DoD/VA CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF **UNCOMPLICATED PREGNANCY**

Department of Defense
Veterans Administration

Version 1.03

Prepared by:

THE MANAGEMENT OF **UNCOMPLICATED PREGNANCY**
Working Group

With support from:

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THE MANAGEMENT OF UNCOMPLICATED PREGNANCY

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INTRODUCTION

INTRODUCTION

At first blush, many will question the need to put effort into the development of a practice guideline for uncomplicated pregnancies when such care seems so rudimentary and simplistic. However, the following points exemplify why a practice guideline for care of pregnant women with uncomplicated pregnancies is a worthy endeavor.

1. Antenatal care is one of the largest service lines within military medicine. Supervision of normal pregnancy (V220 and V221) accounted for almost 600,000 outpatient visits to military treatment facilities in fiscal year 1999, making normal pregnancy the fifth most common reason for a patient visit to a military treatment facility during that time period (Standard Ambulatory Data Record data set, January 2000). Additionally, the top five inpatient Diagnostic Related Groups (DRG) within military hospitals for that same time period were related to birth (DRGs 373, 391, 630, 372 and 371) (Standard Inpatient Data Record data set, December 1999).

2. Current antenatal care is steeped in traditionalistic practice that, for the most part, has not undergone scientific evidence-based scrutiny.

3. There is an element of consumerism in childbearing that is rather unique in medical practice, as many of our pregnant women enter the patient-provider relationship with specific goals and processes selected as a benchmark of the quality of their care and the qualifications of their care providers.

4. Patient and provider satisfaction with antenatal care in Department of Defense (DoD)/Veterans Administration (VA) facilities will become increasingly important as patients are allowed greater freedom to choose their providers and healthcare facilities in the future.

Thus, the primary goal of the Uncomplicated Pregnancy Guideline is to improve patient and provider satisfaction with antenatal care. Towards that end, this guideline recommends some rather significant changes from what many consider as traditional antenatal care. Some of the more significant changes include the following:

1. Change in 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.

2. Pregnant women and providers will each be aware of the specific expectations for every visit, thus promoting a partnership with a common goal of a healthy infant and mother. Enhancing patient education will be a hallmark of this healthcare partnership and the goal-oriented prenatal care system.

3. A standardized care plan within the Uncomplicated Pregnancy Guideline is expected to improve overall patient satisfaction and lessen inter-provider variability, which is often perceived by pregnant woman in a negative manner and as a sign of clinical naiveté and uncertainty.

Perhaps the most important aspect of the Uncomplicated Pregnancy Guideline is to provide a scientific evidence-base for practice interventions and evaluations. The development of this guideline incorporated information from several existing evidence-based guidelines/reports, to include the following:

- Institute for Clinical Systems Improvement (ICSI) - *Health Care Guideline: Routine Prenatal Care,* July 2000.
- Guide to Clinical Preventive Services (CPS) Second Edition, *Report of the U.S. Preventive Services Task Force, 1996.*

The Working Group would like to acknowledge the frequent use of the American College of Obstetricians and Gynecologists (ACOG) technical bulletins and guidelines as a respected source for expert opinion.

The Working Group has taken great care to scrutinize each element of traditional prenatal care. Interventions with an adequate scientific foundation are graded with an "A" or "B" recommendation. Interventions without a sound scientific basis were subjected to an in-depth analysis by an interdisciplinary group of expert prenatal care providers and a consensus decision was made to continue or discontinue the intervention, if there was lack of evidence of benefit or a negative cost-effective analysis.

Finally, the academic members of our healthcare team hope that the elements of antenatal care identified in this guideline will provide fruitful ground for clinical research within our DoD/VA healthcare system.

Modifications to the guideline will undoubtedly be necessary as a result of lessons learned and new research and practice-based evidence. The developers believe that this guideline should always be considered "a work in progress."

KEY POINTS

Change the traditional interval-based visit template to a system with specific gestational age visits, each having a specific well-defined goal and objectives.

- Standardized prenatal care for lower risk patients to minimize variation.
- Standardized care plan to improve overall patient satisfaction with prenatal care.
- Explicit, evidence-based interventions for screening and management.
- Standardized education of patients and providers.
- Standardized counseling for antenatal diagnostic screening.
- Standardized prenatal screen to identify women with high-risk pregnancies.
- Accompanying tool kit to empower implementation.

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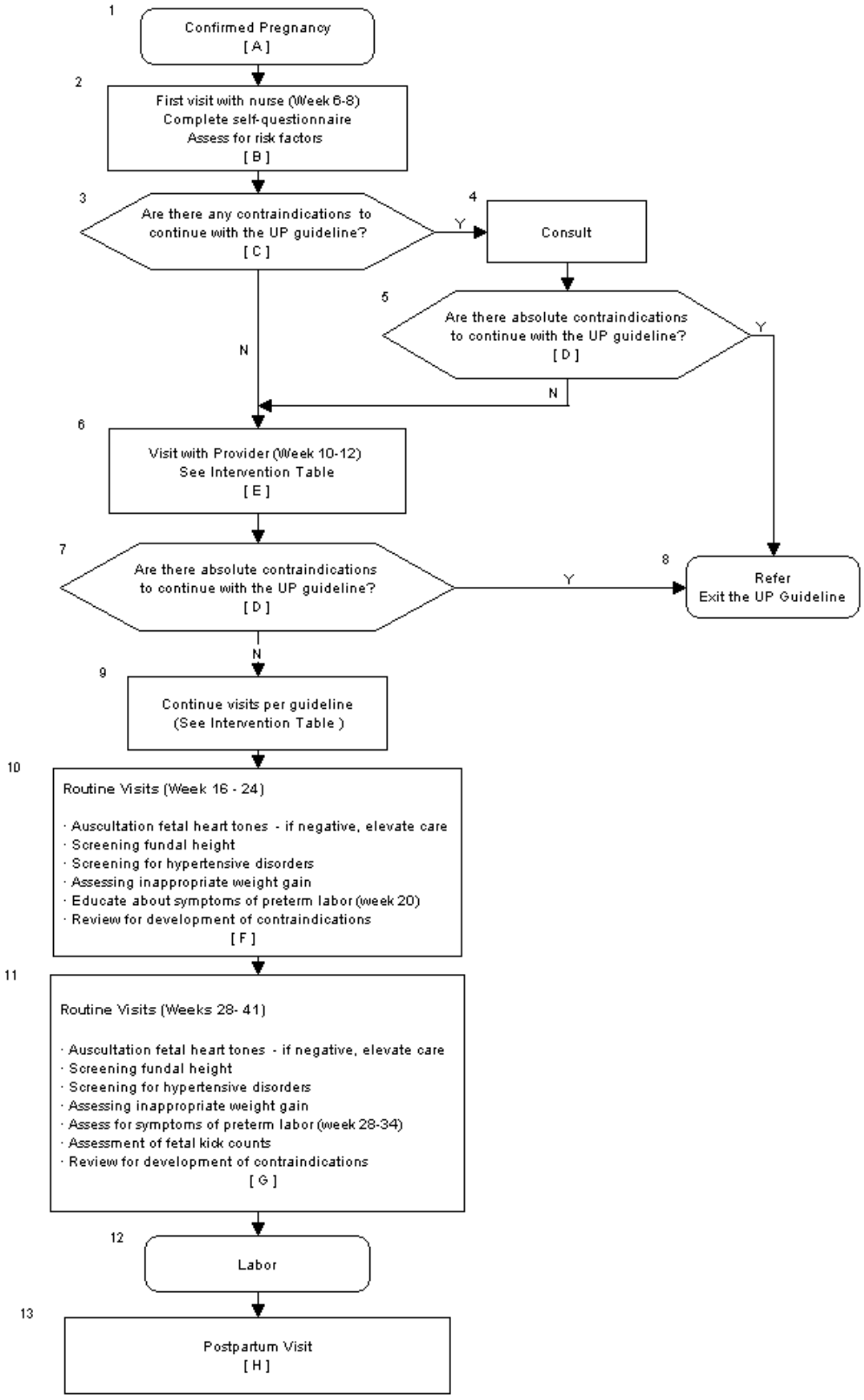
DoD/VA CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF **UNCOMPLICATED PREGNANCY**

ALGORITHM AND ANNOTATIONS

DoD/VA Clinical Practice Guideline for Management of Uncomplicated Pregnancy



ANNOTATIONS

A. Confirmed Pregnancy

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

B. First Visit with Nurse: 6 To 8 Weeks
Complete Self-Questionnaire
Assess For Risk Factors

ANNOTATION

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. The following table contains a checklist of the data collected during the first visit with the nurse and/or health care provider (Family Practitioner, Certified Nurse-Midwife or Obstetrician/Gynecologist [OB/GYN]). These data are required to assess the appropriateness of using the Uncomplicated Pregnancy Guideline follow-up. In addition, all active duty pregnant women are required to have an occupational health screening per AR40-501 exception to policy.

Table 1. Prenatal Risk Assessment Checklist

Risk	Questionnaire *(see Appendix A-1)*	History Taking	Physical Exam (First Visit with Provider)	Lab
Past OB history - If prior macrosomia or prior gestational diabetes mellitus (GDM)	√			Glucola for GDM
Drug use/alcohol use/smoking	√	√		
Prescription, over-the-counter, and herbal medications	√	√		
Thyroid disorders	√		√	
Gastrointestinal disorders	√	√		
Hypertension	√	√	√	
Cardiovascular diseases - pulmonary	√			
Diabetes mellitus (DM) – Type 1 or 2 - Family history of DM in first or second degree relative	√	√		Glucola for GDM
Renal disorder	√			
Autoimmune disorder (AIDS)/ Lupus	√			
Blood disorders	√			
Sexually transmitted disease (STD)	√	√	√	√
Human immunodeficiency virus (HIV)	√			√
Tuberculosis	√	√		
Cancer	√			
Transplant	√			
Surgery/cesarean/breast/gynecology	√			
Mental disease	√			
Uterine abnormality	√			
Genetic disease/family history of genetic disease	√			
Religion		√		
Language barrier		√		
Diet restriction	√			
Eating disorder	√	√		

Risk	Questionnaire *(see Appendix A-1)*	History Taking	Physical Exam (First Visit with Provider)	Lab
Body mass index (BMI) - If >29			√	Glucola for GDM
Age (<16 or >40)	√			
Vital signs			√	
Domestic violence	√	√	√	
Homeless		√		
Blood pressure			√	
Cardiac abnormality	√		√	
Vaginal bleeding	√	√	√	
Pelvic exam			√	Cervical smear
Dating criteria	√	√	√	
Complete blood count (CBC)				√
(ABO Rh) blood typing				√
Rapid plasma reagent (RPR)				√
Rubella test				√
Hepatitis B surface antigen test				√
Gonorrhea and chlamydia test				√
Urinalysis and culture				√
Antibody screen				√

Initial OB labs should be reviewed and documented at the following visit.

C. Are There Any Contraindications To Continue With The Uncomplicated Pregnancy Guideline?

ANNOTATION

Indications for Referral to Physician on First Visit

Past OB/GYN History:

- Prior preterm delivery (<37 weeks)
- Intrauterine fetal demise (IUFD) – 10 weeks after cardiac activity
- Prior cervical/uterine surgery
- Prior preterm labor requiring admission (e.g., early cervical change)
- Fetal anatomic abnormality (e.g., open neural tube defects in prior child or first degree relative)
- Past complicated pregnancy

Medical History:

- Pre-existing diabetes
- Gestational diabetes
- HIV
- Chronic hypertension
- Systemic disease that requires ongoing care (e.g., severe asthma, lupus, and inflammatory bowel disease)
- Current mental illness requiring medical therapy
- Cancer
- Seizure disorders
- Hematologic disorders
- Recurrent urinary tract infections/stones

Psycho-Social:

- Substance use disorders
- Eating disorders
- Postpartum depression

Conditions in Current Pregnancy:

- Relative BMI <16.5
- Age (<16 or >40 years at delivery)
- Vaginal bleeding

D. Are There Absolute Contraindications To Continue With The Uncomplicated Pregnancy Guideline?

ANNOTATION

Absolute Contraindications to the Uncomplicated Pregnancy Guideline:

Pregnant women identified as having any of the following conditions should exit the Uncomplicated Pregnancy Guideline.

- Pre-existing diabetes
- Gestational Diabetes Mellitus (GDM)
- Fetal anomaly or abnormal presentation (≥36 weeks)
- Multiple gestation
- Placenta previa
- Chronic hypertension
- Systemic disease that requires ongoing care (e.g., severe asthma, lupus, and inflammatory bowel disease)
- Drug abuse
- HIV (or abnormal screen)

Relative Contraindications to the Uncomplicated Pregnancy Guideline:

Pregnant women identified as having one or more of the following conditions should be evaluated by a healthcare provider (experienced in obstetrics) to determine the risk of continuing with the Uncomplicated Pregnancy Guideline.

- Age (<16 or >40 years at delivery)
- Past complicated pregnancy
- Prior preterm delivery (<37 weeks)
- Prior preterm labor requiring admission (e.g., early cervical change)
- Intrauterine fetal demise (IUFD) – 10 weeks after cardiac activity was first noted
- Prior cervical/uterine surgery
- Fetal anatomic abnormality (e.g., open neural tube defects in prior child or first degree relative)
- Abnormal fetal growth
- Preterm labor requiring admission (i.e., regular uterine contractions and cervical change)
- Abnormal amniotic fluid
- Second or third trimester bleeding
- Relative BMI <16.5
- Hematologic disorders
- Severe anemia (<24 percent hematocrit)
- Cancer
- Seizure disorders

- Recurrent urinary tract infection/stones
- Substance use disorders (alcohol/tobacco)
- Eating disorders
- Surgery
- Abnormal screen – antibody, hepatitis, syphilis, and Papanicolaou (PAP)
- Abnormal maternal serum analyte test (e.g., triple screen)
- Current mental illness requiring medical therapy

E. Visit With Provider - Weeks 10-12

ANNOTATION

See *Prenatal Care Interventions and Interventions Summary Table*.

F. Routine Visits - Weeks 16-27

ANNOTATION

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 inappropriate weight gain
- Educate about symptoms of preterm labor (week 20)
- Review for development of contraindications – exit the Uncomplicated Pregnancy Guideline if absolute contraindications are identified

For specific interventions see *Prenatal Care Interventions – Weeks 16-27.*

G. Routine Visits - Weeks 28-41

ANNOTATION

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 inappropriate weight gain
- Assess for symptoms of preterm labor (week 28)
- Assessment of fetal kick counts
- Review for development of contraindications - exit the Uncomplicated Pregnancy Guideline if absolute contraindications are identified

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

H. Postpartum Visit

ANNOTATION

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 8 weeks after delivery. Eight weeks is the optimal time to decrease the rate of false positive cervical smears, though consideration of the mother's schedule should also be taken into account.
- Tests that should be performed at this visit include the cervical smear, pelvic exam, and breast exam.
- Topics addressed at this exam should include contraception, postpartum depression, feeding method, sexual activity, weight, exercise and the woman's assessment of her adaptation to motherhood.

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) verses 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). 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 6 versus 8 weeks postpartum, to determine if this remains a significant problem.

The postpartum Pap smear is of value due to 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, more recent study by Jazayeri et al, who found that in patients without risk factors for cervical intraepithelial neoplasia and a normal Pap smear in pregnancy, there was no significant difference between their prenatal and postpartum smears (Jazayeri et al., 1999).

The Working Group recommends that the following topics be considered for discussion at the postpartum visit: contraception, postpartum depression, feeding method, sexual activity, weight, exercise, and the woman's assessment of her adaptation to motherhood. There is no evidence to recommend for or against discussion of specific topics. Topics to be addressed at this visit are ultimately based on the discretion of the provider and the needs of the woman.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Postpartum visit at eight weeks.	Rarick & Tchabo, 1994	I	Good	B
2	Tests traditionally performed at this visit include the cervical smear, pelvic exam, and breast exam.	Londo et al., 1994 Weiss et al., 1989	II	Fair	B
3	Topics of postpartum visit.	Working Group Consensus	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

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PRENATAL CARE INTERVENTIONS

PRENATAL CARE INTERVENTIONS
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INTERVENTIONS (Weeks 38-41)

INTERVENTIONS NOT RECOMMENDED DURING PREGNANCY

PRENATAL CARE INTERVENTION SUMMARY TABLE

Antenatal care for all pregnant women who meet criteria for the Uncomplicated Pregnancy Guideline should include the following interventions. *It is recommended that each intervention be completed by the indicated week (NOTE: Between weeks 38-41, weekly visits are recommended).*

		WEEK							
Interventions		**6-8**	**10-12**	**16-20**	**24**	**28**	**32**	**36**	**38-41**
Interventions At All Visits									
I-1	Screening for hypertensive disorders	√	√	√	√	√	√	√	√
I-2	Breastfeeding education	√	√	√	√	√	√	√	√
I-3	Exercise during pregnancy	√	√	√	√	√	√	√	√
I-4	Influenza vaccine (*season-related)*	√	√	√	√	√	√	√	√
First Visit With Nurse [6-8 Weeks]									
I-5	Screening for tobacco use - offer cessation	√							
I-6	Screening for alcohol use - offer cessation	√							
I-7	Screening for drug abuse - offer treatment	√							
I-8	Screening for domestic abuse	√			√		√		
I-9	Screening for RH status	√							
I-10	Screening for rubella	√							
I-11	Screening for varicella	√							
I-12	Screening for hepatitis B	√							
I-13	Screening for syphilis rapid plasma reagin	√							
I-14	Screening for asymptomatic bacteriuria	√							
I-15	Screening for HIV - counsel	√							
I-16	Immunization - Td booster (first trimester)	√							
I-17	Immunization - hepatitis B (first trimester)	√							
First Visit With Provider [10-12 Weeks]									
I-18	Assessing weight gain (inappropriate)		√	√	√	√	√	√	√
I-19	Auscultation fetal heart tones		√	√	√	√	√	√	√
I-20	Screening fundal height		√	√	√	√	√	√	√
I-21	Screening for gonorrhea		√						
I-22	Screening for chlamydia		√						
I-23	Screening for cervical cancer		√						
I-24	Counseling for cystic fibrosis screening		√						
Weeks: 16-27									
I-25	Maternal serum analyte screening			√					
I-26	Routine ultrasound			√					
I-27	Counseling for family planning			√					
I-28	Educate regarding preterm labor			√	√				
Weeks: 28-37									
I-29	Assess for preterm labor					√	√	√	
I-30	Daily fetal movement counts					√	√	√	√
I-31	Screening for gestation diabetes					√			
I-32	Iron supplementation					√			
I-33	Anti-D prophylaxis for Rh-negative women					√			
I-34	Screening for Group B Streptococcus (GBS)							√	
I-35	Assessment of fetal presentation							√	√
Weeks: 38-41									
I-36	Weekly cervical check (stripping/sweeping)								√
I-37	Post-dates antenatal fetal testing								√

INTERVENTIONS AT ALL VISITS

I-1 Screening for Hypertensive Disorders of Pregnancy — Weeks: All

BACKGROUND

Hypertension in pregnancy can be defined as either a diastolic pressure ≥90 mmHg or systolic pressure ≥140 mmHg recorded on two separate occasions more than six hours apart, at any time during the gestation. Hypertension detected at a gestational age of <20 weeks 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 ≥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 monitoring and care outside of the scope of this guideline.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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.
2. Women diagnosed with hypertension during pregnancy should exit the Uncomplicated Pregnancy Guideline.
3. Korotkoff 5 sound (disappearance of sound) will be used to determine the diastolic pressure.

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 accurately differentiate 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).

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. Healthcare providers are referred to appropriate documents for further descriptions and discussion (USPSTF, 1996; ACOG, 1996; NIH Working Group on High Blood Pressure in Pregnancy, 2000). Also, see VA/DoD guidelines for Hypertension in Primary Care.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine blood pressure screening at each prenatal visit.	NIH Working Group on High Blood Pressure in Pregnancy, 2000 USPSTF, 1996 ACOG, 1996	III	Good	B
2	Women diagnosed with hypertension are excluded from the Uncomplicated Pregnancy Guideline.	NIH Working Group on High Blood Pressure in Pregnancy, 2000 ACOG, 1996 Cunningham & Lindheimer, 1992 Working Group Consensus	III	Good	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-2 Breastfeeding Education **Weeks: All**

BACKGROUND

Breastfeeding is the most nutritious form of feeding for 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 decrease in incidence of both ovarian (Gwinn et al., 1990) and breast cancers (Layde et al., 1989). Between 50 and 90 percent of expectant mothers decide how they will feed their children 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend offering breastfeeding education to all pregnant women at 10 to 12 weeks or the first visit with the provider.
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.
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.
4. Recommend including family/significant others in breastfeeding education.

DISCUSSION

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, as to engender a supportive environment for questioning. The BEST Start Program is one that focuses on asking the woman 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 breast-feeding. 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.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Breastfeeding inquiry.	Hartley & O'Connor, 1996	II-2	Fair	B
2	Breastfeeding education.	American Academy of Pediatrics, 1997 Hill & Humenick, 1993 Hill, 1991	III III II-3	Fair	B
3	Longitudinal breastfeeding education.	Berens, 2001	III	Fair	C
4	Family/significant other participation in breastfeeding education.	Berens, 2001 Humenick et al., 1997	III II-1	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-3 Exercise During Pregnancy — Weeks: All

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 (Clapp et al., 2000).

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

DISCUSSION

A meta-analysis by Lokey et al. (1991) combined results from 18 studies and showed that women who exercised during their pregnancies did not differ in any negative way from sedentary women for any of the measured outcome variables: maternal weight gain, infant birth weight, length of gestation, length of labor and Apgar score. Hatch et al. (1993) and Clapp et al. (2000) found that for low-risk women, maternal exercise enhanced fetoplacental growth and was not associated with adverse maternal or fetal outcomes. 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. Among both groups of women, there were no associated adverse maternal, fetal or neonatal effects and there were varying degrees of benefit.

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).

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., kick boxing, hockey, football, sky diving, soccer, and horseback riding) should be avoided during pregnancy (Hammer et al., 2000).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Regular exercise for all pregnant women.	Campbell & Mottola, 2001 Clapp et al., 1999, 2000, 2001 Sternfeld et al., 1995 ACOG, 1994 Sady et al., 1989	I	Good	A
2	Individualized exercise programs, based on the woman's pre-pregnancy activity level.	Clapp et al., 1999 Sternfeld et al., 1995 ACOG, 1994	II-2	Good	B
3	High altitude, contact sports and scuba diving (not recommended).	Hammer et al., 2000 Camporsei, 1996 Alderman et al., 1995	II-2	Good	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

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. Immunization of pregnant women for influenza has been found to be safe for both the mother and the fetus.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend immunizing for influenza all pregnant women who will be in the second or third trimester during the epidemic season.

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, 1991). See the VHA/DoD Guideline for Preventive Indicators.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Influenza immunization.	ACOG, 1991 Englund et al., 1998	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

INTERVENTIONS
FIRST VISIT WITH NURSE [6-8 WEEKS]

I-5 Screening for Tobacco Use - Offer Cessation — Week: 6-8

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 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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.
2. If the screening is positive, cessation should be strongly recommended.
3. There is insufficient data to recommend for or against pharmacologic therapy for tobacco cessation in pregnancy.

DISCUSSION

No systematic reviews or RCTs were found that compared a complete strategy of screening and offering treatment for tobacco use compared to placebo. Two RCTs and two systematic reviews were identified.

A systematic review of smoking cessation interventions (Lumley et al., 2001) found that there was benefit to the interventions in terms of increased rates of smoking cessation in late pregnancy and decreased low birthweight. There were no significant findings regarding maternal morbidity or mortality or neonatal mortality or patient satisfaction. A recent RCT of nicotine replacement therapy showed no effect on cessation rates and was not powered to reassure clinicians regarding safety (Wisborg et al., 2000). Several studies demonstrate an underreporting rate for tobacco use between 10 and 24 percent in pregnancy, highlighting the need for screening. The sensitivity of questionnaire data for smoking status is overall "fair" (Boyd et al., 1998; Campbell, Sanson-Fisher et al., 2001; Jedrychowski et al., 1998; Kahrrazi et al., 1999).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for tobacco use.	Lumley et al., 2001 Dolan-Mullen et al., 1991	I	Good	A
2	Cessation of tobacco use.	Wisborg et al., 2000 Panjari et al., 1999 Dolan-Mullen et al., 1994	I	Good	A

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #5

I-6 Screening for Alcohol Use - Offer Cessation **Week: 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend routine screening for alcohol consumption using a standardized tool (refer to the VHA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders – Appendix A-1 for screening tools).
2. If the screening is positive, cessation should be strongly recommended.
3. There is insufficient evidence regarding which cessation intervention tool is the most effective.
4. A positive screening does not exclude the pregnant women from the Uncomplicated Pregnancy Guideline.

DISCUSSION

One evaluation of an overall screening and treatment study showed good identification of pregnant drinkers with the T-ACE Study, 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for evidence of problem drinking, using a standardized tool.	Handmaker et al., 1999 Chang et al., 1999 Reynolds et al., 1995	I	Fair	B
2	If the screening is positive, recommending cessation.	Handemaker et al., 1999 Chang et al., 1999 Reynolds et al., 1995	I	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #7.

I-7 Screening for Drug Abuse - Offer Treatment — Weeks: 6-8

BACKGROUND

As many as 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend routine screening for illicit drug use using a self-report method.
2. Recommend pregnant women identified as abusing drugs be offered treatment, as per the VHA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.
3. Pregnant women identified as abusing drugs are excluded from the Uncomplicated Pregnancy Guideline.

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. The best tests for detection of substance abuse are the Substance Abuse Subtle Screening Inventory and a modified CAGE questionnaire (Midanik et al., 1998).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine screening for illicit drug use.	Horrigan et al., 1996	II-2	Fair	B
2	If the screening is positive, offer treatment.	Howell et al., 1999	II-3	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-8 Screening for Domestic Abuse — Weeks: 8, 24, 32

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. However, 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). Healthcare providers need to be aware that a woman's decision to leave an abusive relationship may result in an escalation of violence.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend routine screening for domestic abuse at weeks 8, 24, and 32, using the following three simple/direct questions:
    - 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 have sexual activities?
2. There is insufficient evidence to recommend for or against specific interventions for identifying domestic abuse in pregnancy.
3. If the screening is positive, follow appropriate medical/legal mandates for reporting requirements for state/branch of service.

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 any consistent associations.

One non-randomized trial of poor quality found a decreased frequency and severity of violence at 6 and 12 months postpartum for women offered 3 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).

Three simple questions by a primary provider during a prenatal visit will detect abuse approximately as well 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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine screening during pregnancy for domestic abuse.	Gazmararian et al., 1996	II-2	Fair	B
2	Routine screening for domestic abuse with three simple/direct questions at weeks 8, 24, and 32.	McFarlane et al., 1992	II-2	Fair	B
3	Insufficient evidence for specific interventions for identifying domestic abuse in pregnancy.	McFarlane et al., 2000 Parker et al., 1999	III	Poor	I

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #9.

I-9 Screening for Rh Status — Weeks: 6-8

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 per 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend routine antibody screening for Rh status at the initial prenatal visit via indirect-antiglobulin (Coombs') testing.
2. Pregnant women with positive screens should be referred for consultation to assist with further management.
3. There is insufficient evidence to recommend for or against routine repeat testing at 28 weeks' gestation.

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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for Rh status.	Howard et al., 1998 Bowell et al., 1986	II-2	Fair	C
2	Repeat screening at 28 weeks (not recommended).	Working Group Consensus	III	Poor	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #13.

I-10 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 sixteen 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

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 (CDC, 1994). Approximately 20 percent of infants born to mothers infected with rubella during the first 3 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, 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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Serum screening for rubella status at the initial prenatal visit.	McElhaney et al., 1999	II-2	Fair	B
2	Counseling seronegative pregnant women to avoid exposure.	Working Group Consensus	III	Poor	B
3	Vaccinating seronegative pregnant women in the immediate postpartum period.	Horstman et al., 1985	II-2	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-11 Screening for Varicella — Weeks: 6-8

BACKGROUND

Varicella infection during pregnancy may lead to poor outcomes for both mother and fetus. The incidence of varicella in pregnancy is less than 1 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

DISCUSSION

A single systematic review was identified. The CDC 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. Also, varicella infections during pregnancy may result in higher rates of complications from the infection, such as varicella pneumonia and death (Smith et al., 1998).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine varicella screening.	Smith et al., 1998	I	Good	B
2	Postpartum varicella immunization in seronegative pregnant women.	CDC	I	Good	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-12 Screening for Hepatitis B — Weeks: 6-8

BACKGROUND

Each year in the United States an estimated 22,000 infants are born to women with chronic hepatitis B virus. The incidence of acute hepatitis B in pregnancy is 1 to 2/1,000 and the prevalence of chronic hepatitis B is 5 to 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). Perinatal transmission of hepatitis B virus occurs if the mother has an acute infection during late pregnancy or the early postpartum period or if the mother is a chronic hepatitis B antigen carrier.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend routine screening for hepatitis B surface antigen at the initial prenatal visit.
2. Consider rescreening all pregnant women with hepatitis risk factors identified during the pregnancy (e.g., IV drug use, exposure to hepatitis, STDs, new tattoos, and blood transfusion).

DISCUSSION

ACOG recommends universal screening of all pregnant women for hepatitis B early in pregnancy (ACOG, 1993).

ACOG recommends that infants of seropostive mothers receive hepatitis B immune globulin (HBIG) immediately after birth (ACOG, 1993). Perinatal transmission of hepatitis B virus occurs if the mother has an acute infection during late pregnancy or the early postpartum period or if the mother is a chronic hepatitis B

carrier (Levy & Koren, 1991). 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).

No alternative screening tests are recommended in the literature.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for hepatitis B at first prenatal visit.	ACOG, 1993	III	Fair	B
2	Rescreening pregnant women with risk factors for hepatitis.	Duff, 1998	III	Fair	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-13 Screening for Syphilis Rapid Plasma Reagin (RPR) Weeks: 6-8

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. Congenital syphilis can be prevented by screening for maternal syphilis, treating and tracking all confirmed cases.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend routine screening for syphilis using serologic testing (i.e., RPR or Venereal Disease Research Laboratory [VDRL]) at the initial prenatal visit.
2. Recommend confirmatory test using a more specific treponemal assay (FTA-ABS, MHA-TP, HATTS) for pregnant women who test positive.
3. Strongly recommend therapy with penicillin G antibiotic for pregnant women who have confirmed syphilis, as recommended by other STD guidelines.
4. Recommend appropriate medical/legal mandates follow-up and state/service branch reporting requirements for pregnant women screening positive.

DISCUSSION

Three cohort studies were identified. Strong association was identified 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine syphilis screening.	Donders et al., 1993 Dorfman & Glaser, 1990	II-3	Fair	B
2	Confirmatory syphilis testing in pregnant women with positive screens.	Hart, 1986	II-2	Fair	B
3	Treatment of confirmed positive.	CDC, 1998	II-2	Fair	A

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-14 Screening for Asymptomatic Bacteriuria (ASB) Weeks: 6-8

BACKGROUND

Bacteriuria occurs in 2 to 7 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Strongly recommend screening for ASB at initial obstetrical visit via urine culture and sensitivity.
2. There is insufficient evidence to recommend for or against repeat screening throughout the remainder of pregnancy.
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.
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.

DISCUSSION

There have been no reported trials comparing a screening and treating strategy versus a no screening strategy. Two to seven percent of pregnant women develop ASB; 80 percent of these women will be detected with a urine culture at their initial visit (USPSTF, 1995).

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 (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/or bacteriuria, and rapid enzymatic screening tests do not accurately detect ASB in pregnancy (Millar et al., 2000).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for ASB at the initial prenatal visit by urine culture.	Smaill, 2001 USPSTF, 1996 Romero et al., 1989	I	Good	A
2	Repeat screening throughout pregnancy.	Working Group Consensus	III	Poor	I
3	A three to seven day course of appropriate antibiotics based on positive culture and sensitivity, and woman's history of medication allergies.	Smaill, 2001	I	Good	A
4	TOC after completion of antibiotic therapy.	Working Group Consensus	III	Poor	I

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #18.

I-15 Screening for HIV – Counsel — Weeks: 6-8

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Strongly recommend routine testing at the initial prenatal visit.
2. Pregnant women who test positive for HIV should be referred for treatment and counseling.
3. Recommend retesting all high risk pregnant women during the early third trimester and offer repeat testing for patients who refused the first test.
4. Pregnant women identified with HIV are excluded from the Uncomplicated Pregnancy Guideline.

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 6 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine HIV screening.	CDC, 1995 AAP/ACOG, 1995	I	Good	A
2	Retest high risk women.	Tookey et al., 1998 Higgins, et al., 1991	II-2	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-16 Immunization - Td Booster (First Trimester) 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 vaccine is made up of bacterial toxins which 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Strongly recommend routine screening for Td booster status at the initial prenatal visit.
2. If there is no documentation of Td booster within the last ten years, Td booster should be provided. There are no contraindications other than a previous severe reaction to Td vaccination, such as anaphylaxis, generalized uriticaria or angioedema.
3. 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.

DISCUSSION

Effective antibody response is 95 to 100 percent in healthy adults after primary vaccination series. Immunity wanes over years and the precise duration of immunity is unknown for a specific individual, 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for Td booster status at the first prenatal visit.	USPSTF, 1996 ACOG, 1991	II-1	Good	A
2	If no documentation of Td booster within the last ten years, provide Td booster. There are no contraindications other than documented allergies to administration of Td during pregnancy.	ICSI, 2001 Fingar et al., 1998 USPSTF, 1996	II-1	Good	A
3	Pregnant women deemed unlikely to have received initial three dose vaccination (immigrants from under-developed countries) should receive an initial three dose series.	ICSI, 2001 Fingar et al., 1998 USPSTF, 1996	II-2	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-17 Immunization - Hepatitis B (First Trimester) Weeks: 6-8

BACKGROUND

Each year in the United States an estimated 22,000 infants are born to women with chronic hepatitis B virus. Infection with hepatitis B is associated with multiple sexual partners, presence of a sexually transmitted disease, personal or significant other's use of illicit drugs, household contact with hepatitis B, working in a health care field or public safety field, and working with patients who live in chronic residential facilities or who are on dialysis. Hepatitis B infection during pregnancy can lead to preterm labor and liver failure in the mother and perinatal transmission to the fetus. Pregnancy is not a contraindication to immunization with hepatitis B vaccine.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend immunizing for hepatitis B all pregnant women with high-risk factors predicting positive hepatitis B during pregnancy.

DISCUSSION

Four descriptive and cohort studies were identified. The use of high risk factors to predict hepatitis B positive patients is variable. In one study 10 of 11 hepatitis B surface antigen positive women had historical risk factors (Kuller et al., 1991). In a pilot voluntary screening test at a large urban center only 8 of 20 hepatitis B surface antigen positive women had recognized risk factors (Cozen et al., 1993). Several studies show very low prevalence rates of hepatitis B in rural and private settings (Murnane et al., 1992). Maternal and fetal safety has been reported in one cohort study (Levy & Koran, 1991).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Hepatitis B immunization.	CDC AAP/ACOG	II-3	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

INTERVENTIONS
FIRST VISIT WITH PROVIDER [10-12 WEEKS]

I-18 Assessing Weight Gain (Inappropriate) Weeks: All

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 retardation, and low birth weight. Screening for inappropriate weight gain allows for early intervention to prevent these complications.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend assessing and documenting body mass index (BMI) of all pregnant women at the initial visit.
2. Pregnant women found to have a BMI <20 should be referred for nutrition counseling and considered at increased risk for fetal growth restriction.
3. Recommend screening for inappropriate weight gain for all women at every visit during pregnancy.
4. Pregnant women with inadequate weight gain at 28 weeks who are unresponsive to nutritional treatment exit the Uncomplicated Pregnancy Guideline.

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 have been based on the prepregnancy BMI. Women with a BMI below 19.8 kg per m^2 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 per m^2 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 per m^2) 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 per m^2) are advised to gain at least 6.8 kg (15 lb) (IOM, 1990). A recent prospective study found that maternal nutrition in industrialized populations seems to have no significant effect on placental and birth weights, but it did not look specifically at weight gain as a variable (Matthews et al., 1999).

Maternal BMI under 20 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.

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 increased the risk of antepartum stillbirth, especially term antepartum stillbirth, whereas weight gain during pregnancy was not associated with risk (Stephansson et al., 2001).

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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine assessment of BMI at first visit.	Sebire et al., 2001	II-2	Fair	B
2	Nutrition counseling for inadequate weight gain or initial BMI <20.	Kramer, 2000 Sebire et al., 2001	II-2	Fair	B
3	Routine screen for inappropriate weight gain.	Kelly et al., 1997	III	Fair	C
3 4	The practical evaluation period of 24 to 28 weeks.	Kelly et al., 1997	II-2	Fair	C
5	Individualized weight gain.	IOM, 1990	III	Fair	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-19 Auscultation Fetal Heart Tones — Weeks: 10-12

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Auscultation of fetal heart tones.	Engstrom, 1985 Jimenez et al.,1983 Working Group Consensus	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-20 Screening Fundal Height — Weeks: All

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

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 3 centimeters; any difference greater than 3 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Fundal height measurement at 20 to 36 weeks.	Engstrom & Work, 1992 Lindard, et al., 1990 Mathai et al., 1987 Pearce & Campbell, 1987 Wise & Engstrom, 1985 Jimenez et al., 1983 Calvert et al., 1982 Quaranta et al., 1981	I	Good	B
2	Fundal height measurement after 36 weeks.	Working Group Consensus	III	Poor	I

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-21 Screening for Gonorrhea — Weeks: 10-12

BACKGROUND

The CDC (1998) reports that there are approximately 1 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend screening for gonorrhea in all pregnant women.
2. Pregnant women with positive cultures should be treated with ceftriaxone, per CDC guidelines.
3. Pregnant women with positive screens for gonorrhea should be screened for other STDs.
4. Recommend performing a 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.
5. Recommend counseling to decrease rate of reinfection.
6. Recommend referring partner for testing and treatment, as appropriate. Pregnant women must abstain from intercourse pending TOC.

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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine gonorrheal screening during pregnancy.	CDC, 1998	II-2	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-22 Screening for Chlamydia — Weeks: 10-12

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 5 and 15 percent. The morbidity and mortality rates for pregnant and nonpregnant women are equal.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend screening all pregnant women for chlamydia trachomatis at the initial physical examination.
2. Pregnant women with positive cultures should be treated with azithromycin or erythromycin, per CDC guidelines.
3. Pregnant women with positive screens for chlamydia should be screened for other STDs.
4. Recommend performing a 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.
5. Recommend counseling to decrease rate of reinfection.
6. Recommend referring partner for testing and treatment, as appropriate. Pregnant women must abstain from intercourse pending TOC.

DISCUSSION

The CDC reports that there are about 4 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 2 to 37 percent (Hammerschlag et al., 1979; Leu, 1991).

Chlamydia is the presumed cause of 25 to 50 percent of the 2.5 million 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 postabortal 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, 2000).

Early detection and treatment of chlamydial 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 chlamydial infections. High rates of reinfection emphasize the need for measures to prevent future infection (Vuylsteke et al., 1993).

High-risk profiles for asymptomatic chlamydial 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 chlamydial infection (Stergachis et al., 1993).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine screening for chlamydia trachomatis at initial physical examination.	Hammerschlag et al., 1979	II-2	Fair	B
2	Treatment per CDC guidelines for positive cultures.	Blackwell et al., 1993	II-2	Fair	A
3	Screening for other STDs, if chlamydia screen is positive.	Vuylsteke et al., 1993	II-2	Fair	B
4	TOC after completion of antibiotic therapy.	Working Group Consensus	III	Poor	C
5	Counseling to prevent reinfection.	Vuylsteke et al., 1993	II-2	Fair	C
6	Report per Public Health guidelines and requirements.	Working Group Consensus	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-23 Screening for Cervical Cancer — Weeks: 10-12

BACKGROUND

Population-based studies have shown that early detection of cervical neoplasia through Pap (cervical) smear testing may provide an opportunity to prevent or delay progression to invasive cancer. In spite of this history of success, the incidence of invasive cervical cancer in Caucasian women under 35 is increasing, suggesting a need for continued vigilance. Prenatal visits during pregnancy provide an opportunity to test reproductive aged women who may have missed earlier opportunities for screening.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend screening all pregnant women for cervical cancer at the first prenatal visit, or as early in pregnancy as possible.
2. Recommend performing cervical screening in pregnancy with a brush sampler and spatula.
3. Recommend women with abnormal cervical smears during pregnancy be managed based on local algorithms, which may include repeat testing, observation or colposcopy.

DISCUSSION

Cervical dysplasia rates in pregnancy are equivalent to those found in non-pregnant women (Lurain & Gallop, 1979).

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. Colposcopy during pregnancy is beyond the scope of this guideline.

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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening cervical smear in pregnancy.	Lurain & Gallop, 1979	II-2	Good	B
2	Method of cervical smears.	Hoffman et al., 1991 Koonings et al., 1992	I	Good	A
3	Management of abnormal cervical smears.	LaPolla et al., 1988	III	Fair	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-24 Counseling For Cystic Fibrosis Screening — Weeks: 10-12

BACKGROUND

Cystic fibrosis (CF) is the most common autosomal recessive genetic disease among Caucasians, with a frequency of 1/3,300 (ACOG, 2001). It also affects other races, though at significantly lower rates. Affected individuals experience substantial morbidity and early death, and require lifelong medical care as a result of their disease. Although there is currently no gene therapy available to treat CF, some couples wish to know if their child will be affected, and subsequently choose to terminate the pregnancy.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend educating all pregnant women using a CF carrier-screening brochure about a possible risk of CF.
2. Recommend offering CF screening to all pregnant women who desire it.
3. Recommend referring all pregnant women with a family history of CF for genetic counseling.
4. For couples who desire screening at <18 weeks' gestation, only one partner should be initially screened; if the screening is positive then the other partner should be screened.
5. For couples who desire screening at >18 weeks' gestation, both partners should be screened simultaneously. This reduces the increased time frame of sequential screenings and provides couples wishing to terminate the pregnancy faster access to the screening results.

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 NIH. There is currently no literature to show positive or negative outcomes from this intervention. The patient education carrier-screening brochure describes the frequency of the carrier state of CF as 1/29 for Caucasians. The detection rate of the test is 80 percent, using the core panel of 25 mutations. Currently, there is a lack of available gene therapy. CF carrier frequency is much less in Asian Americans (1/90), in African Americans (1/65), and in Hispanic Americans (1/46) (ACOG, 2001). These materials explain the relative risks for carrying CF, screening options, and subsequent options, should a couple learn that they carry the CF gene.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Educate all pregnant women with a CF carrier-screening brochure about a possible risk of CF.	ACOG, 2001	III	Poor	I
2	Offer CF screening to all pregnant women who desire it.	ACOG, 2001	III	Poor	I
3	Offer formal genetic counseling to all pregnant women with a family history of CF.	ACOG, 2001	III	Poor	I

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

INTERVENTIONS
WEEKS: 16-27

I-25 Maternal Serum Analyte Screening — Weeks: 15-20

BACKGROUND

Maternal serum analyte screening with multiple serum markers (e.g., alphafetoprotein, human chorionic gonodatropin [HCG], and unconjugated estriol) 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).

ONTDs occur in 1 to 2/1,000 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 1 infants/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 specific fetal aneuploid conditions commonly detected through maternal serum analyte screening include Down Syndrome (trisomy 21) or Edward's Syndrome (trisomy 18). Sex chromosome abnormalities or other aneuploid conditions are less reliably detected.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend offering multiple marker maternal serum analyte screening to all pregnant women at gestational ages between 15 and 20 weeks. The ideal screening period is 15 to 18 weeks in order to maximize test accuracy and allow time for adequate follow-up counseling and testing.
2. Recommend providing pre-test patient education and counseling to ensure that women understand screening test limitations and false-positive rates, as well as the need for subsequent diagnostic tests for screen-positive women.
3. If the screening is positive, targeted ultrasound examinations can be used for risk modification and counseling prior to making the decision for invasive testing.
4. Pregnant women with persistent unexplained elevations of maternal serum alphafetoprotein (MSAFP) are at increased risk for adverse perinatal outcome and should exit the Uncomplicated Pregnancy Guideline.

DISCUSSION

Analysis of maternal serum samples in the early second trimester has been demonstrated to be a useful method of screening pregnant women for various adverse fetal conditions. Currently, the use of multiple serum markers, such as MSAFP, HCG, and unconjugated estriol is the most standard approach; however, some laboratories limit analysis to MSAFP and HCG, while others add inhibin A. The detection rate increases somewhat with additional markers; however, none of the regimens is vastly superior in clinical practice to recommend use of two, three, or four markers. Use of only MSAFP is inferior to the multiple marker screening for the detection of fetal aneuploidy; therefore, single analyte screening with MSAFP is not recommended. Due to variations in laboratory methods, values are generally reported as multiples of the median (MOM) for each specific lab and computerized programs are used to correct for various factors (e.g., age, weight, and ethnicity).

In a low-risk population of pregnant women, abnormal screening values are generally accepted as a MSAFP ≥2.5 MOM and a calculated mid-trimester risk for Down Syndrome of ≥1/270.

Maternal serum analyte screening should be considered a pure screening modality as there is a relatively high false-positive rate (i.e., 5 to 7 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 is 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 testing (amniocentesis) 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 aged less than 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 with an age of 35 or more 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 alphafetoprotein (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 exit the Uncomplicated Pregnancy Guideline.

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 uncongugated estriol ("triple screen") increases detection to 56 to 75percent 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 (0.2 to 1.3 percent).

Edward's Syndrome (trisomy 18) occurs in approximately 1/5,000 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. 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 triple screen is a cost effective alternative to routine amniocentesis. This alternative practice could make 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. Low-risk women can be counseled and educated by healthcare providers providing care within the scope of the Uncomplicated Pregnancy Guideline. Any pregnant women determined to have a fetus with a serious structural abnormality or fetal aneuploidy should receive specialized prenatal care and exit the Uncomplicated Pregnancy Guideline.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Offer multiple marker maternal serum analyte screening to all pregnant women at gestational ages between 15 and 20 weeks.	ACOG, 2001 Haddow et al., 1992	II-1	Good	B
2	Provide pre-test patient education and counseling.	Nadel et al., 1990	II-2	Good	B
3	Women at high risk for fetal aneuploidy (age ≥35 at delivery or prior first child or fetus with aneuploidy) require genetic counseling.	Haddow et al.,1994	II-1	Good	B
4	Screen-positive women require targeted ultrasound examination for risk modification and counseling prior to decision for invasive testing.	Smith-Bindman et al., 2001	II-1	Good	B
5	Women with persistent unexplained elevations of maternal serum AFP are at increased risk for adverse prenatal outcome.	ACOG, 2001	II-1	Good	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-26 Routine Ultrasound **Weeks: 16-20**

BACKGROUND

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 women with complicated pregnancies. However, the routine use of this technology in uncomplicated pregnancies remains controversial.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend counseling and educating all pregnant women prior to scheduling sonographic study. Education will include information on potential benefits, limitations, and safety of prenatal ultrasound.

Documentation of education and counseling is recommended; however, written informed consent is not deemed necessary.

2. Recommend offering a complete obstetric sonographic examination between 16 and 20 weeks' gestation to all low-risk consenting pregnant women (see Appendix A-2: Standard for Performance of Antepartum Obstetrical Ultrasound Examination).
3. Strongly recommend all complete obstetric sonographic studies be performed and interpreted by qualified healthcare providers (see Appendix A-2: Standard for Performance of Antepartum Obstetrical Ultrasound Examination).

DISCUSSION

One meta-analysis of controlled trials of routine versus selective ultrasound evaluation before 24 weeks' gestation found 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) with routine screening, but 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 critized 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 at 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 between facilities and providers, but that all efforts should be made to have obstetric sonographic studies performed by experienced and skilled obstetric sonologists.

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).

The rate of "indicated" mid-trimester obstetric ultrasound examinations in most pregnant populations ranges from approximately 50 to 90 percent. Therefore, the impact of initiating a routine sonographic screening program is anticipated to have differing impacts on resource allocation at individual healthcare facilities.

A follow-up study of children at ages 8 to 9 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).

Perinatal ethicists have provided compelling arguments that the decision to undergo mid-trimester sonograms should be left to the woman out of respect for patient autonomy, which is similar to offering maternal serum analyte screening to low-risk women.

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 sonologists and physicians interpreting the images, and the use of routine mid-trimester sonography in conjunction with maternal serum analyte screening (Ecker & Frigoletto, 1999).

In light of the current controversy surrounding the routine use of mid-trimester sonography and the lack of recommendations for routine use by expert groups (ACOG 1997; American Institute of Ultrasound in Medicine [AIUM]), the following reasons are presented to support the Working Group's recommendation for offering routine mid-trimester sonographic screening to DoD/VA patients:

- 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).
- 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.
- Routine sonographic screening should be offered to pregnant women through an informed consent process, so that each individual patient is provided information regarding the safety, anticipated benefits (e.g., correction of incorrect gestational dating, detection of multiple gestations, and detection of some serious fetal anomalies), and potential for false-positive sonographic findings which may cause parental anxiety and result in the need for subsequent diagnostic testing. After being informed of these issues, each low-risk woman without an established indication for mid-trimester sonograms should be offered such a study.
- Accurate gestational dating improves the accuracy of maternal serum analyte screening.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Counsel and educate prior to scheduling sonographic study.	Chervanak & McCullough, 1992 Working Group Consensus	III	Fair	B
2	Complete obstetric sonographic examination for all low-risk women.	Society of Obstetricians and Gynaecologists of Canada [SOGC], 1999 Working Group Consensus	III	Fair	B
3	Complete obstetric sonographic studies performed and interpreted by qualified healthcare providers.	ACOG Practice Patterns, 1997 Crane et al., 1994 AIUM Guidelines	I	Good	A

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #28.

I-27 Counseling for Family Planning — Weeks: Start at Week 20

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

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 led to joint decisions being made and encouraged 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., 1999).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Antepartum counseling for family planning.	Pati & Cullins, 2000	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-28 Educate Regarding Preterm Labor — Week: 20

BACKGROUND

Preterm delivery, defined as delivery prior to 37 weeks' gestation occurs in approximately 11 percent of all pregnancies in the United States (Berkowitz & Papiernik, 1993) and the rate of preterm delivery has not declined appreciably over the last several decades, in spite of extensive and costly research initiatives. Preterm delivery is the primary cause of adverse perinatal outcomes, accounting for approximately 75 percent of perinatal deaths in the U.S. While it is apparent that there are multiple pathways to delivery of a preterm infant, the primary cascade of events leading to the majority of preterm deliveries remains somewhat enigmatic and is referred to as idiopathic preterm labor and delivery. The likelihood that a specific patient will develop preterm labor has been subjected to risk assessment and profiling, so that preventive or early treatment efforts may be explored. Accordingly, early efforts at lowering the preterm delivery rate focused primarily on the use of risk factor profiling. Unfortunately, subsequent analysis of such risk profiles demonstrated that only approximately 50 percent of women who deliver prematurely have an identified risk factor. Furthermore, the majority of women with at least one risk factor deliver at term. Consequently, all pregnant women must be considered at

risk for preterm labor until they reach term. A maximum reduction in preterm deliveries requires a high state of vigilance by both patients and care providers.

An individual pregnant woman's risk for preterm labor and delivery can potentially span a wide spectrum and depends on a multitude of factors. Some of these factors are addressed in other portions of the Clinical Practice Guideline for the Management of Uncomplicated Pregnancy, such as domestic violence, smoking, bacterial vaginosis, malnutrition, and will not be expanded further in this section. However, even in the absence of such factors, all pregnant women remain at risk for preterm labor and delivery; thus, interventions directed at reducing preterm labor and delivery employed in the guideline will be as follows:

- Screen every pregnant woman for clinically substantive risk factors that are anticipated to result in a sufficiently high enough risk for preterm delivery to warrant care outside of the scope of the guideline (see Table 2). Essentially, pregnant women with any condition or risk factor that results in having at least a 10 percent or greater risk for preterm delivery will exit the Uncomplicated Pregnancy Guideline.

- Educate each patient in the mid portion of the second trimester about early symptoms of preterm labor and appropriate responses if she experiences any of these symptoms.

- Inquire about the presence of clinical signs or symptoms of preterm labor at each visit between 20 and 36 weeks' gestation. Initiate appropriate evaluation and intervention for any positive responses.

This specific intervention will focus on screening patients for clinically significant risk factors for preterm labor, providing the initial patient education of early symptoms of preterm labor, and instructing the pregnant woman in the appropriate response if she experiences any of symptoms suggestive of preterm labor.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Pregnant women will be screened for factors that would result in a 10 percent or greater risk of preterm delivery and, if present, will be excluded from further care in the Uncomplicated Pregnancy Guideline. Risk factors that would place a patient at a > 10 percent risk of preterm delivery include the following:

    - Prior spontaneous preterm delivery (following preterm labor or preterm premature rupture of membranes)
    - History of cervical incompetence
    - Tobacco abuse and poor nutrition (i.e., BMI <18)

2. Pregnant women will be educated about the most common symptoms of preterm labor:

    - Low, dull backache
    - 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"
        - Abdominal cramping (may be associated with diarrhea)
        - Increased uterine activity compared to previous patterns.
    - Increased pelvic pressure (may be associated with thigh cramps)
    - Change in vaginal discharge such as change in color of mucus, leaking of clear fluid, spotting or bleeding
    - Vaginal discharge associated with itching or fish-like odor immediately after intercourse
    - General sensation that "something feels different" (e.g., agitation, flu-like syndrome, and sensation that baby has "dropped")

3. If the pregnant woman experiences any of the above symptoms or is unsure about the presence of any of the above, she should lie down on her side with one of her hands on her lower abdomen to palpate for

uterine contractions 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.

4. Educate 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 successful prolongation of the pregnancy and the probability of a healthy infant.

DISCUSSION

Efforts to reduce the rate of preterm births over the past several decades (which have been largely unsuccessful) have evolved from patient categorization based on scoring and weighting of risk factors towards education and intervention of identified risk factors or early signs and symptoms of preterm labor. Most identified risk factors for preterm labor in a healthy woman with a singleton gestation only modestly increase the risk for preterm delivery. Of the women who deliver prematurely, only 50 percent have an identified risk factor. The strongest risk factor for preterm delivery is a history of prior preterm delivery; however, this group of patients makes up a minority of women delivering prematurely. While intervention trials involving education and modified antenatal care have had heterogeneous results, it appears that education and intervention for women with risk factors may modestly reduce the risk for preterm delivery (Katz et al., 1990; Morrison, 1990; Herron et al., 1982; St Pierre et al., 1996). The intervention with the greatest proven impact on improving perinatal outcome with regards to prematurity is early diagnosis and treatment with tocolytics and corticosteroids for appropriate pregnant women. Parenteral corticosteroids have been shown to markedly reduce perinatal mortality and morbidity in the infant delivered between 24 and 34 weeks' gestation; however, to attain the maximal benefit the corticosteroids must be administered at least 48 hours prior to delivery, again emphasizing the importance of vigilant surveillance with early diagnosis and treatment of preterm labor.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Educate about the common symptoms of preterm labor.	Katz et al., 1990 Morrison, 1990 Ross et al., 1986 Herron et al., 1982	II-2	Good	A
2	Screen for risk factors for preterm delivery.	Lockwood &Kuczynski, 1999 Knox et al., 1993 Holbrook et al. 1989 Ross et al., 1986	II-2	Fair	B
3	Perform intensive self-assessment if unsure about the presence of preterm labors symptoms prior to self-referral.	Working Group Consensus	III	Poor	I
4	Educate the pregnant woman that she is a vital link in the early detection and treatment of preterm labor.	Katz et al., 1990 Herrron et al., 1982	II-2	Good	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

While the majority of women will have been previously screened during the first trimester for the risk factors cited in Table 2 and excluded from the Uncomplicated Pregnancy Guideline as appropriate, a repeat screening at approximately 20 weeks is recommended. Risk factors which do not require exclusion from the guideline

should be noted and listed in the Problem List so that subsequent providers may offer appropriate follow-up and surveillance. Women with a risk factor deemed to place them at moderate risk for preterm labor and delivery, yet remain within the Uncomplicated Pregnancy Guideline, should receive enhanced education regarding early detection and intervention of preterm labor.

Table 2: Risk Factors for Preterm Delivery

Risk Factor	Relative Increase in Risk for PTD*	Reference	Exclude from Uncomplicated Pregnancy Guideline
Age <17 or >35	Low	Wen et al., 1990	No
African American race	High	Wen et al., 1990	No
Prior spontaneous preterm delivery	High	Iams et al., 1998	Yes
Vaginal bleeding in more than one trimester	Moderate	Strobino & Pantel-Silverman, 1989	Yes[▽]
Stressful job or more than 3 hours working on feet per 8-hour work day	Low	Mourkewich et al., 2000 Luke et al., 1995 Teitelman et al., 1990	No (attempt to modify work environment/demands)
Smoking	Moderate	Kramer, 1987 Cnattingius et al., 1999	No (see Smoking Intervention)
Cervical surgery (Cone, Loop Electrosurgical Excisional Procedure [LEEP])	Low	Kramer, 1987	No
Poor nutrition or low pre-pregnancy weight (BMI <18)	Moderate	Buescher et al., 1993 Kramer, 1993 Higgins et al., 1989	No
Multiple first trimester abortions	Low	Lettieri et al., 1993	No
Mullerian Anomaly	High	Lettieri et al., 1993	Yes
Abdominal surgery between 20 and 36 weeks' gestation	High	Dudley & Cruikshank, 1990 Coleman et al., 1997	Yes
Cocaine or methamphetamine use	High	St. Pierre et al., 1996	Yes
Single parent	Low	Lettieri et al., 1993	No
Placenta previa persisting after 24 weeks	High	Lettieri et al., 1993	Yes
Lower genital tract infection at 24 weeks' gestation (Gonoccus, chlamydia, Bacterial Vaginosis)[‡]	Low (if treated appropriately)	Andrews et al., 2000 Goldenberg et al., 2000 Hauth et al., 1995	No
Cervical dilation ≥2cm at 24 - 28 weeks' gestation[‡]	High	Papernik et al., 1986 Stubbs et al.,1986 Copper et al., 1995	Yes (symptomatic patient)
Soft consistency of the cervix and nulliparous woman at 24 - 28 weeks[‡]	High	Copper et al., 1995	Yes
Signs/symptoms as listed in Recommendation #2	Moderate	Iams et al., 1990 Kragt, 1990 Kramer, 1987	No

** Increase in Relative Risks (RR): Low = 1.0 – 1.99; Moderate = 2.0 – 2.99; and High = ≥3.0*

[‡] 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 as listed in Recommendation #2.

While vaginal bleeding in more then 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.

Reinforce Education of Patient About Preterm Labor Risk **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. Potential etiologies for these delays include denial, naïveté, receiving misinformation from others, or ignorance.

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. There is no solid medical evidence base suggesting that there is an effective medical intervention that "cures" preterm labor; however, there is an evidence base for the ability to delay preterm delivery for several days in women destined to deliver prematurely. While in itself, a few extra days in-utero has no clinically significant positive impact on perinatal outcome, when those few extra days are used to administer parenteral corticosteroids to the fetus (via the mother) in appropriate clinical situations, dramatic improvements in the perinatal outcome are realized. Therefore, a critical component of optimizing perinatal outcomes in preterm infants is early recognition and intervention of women with preterm labor. Towards this end, comprehensive patient education is the key element in maintaining the balance between vigilant surveillance and timely reporting of potential early symptoms of preterm labor and the maintenance of a normal lifestyle.

This specific intervention will focus on enhancing the pregnant woman's awareness of early symptoms of preterm labor and her appropriate response if she experiences such symptoms, as well as reinforcing the elements of her normal lifestyle that she can continue to enjoy and experience as long as her pregnancy remains uncomplicated.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Pregnant women will be educated about the most common symptoms of preterm labor:
    - Low, dull backache
    - 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"
        - Abdominal cramping (may be associated with diarrhea)
        - Increased uterine activity compared to previous patterns
    - Increased pelvic pressure (may be associated with thigh cramps)
    - Change in vaginal discharge, such as change in color of mucus, leaking of clear fluid, spotting or bleeding
    - Vaginal discharge associated with itching or fish-like odor immediately after intercourse
    - General sensation that "something feels different" (e.g., agitation, flu-like syndrome, and sensation that baby has "dropped")
2. If the pregnant woman experiences any of the above symptoms or is unsure about the presence of any of the above, she 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 4 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. 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 as long 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 be told to limit her activity to no more than two hours per session.
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, such as a nurse, they should limit their work week to 40 hours and workday to 8 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 3 hours.
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

The providers and pregnant woman will need to maintain an on-going dialogue regarding the potential early symptoms of preterm labor as well as the ability of the woman to maintain a normal lifestyle as long as her pregnancy remains uncomplicated.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Educate about the common symptoms of preterm labor.	Katz et al., 1990 Morrison, 1990 Ross et al., 1986 Herron et al., 1982	II-2	Good	A
2	Perform intensive self-assessment if unsure about the presence of preterm labors symptoms prior to self-referral.	Working Group Consensus	III	Poor	I
3	Educate the pregnant woman that she is a vital link in the early detection and treatment of preterm labor.	Katz et al., 1990 Herron et al., 1982	II-2	Good	B
4	A regular, moderate exercise program does not increase the risk for preterm labor.	See Intervention I-3 “Exercise During Pregnancy”	II-1	Good	B
5	Physically demanding labor/work and prolonged standing increase risk for preterm birth, hypertension and preeclampsia.	Mozurkewich et al., 2000 Gabbe & Turner, 1997 AAP/ACOG, 1997 Luke et al., 1995 Teitelman et al., 1990	II-2	Good	B
6	Coitus is not associated with an increased risk for preterm labor.	Read & Klebanoff, 1993	II-2	Good	A

INTERVENTIONS
WEEKS: 28-37

I-29 Assess for Preterm Labor — Weeks: 28 -34

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' gestations. 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 that will remove the patient from care within the Uncomplicated Pregnancy Guideline.
- Provide patient education regarding early clinical signs and symptoms of preterm labor and appropriate responses.
- Inquire about the presence of clinical signs or symptoms of preterm labor at each visit between 24 and 36 weeks' gestation.

This specific intervention will focus on patient education of early symptoms of preterm labor and her appropriate response.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. All pregnant women at risk for preterm labor at week 28 will be asked if they have experienced any of the following symptoms since the previous visit:
    - Low, dull backache
    - Menstrual-like cramps or sensation the "baby is rolling up in a ball"
    - Increased pelvic pressure (may be with thigh cramps)
    - Abdominal cramping (may be associated with diarrhea)
    - Increased uterine activity compared to previous patterns (more than 4 contractions per hour)
    - Change in vaginal discharge such as change in color of mucus, leaking of clear fluid, spotting or bleeding
    - Sensation that "something feels different" (e.g., agitation, flu-like syndrome, and sensation that baby has "dropped")
2. If the pregnant woman experiences any of the above symptoms or is unsure about the presence of any of the above, she 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 4 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 hetererogenous results in prospective trials, there are no obvious harmful effects and such efforts are anticipated to foster provider-patient relationship and empower the pregnant woman with a positive sense of active promotion of her baby's health.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Educate the pregnant woman that she is a vital link in the early detection and treatment of preterm labor.	Katz et al., 1990 Herrron et al., 1982	II-2	Good	B
2	Perform intensive self-assessment if unsure about the presence of preterm labors symptoms prior to self-referral.	Working Group Consensus	III	Poor	I

I-30 Daily Fetal Movement Counts — Weeks: 28 - 37

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend instructing all pregnant women about the importance of assessing fetal movement on a daily basis beginning in the third trimester.
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 health care facility.

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; Sadofsky & Yaffe, 1973; Pearson & Weaver, 1976; Neldam, 1980).

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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Instruct all pregnant women to assess fetal movement on a daily basis beginning in the third trimester.	Moore & Piacquadio, 1989 Neldam, 1980	II-1	Good	B
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 health care facility.	Moore & Piacquadio, 1989 Neldam, 1980 Pearson & Weaver, 1976 Sadofsky & Yaffe, 1973	II-1	Good	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-31 Screening for Gestational Diabetes — Week: 28

BACKGROUND

Routine screening of all pregnant women for 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 receive specialized prenatal care, which falls outside the scope of the Uncomplicated Pregnancy Guideline.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend screening all pregnant women for GDM at 24 to 28 weeks' gestation.
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 3-hour GTT.
3. In the 3-hour GTT a 100 gram-glucose load is administered to a woman who has fasted overnight (minimum 8 hours). Blood draws are performed fasting and at 1, 2 and 3 hours after the oral glucose load.
4. Two acceptable sets of threshold values for the 3-hour 100 gram GTT that 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. Pregnant women diagnosed with gestational diabetes using these criteria will exit the Uncomplicated Pregnancy Guideline.

5. As impairment of glucose metabolism is a spectrum, pregnant women with just one abnormal value on the 3-hour GTT should exit the Uncomplicated Pregnancy Guideline and be managed using one of the following methods:
    - Undergo a repeat 3-hour 100 gram glucose challenge test approximately one month following the initial test.
    - Have dietary management and intermittent postprandial glucose testing performed in a manner similar to women with gestational diabetes.
    - Pregnant women with a repeat GTT test that shows normal value may reenter the Uncomplicated Pregnancy Guideline.

DISCUSSION

GDM is defined as marked impairment of glucose metabolism first identified in pregnancy. Incidence is usually quoted as 2 to 3 percent, with a range of .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 (Stephenson, 1993; Garner et al., 1997). 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 1-hour screen, but a normal 3-hour diagnostic test early in pregnancy, should undergo repeat testing with the 3-hour GTT at 24 to 28 weeks' gestation. Additionally, women with a normal 1-hour screen early in pregnancy should also undergo repeat screening with a 1-hour 50 gram GTT at 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 1-hour screen used to select the subpopulation of women for the diagnostic 3-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 3-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 3-hour GTT. The threshold values for identifying women to undergo the 3-hour diagnostic test should be decided upon after careful review of internal pregnancy outcome information, population demographics and clinic resources. Pregnant women who have a 1-hour GTT result ≥200mg/dL have sufficient glucose impairment to be considered indicative of gestational diabetes without further diagnostic testing by a 3-hour GTT and should immediately begin appropriate treatment and monitoring, in lieu of undergoing diagnostic testing with the 3-hour GTT.

There are two acceptable sets of threshold values for the 3-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 vales 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. Recently, 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 1 to 3 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 3-hour GTT approximately one month later, or initiating dietary modification and glucose monitoring similar to women with established GDM.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Perform a routine screening for GDM at 28 weeks with a random 1-hour 50 gram glucose challenge test.	Griffen et al., 2000 Danilenko-Dixon et al., 1999 Williams et al., 1999	II-2	Fair	B
2	Early screening of selected pregnant women with risk factors for GDM.	Working Group Consensus	III	Poor	I
3	Method of screening is a random 1-hour 50 gram glucose challenge.	ACOG, 2001 Naylor et al., 1997	II-1 II-3	Good	A
4	All pregnant women with a 1-hour positive test require a 3-hour GTT.	ACOG, 2001	III	Fair	B
5	Acceptable sets of threshold values for the 3-hour 100 gram glucose challenge.	ACOG, 2001 Data from Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2000	II-3 II-3	Fair	B
6	One abnormal value on a 3-hour GTT requires dietary management and glucose monitoring, or a repeat 3-hour GTT approximately one month after the initial test.	ACOG, 2001 Lindsay et al., 1989 Langer et al., 1987	III II-2 II-2	Fair	C
7	One abnormal value on a 3-hour GTT requires care outside of the scope of the Uncomplicated Pregnancy Guideline.	Working Group Consensus	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-32 Iron Supplementation — Week: 28

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 can not be met by diet alone. Maternal anemia may affect oxygen delivery to the fetus resulting in abnormal growth and development. Anemia may also increase symptoms of fatigue in the mother.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. There is insufficient evidence to recommend for or against routinely supplementing iron for all pregnant women who are not anemic. Women exhibiting signs or symptoms of anemia at any time during their pregnancy should be evaluated upon presentation.

2. Recommend supplementing with at least 50 mg elemental iron (325 mg ferrous sulfate) twice-a-day (bid) in all pregnant women diagnosed with anemia (hematocrit <30). Diagnosis of anemia may vary with smoking status and altitude. Clinical correlation with local laboratory is advised.

DISCUSSION

A large RCT of selective versus routine iron supplementation demonstrated benefits and harms from the selective approach, but found no clear-cut clinical benefits from routine iron supplementation in pregnancy (Hemminki & Rimpela, 1991).

More recently published trials confirm the improvements in hematological status but did not evaluate other clinical outcomes (O'Brien et al., 1999; Milman et al., 2000).

A Cochrane systematic review found no evidence to recommend for or against routine iron supplementation (Mahomed, 2001).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine iron supplementation.	Mohamed, 2001	II-3	Fair	I
2	Selective iron supplementation.	Hemminki & Rimpela, 1991	I	Good	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #52.

I-33 Anti-D Prophylaxis for Rh-Negative Pregnant Women — Week: 28

BACKGROUND

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 per 1,000 live births.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend administering anti-D prophylaxis to all unsensitized D-negative pregnant women.
2. 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.

DISCUSSION

The term "isoimmunization" refers to the detection of maternal antibodies to the Rhesus D antigen determined from delivery to 12 months after the end of the pregnancy studied.

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.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Anti-D prophylaxis for unsensitized D-negative pregnant women.	Crowther,2001 Urbaniak, 1998	I	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #58.

I-34 Screening for Group B Streptococcus (GBS) Week: 36

BACKGROUND

In the absence of a preventive strategy, 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) has been proven to decrease the incidence of early-onset GBS infections of the newborn.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend screening all pregnant women for GBS at 35 to 37 weeks' gestation, using a rectovaginal culture and selective broth media to identify colonized women.
2. Pregnant women with positive rectovaginal cultures should be treated with intrapartum IV chemoprophylaxis with either Penicillin or Ampicillin (if no contraindications) **[(a)].**
3. 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)] 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:

- *Administer vancomycin 2 gm IV load, followed by 1 gm IV every 12 hours, for immediate hypersensitivity reaction (anaphylaxis, dyspnea, rapid onset of urticarial rash).*
- *Administer cefazolin 2gm IV load, followed by 1 gm IV every 8 hours, for allergic reaction other than immediate hypersensitivity.*

DISCUSSION

Consensus guidelines recommending two alternative approaches for the prevention of the early-onset GBS infections were issued by the Centers for Disease Control (1996) and subsequently endorsed by the American College of Obstetricians and Gynecologists, American Academy of Pediatrics, and American Academy of Family Practice. Subsequently, surveillance data obtained by the CDC and a review of cohort studies has demonstrated that the screening-based approach is more effective in reducing neonatal infections than the alternative risk-factor based approach. It is therefore recommended that each health care institution utilize the screening-based approach.

Administration of intrapartum antibiotics to women colonized with GBS leads to large and significant reductions in early onset neonatal sepsis with GBS (NNT =20; 95 percent confidence interval 13 to 40) (Smaill, 2001).

A risk-factor based strategy leads to treatment of fewer mothers and lower costs than a screening strategy, but also prevents fewer cases of neonatal GBS sepsis. Both strategies are less expensive and more effective than a strategy based on testing at 28 weeks' gestation (Benitz et al., 1999; Mohle-Boetani et al., 1999; Rouse, 1994).

- Culture-based versus risk-factor based preventive strategies: The ideal prevention strategy remains somewhat controversial and may vary between institutions and patient populations. Surveillance data from the CDC and multiple cohort studies have shown that the culture-based screening approach is more effective in preventing early-onset neonatal GBS infections. However, a culture-based approach exposes more women to antibiotics compared to a risk-factor based approach. This increased intrapartum antibiotic usage will likely increase the potential for adverse maternal reaction (anaphylaxis), and potential increase in non-GBS infections from resistant bacteria in newborns exposed to intrapartum antibiotics. This increase in non-GBS infections appears to be restricted to a few institutions and primarily in low-birth weight neonates who may also have been exposed to prolonged antibiotic agents used for purposes other than solely GBS prophylaxis. A risk-factor based approach appears to prevent fewer infections and may result in more frequent failure to treat women with indications due to provider error or failure to prevent infection due to late administration of antibiotic agents (Lin et al., 2001). Therefore, the consensus opinion of the Working Group was to recommend the culture-based approach.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Pregnant women will be screened for GBS at 35 to 37 weeks' gestation using a rectovaginal culture and selective broth media to identify colonized women.	Main, 2000 Main & Slagle, 2000 Locksmith, 1999 CDC, 1996 ACOG, 1996 Yancey et al., 1996	II-1	Good	B
2	Treat positive rectovaginal cultures with intrapartum IV chemoprophylaxis with either Penicillin or Ampicillin.	Smail, 2001 Main, 2000 Main & Slagle, 2000 Locksmith, 1999 Boyer, 1996 CDC, 1996 ACOG, 1996	I	Good	A
3	Women who have had a previous child with early-onset GBS infection or GBS bacteruria in the current pregnancy should	CDC, 1996 ACOG, 1996	II-1	Good	A

	Recommendations	Sources of Evidence	QE	Overall Quality	R
	receive intrapartum antibiotics, without screening cultures.				
4	Pregnant woman presenting in labor <37 weeks' gestation should receive intrapartum IV chemoprophylaxis.	Boyer, 1996 CDC, 1996 ACOG, 1996	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).	CDC, 1996 ACOG, 1996	II-1	Fair	B
6	Prophylactic antibiotics should be administered at least two hours prior to delivery, when possible [(b)].	Lin et al., 2001 De Cueto et al., 1998	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

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #43.

[(b)] 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 2 hours of maternal administration. Thus, withholding of IAP from women solely on the basis of anticipated admission-delivery interval should be discouraged.

I-35 Assessment of Fetal Presentation — Week: 36

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend screening for non-cephalic presentation for all patients at 36 weeks' gestation.
2. There is insufficient evidence to recommend for or against Leopolds versus cervical exam as the best screening method to determine fetal presentation.
3. Recommend ultrasound for confirmation, if non-cephalic presentation is suspected.
4. Recommend offering external cephalic version at 37 weeks or beyond, if non-cephalic presentation is confirmed and there are no contraindications. Exit the Uncomplicated Pregnancy Guideline.

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 affect 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 affect on maternal mortality (Hannah et al., 2000; Hofmeyer & Hannah, 2001).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for non-cephalic presentation at 36 weeks' gestation.	Hofmeyr, 2001a	II-2	Fair	B
2	Leopolds versus cervical exam for determining fetal presentation.	Lydon-Rochelle et al., 1993 Thorp et al., 1991	II-2	Fair	I
3	Ultrasound for presentation confirmation.	Thorp et al., 1991	II-2	Good	B
4	External cephalic version at 37 weeks or beyond, if there are no contraindications.	Hofmeyr & Kulier, 2001a & 2001b	I	Good	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

INTERVENTIONS
WEEKS: 38-41

I-36 Weekly Cervical Check (Stripping/sweeping) — 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend offering routine membrane stripping to all pregnant women every visit beginning at 38 weeks.

DISCUSSION

Membrane stripping lessens the incidence of post-dates pregnancies and the need for medical inductions (NNT of 11 and 7 respectively) (Boulvain et al., 1999 & 2001). 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). No "serious maternal morbidity/mortality," cesarean-sections, instrumental delivery rates, or maternal infection was found. Pregnant women in the stripping group were less likely to have a post-partum hemorrhage (NNT=19), although concern about applying this result is warranted (Boulvain et al., 1999 & 2001).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Membrane stripping at each visit beginning at 38 weeks.	Boulvain et al., 1999	I	Good	A

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #40.

I-37 Post-Dates Antenatal Fetal Testing — Week: 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 both have been topics of debate in the medical community.

RECOMMENDATIONS

The Working Group's recommendations for women in low risk pregnancy:

1. Strongly recommend antepartum fetal testing beginning at 41 weeks.
2. Testing should consist of weekly AFI (amniotic fluid index) and twice weekly NST (non-stress testing).
3. An AFI of less than 5 or a non-reactive NST should prompt further evaluation to determine the need for delivery. These women should exit the Uncomplicated Pregnancy Guideline.

DISCUSSION

Much debate has arisen concerning the appropriate timing and usefulness of antenatal testing. 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 utilized a twice-weekly NST and once weekly 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Antepartum fetal testing beginning at 41 weeks.	Rosen et al., 1995 Guidetti et al., 1989	I	Good	A
2	Antepartum testing should consist of weekly AFI and biweekly NST.	ACOG, 1999	III	Fair	B
3	Abnormal testing may indicate fetal compromise and should prompt further surveillance or delivery	Manning et al., 1993 Rutherford et al., 1987 Chamberlain, 1984	II-2 III II-2	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

INTERVENTIONS NOT RECOMMENDED IN PRENATAL CARE

I-38 Screening with Fetal Fibronectin

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 routine fetal fibronectine screening in all pregnant women.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against routine screening for preterm birth with fetal fibronectin test.

DISCUSSION

Several prospective cohort studies have shown no improvement in outcomes for either mother or baby (Faron et al., 1988; Leitech et al., 1999). 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.

No trials were found comparing a strategy of screening and intervening versus no screening for elevated fetal fibronectin in asymptomatic pregnant women to improve any outcomes. No studies (controlled trials or cohort studies) were found comparing interventions for pregnant women with elevated fetal fibronectin levels versus no interventions in affecting any outcomes.

Prospective studies have demonstrated that a single measurement of fetal fibronectin at 23-24 weeks in asymptomatic women is somewhat helpful in predicting preterm delivery when positive, but not helpful in excluding preterm delivery when it is negative (USPSTF, 1996). However, many pregnant women at low-risk for preterm delivery who have elevated fetal fibronectin levels will not deliver preterm. Serial testing is more sensitive but less specific at predicting preterm delivery than is testing only once (USPSTF, 1996).

Combining screening for fetal fibronectin with other screening modalities (such as ultrasonography for cervical length at 24 weeks or clinical preterm birth-risk scores) is more predictive of preterm delivery than only screening for fetal fibronectin (USPSTF, 1996).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine fetal fibronectin screening at 24 weeks estimated gestational age (EGA) for prevention of preterm labor (not recommended).	Revah et al., 1998 Goldenberg et al., 1996 Greenhagen et al., 1996 Hellemans et al., 1995 Lockwood et al., 1993	I	Good	D
		Leitech et al., 1999 Faron et al., 1988	II-2	Fair	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #30

I-39 Cervical Examination

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 support routine digital cervical examination for screening in all pregnant women.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against performing cervical examination to screen for preterm birth prevention in low risk asymptomatic pregnant women.

DISCUSSION

A large RCT of routine cervical examinations during pregnancy failed to show a statistically or clinically significant difference in rate 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 (1) versus six (6) in the experimental arm of the study.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine cervical examination at 28 weeks for prevention of preterm labor (not recommended).	Buekens et al., 1994	I	Good	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-40 Antenatal Pelvimetry

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against the use of antenatal pelvimetry (clinical or radiographic) in routine prenatal care.
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.

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 4 trials are summarized in a Cochrane review (Pattinson, 2001). The performance of x-ray pelvimetry may be harmful and is associated with significant increase in cesarean section rate (odds ratio=2.17) and radiographic exposure to the fetus (Parsons & Spellacy, 1985).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine clinical pelvimetry for estimation of adequacy for trial of labor (not recommended).	Pattinson, 2001	I	Fair	D
2	X-ray pelvimetry may be harmful (not recommended).	Pattinson, 2001	I	Fair	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #44.

I-41 Routine Urine Dipstick Test

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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).
2. Recommend the use of selective laboratory urinalysis for pregnant women with signs or symptoms of preeclampsia.

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 1-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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine urine dipstick testing (not recommended).	Kuo et al., 1992	II-2	Fair	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-42 Routine Edema Evaluation

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. The NIH consensus recommended, "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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against routine evaluation for edema in pregnancy

DISCUSSION

We found no articles 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). We found no data on 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, 2001) of several interventions for edema showed that rutoside (a flavinoid) 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 increased 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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine evaluation for edema in pregnancy (not recommended).	Young & Jewell, 2001 Kent et al., 1999 ACOG Technical Bulletin 219, 1996	II-1	Fair	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #46.

I-43 Screening for Cytomegalovirus (CMV)

BACKGROUND

Cytomegalovirus (CMV) is the most common congenitally acquired infection (0.2 to 2 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. The evidence is insufficient to recommend for or against routine screening for CMV.
2. Recommend counseling pregnant women about methods to prevent acquisition of CMV during pregnancy.

DISCUSSION

Primary CMV infections during pregnancy compose 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, health care 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).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine testing of pregnant women for CMV.	Working Group Consensus	III	Poor	I
2	Counseling of day care workers on good hand washing.	Working Group Consensus	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-44 Screening for Parvovirus

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against routine testing for parvovirus in pregnancy.

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 seriologic screening has no role in the prevention of parvovirus and the associated adverse outcomes (Guidozzi et al., 1994).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine testing for parvovirus (not recommended).	Guidozzi et al., 1994	II-3	Fair	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-45 Screening for Toxoplasmosis

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

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; Wong & Remington, 1994; Wallon et al., 1999).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine screening for toxoplasmosis (not recommended).	Wallon et al., 1999 Frenkel, 1995 Wong & Remington, 1994	I II-3 II-3	Fair	D
2	Educate about prevention.	Working Group Consensus	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-46 Screening for Bacterial Vaginosis

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

DISCUSSION

Three randomized control trials and two systematic reviews were identified. Evidence from these studies showed no improved pregnancy outcomes in asymptomatic, low-risk women screened for bacterial vaginosis (Carey et al., 2000; Kurkinen-Raty et al., 2000; Vermeulen & Bruinse, 1999). Pregnant women who are symptomatic or who have 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 with a seven day course of *oral* metronidazole (Brocklehurst et al., 2001; Guise et al., 2001). The treatment of asymptomatic bacterial vaginosis in pregnant women does not reduce the occurrence of preterm delivery or other adverse perinatal outcomes (Carey et al., 2000).

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine screening for bacterial vaginosis (not recommended).	Guise et al., 2001 Carey, 2000	I	Good	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-47 Vitamin Supplementation

BACKGROUND

Multivitamin supplementation throughout pregnancy is commonly practiced and expected by women in the United States. This tradition is based on the assumption that women have increased nutritional requirements during pregnancy that can not be met by diet alone.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend that multivitamin supplements taken one month preconceptually should be continued through the first trimester.
2. Strongly recommend that folate supplement taken one month preconceptually should be continued through the first trimester.
3. The evidence is insufficient to recommend for or against routine multivitamin, pyridoxine and vitamin D supplementation beyond the first trimester.

4. Recommend that women who have delivered a child with an open neural tube defect (NTD) should supplement their diets with 4 mg folate for at least one month prior to conception and through the first trimester to reduce the risk of recurrence.
5. Recommend that 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).
6. Recommend that pregnant women on restrictive diets should have nutrition consultation to customize vitamin supplementation regimen.

DISCUSSION

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, however, did not 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 B6) 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. One epidemiologic study demonstrated an association between periconceptual vitamin supplementation and a decrease in cardiac defects, NTDs and cleft palate. However, other than folic acid's protecting against NTDs, it is not clear what nutrient or combination of nutrients might effect risk of other specific defects.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine vitamin supplementation during pregnancy.	Mahomed, 2001 Mahomed & Gulmezoglu, 2001a Mahomed & Gulmezoglu, 2001b	III	Fair	I
2	Continuation of preconceptual vitamin supplements until the end of the first trimester.	Werler et al., 1999	II-3	Good	B
3	Continuation of preconceptual folate until the end of the first trimester.	Lumley et al., 2001	I	Good	A

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #51.

I-48 Immunization - MMR

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.

RECOMMENDATIONS

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against routine measles/mumps/rubella (MMR) immunization during pregnancy.

DISCUSSION

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).

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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine administration of MMR during pregnancy (not recommended).	Krogh et al., 1989	II-2	Poor	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-49 Immunization - Varicella

BACKGROUND

The CDC recommends that all adults should 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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

DISCUSSION

Four cohort studies were identified. Among U.S. women of childbearing age, the mean incidence of varicella is 2.16/1000/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 1/7500 based on 8 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 having 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, they 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine varicella vaccination in pregnancy (not recommended).	Smith et al., 1998	II-2	Poor	D
2	Seriological testing early in pregnancy for pregnant women with a negative or uncertain history.	Smith et al., 1998	II-2	Poor	B
3	Postpartum varicella immunization.	ACOG Guideline for Perinatal Care, 1998	III	Fair	B

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-50 Ultrasound (US) Evaluation of Cervical Length At Week 24

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against routine cervical length screening at 24 weeks' gestation.

DISCUSSION

No systematic reviews or RCTs comparing routine ultrasound evaluation of cervical length versus no screening were found. Observational studies have generally found that cervical length of less than 3cm or funneling of the internal os more than 5mm at 18 to 24 weeks' gestation is associated with an increased risk of preterm delivery. In one large study these findings were present in 3.6 percent of the pregnant population. The positive predictive value for delivery prior to 37 weeks was 27 percent (Taipale & Hiilesmaa, 1998). In another large study examining methods of detecting subsequent preterm delivery in a low risk population, cervical length of less than 25mm was detected in 8.5 percent of women using transvaginal sonography. The positive predictive value for delivery at 35 weeks or less was only 14 percent (Iams et al., 2001). Given the low prevalence and positive predictive value of these findings, routine screening of asymptomatic, low risk pregnant women is not recommended at this time.

Four other studies have shown that pregnant women with short cervices detected via routine transvaginal ultrasound screening have a greater risk of preterm delivery than do pregnant women without short cervices. The predictive value varied depending on the study and cervical length, 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 women'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 ($\leq$15mm) may deliver preterm. Less than 2 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).

Until effective intervention for women with a shortened cervix identified in late 2nd trimester has been developed, routine screening of cervical length by transvaginal sonography is not warranted.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Routine cervical length screening at 24 weeks' gestation (not recommended).	Iams, 2001 Heath et al., 2000 Hibbard et al., 2000 Heath et al., 1998 Taipale & Hiilesmaa, 1998 Iams et al., 1996	II-2	Fair	D

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)
Evidence Appraisal Report Question #29.

I-51 Repeat Screening for Anemia, Syphilis, and Isoimmunization

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

1. Recommend against routine repeat screening for blood group antibodies.
2. Recommend against routine repeat screening for anemia and syphilis.
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.

DISCUSSION

Repeat screening for anemia, syphilis and antibody development has been commonly practiced by obstetrical providers. 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

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Repeat antibody screening (not recommended).	Davis & Abbott, 1986	II-2	Fair	D
2	Repeat anemia and syphilis screen (not recommended).	Working Group Consensus	III	Poor	D
3	Repeat anemia and syphilis screen for high risk pregnant women.	Working Group Consensus	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

I-52 Screening for Hypothyroidism

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

The Working Group's Recommendations For Women In Low Risk Pregnancy:

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

DISCUSSION

First trimester hypothyroxinemia (a low for gestational age circulating maternal free T_4, 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 T_4 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 T_4 levels are low (normal maternal T_3 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 T_4 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, can not be recommended at this time.

EVIDENCE

	Recommendations	Sources of Evidence	QE	Overall Quality	R
1	Screening for thyroid deficiency (not recommended).	Escobar et al., 2000 Haddow et al., 1999 Pop et al., 1995	III	Poor	D
2	Adequacy of nutritional iodine.	Utiger, 1999	III	Poor	C

QE = Quality of Evidence; R = Recommendation (See Appendix B-1)

DoD/VA CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF **UNCOMPLICATED PREGNANCY**

APPENDICES

APPENDIX A-1
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 annotation B table 1)

Immediate Concerns	
1	Are you currently having any **vaginal bleeding**?
2	Are you currently experiencing any significant **abdominal pain/cramping**?
3	Do you have a history of **ectopic pregnancy**?
4	Do you have a history of any **severe pelvic infections** requiring hospitalization?
5	Do you have a history of **pelvic surgery for either infertility or infection?**
6	Do you have **diabetes that requires medication**?
7	Do you have any **other chronic medical condition** that requires medication?
Infections	
8	Do you currently have, have you ever had or been exposed to t**uberculosis**, or have you lived with anyone who had tuberculosis?
9	Were you ever **stationed overseas**?
10	Were you **born outside of the United States**?
11	Do you currently have, have you ever had or been exposed to **hepatitis**?
12	Do you currently have, have you ever had or been exposed to any **sexually transmitted diseases** including chlamydia, herpes, gonorrhea, syphilis, venereal warts, HPV or HIV?
13	Have you had a **rash or viral illness** since your last menstrual period?
14	Do you live in a house with **cats**?
Medical History	
15	Do you currently have or have you ever had **kidney or bladder problems, urine tract infection, or cystitis**?
16	Do you currently have or have you ever had **ulcers, stomach problems, or colitis**?
17	Do you currently have or have you ever had an **abnormal Pap smear or female or gynecological problems**?
18	Have you ever had **infertility problems**?
19	Do you currently have or have you ever had **heart disease**?
20	Do you currently have or have you ever had **rheumatic fever**?
21	Do you currently have or have you ever had **high blood pressure**?
22	Do you currently have or have you ever had **pneumonia or asthma**?
23	Do you currently have or have you ever had **epilepsy or seizures**?
24	Do you currently have or have you ever had **emotional problems**?
25	Do you currently have or have you ever had **thyroid problems**?
26	Do you currently have or have you ever had **diabetes?**
27	Do you currently have or have you ever had **varicose veins or blood clots in your legs**?
28	Do you currently have or have you ever had **bleeding tendencies**?
29	Are you currently in need of or have you ever had an **operation**?
30	Do you currently have or have you ever had **broken bones or concussions**?
31	Are you currently having or have you ever had **blood transfusions**?
32	Do you currently have or have you ever had **lupus or other autoimmune diseases**?
33	Are you **allergic to any medications**?
Genetic Screening	
34	Will you be **35 years old or older** when the baby is due?
35	Have you, the baby's father, or anyone in either of your families ever had **Down's syndrome** (mongolism)?

36	Have you, the baby's father, or anyone in either of your families ever had any other **chromosomal abnormality**?
37	Have you, the baby's father, or anyone in either of your families ever had **neural tube defect** (e.g., Spina Bifida or Meningomyelocele)
38	Have you, the baby's father, or anyone in either of your families ever had **anencephaly**?
39	Have you, the baby's father, or anyone in either of your families ever had **hemophilia or other bleeding disorders**?
40	Have you, the baby's father, or anyone in either of your families ever had **muscular dystrophy**?
41	Is there a family history of **multiple births**?
Miscellaneous	
42	Do you wear **seat belts**?
43	Do you live with anyone who **hits you or hurts you** in any way?
44	Have you, the baby's father, or anyone in either of your families ever had **cystic fibrosis**?
45	Have you, the baby's father, or anyone in either of your families ever had **sickle cell disease**?
46	Do you or the baby's father have a **birth defect**?
47	Have you or the baby's father have any close relatives with **mental retardation?**
48	Do you, the baby's father, or a close relative in either of your families have a **birth defect, family disorder, or a chromosomal abnormality not listed above**?
Social & Lifestyle History	
49	Do you **smoke**?
50	Do you use **alcohol**?
51	Have you used **marijuana, LSD, speed, heroin, crystal, crack, or cocaine?**
52	What **medicines or recreational drugs have you taken since becoming pregnant** (include all prescription and nonprescription drugs)?
53	What is your **occupation**?
54	Is this a **planned pregnancy**?
55	What is the **highest level of education** you have completed?
56	Are you a **vegetarian**?
57	Since becoming pregnant, have you been **exposed to any x-rays or toxic chemicals?**
Menstrual History	
58	What was the **first day of your last normal menstrual period**?
59	Was your **last menstrual period on time**?
60	Have you taken **birth control pills or Depo Provera** in the last year?
61	How many **days from the first day of your period to the first day of your next period?**
62	How many **days does your period last**?
Pregnancy History	
63	How many **previous pregnancies** did you have (include miscarriages and abortions)?
64	For each pregnancy what was **the date, hospital, number of weeks pregnant, type of delivery (vaginal/c-section), birth weight, sex, and what were the complications** (if any)?

APPENDIX A-2
Standard for Performance of Antepartum Obstetrical Ultrasound Examination

See: http://www.aium.org/consumer/standards/obstetrical.pdf

APPENDIX B-1
Guideline Development Process

The Guideline for the Management of Uncomplicated Pregnancy is the product of many months of diligent effort and consensus building among knowledgeable individuals from the Veterans Administration (VA), Department of Defense (DoD), academia, and guideline facilitators from the private sector. An experienced moderator facilitated the multidisciplinary Working Group that included obstetricians, midwives, internists, family practitioners, physician's assistants, nurses, and pharmacists, as well as consultants in the field of guideline and algorithm development.

The guideline is designed to address the management of uncomplicated pregnancy from initial encounter in the clinic through parturition, and provides an overview of screening and monitoring options as well as discussion about general clinical approaches to uncomplicated pregnancy. Complications or unusual situations are not covered in this guideline

DEVELOPMENT PROCESS

"Only well-focused questions and search terms will lead to a successful search for evidence" (AHCPR, 1996). The process of developing this guideline was evidence-based whenever possible. Evidence-based practice integrates clinical expertise with the best available clinical evidence derived from systematic research. Where evidence is ambiguous or conflicting, or where scientific data are lacking, the clinical experience of the multidisciplinary Working Group was used to guide the development of consensus-based recommendations. The developers incorporated the evidence and recommendations into a format that would maximally facilitate clinical decision-making (Woolf, 1992). The review of the literature, the evaluation of evidence, and the development of the guideline proceeded in sequential steps.

The Institute for Clinical Systems Improvement (ICSI) - *Health Care Guideline: Routine Prenatal Care* (2000) was identified by the Working Group as an appropriate seed guideline. It served as the starting point for the development of questions and key terms.

Fifty-six researchable questions and associated key terms were developed by the Working Group after orientation to the seed guideline and to goals that had been identified by the Working Group. The questions specified:

- Population - characteristics of the target population
- Intervention - diagnostic, screening, therapy, and assessment
- Control - the type of control used for comparison
- Outcome - the outcome measure for this intervention (morbidity, mortality, patient satisfaction, and cost)

A systematic search of the literature was conducted. It focused on the best available evidence to address each key question, and ensured maximum coverage of studies at the top of the hierarchy of study types: evidence-based guidelines, meta analyses, and systematic reviews (Cochrane, EBM, and EPC reports). The ICSI Guideline evidence was carefully reviewed. The Working Group agreed that ICSI, Cochrane or other meta-analyses addressed 32 of the questions. Three questions were not researched because legal mandates preclude debate.

At this point, the focus shifted to the 21 remaining questions that required further study. The search continued using well-known and widely available databases that were appropriate for the clinical subject. Limits on language (English), time (1990 through June 2001) and type of research (randomized controlled trials [RCT]) were applied. The search included MEDLINE and additional specialty databases, depending on the topic.

The search strategy did not cast a wide net. Once definitive clinical studies that provided valid relevant answers to the question were identified, the search stopped. It was extended to studies/reports of lower quality (observational studies) only if there were no high quality studies.

The results of the search were organized and reported using reference manager software. At this point, additional exclusion criteria were applied. Typical exclusions were studies with physiological endpoints, or studies of populations that were not comparable to the population of interest (e.g., studies of practices in Third World counties).

Evidence Appraisal Reports for each of the 21 unanswered questions were prepared by the Center for Evidence-based Practice at the State University of New York, Upstate Medical University, Department of Family Medicine (these reports are available by request). Each report covered:

- Summary of findings
- Methodology
- Search terms
- Resources searched
- Articles critically appraised
- Findings

The Working Group suggested some additional references. Copies of specific articles were provided to participants on an as-needed basis. This document includes references through June, 2001.

The clinical experts and research team evaluated the evidence for each question according to criteria proposed by the U.S. Preventive Services Task Force (USPSTF) (2001). See "Rating the Evidence," below.

The Working Group participated in two face-to-face sessions to reach a consensus about the guideline recommendations and to prepare a draft document. The draft was revised by the experts through numerous conference calls and individual contributions to the document. The guideline presents evidence-based recommendations that have been thoroughly evaluated by practicing clinicians.

The final draft was reviewed by four experts in obstetrics and gynecology as well as by family practitioners and midwives from the DoD and VA. Their feedback was integrated into the final draft. Nonetheless, this document is a work in progress. It will be updated every two years, or when significant new evidence is published.

RATING THE EVIDENCE

Evidence-based practice involves integrating clinical expertise with the best available clinical evidence derived from systematic research. The Working Group reviewed the evidence and graded it using the rating scheme developed by the USPSTF (2001). The experts themselves, after an orientation and tutorial on the evidence grading process, formulated Quality of Evidence ratings (see Table 1), a rating of Overall Quality (see Table 2), a rating of the Net Effect of the Intervention (see Table 3), and an overall Recommendation (see Table 4).

TABLE 1: Quality of Evidence (QE)

I	At least one properly done RCT
II-1	Well designed controlled trial without randomization
II-2	Well designed cohort or case-control analytic study
II-3	Multiple time series, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, case reports, and expert committees

TABLE 2: Overall Quality

Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; *or* Moderate grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

TABLE 3: Net Effect of the Intervention

Substantial	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.
Moderate	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.
Small	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.
Zero or Negative	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.

TABLE 4: Grade the Recommendation

A	A strong recommendation that the intervention is always indicated and acceptable
B	A recommendation that the intervention may be useful/effective
C	A recommendation that the intervention may be considered
D	A recommendation that a procedure may be considered not useful/effective, or may be harmful.
I	Insufficient evidence to recommend for or against – the clinician will use clinical judgment

Abstract of the USPSTF:

- Once assembled, admissible evidence is reviewed at three strata: (1) the individual study, (2) the body of evidence concerning a single linkage in the analytic framework, and (3) the body of evidence concerning the entire preventive service. For each stratum, the Task Force uses explicit criteria as general guidelines to assign one of three grades of evidence: good, fair, or poor.

- Good or fair quality evidence for the entire preventive service must include studies of sufficient design and quality to provide an unbroken chain of evidence-supported linkages, generalizable to the general primary care population, that connect the preventive service with health outcomes. Poor evidence contains a formidable break in the evidence chain such that the connection between the preventive service and health outcomes is uncertain.

- For services supported by overall good or fair evidence, the Task Force uses outcomes tables to help categorize the magnitude of benefits, harms, and net benefit from implementation of the preventive service into one of four categories: substantial, moderate, small, or zero/negative.

- The Task Force uses its assessment of the evidence and magnitude of net benefit to make a recommendation, coded as a letter: from A (strongly recommended) to D (recommend against). It gives an "I" recommendation in situations in which the evidence is insufficient to determine net benefit (Harris et al., 2001).

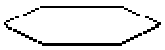
ALGORITHMS

The overall view of the uncomplicated pregnancy guideline is presented in an algorithmic format. There are indications that this format improves data collection and clinical decision-making and helps to change patterns of resource use. It allows the clinician 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 (SMDMC, 1992). Arrows connect the numbered boxes indicating the order in which the steps should be followed.

Rounded rectangles represent a clinical state or condition.



Hexagons represent a decision point in the guideline, formulated as a question that can be answered Yes or No. A horizontal arrow points to the next step if the answer is YES. A vertical arrow continues to the next step for a negative answer.

Rectangles represent an action in the process of care.

Ovals represent a link to another section within the guideline.

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. The reference list at the end of each section includes all the sources used—directly or indirectly—in the development of the annotation text. A complete bibliography is provided at the end of the document.

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APPENDIX B-2
Acronym List

AAP	American Academy of Pediatrics
ACOG	American College of Obstetricians and Gynecologists
AFI	Amniotic Fluid Index
AFP	Alphafetoprotein
AIDS	Autoimmune Disorder
AIUM	American Institute of Ultrasound in Medicine
ASB	Asymptomatic Bacteriuria
bid	Twice a Day
BMI	Body Mass Index
BP	Blood Pressure
CAGE	Alcohol Abuse/Dependency Screening Instrument
CBC	Complete Blood Count
CDC	Centers for Disease Control
CF	Cystic Fibrosis
CI	Confidence Interval
CMV	Cytomegalovirus
CPD	Cephalopelvic Disproportion
CPG	Clinical Practice Guideline
CPS	Clinical Preventive Services
CREOG	Committee on Resident Education in Obstetrics and Gynecology
CRS	Congenital Rubella Syndrome
DE	Dependent Edema
DoD	Department of Defense
DM	Diabetes Mellitus
DRG	Diagnosis Related Groups
EDC	Estimated Date of Confinement
EGA	Estimated Gestational Age
GBS	Group B Streptococcus
GDM	Gestational Diabetes Mellitus
GTT	Glucose Tolerance Test
HBIG	Hepatitis B Immune Globulin
HCG	Human Chorionic Gonodatropin
HIV	Human Immunodeficiency Virus
HTN	Hypertension
IAP	Intrapartum Antibiotics for Prophylaxis
ICSI	Institute for Clinical Systems Improvement
IOM	Institute of Medicine
IPA	Intrapartum Antibiotics
IUFD	Intrauterine Fetal Demise
IV	Intravenous
LEEP	Loop Electrosurgical Excisional Procedure
MMR	Measles/Mumps/Rubella
MOM	Multiples of the Median
MSAFP	Maternal Serum Alphafetoprotein
NDDG	National Diabetes Data Group
NIH	National Institute of Health
NNT	Number-Needed-To-Treat
NST	Non-Stress Testing
NTD	Neural Tube Defect
OB/GYN	Obstetrician/Gynecologist or Obstetrical/Gynecological
ONTD	Open Neural Tube Defects

Pap	Papanicolaou
PID	Pelvic Inflammatory Disease
PROM	Premature Rupture of Membranes
RCT	Randomized Controlled Trials
RPR	Rapid Plasma Reagin
RR	Relative Risks
SIDS	Sudden Infant Death Syndrome
SOGC	Society of Obstetricians and Gynaecologists of Canada
STD	Sexually Transmitted Disease
Td	Tetanus
TOC	Test of Cure
TSH	Thyroid Stimulating Hormone
US	Ultrasound
USPSTF	United States Preventive Services Task Force
VDRL	Venereal Disease Research Laboratory
VA	Veterans Administration
VHA	Veterans Health Administration

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Colonel Michael Kevin Yancey
29 May 1959 — 27 January 2002

Michael Yancey, champion of the Uncomplicated Pregnancy Guideline, died just weeks before the completion of this work. Through his calm and thorough style, excellent research and immense experience, he inspired us all to improve the care of pregnant women in the U.S. military with the goal of bringing more healthy babies into the world.

The DoD/VA Management of Uncomplicated Pregnancy Working Group dedicates this guideline to the memory of Michael, in celebration of his devotion to his patients, his medical profession and his country. He will be deeply missed.

Michael K. Yancey was born in Casper, Wyoming and raised in Golden, Colorado. He attended McPherson College earning both AA and BA degrees summa cum laude. While there, he met and married Jill Cooney. He attended medical school at the University of Colorado, graduating with honors. Medical school was followed by residency training in Obstetrics and Gynecology at Madigan Army Medical Center, where he received numerous awards and honors culminating in the receipt of the Byron L. Steger Research Award. After a tour of duty at Evans Army Community Hospital, COL Yancey was assigned to Tripler Army Medical Center where he served as Residency Program Director, Chief of Maternal-Fetal-Medicine, and Assistant Chief of the Department of OB/GYN.

COL Yancey's academic awards are numerous. He has authored over 50 articles in peer-reviewed journals, and 10 book chapters. He has made well over 100 presentations to national audiences and has received national recognition for work on infections in pregnancy. He served as a principal investigator on a major study on the progress of labor and received an NIH grant toward these efforts. He was the principal author of the DoD/VA Clinical Practice Guideline for the Management of Uncomplicated Pregnancy. He was the Vice-Chair of the Army Section of the Armed Forces District of the American College Obstetrics and Gynecology. He was a member of the Committee on Resident Education in Obstetrics and Gynecology (CREOG) for the American College of Obstetrics and Gynecology. His work has received the American College of Obstetricians and Gynecologists Outstanding Scientific Paper Awards 6 times. While a consummate researcher, his expertise as a teacher has been equally rewarding. In June 1999, he was awarded the "A" Proficiency Designator, acknowledging his teaching gift and equaling the title of Professor in Army academic medicine. COL Yancey was mentor and friend to well over 100 resident physicians and an equal number of colleagues.

COL Yancey’s military awards include the Army Commendation Medal, the Meritorious Service Medal and the Army Medical Department's Order of Military Medical Merit.

COL Yancey was a family man, dedicated physician and a man of true Christian faith. Jill, his wife of 23 years and their three children, Jensen Adair, Haleigh Kimball, and Reid William survive him.

APPENDIX B-4
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