federal healthcare system. The body of evidence was rated for quality and level of evidence.

Recommendation and Overall Quality Rating

Evidence-based practice involves integrating clinical expertise with the best available clinical evidence derived from systematic research. The Working Group received an orientation and tutorial on the evidence United States Preventative Services Task Force (USPSTF) 2001 rating process, reviewed the evidence and independently formulated Quality of Evidence ratings (see Table A-1), a rating of Overall Quality (see Table A-2), and a Strength of Recommendation (see Table A-3).

<table>
<thead>
<tr>
<th>Table A-1: Quality of Evidence (QE)</th>
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<tbody>
<tr>
<td>I</td>
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<tr>
<td>II-1</td>
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<td>II-2</td>
</tr>
<tr>
<td>II-3</td>
</tr>
<tr>
<td>III</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Table A-2: Overall Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
</tr>
<tr>
<td>Fair</td>
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<tr>
<td>Poor</td>
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</tbody>
</table>
Table A-3: Net Effect of the Intervention

<table>
<thead>
<tr>
<th>Substantial</th>
<th>More than a small relative impact on a frequent condition with a substantial burden of suffering; or A large impact on an infrequent condition with a significant impact on the individual patient level.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>A small relative impact on a frequent condition with a substantial burden of suffering; or A moderate impact on an infrequent condition with a significant impact on the individual patient level.</td>
</tr>
<tr>
<td>Small</td>
<td>A negligible relative impact on a frequent condition with a substantial burden of suffering; or A small impact on an infrequent condition with a significant impact on the individual patient level.</td>
</tr>
<tr>
<td>Zero or Negative</td>
<td>Negative impact on patients; or No relative impact on either a frequent condition with a substantial burden of suffering; or an infrequent condition with a significant impact on the individual patient level.</td>
</tr>
</tbody>
</table>

Table A-4: Final Grade of Recommendation

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>The net benefit of the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Substantial</td>
</tr>
<tr>
<td>Good</td>
<td>A</td>
</tr>
<tr>
<td>Fair</td>
<td>B</td>
</tr>
<tr>
<td>Poor</td>
<td>I</td>
</tr>
</tbody>
</table>

Strength of Recommendations Rating System

A A strong recommendation that the clinicians provide the intervention to eligible patients. Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.

B A recommendation that clinicians provide (the service) to eligible patients. At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.

C No recommendation for or against the routine provision of the intervention is made. At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D Recommendation is made against routinely providing the intervention to asymptomatic patients. At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.

I The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined.
Lack of Evidence – Consensus of Experts

Where existing literature was ambiguous or conflicting, or where scientific data were lacking on an issue, recommendations were based on the clinical experience of the Working Group.

Algorithm Format

The goal in developing the guideline for management of UCP was to incorporate the information into a format which would maximally facilitate clinical decision-making. The use of the algorithm format was chosen in light of the evidence that such a format improves data collection, diagnostic and therapeutic decision-making and changes patterns of resource use. However, few guidelines are published in such a format.

The algorithmic format allows the provider to follow a linear approach to critical information needed at the major decision points in the clinical process, and includes:

- An ordered sequence of steps of care
- Recommended observations
- Decisions to be considered
- Actions to be taken

A clinical algorithm diagrams a guideline into a step-by-step decision tree. Standardized symbols are used to display each step in the algorithm (Society for Medical Decision-Making Committee, 1992). Arrows connect the numbered boxes indicating the order in which the steps should be followed.

A letter within a box of an algorithm refers the reader to the corresponding annotation. The annotations elaborate on the recommendations and statements that are found within each box of the algorithm. Included in the annotations are brief discussions that provide the underlying rationale and specific evidence tables. Annotations indicate whether each recommendation is based on scientific data or expert opinion. A complete bibliography is included in the guideline.

REFERENCES


### APPENDIX B

**Screening Items for Self-Administered Questionnaire – First Visit**

The following questions may help in constructing the self-administered questionnaire for the first visit risk-assessment. Facilities may modify these questions. Please refer to the risk indicators listed in the [Prenatal Risk Assessment Checklist](#) – (See A-2, Table 1)

<table>
<thead>
<tr>
<th>Immediate Concerns</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you currently having any <strong>vaginal bleeding</strong>?</td>
<td></td>
</tr>
<tr>
<td>2. Are you currently experiencing any significant <strong>abdominal pain/cramping</strong>?</td>
<td></td>
</tr>
<tr>
<td>3. Do you have a history of <strong>ectopic pregnancy</strong>?</td>
<td></td>
</tr>
<tr>
<td>4. Do you have a history of any <strong>severe pelvic infections</strong> requiring hospitalization?</td>
<td></td>
</tr>
<tr>
<td>5. Do you have a history of <strong>pelvic surgery for either infertility or infection</strong>?</td>
<td></td>
</tr>
<tr>
<td>6. Do you have <strong>diabetes that requires medication</strong>?</td>
<td></td>
</tr>
<tr>
<td>7. Do you have any <strong>other chronic medical condition</strong> that requires medication?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infections</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Do you currently have, have you ever had or been exposed to <strong>tuberculosis</strong>, or have you lived with anyone who had tuberculosis?</td>
<td></td>
</tr>
<tr>
<td>9. Were you ever <strong>stationed overseas</strong>?</td>
<td></td>
</tr>
<tr>
<td>10. Were you <strong>born outside of the United States</strong>?</td>
<td></td>
</tr>
<tr>
<td>11. Do you currently have, have you ever had or been exposed to <strong>hepatitis</strong>?</td>
<td></td>
</tr>
<tr>
<td>12. Do you currently have, have you ever had or been exposed to any <strong>sexually transmitted diseases</strong> including Chlamydia, herpes, gonorrhea, syphilis, venereal warts, HPV or HIV?</td>
<td></td>
</tr>
<tr>
<td>13. Have you had a <strong>rash or viral illness</strong> since your last menstrual period?</td>
<td></td>
</tr>
<tr>
<td>14. Do you live in a house with <strong>cats</strong>?</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Medical History</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>15. Do you currently have or have you ever had <strong>kidney or bladder problems</strong>, <strong>urinary tract infection</strong>, or <strong>cystitis</strong>?</td>
<td></td>
</tr>
<tr>
<td>16. Do you currently have or have you ever had <strong>ulcers, stomach problems</strong>, or <strong>colitis</strong>?</td>
<td></td>
</tr>
<tr>
<td>17. Do you currently have or have you ever had an <strong>abnormal Pap smear or female or gynecological problems</strong>?</td>
<td></td>
</tr>
<tr>
<td>18. Have you ever had <strong>infertility problems</strong>?</td>
<td></td>
</tr>
<tr>
<td>19. Do you currently have or have you ever had <strong>heart disease</strong>?</td>
<td></td>
</tr>
<tr>
<td>20. Do you currently have or have you ever had <strong>rheumatic fever</strong>?</td>
<td></td>
</tr>
<tr>
<td>21. Do you currently have or have you ever had <strong>high blood pressure</strong>?</td>
<td></td>
</tr>
<tr>
<td>22. Do you currently have or have you ever had <strong>pneumonia or asthma</strong>?</td>
<td></td>
</tr>
<tr>
<td>23. Do you currently have or have you ever had <strong>epilepsy or seizures</strong>?</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>24</strong> Do you currently have or have you ever had <strong>emotional problems</strong>?</td>
<td><strong>24</strong> Do you currently have or have you ever had <strong>emotional problems</strong>?</td>
</tr>
<tr>
<td><strong>25</strong> Do you currently have or have you ever had <strong>thyroid problems</strong>?</td>
<td><strong>25</strong> Do you currently have or have you ever had <strong>thyroid problems</strong>?</td>
</tr>
<tr>
<td><strong>26</strong> Do you currently have or have you ever had <strong>diabetes</strong>?</td>
<td><strong>26</strong> Do you currently have or have you ever had <strong>diabetes</strong>?</td>
</tr>
<tr>
<td><strong>27</strong> Do you currently have or have you ever had <strong>varicose veins or blood clots in your legs</strong>?</td>
<td><strong>27</strong> Do you currently have or have you ever had <strong>varicose veins or blood clots in your legs</strong>?</td>
</tr>
<tr>
<td><strong>28</strong> Do you currently have or have you ever had <strong>bleeding tendencies</strong>?</td>
<td><strong>28</strong> Do you currently have or have you ever had <strong>bleeding tendencies</strong>?</td>
</tr>
<tr>
<td><strong>29</strong> Are you currently in need of or have you ever had an <strong>operation</strong>?</td>
<td><strong>29</strong> Are you currently in need of or have you ever had an <strong>operation</strong>?</td>
</tr>
<tr>
<td><strong>30</strong> Do you currently have or have you ever had <strong>broken bones or concussions</strong>?</td>
<td><strong>30</strong> Do you currently have or have you ever had <strong>broken bones or concussions</strong>?</td>
</tr>
<tr>
<td><strong>31</strong> Are you currently having or have you ever had <strong>blood transfusions</strong>?</td>
<td><strong>31</strong> Are you currently having or have you ever had <strong>blood transfusions</strong>?</td>
</tr>
<tr>
<td><strong>32</strong> Do you currently have or have you ever had <strong>lupus or other autoimmune diseases</strong>?</td>
<td><strong>32</strong> Do you currently have or have you ever had <strong>lupus or other autoimmune diseases</strong>?</td>
</tr>
<tr>
<td><strong>33</strong> Are you <strong>allergic to any medications</strong>?</td>
<td><strong>33</strong> Are you <strong>allergic to any medications</strong>?</td>
</tr>
<tr>
<td><strong>Genetic Screening</strong></td>
<td></td>
</tr>
<tr>
<td><strong>34</strong> Will you be <strong>35 years old or older</strong> when the baby is due?</td>
<td><strong>34</strong> Will you be <strong>35 years old or older</strong> when the baby is due?</td>
</tr>
<tr>
<td><strong>35</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>Down’s syndrome</strong> (mongolism)?</td>
<td><strong>35</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>Down’s syndrome</strong> (mongolism)?</td>
</tr>
<tr>
<td><strong>36</strong> Have you, the baby’s father, or anyone in either of your families ever had any other <strong>chromosomal abnormality</strong>?</td>
<td><strong>36</strong> Have you, the baby’s father, or anyone in either of your families ever had any other <strong>chromosomal abnormality</strong>?</td>
</tr>
<tr>
<td><strong>37</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>neural tube defect</strong> (e.g., Spina Bifida or Meningomyelocele)</td>
<td><strong>37</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>neural tube defect</strong> (e.g., Spina Bifida or Meningomyelocele)</td>
</tr>
<tr>
<td><strong>38</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>anencephaly</strong>?</td>
<td><strong>38</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>anencephaly</strong>?</td>
</tr>
<tr>
<td><strong>39</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>hemophilia or other bleeding disorders</strong>?</td>
<td><strong>39</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>hemophilia or other bleeding disorders</strong>?</td>
</tr>
<tr>
<td><strong>40</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>muscular dystrophy</strong>?</td>
<td><strong>40</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>muscular dystrophy</strong>?</td>
</tr>
<tr>
<td><strong>41</strong> Is there a family history of <strong>multiple births</strong>?</td>
<td><strong>41</strong> Is there a family history of <strong>multiple births</strong>?</td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
<td></td>
</tr>
<tr>
<td><strong>42</strong> Do you wear <strong>seat belts</strong>?</td>
<td><strong>42</strong> Do you wear <strong>seat belts</strong>?</td>
</tr>
<tr>
<td><strong>43</strong> Do you live with anyone who <strong>hits you or hurts you</strong> in any way?</td>
<td><strong>43</strong> Do you live with anyone who <strong>hits you or hurts you</strong> in any way?</td>
</tr>
<tr>
<td><strong>44</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>cystic fibrosis</strong>?</td>
<td><strong>44</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>cystic fibrosis</strong>?</td>
</tr>
<tr>
<td><strong>45</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>sickle cell disease</strong>?</td>
<td><strong>45</strong> Have you, the baby’s father, or anyone in either of your families ever had <strong>sickle cell disease</strong>?</td>
</tr>
<tr>
<td><strong>46</strong> Do you or the baby’s father have a <strong>birth defect</strong>?</td>
<td><strong>46</strong> Do you or the baby’s father have a <strong>birth defect</strong>?</td>
</tr>
<tr>
<td><strong>47</strong> Do you or the baby’s father have any close relatives with <strong>mental retardation</strong>?</td>
<td><strong>47</strong> Do you or the baby’s father have any close relatives with <strong>mental retardation</strong>?</td>
</tr>
<tr>
<td><strong>48</strong> Do you, the baby’s father, or a close relative in either of your families have a <strong>birth defect, family disorder, or a chromosomal abnormality not listed above</strong>?</td>
<td><strong>48</strong> Do you, the baby’s father, or a close relative in either of your families have a <strong>birth defect, family disorder, or a chromosomal abnormality not listed above</strong>?</td>
</tr>
<tr>
<td><strong>Social &amp; Lifestyle History</strong></td>
<td></td>
</tr>
<tr>
<td><strong>49</strong> Do you <strong>smoke</strong>?</td>
<td><strong>49</strong> Do you <strong>smoke</strong>?</td>
</tr>
<tr>
<td><strong>50</strong> Do you drink <strong>alcohol</strong>?</td>
<td><strong>50</strong> Do you drink <strong>alcohol</strong>?</td>
</tr>
<tr>
<td><strong>51</strong> Have you used <strong>marijuana, LSD, speed, heroin, crystal, crack, or cocaine</strong>?</td>
<td><strong>51</strong> Have you used <strong>marijuana, LSD, speed, heroin, crystal, crack, or cocaine</strong>?</td>
</tr>
<tr>
<td><strong>52</strong> What <strong>medicines or recreational drugs have you taken since becoming pregnant</strong> (include all prescription and nonprescription drugs)?</td>
<td><strong>52</strong> What <strong>medicines or recreational drugs have you taken since becoming pregnant</strong> (include all prescription and nonprescription drugs)?</td>
</tr>
<tr>
<td>Question</td>
<td>Details</td>
</tr>
<tr>
<td>----------</td>
<td>---------</td>
</tr>
<tr>
<td>53</td>
<td>What is your <strong>occupation</strong>?</td>
</tr>
<tr>
<td>54</td>
<td>Is this a <strong>planned pregnancy</strong>?</td>
</tr>
<tr>
<td>55</td>
<td>What is the <strong>highest level of education</strong> you have completed?</td>
</tr>
<tr>
<td>56</td>
<td>Are you a <strong>vegetarian</strong>?</td>
</tr>
<tr>
<td>57</td>
<td>Since becoming pregnant, have you been <strong>exposed to any X-rays or toxic chemicals</strong>?</td>
</tr>
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</table>

**Menstrual History**

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>58</td>
<td>What was the <strong>first day of your last normal menstrual period</strong>?</td>
</tr>
<tr>
<td>59</td>
<td>Was your <strong>last menstrual period on time</strong>?</td>
</tr>
<tr>
<td>60</td>
<td>Have you taken <strong>birth control pills or Depo Provera</strong> in the last year?</td>
</tr>
<tr>
<td>61</td>
<td>How many <strong>days from the first day of your period to the first day of your next period</strong>?</td>
</tr>
<tr>
<td>62</td>
<td>How many <strong>days does your period last</strong>?</td>
</tr>
</tbody>
</table>

**Pregnancy History**

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>63</td>
<td>How many <strong>previous pregnancies</strong> have you had (include miscarriages and abortions)?</td>
</tr>
<tr>
<td>64</td>
<td>For each pregnancy what was the <strong>date, hospital, number of weeks pregnant, type of delivery (vaginal/C-section), birth weight, sex, and what were the complications (if any)</strong>?</td>
</tr>
</tbody>
</table>
APPENDIX C
Hemoglobinopathies

Sickle Cell Disease

Sickle cell disease refers to a group of autosomal recessive disorders involving abnormal hemoglobin (hemoglobin S). Asymptomatic individuals with heterozygous Hb S genotypes (carriers) are said to have sickle cell trait. The most severe form of the disease, Hb SS (homozygous Hb S), is called sickle cell anemia.

Sickle cell disorders are found not only in patients who have the hemoglobin genotype SS, but also in those who have Hb S and one other abnormality of α-globin structure or β-globin production. The most common of these are Hb SC disease and Hb S/β-thalassemia. When inherited with Hb S, these may cause clinically significant hemolytic anemia similar to Hb SS.

Sickle cell disease occurs most commonly in people of African origin. Approximately one in 12 African Americans has sickle cell trait. One in every 300 African-American newborns has some form of sickle cell disease, and approximately one in 600 has sickle cell anemia. Hemoglobin S is also found in high frequency in other populations such as Greeks, Italians (particularly Sicilians), Turks, Arabs, Southern Iranians, and Asian Indians.

The diagnosis of hemoglobinopathies, including sickle cell disorders, is made by hemoglobin electrophoresis. In the homozygous form, nearly all the hemoglobin is Hb S with small amounts of Hb A2 and Hb F. Heterozygous sickle cell trait (Hb AS) is identified by a larger percentage of Hb A and an asymptomatic course. Solubility tests (Sickledex) alone are inadequate for diagnosis of sickle cell disorders because they cannot distinguish between the heterozygous AS and homozygous SS genotypes. In addition, they fail to detect other pathologic variants such as Hb C trait, β-thalassemia trait, Hb E trait, Hb B trait, and Hb D trait.

The Thalassemias

The thalassemias represent a wide spectrum of hematologic disorders that are characterized by a reduced synthesis of globin chains, resulting in microcytic anemia. Thalassemias are classified according to the globin chain affected, with the most common types being α-thalassemia and β-thalassemia.

Alpha-Thalassemia

Alpha-thalassemia usually results from a gene deletion of two or more copies of the four α-globin genes. Deletion of one α-globin gene (α−/αα) is clinically unrecognizable, and laboratory testing yields normal results. Deletion of two α-globin genes causes α-thalassemia trait, a mild asymptomatic microcytic anemia. The deletions can be on the same chromosome or in cis (αα/−−), or on each chromosome or in trans (α−/α−). Individuals with these chromosomal abnormalities are referred to as carriers and are at an increased risk for having a child with a more severe form of thalassemia caused by deletions of three or four copies of the α-globin gene (α-thalassemia major).

Alpha-thalassemia trait (α-thalassemia minor) is common among individuals of Southeast Asian, African, and West Indian descent. It also is common in individuals with Mediterranean ancestry. Individuals with Southeast Asian ancestry are more likely to carry two gene deletions in cis or on the same chromosome (−−/αα) and are at an increased risk for offspring with Hb Bart's or Hb H disease. Hemoglobin H disease, which is caused by the deletion of three α-globin genes, usually is associated with mild to moderate hemolytic anemia. Alpha-thalassemia major (Hb Bart's) results in the absence of α-globin (−−−−); this is associated with hydrops fetalis, intrauterine death, and preeclampsia.

Beta-Thalassemia

Beta-thalassemia is caused by a mutation in the β-globin gene that causes deficient or absent β-chain production, which results in absence of Hb A. Classification of β-thalassemias is based on a description of the molecular mutation or by clinical manifestations. Individuals who are heterozygous for this mutation have β-thalassemia minor. Those who are homozygous have β-thalassemia major (Cooley's Anemia) or a milder form called thalassemia intermedia. Beta-thalassemia major is characterized by severe anemia with resultant extramedullary erythropoiesis, delayed sexual development, and poor growth. Elevated levels of Hb F in individuals with β-thalassemia major partially compensate for the absence of Hb A; however, death usually occurs by age 10 years.
unless treatment is begun early with periodic blood transfusions. With transfusion, the severe anemia is reversed and extramedullary erythropoiesis is suppressed. In homozygotes with the less severe $\beta$-thalassemia mutations, often referred to as $\beta$-thalassemia intermedia, variable but decreased amounts of $\beta$-chains are produced and, as a result, variable amounts of Hb A are produced. The genes for Hb S and $\beta$-thalassemia usually behave as alleles, with only one gene inherited from each parent. The expression of the resulting Hb S/$\beta$-thalassemia is determined by the type of $\beta$-thalassemia mutation (6).

Beta-thalassemia minor, common in individuals of Mediterranean, Asian, Middle Eastern, Hispanic, and West Indian descent, varies in severity of disease. Depending on the amount of $\beta$-chain production, it usually is associated with asymptomatic mild anemia. Beta-thalassemia minor often occurs in association with Hb S. In the most severe form, no normal $\beta$-globin chains are produced. This results in a clinically severe syndrome called sickle cell $\beta$-thalassemia, in which no Hb A is produced.
## APPENDIX D
### Risk Factors – Preterm Birth

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Surveillance</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. African American race</td>
<td>Normal</td>
<td>Wen et al., 1990</td>
</tr>
<tr>
<td>2. Age &lt;17 or &gt;35</td>
<td>Normal</td>
<td>Wen et al., 1990</td>
</tr>
<tr>
<td>4. Single parent</td>
<td>Normal</td>
<td>Lettieri et al., 1993</td>
</tr>
<tr>
<td>4. Smoking</td>
<td>Normal</td>
<td>Kramer, 1987</td>
</tr>
<tr>
<td>5. Multiple first-trimester abortions</td>
<td>Normal</td>
<td>Lettieri et al., 1993</td>
</tr>
<tr>
<td>7. Poor nutrition or low pre-pregnancy weight (BMI &lt; 18)</td>
<td>Normal</td>
<td>Buescher et al., 1993</td>
</tr>
<tr>
<td>8. Stressful job or more than 3 hours working on feet per 8-hour work day</td>
<td>Normal</td>
<td>Moizurkewich et al., 2000</td>
</tr>
<tr>
<td>8. Lower genital tract infection at 24 weeks' gestation (gonococcus, Chlamydia, bacterial vaginosis) **</td>
<td>Normal</td>
<td>Goldberg et al., 2000</td>
</tr>
<tr>
<td>8. Lower genital tract infection at 24 weeks' gestation (gonococcus, Chlamydia, bacterial vaginosis) **</td>
<td>Normal</td>
<td>Hauth et al., 1995</td>
</tr>
<tr>
<td>9. Periodontal disease</td>
<td>Normal</td>
<td>Goepfer et al., 2004</td>
</tr>
<tr>
<td>10. Anemia</td>
<td>Normal</td>
<td>Meis et al., 1995</td>
</tr>
<tr>
<td>11. Abdominal surgery between 20 and 36 weeks' gestation</td>
<td>HIGH</td>
<td>Dudley &amp; Cruikshank, 1990</td>
</tr>
<tr>
<td>12. Multiple gestation (the risk rises in direct proportion to the number of fetuses)</td>
<td>HIGH</td>
<td>Coleman et al., 1997</td>
</tr>
<tr>
<td>14. Prior spontaneous preterm delivery (risk rises with number of PTBs, African American ethnicity and decrease of gestational age in prior PTB)</td>
<td>HIGH</td>
<td>Iams et al., 1998</td>
</tr>
<tr>
<td>15. Vaginal bleeding in more than one trimester * Unexplained vaginal bleeding</td>
<td>HIGH</td>
<td>Strobino &amp; Pantel-Silverman, 1989</td>
</tr>
<tr>
<td>16. Cervical dilation &gt;2cm at 24 - 28 weeks' gestation **</td>
<td>HIGH</td>
<td>Papernik et al., 1986</td>
</tr>
<tr>
<td>17. Placenta previa persisting after 24 weeks</td>
<td>HIGH</td>
<td>Lettieri et al., 1993</td>
</tr>
<tr>
<td>18. Soft cervical consistency at 24-28 weeks **</td>
<td>HIGH</td>
<td>Copper et al., 1995</td>
</tr>
<tr>
<td>19. Cocaine or methamphetamine use</td>
<td>HIGH</td>
<td>St. Pierre et al., 1996</td>
</tr>
<tr>
<td>20. Use of assisted reproductive technology</td>
<td>HIGH</td>
<td>Jackson et al., 2004</td>
</tr>
<tr>
<td>21. Mullerian Anomaly</td>
<td>HIGH</td>
<td>Lettieri et al., 1993</td>
</tr>
</tbody>
</table>
Adapted from Preterm Birth: Causes, Consequences, and Prevention at http://www.nap.edu/catalog/11622.html

* While vaginal bleeding in more than one trimester increases the risk for preterm delivery by a RR of approximately 2.5, removal of the pregnant woman from the Uncomplicated Pregnancy Guideline is recommended based on additive risks for fetal growth restriction, fetal demise, nonreassuring fetal testing, and intrapartum/postpartum problems.

** Cervical examination (digital or sonographic) and testing for gonorrhea, Chlamydia, or bacterial vaginosis in the midtrimester are not recommended as routine interventions in the antenatal care of a woman with an uncomplicated pregnancy; however, a digital or sonographic cervical examination and evaluation for lower genital tract infection may be performed during the evaluation of a woman presenting with signs or symptoms of preterm labor.

REFERENCES


APPENDIX E
Prenatal Screening for Fetal Chromosomal Abnormalities

1. Woman in first trimester
   2. Initial Counseling [C1]
      - Woman declines testing & screening
      - Women interested in screening or counseling
      - Women request diagnostic test
         3. MFM genetic counseling [C3]
            Consider genetic ultrasound
            4. Request diagnostic testing?
               Yes
               No
               5. Screening result high risk?
                  Yes
                     6. Prompt MFM genetic counseling [C2]
                     7. Initiate testing based on gestational age, availability and patient preferences
                        amniocentesis, CVS
                     8. Test results indicate anomalies?
                        Yes
                        No
                        Counseling:
                        - Options
                        - Preparation for consequences
                  No
                  No
                  9. Woman interested in screening?
                     Yes
                     10. Signs Consent Form
                     11. Initiate screening strategy
                     12. Signs Declination Form
                     13. Continue routine care including anatomic ultrasound
                     14. Counseling:
                        - Options
                        - Preparation for consequences
<table>
<thead>
<tr>
<th>Benefits</th>
<th>Age Only</th>
<th>First Trimester</th>
<th>First and Second Trimesters Combined</th>
<th>Second Trimester</th>
<th>Ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td>No cost for this screening</td>
<td>Highest detection rate in the first trimester</td>
<td>Early answers and high detection rate</td>
<td>The highest detection rate overall</td>
<td>The highest detection rate without ultrasound (NT) measurements</td>
<td>Widely available screen for most common anomalies</td>
</tr>
<tr>
<td>Requires NT ultrasound measurement, not widely available</td>
<td>No answer given in the first trimester</td>
<td>No answer given in the first trimester</td>
<td>Best second trimester test Screens for ONTD</td>
<td>No answer given in the first trimester</td>
<td>Detailed genetic screening ultrasound also looks for structural, non-genetic problems</td>
</tr>
<tr>
<td>Problems</td>
<td>80% of babies with Down syndrome born to mothers &lt;35</td>
<td>No screening for ONTD</td>
<td>Not screened</td>
<td>No answer given in the first trimester</td>
<td>Outdated</td>
</tr>
<tr>
<td>Timing</td>
<td>N/A</td>
<td>10 3/7 to 13 6/7</td>
<td>10 3/7 - 13 6/7 and 15 0/7 - 21 6/7</td>
<td>10 3/7 - 13 6/7 and 15 0/7 - 21 6/7</td>
<td>15 0/7 - 21 6/7</td>
</tr>
<tr>
<td>Down Syndrome Detection Rate</td>
<td>15-30%</td>
<td>83%</td>
<td>90.40%</td>
<td>92%</td>
<td>87%</td>
</tr>
<tr>
<td>Test Positive Rate</td>
<td>Varies with Age</td>
<td>5%</td>
<td>1.2% and 3.7%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Odds of Being Affected with Positive Screen</td>
<td>Age Dependant</td>
<td>1 in 23</td>
<td>1 in 7 and 1 in 16</td>
<td>1 in 22</td>
<td>1 in 23</td>
</tr>
<tr>
<td>False Positive Rate</td>
<td>96%</td>
<td>86% and 94%</td>
<td>95%</td>
<td>95%</td>
<td>96%</td>
</tr>
<tr>
<td>Trisomy 18 Detection Rate</td>
<td>80%</td>
<td>90%</td>
<td>90%</td>
<td>90%</td>
<td>80%</td>
</tr>
<tr>
<td>Open Neural Tube (ONT)Detection Rate</td>
<td>N/A</td>
<td>Not Screened</td>
<td>80%</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Markers</td>
<td>&gt;34 yrs</td>
<td>NT + PAPP-A + hCG</td>
<td>NT + PAPP-A + hCG + AFP + hCG + uE3 + inhibin</td>
<td>NT + PAPP-A, AFP + hCG + uE3 + inhibin</td>
<td>AFP + hCG + uE3</td>
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**Data based on ACOG, 2007; SOPG, 2007; SURUSS; FASTER**
### Table E-2. Prenatal Screening Tests – Indications and Purpose

<table>
<thead>
<tr>
<th>Test</th>
<th>Recommended for</th>
<th>Purpose</th>
</tr>
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<tr>
<td><strong>Prenatal Screening - Ultrasound Tests</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>A1</strong> First trimester screen NT measurement (With B1)</td>
<td>Offer to high-risk women. Order this screening test during the first trimester (between 11 weeks, 0 days and 13 weeks, 6 days). Crown-rump length (CRL) must be between 42-79 mm).</td>
<td>Use when mother wants to know the aneuploidy risk prior to 14 weeks. Use with B1. See below.</td>
</tr>
<tr>
<td><strong>A2</strong> Second-trimester routine or basic ultrasound</td>
<td>For routine screening of low-risk women or screening for women who decline aneuploidy screening.</td>
<td>Widely available screen for most common major anomalies. For abnormal result offer follow-up with A3 +/- B2.</td>
</tr>
<tr>
<td><strong>A3</strong> Comprehensive or genetic ultrasound</td>
<td>Offer to high-risk women as a primary or follow-on test.</td>
<td>Comprehensive screening ultrasound looks for markers of genetic abnormalities and other structural, non-genetic problems. For abnormal result offer A3 or amniocentesis.</td>
</tr>
<tr>
<td><strong>Prenatal Screening - Serum Marker Tests</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>B1</strong> First trimester screen (with NT measurement [A1])</td>
<td>Offer to high-risk women. Order this screening test during the first trimester (between 11 weeks, 0 days and 13 weeks, 6 days). Crown-rump length (CRL) must be between 42-79 mm).</td>
<td>Use when mother wants to know the DS risk prior to 14 weeks. Does not detect ONTD. For abnormal result offer choice of CVS, A3 or amniocentesis.</td>
</tr>
<tr>
<td><strong>B3</strong> Single screen maternal serum screen, alpha fetoprotein only</td>
<td>Offer to high-risk women who have previously undergone first-trimester testing (e.g., mothers who undergo early amniocentesis, chorionic villous samplings or first-trimester screening). Ideal time period is 16-18 weeks gestation; however, reference medians are available for 14-25 weeks in some labs.</td>
<td>Screen for fetal risk of Open Neural Tube Defect (i.e., spina bifida, anencephaly). For abnormal result offer A3 and/or amniocentesis.</td>
</tr>
<tr>
<td><strong>B1 B2</strong> Serum integrated screen (first- and second-trimester serum only) OR integrated screen (first trimester NT (A1) and first- and second-trimester serum screening)</td>
<td>First specimen drawn between 10 weeks, 3 days and 13 weeks, 6 days’ gestation. Crown rump length (CRL) must be between 36-79mm. Result not provided in first trimester.</td>
<td>First-trimester serum specimen measures PAPP-A. Specimen 2 measures hCG, AFP, uE3 and DIA. When combined with a first-trimester certified ultrasound for nuchal translucency (NT), yields the best detection rate and lowest false-positive rate of all prenatal screens. Result given in second trimester. For abnormal result offer A3 or amniocentesis.</td>
</tr>
<tr>
<td><strong>B2</strong> Quad screen maternal serum</td>
<td>The quad test is the most economical prenatal screening test.</td>
<td>Quad screen for fetal risk of Down syndrome (trisomy 21), trisomy 18,</td>
</tr>
<tr>
<td>Test</td>
<td>Recommended for</td>
<td>Purpose</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
<td>---------</td>
</tr>
<tr>
<td>Quad test - best second-trimester serum screen available. Ideal time period is 16-18 weeks’ gestation; however, reference medians are available for 14-25 weeks.</td>
<td>and open neural tube defect (ONTD), spina bifida. Better detection rate and a lower false-positive rate than the triple screen. <strong>For abnormal result offer A3 or amniocentesis.</strong></td>
<td></td>
</tr>
<tr>
<td>First specimen drawn between 10 weeks, 3 days and 13 weeks, 6 days’ gestation. Crown rump length (CRL) must be between 36-79 mm and a nuchal translucency measurement must be obtained. Initial result provided in first trimester. Final result provided in second trimester for women having follow-on second-trimester serum measurements.</td>
<td>Specimen 1 measures PAPP-A. Specimen 2 measures hCG, AFP, uE3 and DIA. An interpretation is provided after the first draw so that pregnancies at very high risk for DS can be identified in the first trimester. For abnormal first-trimester result offer choice of CVS, A3 or amniocentesis. For intermediate first-trimester result follow on second-trimester serum marker measurement. For abnormal second-trimester result offer A3 and amniocentesis. For low-risk first- or second-trimester result offer A2.</td>
<td></td>
</tr>
</tbody>
</table>

### Prenatal Diagnosis - Amniotic Fluid and Chromosome Analyses

<table>
<thead>
<tr>
<th>Test</th>
<th>Recommended for</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offered in the first trimester to high-risk women. Indications may include: - Women older than 34 years of age - Abnormal first-trimester screen result - Fetal structural abnormalities - Family history of chromosomal abnormality or metabolic or genetic disorder.</td>
<td>First-trimester diagnostic testing (10-14 weeks gestation). Follow up with genetic counseling for abnormal result.</td>
<td></td>
</tr>
<tr>
<td>Not recommended: -Higher rates of failure, pregnancy loss and fetal injury than CVS or routine amniocentesis (D1, D3).</td>
<td>Prenatal diagnosis 10-15 weeks’ gestation. Follow up with genetic counseling for abnormal result.</td>
<td></td>
</tr>
<tr>
<td>Indications include: - Abnormal first- or second-trimester screening test(s) - Fetal ultrasound abnormalities - Family history of chromosome abnormality or genetic disorder - Elevated risk for open neural tube defect risk (do amniotic fluid AFP with Reflex to Acetylcholinesterase).</td>
<td>Prenatal diagnosis in pregnant patient after 14 weeks’ gestation. Follow up with genetic counseling for abnormal result.</td>
<td></td>
</tr>
</tbody>
</table>
Table E- 3. Timing Opportunities for Prenatal Screening

<table>
<thead>
<tr>
<th>Gestational Age (Weeks)</th>
<th>Initial Counseling</th>
<th>Detailed Counseling</th>
<th>Post-test Counseling</th>
<th>Late Entry Counseling</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 to 7</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>8 to 9</td>
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<td>10</td>
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<td>20</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- First Trimester Ultrasound; Nuchal Translucency Measurement (A1)
- Basic Ultrasound (A2)
- Comprehensive (Genetic) Ultrasound (A3)
- First-Trimester Analytes (B1)
- Second-Trimester Analytes (B2)
- MSAFP (B3)
- CVS (D1)
- Early Amniocentesis (D2)
- Genetic Amniocentesis (D3)
Institutional Considerations

The process of reviewing scientific evidence and addressing implementation and ethical issues is as important as the specific findings and recommendations of this guideline. With a wide array of new testing technologies and candidate disorders for screening it is more important than ever to establish an objective process of accumulating scientific evidence for forming policy decisions. Accordingly, each institution needs to establish testing strategies they will make available to their beneficiaries. These strategies should take into account the principles and recommendations from above. Accordingly, each institution should have available one or more tests/testing strategies from each of the groups below.

Given the complexity of the varied testing strategies, it is not feasible for every institution to offer the spectrum of potential testing strategies. Institutions need to provide one or more screening strategies giving a first-trimester result and one or more strategies giving a second-trimester result. Each institution must also provide or arrange for access to routine and comprehensive ultrasound, CVS, amniocentesis, and basic and comprehensive counseling.

Table E-4. Institutional Considerations

<table>
<thead>
<tr>
<th>Options</th>
<th>Name / Type of Test</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Trimester Result</td>
<td>1T US + 1T Serum</td>
<td>First Trimester Combined</td>
<td>1T &lt; 15 weeks</td>
</tr>
<tr>
<td></td>
<td>1T US + 1T and 2T Serum</td>
<td>Contingency</td>
<td>1T &lt; 15 weeks and 2T &gt; 15 weeks</td>
</tr>
<tr>
<td>2nd Trimester Result</td>
<td>1T US + 1T and 2T Serum</td>
<td>Integrated Screen</td>
<td>2T &gt; 15 weeks</td>
</tr>
<tr>
<td></td>
<td>1T Serum + 2T Serum</td>
<td>Serum Integrated Screen</td>
<td>2T &gt; 15 weeks</td>
</tr>
<tr>
<td></td>
<td>2T Serum</td>
<td>Quad Screen</td>
<td>2T &gt; 15 weeks</td>
</tr>
</tbody>
</table>

Key: 1T – First Trimester; 2T – Second Trimester
APPENDIX F
Questions for Literature Search

1. In women experiencing a normal pregnancy does use of the “Centering Pregnancy” model vs. routine care affect neonatal morbidity, rate of preterm delivery, birth weight, patient satisfaction, length of breastfeeding, healthcare cost or utilization, APGAR scores, length of gestation, or method of delivery?

2. Does testing a pregnant woman with maternal serum analyte testing in the first trimester and/or performing ultrasound measurement of nuchal translucency in the second trimester, either individually or in combination use, improve fetal or maternal outcomes?

3. In women who are candidates for genetic testing, do the credentials of the provider performing the counseling affect maternal or fetal outcomes, or patient satisfaction?

4. In women with a history of preterm birth, does treatment with progesterone decrease the rate of preterm delivery?

5. In pregnant women with a history of LEEP, what is the effect on preterm delivery of increased surveillance for preterm labor, either by cervical length via US or fetal fibronectin when compared with routine care? Are these patients uncomplicated?

6. In women with a history of preterm birth, does screening for cervix incompetence decrease the rate of preterm delivery?

7. In pregnant women with a history of GDM, what is the effect of 1st trimester screening on timing of GDM diagnosis, macrosomia, mode of delivery, and fetal morbidity and mortality?

8. In pregnant women undergoing 3H GTT testing for GDM, what is the effect of up to three days of a high-carbohydrate diet prior to the testing versus no special diet prior to the testing on the specificity and sensitivity of the test?

9. In pregnant women with a history of gastric bypass, when should screening for GDM start and what is the optimal screening method to maximize accurate diagnosis of GDM?

10. In pregnant women with a history of gastric bypass, what is the effect of conducting goal-oriented visits, versus standard care, on maternal/fetal morbidity, preterm birth, birth weight, and patient satisfaction?

11. In pregnant women with PCOS what is the optimal timing and frequency for screening for GDM? Are these patients still uncomplicated?

12. What is the effect on infant and maternal morbidity/mortality, specifically neonatal GBS sepsis and timing of delivery, of treating women with ANY amount of GBS isolated in their urine versus treating only those with >100K CFU isolated?

13. In pregnant women at term with positive GBS screening, does stripping or sweeping of membranes compared to not stripping or sweeping of membranes increase GBS sepsis of neonate or chorioamnionitis?

14. In women with a history of ectopic pregnancy, what is the effect of early US on the timing and incidence of detection of ectopic pregnancy, method of resolution of ectopic pregnancy, hospitalization rates, and maternal morbidity?

15. In pregnant women with partners with a history of HSV disease, what is the effect of serum HSV testing of the partner, as well as transmission prevention education on the incidence of maternal primary HSV in pregnancy, and the incidence of neonatal HSV?

16. In pregnant women with a history of HSV, what is the effect of suppressive theory at term versus no suppression on incidence of maternal HSV, neonatal HSV, and C-section rates with HSV presence as an indication?
17. In women experiencing a normal pregnancy, what is the effect of elective induction at term versus no elective induction on mode of delivery, APGAR scores, fetal outcomes, and patient satisfaction?

18. In pregnant women who test positive for HbSAg what is the effect of maternal hepatitis B vaccination before delivery on the incidence of vertical Hepatitis B transmission to the infant?

19. In women experiencing a normal pregnancy that are asymptomatic, does screening for bacterial vaginosis, and subsequently treating, decrease the rate of preterm delivery?
## APPENDIX G
Acronym List

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAP</td>
<td>American Academy of Pediatrics</td>
</tr>
<tr>
<td>ACS</td>
<td>American Cancer Society</td>
</tr>
<tr>
<td>ACOG</td>
<td>American College of Obstetricians and Gynecologists</td>
</tr>
<tr>
<td>AFI</td>
<td>Amniotic Fluid Index</td>
</tr>
<tr>
<td>AFP</td>
<td>Alphaetoprotein</td>
</tr>
<tr>
<td>AIUM</td>
<td>American Institute of Ultrasound in Medicine</td>
</tr>
<tr>
<td>ASB</td>
<td>Asymptomatic Bacteriuria</td>
</tr>
<tr>
<td>bid</td>
<td>Twice a Day</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>BPD</td>
<td>BiParielal Dianeter</td>
</tr>
<tr>
<td>CAGE</td>
<td>Alcohol Abuse/Dependency Screening Instrument</td>
</tr>
<tr>
<td>CBC</td>
<td>Complete Blood Count</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioral Therapy</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control</td>
</tr>
<tr>
<td>CF</td>
<td>Cystic Fibrosis</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>CMV</td>
<td>Cytomegalovirus</td>
</tr>
<tr>
<td>CNM</td>
<td>Certified Nurse Midwife</td>
</tr>
<tr>
<td>CPD</td>
<td>Cephalopelvic Disproportion</td>
</tr>
<tr>
<td>CPG</td>
<td>Clinical Practice Guideline</td>
</tr>
<tr>
<td>CPS</td>
<td>Clinical Preventive Services</td>
</tr>
<tr>
<td>CRS</td>
<td>Congenital Rubella Syndrome</td>
</tr>
<tr>
<td>DE</td>
<td>Dependent Edema</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
</tr>
<tr>
<td>ECT</td>
<td>Electroconvulsive Therapy</td>
</tr>
<tr>
<td>EDC</td>
<td>Estimated Date of Confinement</td>
</tr>
<tr>
<td>EDD</td>
<td>Estimated Date of Delivery</td>
</tr>
<tr>
<td>EDPS</td>
<td>Edinburgh Postnatal Depression Scale</td>
</tr>
<tr>
<td>EGA</td>
<td>Estimated Gestational Age</td>
</tr>
<tr>
<td>fFN</td>
<td>Fetal Fibronectin</td>
</tr>
<tr>
<td>FL</td>
<td>Femur Length</td>
</tr>
<tr>
<td>GBS</td>
<td>Group B Streptococcus</td>
</tr>
<tr>
<td>GDM</td>
<td>Gestational Diabetes Mellitus</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>GTT</td>
<td>Glucose Tolerance Test</td>
</tr>
<tr>
<td>HBIG</td>
<td>Hepatitis B Immune Globulin</td>
</tr>
<tr>
<td>HC/AC</td>
<td>Head/Abdominal circumference</td>
</tr>
<tr>
<td>HCG</td>
<td>Human Chorionic Gonadotropin</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HPV</td>
<td>Human Papillomavirus</td>
</tr>
<tr>
<td>HSV</td>
<td>Herpes Simplex Virus</td>
</tr>
<tr>
<td>IAP</td>
<td>Intrapartum Antibiotics for Prophylaxis</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>IPT</td>
<td>Interpersonal Therapy</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>LBW</td>
<td>Low Birth Weight</td>
</tr>
<tr>
<td>LEEP</td>
<td>Loop Electrosurgical Excisional Procedure</td>
</tr>
<tr>
<td>LMP</td>
<td>Last Menstrual Period</td>
</tr>
<tr>
<td>MDD</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>MFM</td>
<td>Maternal-Fetal Medicine Physician</td>
</tr>
<tr>
<td>MMR</td>
<td>Measles/Mumps/Rubella</td>
</tr>
<tr>
<td>MOM</td>
<td>Multiples of the Median</td>
</tr>
<tr>
<td>MSAFP</td>
<td>Maternal Serum Alphafetoprotein</td>
</tr>
<tr>
<td>NDDG</td>
<td>National Diabetes Data Group</td>
</tr>
<tr>
<td>HBV</td>
<td>Hepatitis B Virus</td>
</tr>
<tr>
<td>HC/AC</td>
<td>Head/Abdominal Circumference</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institute of Health</td>
</tr>
<tr>
<td>NNT</td>
<td>Number-Needed-To-Treat</td>
</tr>
<tr>
<td>NRT</td>
<td>Nicotine Replacement Therapy</td>
</tr>
<tr>
<td>NST</td>
<td>Non-Stress Testing</td>
</tr>
<tr>
<td>NT</td>
<td>Nuchal Translucency</td>
</tr>
<tr>
<td>NTD</td>
<td>Neural Tube Defect</td>
</tr>
<tr>
<td>OB/GYN</td>
<td>Obstetrician/Gynecologist or Obstetrical/Gynecological</td>
</tr>
<tr>
<td>OIA</td>
<td>Optical Immunoassay</td>
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<tr>
<td>ONTD</td>
<td>Open Neural Tube Defects</td>
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<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>Pap</td>
<td>Papanicolaou</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase Chain Reaction</td>
</tr>
<tr>
<td>PID</td>
<td>Pelvic Inflammatory Disease</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
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<tr>
<td>---------</td>
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</tr>
<tr>
<td>PPD</td>
<td>Purified Protein Derivative</td>
</tr>
<tr>
<td>PROM</td>
<td>Premature Rupture of Membranes</td>
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<tr>
<td>PTB</td>
<td>Preterm Birth</td>
</tr>
<tr>
<td>PTD</td>
<td>Preterm Delivery</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized Controlled Trials</td>
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<tr>
<td>RPR</td>
<td>Rapid Plasma Reagin</td>
</tr>
<tr>
<td>RR</td>
<td>Relative Risks</td>
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<tr>
<td>SBS</td>
<td>Shaken Baby Syndrome</td>
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<td>SIDS</td>
<td>Sudden Infant Death Syndrome</td>
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<td>SOGC</td>
<td>Society of Obstetricians and Gynaecologists of Canada</td>
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<tr>
<td>SSRI</td>
<td>Selective Serotonin Reuptake Inhibitors</td>
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<td>Tetanus-diphtheria</td>
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<td>Tdap</td>
<td>Tetanus, diphtheria, and acellular pertussis</td>
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<tr>
<td>TOC</td>
<td>Test of Cure</td>
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<tr>
<td>TORCH</td>
<td>Toxoplasmosis, Other infections, Rubella, Cytomegalovirus, Herpes simplex virus</td>
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<tr>
<td>TSH</td>
<td>Thyroid Stimulating Hormone</td>
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<td>US</td>
<td>Ultrasound</td>
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<td>USPSTF</td>
<td>United States Preventive Services Task Force</td>
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<td>VBAC</td>
<td>Vaginal Birth After Cesarean Delivery</td>
</tr>
<tr>
<td>VDRL</td>
<td>Venereal Disease Research Laboratory</td>
</tr>
</tbody>
</table>
APPENDIX H
Participant List

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APPENDIX I
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