ICSI Institute for Clinical Systems Improvement

Health Care Guideline

Routine Prenatal Care

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ICSI
Institute for Clinical Systems Improvement

Health Care Guideline:
Routine Prenatal Care

Fifteenth Edition
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Text in blue in this table indicates a linked corresponding annotation.

Event [1]	Preconception Visit [2]	Visit 1 [3] 6-8 weeks **	Visit 2 10-12 weeks	Visit 3 16-18 weeks	Visit 4 22 weeks
Screening Maneuvers	Risk profiles [4] Height and weight/BMI [5] Blood pressure [6] History and physical [7] Cervical cancer screening [2] Rubella/rubeola [8] Varicella [9] Domestic violence [10] Depression [11]	Risk profiles [4] GC/Chlamydia [4] Height and weight/BMI [5] Blood pressure [6] History and physical 7* Rubella [8] Varicella [9] Domestic violence [10] Depression [11] CBC [16] ABO/Rh/Ab [17] Syphilis [18] Urine culture [19] HIV [20] [Blood lead screening [21]] Viral hepatitis [26]	Weight [5] Blood pressure [6] Fetal aneuploidy screening[24] Fetal heart tones [28]	Weight [5] Blood pressure [6] Depression [11] Fetal aneuploidy screening [24] Fetal heart tones [28] OB Ultrasound (optional) [29] Fundal height [30] Cervical assessment [31]	Weight [5] Blood pressure [6] Fetal heart tones [28] Fundal height [30] Cervical assessment [31]
Counseling Education Intervention	Preterm labor [12] Substance use [2] Nutrition and weight [2] Domestic violence [10] List of medications, herbal supplements, vitamins [13] Accurate recording of menstrual dates [14]	Preterm labor [12] [VBAC [22]] Prenatal and lifestyle education [23] • Physical activity • Nutrition • Follow-up of modifiable risk factors • Nausea and vomiting • Warning signs • Course of care • Physiology of pregnancy Discuss fetal aneuploidy screening [24]	Preterm labor education[12] Prenatal and lifestyle education [23] • Fetal growth • Review labs from visit 1 • Breastfeeding • Nausea and vomiting • Physiology of pregnancy • Follow-up of modifiable risk factors	Preterm labor education[12] Prenatal and lifestyle education [23] • Follow-up of modifiable risk factors • Physiology of pregnancy • Second-trimester growth • Quickening Preterm labor prevention [31]	Preterm labor education[12] Prenatal and lifestyle education [23] • Follow-up of modifiable risk factors • Classes • Family issues • Length of stay • Gestational diabetes mellitus [32] (GDM) Preterm labor prevention [31]
Immunization & Chemoprophylaxis	Tetanus booster [27] Rubella/MMR [8] [Varicella/VZIG [9]] Hepatitis B vaccine [26] Folic acid supplement [15]	Tetanus booster [27] Nutritional supplements [25] Influenza [27] [Varicella/VZIG [9]] Pertussis [27]		[Progesterone [31]]	[RhoGam [17]]

Numbers refer to specific annotations.

[Bracketed] items refer to high-risk groups only.

* It is acceptable for the history and physical and laboratory tests listed under Visit 1 to be deferred to Visit 2 with the agreement of both the patient and the clinician.

** Should also include all subjects listed for the preconception visit if none occurred.

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Event	Visit 5 28 weeks	Visit 6 32 weeks	Visit 7 36 weeks	Visit 8-11 38-41 weeks	Visit Post-Partum 4-6 weeks
Screening Maneuvers	Preterm labor risk [4] Weight [5] Blood pressure [6] Depression [11] Fetal heart tones [28] Fundal height [30] Gestational diabetes mellitus (GDM) [32] Domestic violence [10] [Rh antibody status [17]] [Hepatitis B Ag [26]] [GC/Chlamydia [4]]	Weight [5] Blood pressure [6] Fetal heart tones [28] Fundal height [30]	Weight [5] Blood pressure [6] Fetal heart tones [28] Fundal height [30] Cervix exam as indicated [34] Confirm fetal position [35] Culture for group B streptococcus [36]	Weight [5] Blood pressure [6] Fetal heart tones [28] Fundal height [30] Cervix exam as indicated [34]	Cervical cancer screening [2] [GC/Chlamydia [4]] Height and weight/BMI [5] Blood pressure [6] History and physical [7] Domestic violence [10] Depression [11] Gestational diabetes mellitus (GDM) [32]
Counseling Education Intervention	Psychosocial risk factors [4] Preterm labor education[12] Prenatal and lifestyle education [23] • Follow-up modifiable risk factors • Work • Physiology of pregnancy • Preregistration • Fetal growth Preterm labor prevention [31] Awareness of fetal movement [33]	Preterm labor education[12] Prenatal and lifestyle education [23] • Follow-up of modifiable risk factors • Travel • Contraception • Sexuality • Pediatric care • Episiotomy Labor and delivery issues Warning signs/pregnancy-induced hypertension [VBAC [22]] Preterm labor prevention [31]	Prenatal and lifestyle education [23] • Follow-up of modifiable risk factors • Postpartum care • Management of late pregnancy symptoms • Contraception • When to call provider • Discussion of postpartum depression	Prenatal and lifestyle education [23] • Follow-up of modifiable risk factors • Postpartum vaccinations • Infant CPR • Post-term management Labor and delivery update Breastfeeding	Contraception Discussion of postpartum depression Breastfeeding concerns and support
Immunization & Chemoprophylaxis	[ABO/Rh/Ab [17]] [RhoGAM [17]] [Hepatitis B Ag [26]]				Tetanus/pertussis [27]

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Evidence Grading

Literature Search

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2009 through January 2012.

A PubMed search of clinical trials, systematic reviews, meta-analyses and practice guidelines using the following topics was performed: work and pregnancy, FASD, homelessness, varicella, rubella, genetic screening for hemoglobinopathies, aneuploidy screening, hypertension, domestic violence, cervical assessment and VBAC.

GRADE Methodology

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

This document is in transition to the GRADE methodology

Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available Systematic Reviews in literature searches.
- All existing Class A (RCTs) studies have been considered as high quality evidence unless specified differently by a work group member.
- All existing Class B, C and D studies have been considered as low quality evidence unless specified differently by a work group member.
- All existing Class M and R studies are identified by study design versus assigning a quality of evidence. Refer to Crosswalk between ICSI Evidence Grading System and GRADE.
- All new literature considered by the work group for this revision has been assessed using GRADE methodology

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Crosswalk between ICSI Evidence Grading System and GRADE *(mini GRADE)*

ICSI GRADE System	Previous ICSI System	
High, if no limitation	**Class A:**	Randomized, controlled trial
Low	**Class B:**	[observational] Cohort study
	Class C:	[observational] Non-randomized trial with concurrent or historical controls
Low		Case-control study
Low		Population-based descriptive study
***Low**		Study of sensitivity and specificity of a diagnostic test
* Following individual study review, may be elevated to Moderate or High depending upon study design		
	Class D:	[observational]
Low		Cross-sectional study Case series Case report
Meta-analysis	**Class M:**	Meta-analysis
Systematic Review		Systematic review
Decision Analysis		Decision analysis
Cost-Effectiveness Analysis		Cost-effectiveness analysis
Low	**Class R:**	Consensus statement
Low		Consensus report
Low		Narrative review
Guideline	**Class R:**	Guideline
Low	**Class X:**	Medical opinion

Evidence Definitions:

High Quality Evidence = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a **Reference** throughout the document.

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Foreword

Introduction

There is near-universal agreement that prenatal care is both beneficial and cost effective. Care designed to help bring healthy babies into the world is regarded as the highest of aspirations. Yet when examined critically, not all prenatal care can be shown to demonstrably improve maternal or neonatal health. This guideline has been designed to highlight the medical interventions, risk stratification, counseling maneuvers and prophylaxis most likely to positively affect such outcomes.

The guideline emphasizes prenatal care that applies to the greatest number of patients. When possible, recommendations are designed to apply to all patients receiving prenatal care or planning a pregnancy. When universal recommendations are not feasible, the guideline tries to provide clinical information that would apply to a sizable population of pregnant women, rather than discuss management of clinical problems that pertain to only a small number of patients.

The guideline is arranged in a format familiar to clinicians who provide prenatal care. The clinical interventions, patient education and counseling are organized for care delivery at specific times in the pregnancy related to gestational age; specific clinical recommendations for pre-conception and postpartum patient visits are included, too. The interventions described for each visit are designed to foster both patient value and cost-effective care.

There are many aspects of prenatal care that lend themselves to a shared decision-making process with the patient. Indeed, prenatal care may be unique in the degree to which such mutual decisions between patient and clinician shape care delivery. The guideline includes and fully supports the ICSI Shared Decision-Making Model, as shown in Appendix H.

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Scope and Target Population

This guideline pertains to the care of all women who are pregnant or are considering pregnancy. All visits are outpatient/clinic based. (See the ICSI Management of Labor guideline for hospital-based care.)

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Aims

1. Increase the percentage of patients pregnant or planning a pregnancy who receive timely, comprehensive screens for risk factors. *(Annotation #4)*
2. Increase the percentage of pregnant patients or women planning pregnancy who receive timely, prenatal counseling and education as outlined in the guideline. *(Annotations #4, 12)*
3. Increase the percentage of first-trimester pregnant patients who have documentation of counseling about appropriate aneuploidy screening. *(Annotation #24)*
4. Increase the percentage of VBAC-eligible pregnant patients who have a collaborative conversation with their clinican about the risks and benefits of VBAC. *(Annotation #22)*
5. Increase the percentage of pregnant patients who have appropriate interventions for preterm birth (PTB) risk factors. *(Annotations #4, 31)*

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Clinical Highlights

- Identify patients with greater potential for high-risk pregnancy and provide appropriate preconception counseling. *(Annotation #4, Aim #1)*
- Each pregnant patient and each patient planning a pregnancy should receive a comprehensive risk assessment and appropriate risk-related interventions, including risks for preterm labor, relevant infectious diseases, and relevant genetic disorders. *(Annotations #2, 4, 12; Aim #2, 5)*
- Each pregnant patient should receive visit-specific screening tests, education, immunizations and chemoprophylaxis as described in the schedule of prenatal visits. *(Annotation #1; Aim #2)*
- Each pregnant patient should be counseled regarding the limitations and benefits of each aneuploidy test and offered the screening and diagnostic tests. *(Annotation #24; Aim #3)*
- For patients with previous Caesarean section, provide education of risks and benefits associated with vaginal birth after Caesarean (VBAC). Assess and document patient's desire and appropriateness for VBAC. *(Annotation #22; Aim #4)*

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Implementation Recommendation Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- Use of simple prenatal forms and checklists can provide an inexpensive and effective means of improving implementation of periodic health maintenance and increase the likelihood that clinicians will put clinical evidence into practice.
- Use of electronic medical records with electronic interfaces allowing transfer of pertinent patient information between clinicians can significantly improve clinician acceptance and implementation of these recommendations.

(Kirkham, 2005a [Low Quality Evidence]; Cheney, 1987 [High Quality Evidence])

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Related ICSI Scientific Documents

Guidelines

- Immunizations
- Management of Labor Guideline and Admission for Routine Labor Order Set
- Prevention and Management of Obesity
- Preventive Services for Adults

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Definition

Clinician – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

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Algorithm Annotations

1. Number of Prenatal Visits

Prenatal visits are organized as described in the table on the cover of this guideline. All prenatal visits, including the preconception visit, are organized to include:

- screening and assessment maneuvers;
- counseling, education and intervention; and
- immunization and chemoprophylaxis.

In 1989, the Expert Panel on the Content of Prenatal Care established guidelines on the timing and content of prenatal care, including a schedule consisting of fewer prenatal visits than traditional models provided. This reduced schedule of visits applied to women considered at low risk of adverse perinatal outcomes. Timing and focusing prenatal visits at these intervals, along with providing designated education pieces at each visit, should serve to provide a more comprehensive and satisfying prenatal program than has existed in the past *(American College of Obstetricians and Gynecologists, 1989 [Low Quality Evidence]; Public Health Service Expert Panel, 1989 [Low Quality Evidence])*.

The overall utility of prenatal care as a series of visits conducted from the time of conception through parturition has been well established. However, as Huntington and Connell have stated, "The evidence that prenatal care pays for itself is simply not strong enough to merit the virtual certainty with which this claim has been espoused" *(Huntington, 1994 [Low Quality Evidence])*. As the United Kingdom's Royal College of Obstetrics and Gynecology has described, both the individual components and overall package of prenatal care should conform to criteria for any successful health-screening program. In particular, the work group stresses the following points:

- The condition being screened for is an important health problem.
- The screening test, assessment or treatment is safe and acceptable.
- The natural history of the condition is understood.
- Early detection and treatment have benefit over later detection and treatment.
- The screening test, assessment or treatment is valid and reliable.
- There are adequate facilities for testing and resources for treatment.
- The objectives of screening justify the costs.

(National Collaborating Centre for Women's and Children's Health, 2003 [Low Quality Evidence])

Alternative prenatal care schedules for women at low risk for adverse perinatal outcomes have been shown to deliver equivalent outcomes of preterm delivery, preeclampsia, Caesarean delivery, low birth weight, and patient satisfaction rates. The research in this area includes the results of a randomized controlled trial. This guideline presents a schedule of visits in keeping with these studies *(Villar, 2003 [Systematic Review]; Carrol, 2001 [Systematic Review]; Clement, 1999 [High Quality Evidence])*.

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2. Preconception Visit

A preconception visit is defined as any encounter between a woman of childbearing age and a health care professional for any issue related to possible pregnancy or contraception occurring within 12 months of pregnancy. This includes the following reasons for an encounter:

- Pregnancy planning or questions
- Fertility problems
- Contraception
- Periodic health assessment (including Pap testing)
- Recent amenorrhea, but pregnancy testing is negative
- Pregnant, but plans to abort pregnancy
- Any visit with gynecologic concerns
- Other encounters that lead the clinician to believe the patient is likely to become pregnant soon

An age-appropriate periodic health assessment as described in the ICSI Preventive Services guidelines should be performed. The Preventive Services guidelines should be consulted regarding the indicated frequency of screening, counseling and immunization maneuvers. Patients who have been identified with gestational diabetes in previous pregnancies should have glucose testing.

Preconception discussion should include information about proper nutrition, including preconceptual use of folic acid, ideal body weight, and substance abuse in the preconception period. Obese women should be encouraged to begin a weight reduction program involving diet, exercise and behavior modification. In some cases, bariatric surgery prior to conception also should be discussed *(Moos, 2008 [Low Quality Evidence]; Practice Committee of the American Society for Reproductive Medicine, 2008 [Low Quality Evidence])*.

Pregnant women failing to receive a preconception visit should undergo an age-appropriate periodic health assessment at the first prenatal visit. This would include those screening maneuvers listed in the visit table.

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3. Expeditious Access to Prenatal Care

Early confirmation of pregnancy is important because it allows for early intervention to mitigate risk factors. This includes early screening. Consensus of the guideline work group is that confirmation as soon as possible within the first two weeks of clinician awareness is an attainable goal for each medical group.

Confirmation may be by pregnancy test or by a combination of history and exam. If the confirmation test is negative, the patient should be treated as a prepregnancy visit.

The clinic visit can be done by a nurse, nurse practitioner, clinician or midwife. This may include a pregnancy test, examination or ultrasound for ectopic pregnancy or miscarriage.

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4. Risk Profile Screening

Risk evaluation at the preconception visit or first prenatal visit should include an evaluation of the following concerns:

A. Preconception risk assessment should be completed at all opportunities, followed by preconception counseling, if indicated. (See Appendix A, "Preconception Risk Assessment Form.")

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A comprehensive assessment should elicit information from the patient regarding the following:

- Modifiable risk factors for preterm labor
- Work-related exposure to chemicals or infectious agents
- Risk for modifiable infectious diseases
- Hereditary disorders
- Use of prescription or over-the-counter medications
- History of physical, emotional or sexual abuse
- Nutritional adequacy
- Alcohol use
- Tobacco use
- Substance abuse
- Gestational diabetes
- Risk for psychiatric disorder

A brief systematic screening for preterm birth risks should be performed at the preconception visit or the first prenatal visit. Likewise, screening should be congruent with the aims outlined in the ICSI Preventive Services guidelines. Clinicians should focus on modifiable risk factors, particularly factors that have been shown to be responsive to clinician counseling or intervention.

Evidence-based recommendations support clinician counseling for tobacco cessation, alcohol use and nutrition. No strong evidence exists against comprehensive counseling and education *(Kirkham, 2005a [Low Quality Evidence]; Mullen, 1999 [Low Quality Evidence]; Chang, 1998 [Low Quality Evidence]; Fenster, 1991 [Low Quality Evidence])*.

Alcohol

Fetal alcohol spectrum disorder (FASD) is the most common preventable cause of mental disability in the western world, with an estimated incidence in North America of 9.1 per 1,000 live births *(Tough, 2005 [Low Quality Evidence])*. The prevalence of alcohol use among pregnant women is more than 12%, and even low levels of alcohol use have been related to negative developmental sequelae. Brief intervention is an effective methodology that has been empirically validated in a number of alcohol-related studies *(O'Connor, 2007 [Low Quality Evidence])*. Studies suggest that consistent screening for prenatal alcohol use with subsequent assessment result in reduced consumption and thus reduced fetal exposure to alcohol *(Chang, 2005 [Low Quality Evidence])*.

The T-ACE and TWEAK screening tools have been validated for assessing alcohol use in pregnant women *(Sarkar, 2009 [Guideline])*. See Appendix I, "T-ACE Screening Tool."

Tobacco cessation

Prenatal tobacco cessation programs can be effective in reducing smoking rates in pregnant women and reducing the incidence of low-birth-weight infants. Therefore, smoking cessation should be discussed at each visit. It provides the opportunity to discuss the impact smoking has on her baby and the fact that even reducing the number of cigarettes smoked each day can lower her risks for preterm labor and can positively impact the size of her baby (*Rosenthal, 2006 [Low Quality Evidence]; American College of Obstetricians and Gynecologists – Committee Opinion, 2005c [Low Quality Evidence])*.

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Intervention early in pregnancy – through written materials, education, counseling and a message from clinician or midwife – will significantly increase the number of women who stop smoking or reduce the number of cigarettes by more than 50%, thereby reducing the number of low-birth-weight babies. It was also noted that with phone counseling between prenatal visits, there is greater success in smoking cessation *(Secker-Walker, 1998 [High Quality Evidence])*.

If a pregnant patient is clearly not going to stop smoking without the use of nicotine replacement and/or cognitive behavioral therapy, and if there is good reason to believe these substances would facilitate cessation in a particular patient, it is reasonable to inform the patient of potential risks and offer that form of support *(Pollak, 2007 [Low Quality Evidence]; U.S. Preventive Services Task Force, 1996 [Systematic Reivew])*.

Domestic violence (see Annotation #10)

Domestic violence can occur before, during and after pregnancy. In a population-based survey, prenatal abuse prevalence was 6.1%. A strong, significant association was identified between abuse prior to pregnancy and abuse during pregnancy *(Martin, 2001 [Low Quality Evidence])*.

Violence during pregnancy has been associated with miscarriage, late entry into prenatal care, stillbirth, premature labor and birth, fetal injury and low birth weight *(The World Report on Violence and Health, 2002 [Low Quality Evidence])*.

Gestational diabetes mellitus (GDM) (see Annotation #32)

Patients who are considered at increased risk for gestational diabetes based on previous pregnancies should be screened with a one-hour glucose test as soon as the patient is confirmed to be pregnant *(American Diabetes Association, 2004 [Low Quality Evidence])*. Women with a history of GDM have a 33-50% risk of recurrence, and some of these recurrences may represent unrecognized type 2 diabetes *(American College of Obstetricians and Gynecologists Practice Bulletin, 2001b [Guideline])*.

B. At risk for preterm birth?

Preterm labor (PTL) risk includes medical and obstetrical history that might cause a woman to be at high risk for preterm delivery.

The guideline work group acknowledges that some factors are associated with a greater magnitude of risk than others for preterm birth. For example, a history of prior preterm birth or myomectomy or multiple gestation this pregnancy is of particular concern. Existing risk assessment scoring tools have not been shown to be reliable predictors of preterm birth. Shorter cervical length as measured by ultrasound is directly associated with preterm labor *(American College of Obstetricians and Gynecologists, 2012 [Low Quality Evidence])*. Risk factors associated with preterm birth may include, but are not limited to, the following:

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Risk factors for preterm birth

Demographics	History	Lifestyle	Infection/ Inflammation	Decidual Hemorrhage	Uterine and Cervical Abnormalities
African-American Less than 12th-grade education Low socioeconomic status Under age 18 or over age 35 Unmarried Homelessness	Any 2nd-trimester loss Cervical cerclage Cervix dilated more than 1 cm before 32 wks gestation Fetal stress, e.g., intra-uterine growth retardation Low BMI Uterine irritability Mental illness e.g., major depression, psychosis, bipolar, schizophrenia Prior cone biopsy or LEEP Prior myomectomy Prior preterm delivery 3 or more 1st- trimester losses	Cocaine, marijuana, benzodiazapene or other street drug use Domestic violence Family or life stress Tobacco use	Abdominal surgery this pregnancy Bacterial vaginosis with symptoms Other systemic infection or febrile illness Periodontal disease Pyelonephritis or UTI Sexually transmitted infections	Trauma Vaginal bleeding after 12 wks this pregnancy	Multiple gestation Polyhydramnios Uterine anomalies Uterine fibroids Shortened cervix

These risk factors for preterm birth are not listed in any particular risk order.
(Goldenberg, 2008 [Low Quality Evidence])

Also see Annotation #31, "Preterm Labor Prevention."

C. Potential workplace hazards/lifestyle risk assessment (see Appendix B, "Workplace Environment/ Lifestyle Risk Assessment Form")

Health care clinicians should elicit information from the patient regarding the following:

- Work-related risks for preterm labor
- Work-related exposure to chemicals or infectious agents

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- Availability of health care professionals at work for blood pressure (BP) monitoring or rest/observation, if indicated
- Risks to pregnancy from physical requirements of the occupation
- Nutritional adequacy for pregnancy (see Annotation #5, "Height and Weight/Body Mass Index [BMI]," for risks of obese patients)
- Lifestyle risks to pregnancy
- Risk of lead exposure (see Appendix F, "Blood Lead Screening Guidelines for Pregnant Women in Minnesota"). Patients who have levels at or above 10 mcg/dL need further evaluation and management.

Work and pregnancy

Because the majority of pregnant women work outside the home, workplace risk factors should be assessed for all pregnant women.

Employment alone does not appear to increase risks to pregnancy. Rates of preterm delivery, low birth weight, fetal malformation and prenatal mortality are not increased among employed women. In fact, an overall reduced risk of adverse outcomes can be attributed to more favorable demographics and behavioral characteristics among employed women *(Berkowitz, 1995 [Low Quality Evidence])*.

Risks of preterm labor, low birth weight or small gestational age for infants from women working with shift changes are small *(Bonzini, 2011 [Systematic Review])*.

Occupational exposure to toxic chemicals – including anesthetic and chemotherapeutic agents, solvents and pesticides – can increase the risk of miscarriage, malformations and other adverse pregnancy outcomes *(Luke, 1995 [Low Quality Evidence])*.

The Council on Scientific Affairs has established guidelines for work in pregnancy *(Council on Scientific Affairs, 1999 [Guideline])*.

D. Infectious disease risks (see Appendix C, "Infectious Diseases in Pregnancy Screening Form")

Women found to be at high risk for one or more infectious diseases may require additional infectious disease testing at 28 weeks:

- Rubella/varicella immunity status
- Human immunodeficiency virus (HIV) status of patient and partner
- History of sexually transmitted infection (STIs)
- Sexual practices that place patient at increased risk for STIs
- Substance abuse, including intravenous (IV) drug use
- Socioeconomic factors that affect access to medical care and increase likelihood of exposure to infectious disease

(Kirkham, 2005a [Low Quality Evidence])

Gonorrhea and chlamydia

All women found to be at high risk for sexually transmitted diseases should be screened for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* at a preconception visit or during pregnancy *(U.S. Preventive Services Task Force, 2007 [Systematic Reivew])*. In addition, all sexually active women age 25 or

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younger should be screened for *C. trachomatis,* regardless of risk status, in keeping with the USPSTF recommendation.

The optimal frequency of screening has not been determined, but due to concerns about reinfection, an additional test in the second trimester is recommended for those at continued risk of acquiring chlamydia *(Andrews, 2000 [Low Quality Evidence])*.

Early detection and treatment of gonococcal and chlamydial infection in asymptomatic women offers the potential benefits of preventing future complications of infection. Similarly, early detection and treatment during pregnancy have the potential to reduce morbidity from obstetric complications.

Gonorrhea

The CDC reports that 336,742 new cases of gonorrhea were reported in 2008. The reported prevalence among women at prenatal clinics was 0.0-3.8% and was up to 7.4% at family planning clinics. Up to 50% of women with gonorrhea are asymptomatic *(Centers for Disease Control, 2008 [Guideline])*.

Pregnant women with gonococcal infections are at increased risk for obstetric complications (stillbirth, preterm delivery, chorioamnionitis, low birth weight and intrauterine growth restriction) *(Elliott, 1990 [Low Quality Evidence])*.

Ongoing data from the CDC Gonococcal Isolate Surveillance Project (GISP), including preliminary data from 2006, demonstrate that fluoroquinolone-resistant gonorrhea is continuing to spread and is now widespread in the U.S. As a consequence, and as reported in MMWR, April 13, 2007, this class of antibiotic is no longer recommended for the treatment of gonorrhea in the U.S. *(Centers for Disease Control, 2007 [Guideline])*.

Chlamydia

In the United States, chlamydial genital infection is the most frequently reported infectious disease, and the prevalence is highest in individuals age 25 and younger. Several important sequelae can result from *C. trachomatis* infection in women; the most serious of these include PID, ectopic pregnancy and infertility. Some women who have uncomplicated cervical infection already have subclinical upper reproductive tract infection *(Centers for Disease Control, 2006a [Guideline])*.

Chlamydia infection in pregnancy increases the risk of miscarriage, preterm labor, PROM, preterm birth, low birth weight, neonatal chlamydia infection, infant mortality and endometritis. Neonatal infection can result in ophthalmia neonatorum and pneumonia *(U.S. Preventive Services Task Force, 2007 [Systematic Review])*.

Tuberculosis and PPD screening

Purified protein derivatives (PPD) screening of all high-risk mothers at a preconception visit or the first OB visit will identify most women who have old infections or active disease (10% of immunocompetent and 40% of HIV positive patients will have a false-negative test). Follow-up chest x-ray is recommended for recent converters if pulmonary symptoms are present before 12 weeks gestation and in all circumstances after 12 weeks gestation.

Important risk factors include poverty, drug use, HIV, new immigrants from tuberculosis endemic areas, and exposure to proven and suspected tuberculosis *(Laibl, 2005 [Low Quality Evidence])*.

Reported cases of tuberculosis in the U.S. decreased from 1992 to 2002. However, the number of cases among foreign-born patients has increased *(Efferen, 2007 [Low Quality Evidence])*.

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Risks of maternal tuberculosis include fetal infection, which can occur as hematogenous spread from the mother, by aspiration of amniotic fluid/endometrium, or airborne after delivery. Congenital tuberculosis symptoms include respiratory distress, fever, liver/spleen enlargement, poor feeding, lethargy and lymphadenopathy *(Laibl, 2005 [Low Quality Evidence])*.

Active tuberculosis can be treated during pregnancy. Inactive tuberculosis could be treated prior to conception if detected *(Weinberger, 1995 [Low Quality Evidence])*. Initiation of treatment for latent infection during pregnancy should be considered based on the risk for progression to active disease *(Efferen, 2007 [Low Quality Evidence])*.

Periodontal disease

Any infection during pregnancy can be a problem and there is an increased risk of periodontal disease in pregnancy. There have been numerous studies evaluating periodontal disease and a correlation to various adverse pregnancy outcomes including preterm delivery and low birth weight. However, the treatment of periodontal disease does not reduce the frequency of these outcomes. It is possible that moderate to severe periodontal disease may be one of potentially numerous markers of inflammatory changes, which may be the underlying etiology. It will be important to continue to follow these studies. The current data support an assessment of oral health as part of prenatal counseling, general preventive dental care in pregnancy and the treatment of periodontal disease as needed during this time *(Chambrone, 2011 [Systematic Review]; George, 2011 [Systematic Review]; Sant'Ana, 2011 [Low Quality Evidence])*.

Herpes simplex virus (HSV)

Since genital herpes simplex virus (HSV) infection during pregnancy poses a risk to the fetus *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*, all pregnant women and their partners should be asked about a history of genital and orolabial HSV infection *(Smith, 1998a [Low Quality Evidence])* (see Appendix A, "Preconception Risk Assessment Form").

Genital herpes infection occurs in one in five women in the United States. Many women of childbearing age are infected, and the rate of vertical transmission at delivery is 30-60% for a primary HSV infection and 3% for a recurrent HSV infection *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*. Genital herpes acquired in pregnancy before delivery does not seem to increase rates of congenital HSV infection if HSV seroconversion is completed by the time labor starts *(Desselberger, 1998 [Low Quality Evidence])*. Neonatal HSV infections are classified as disseminated disease (25%), central nervous system (CNS) disease (30%), and disease limited to the skin, eyes or mouth (45%) *(Whitley, 1988 [Low Quality Evidence])*. Mortality is 30% for disseminated disease and 4% for CNS disease *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*.

Asymptomatic shedding during pregnancy does not predict asymptomatic shedding at delivery *(Arvin, 1986 [Low Quality Evidence])*. Hence, routine screening in asymptomatic patients is not recommended (*American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline]*). Women with an HSV-positive partner should consider abstinence, condom use, antiviral therapy in the HSV-positive partner, and avoidance of orogenital contact if the partner has orolabial HSV infection *(Smith, 1998 [Low Quality Evidence])*.

Primary versus non-primary HSV infection is distinguished based on the combination of positive viral detection and negative serologic tests or evidence of seroconversion *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*.

Primary HSV infection during pregnancy is treated with oral or intravenous antiviral medications based on the severity of the infection. The efficacy of suppression therapy from 36 weeks of gestation until delivery following primary HSV infection is uncertain *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*.

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Women with recurrent genital herpes should be counseled about suppressive therapy. The efficacy of suppressive therapy to prevent recurrences near term (36 weeks of gestation until delivery) has been well established. A systematic review of RCTs showed the rate of recurrent genital HSV outbreak at delivery was reduced by 75%, and the rate of Caesarean delivery for recurrent genital herpes was reduced by 40% *(Sheffield, 2003 [M])*. Recommended treatment is acyclovir 400 mg three times daily or valacyclovir 500 mg two times daily *(Centers for Disease Control, 2006 [Guideline])*. There are no documented increases in adverse fetal effects because of exposure during pregnancy to acyclovir or valacyclovir *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*.

Caesarean delivery is indicated when women have active genital lesions or prodromal symptoms, such as vulvar pain or burning, at the time of delivery. The prodromal symptoms may indicate an impending outbreak *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*. Among women with HSV detected at delivery, neonatal herpes occurred in 1.2% of infants delivered by Caesarean section, compared to 7.7% delivered vaginally *(Brown, 2003 [Low Quality Evidence])*. Caesarean delivery is not recommended for women with a history of HSV infection but no active disease or prodrome during labor *(American College of Obstetricians and Gynecologists Practice Bulletin, 2007b [Guideline])*.

Rubella/Rubeola (see Annotation #8)

Varicella (see Annotation #9)

Syphilis (see Annotation #18)

HIV (see Annotation #20)

Viral Hepatitis B & C (see Annotation #26)

Influenza (see Annotation #27)

E. Genetic risks (see Appendix D, "Prenatal Genetic Risk Assessment Form")

The history of both parents, as well as their family histories, should be reviewed for genetic disorders.

- Age of both parents at baby's birth
- Racial background of both parents, and whether appropriate testing has been done if determined to be in a hereditary-trait risk group
- Substance abuse
- Presence of hereditary defects/disorders in close relatives
- Family history of psychiatric disease/mood disorders
- Serious health conditions of mother
- History of unplanned pregnancy loss

Genetic screening

In the aggregate, common congenital abnormalities are frequent in the general population. A general figure for initial counseling of patients and families is 5% *(Lemyre, 1999 [Low Quality Evidence])*.

The determination of whether a couple, or anyone in the family, has a heritable disorder can easily be accomplished by using a questionnaire format. The genetic screening should be performed at the preconception or initial prenatal visit. Early identification of genetic risks allows a woman and her family to decide whether to conceive or whether to undergo additional testing to determine if the genetic disorder affects this pregnancy *(Simpson, 1991 [Low Quality Evidence])*.

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Hemophilia A is an X-linked disorder with an incidence of 1 in 10,000 males.

Duchenne and Becker **muscular dystrophies** are X-linked disorders of dystrophin structure and function occurring in 1/3,500 live male births *(Monckton, 1982 [Low Quality Evidence])*. Female carriers are usually only mildly affected.

Cystic fibrosis is the most common fatal autosomal recessive disorder among Caucasian children, with an incidence of 1 in 2,500 births *(Ratjen, 2003 [Low Quality Evidence])*. All identified mutations account for about 97% of mutations in most populations *(Kerem, 1997 [Low Quality Evidence])*. It is becoming increasingly difficult to assign a single ethnicity to affected individuals. Therefore, the American College of Obstetricians and Gynecologists recommends offering cystic fibrosis screening to all patients that have not been previously screened *(American College of Obstetricians and Gynecologists – Committee Opinion, 2011 [Low Quality Evidence])*.

Mental retardation

When the etiology is known, causes that occur prenatally account for most cases of mental retardation, regardless of severity. However, the distribution of causes varies with severity. In a population-based study of births between 1980 and 1985 in Norway, 178 children were identified with severe (IQ less than 50) or mild mental retardation (IQ 50 to 70) *(Strømme, 2000 [Low Quality Evidence])*. The following distribution was noted for severe and mild mental retardation, respectively:

- Prenatal – 70 and 51%
- Perinatal (including some with a possible prenatal origin) – 4 and 5%
- Postnatal and acquired – 5 and 1%
- Undetermined timing – 18 and 11%

In many cases, no etiology can be identified despite extensive evaluation. In the Norwegian study, unspecified causes accounted for 4 and 32% of severe and mild mental retardation, respectively. The proportion of cases with unknown cause may be higher in some populations. As an example, in a report of 16,735 cases of mental retardation without autism or cerebral palsy in California between 1987 and 1994, the cause was unknown in two-thirds *(Croen, 2001 [Low Quality Evidence])*.

Among the known prenatal causes of mental retardation, the majority are genetic abnormalities *(Croen, 2001 [Low Quality Evidence]; Strømme, 2000 [Low Quality Evidence])*. Among these are the following disorders *(Shevell, 2003 [M])*:

- Down syndrome, caused by trisomy 21.
- Fragile X syndrome, which occurs in approximately 1 to 2% of individuals with mental retardation, is one of the most common inherited disorders that cause developmental delay and mental retardation *(De Vries, 2003 [Low Quality Evidence])*.
- Mutations in the gene encoding MECP2 (methyl–Cp G binding protein 2), located on the X chromosome, occur in most cases of Rett syndrome, an uncommon cause of severe developmental delay and mental retardation in girls, as well as more mildly affected girls and boys with mild or severe mental retardation.
- Varieties of other disorders are also inherited in X-linked patterns and occur in syndromic or non-syndromic forms; together these account for approximately 10% of mental retardation in males.
- Submicroscopic subtelomeric rearrangements are identified in approximately 5% of children with mental retardation *(De Vries, 2003 [Low Quality Evidence])*. The rate appears to be higher

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in severely affected children and lower in those who are mildly affected *(Shevell, 2003 [Meta-analysis])*. Advances in techniques for genetic profiling, including array-based comparative genomic hybridization (Array-CGH) identify microimbalances as the probable cause of mental retardation in 10% to 16% of individuals *(Engels, 2007 [Low Quality Evidence])*.

Patients with a family history of mental retardation or a history of fragile X mental retardation should receive genetic counseling and should be offered genetic testing to assess their risk for having an affected child *(American College of Obstetricians and Gynecologists, 2006b [Guideline])*.

In cases with three or more pregnancy losses, there is a 3.5-5% risk of a maternal chromosomal rearrangement, and a 1-2% risk of a paternal rearrangement.

Tay-Sachs disease is an autosomal recessive disorder occurring in 1 in 2,500 *(Zinberg, 2001 [Low Quality Evidence])* children of Ashkenazi Jewish parents. Most individuals of Jewish descent in the U.S. are of Ashkenazi descent, so hexosaminidase screening should be offered to all pregnant Jewish patients if they or their partners have not been tested. Pregnancy and oral contraceptives diminish serum levels of hexosaminidase, so leukocyte hexosaminidase A levels should be checked *(American College of Obstetricians and Gynecologists – Committee Opinion, 2005b [Low Quality Evidence]; Eng, 2001 [Low Quality Evidence])*.

Hemoglobinopathies

A complete blood count and hemoglobin electrophoresis are the appropriate laboratory tests for screening for hemoglobinopathies.

The hemoglobinopathies are a heterogeneous group of single-gene disorders that includes the structural hemoglobin variants (e.g., sickle cell disease) and the thalassemias (alpha and beta). More than 270 million people worldwide are heterozygous carriers of hereditary disorders of hemoglobin, and at least 300,000 affected children are born each year.

Genetic screening can identify couples at risk and allow them to make informed decisions regarding reproduction and prenatal diagnosis. Individuals of African, Southeast Asian and Mediterranean ancestry are considered at highest risk. Ethnic groups considered low risk include northern Europeans, Japanese, Native Americans, Inuit (Eskimo) and Koreans.

In individuals of African descent, a CBC and hemoglobin electrophoresis should be performed as part of the initial screening. In the past, other solubility tests had been used to screen for sickle cell but now are considered inadequate and fail to identify important transmissible hemoglobin gene abnormalities affecting fetal outcome. Many individuals with these genotypes are asymptomatic, yet if his or her partner has the sickle cell trait or other hemoglobinopathies, they can produce offspring with more serious hemoglobinopathies.

In individuals of non-African descent, a CBC along with RBC indices is sufficient for initial screening. If the individual shows no abnormality, no further screening is recommended. If the individual has anemia with reduced MCV and normal iron studies, a hemoglobin electrophoresis should be ordered. If this is normal and the individual is not Southeast Asian, no further workup is needed. If the patient is Southeast Asian, consider evaluation for alpha-thalassemia using DNA-based testing. In any of these cases, if the hemoglobin electrophoresis is abnormal, offer testing of the partner to assess reproductive risk.

Management of the hemoglobinopathies in pregnancy varies. Pregnancies in women with sickle cell disease are at increased risk for spontaneous abortion, preterm labor, intrauterine growth retardation (IUGR) and stillbirth. A plan for serial ultrasounds and antepartum fetal testing is reasonable. In women with the alpha-thalassemia trait, the course of pregnancy is not significantly different from those with normal hemoglobin. Until recently, pregnancy in women with beta-thalassemia major was extremely rare because of early death, delay of growth and sexual development in untreated women. Since the

introduction of transfusion therapy and iron chelation therapy in the late 1970s, favorable pregnancy outcomes have been noted. Beta-thalassemia minor causes usually only mild asymptomatic anemia not requiring iron replacement beyond prophylactic dosing in the absence of documented iron deficiency *(American College of Obsetricians and Gynecologists, 2007a [Guideline])*.

Folate chemoprophylaxis against neural tube defects is discussed in Annotation #15, "Folic Acid Supplement."

Fetal aneuploidy screening

A discussion of the rationale and screening for Down syndrome and neural tube defects can be found in Annotation #24, "Fetal Aneuploidy Screening."

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5. Height and Weight/Body Mass Index (BMI)

The patient's BMI should be calculated at the first prenatal visit, and weight gain during pregnancy should be monitored at each subsequent prenatal visit. Clinicians should recognize that pregnant women receive mixed messages from family and the media about appropriate weight gain in pregnancy. The clinician should be prepared to correct these false beliefs.

The Institute of Medicine has devised recommendations for total weight gain and the rate of weight gain based on the pre-pregnant or initial pregnant BMI (if pre-pregnant BMI is not known). A table, modified from the report of the Institute of Medicine, is included here.

Pre-pregnant or Initial Pregnant BMI	BMI (WHO calculations)	Total Weight Gain Range (pounds)	Rate of Weight Gain in Second and Third Trimesters (pounds/week)
Underweight	< 18.5	28-40	1 (range 1.0 to 1.3)
Normal weight	18.5-24.9	25-35	1 (range 0.8 to 1.0)
Overweight	25.0-29.9	15-25	0.6 (range 0.5 to 0.7)
Obese	≥ 30.0	11-20	0.5 (0.4 to 0.6)

Committee to Re-examine Institute of Medicine Pregnancy Weight Guidelines. Report Brief: Weight Gain During Pregnancy: Re-examining the Guidelines, May 2009.

Although evidence to support an absolute weight gain during pregnancy based on fetal or maternal health outcomes is limited, the recommendations of the Institute of Medicine are supported in several ways. A retrospective analysis of 7,259 deliveries found either a rapid or slow weight gain during later pregnancy was associated with greater incidence of preterm birth *(Carmichael, 1997 [Low Quality Evidence]; Siega-Riz, 1996 [Low Quality Evidence])*.

Women with pre-pregnancy BMI mostly in the underweight category had an increased risk of preterm birth *(Spinillo, 1998 [Low Quality Evidence])*. Women with high pre-pregnancy BMI have increased risk for gestational diabetes, hypertension, preeclampsia, dystocia in labor, primary Caesarean section, labor induction, increased wound infection, antepartum venous thromboembolism, and anesthesia complications *(Robinson, 2005 [Low Quality Evidence])*. Women with pre-pregnancy BMI in the obese category had an increased risk of gestational hypertension and significantly higher postpartum BMI at the six-week post-partum visit if weight gain during the pregnancy was greater than 15 pounds. Equally important, that same study showed no adverse effects on perinatal morbidity or mortality among obese women whose weight gain during pregnancy was less than 15 pounds *(Thornton, 2009 [High Quality Evidence])*.

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Bariatric surgery

Pregnancy after bariatric surgery is relatively safe, when compared to the higher risks of gestational diabetes mellitus, pregnancy-related hypertension and fetal macrosomia associated with obesity in pregnancy. Pregnancy after bariatric surgery is not associated with adverse perinatal outcomes more than two years after surgery *(American College of Obstetricians and Gynecologists, 2009a [Guideline]); Guelinckx, 2009 [Low Quality Evidence]; Sheiner, 2004 [Low Quality Evidence])*. However, monitoring for nutritional deficiencies is an important consideration after bariatric surgery, and there have been rare case reports of maternal deaths from intestinal obstruction in pregnancy after roux-en-y bypass procedures *(Moore, 2004 [Low Quality Evidence])*.

The work group recommends that, where available, women who become pregnant after surgery be referred to a perinatologist for consultation. The American College of Obstetricians and Gynecologists also recommends referral to a nutritionist at the beginning of the pregnancy for evaluation of possible nutrient deficiencies (*American College of Obstetricians and Gynecologists Practice Bulletin, 2009a [Guideline])*. With the use of adjustable devices or procedures in conjunction with bariatric surgery, consider consultation with a bariatric surgeon when pregnancy is diagnosed, especially if such an adjustment has been made recently.

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6. Blood Pressure

Blood pressure (BP) screening is recommended at the preconception visit and at all prenatal visits throughout the pregnancy. Meaningful blood pressure measurements require consistent use of correct technique and a cuff of appropriate size (length 1.5 times the upper arm circumference or a cuff with a bladder that encircles 80% or more of the arm). The patient should be in an upright position and the blood pressure should be measured after the patient's arm has rested at heart level for five minutes *(National High Blood Pressure Work Group, 2000 [Low Quality Evidence])*.

Hypertensive disease occurs in 12-22% of all pregnancies and is responsible for approximately 11% of maternal deaths in the U.S (http://www.mchb.hrsa.gov/whusa11/). Diagnosis of hypertension in pregnancy is divided into disorders related to the pregnancy (gestational hypertension and preeclampsia) and hypertensive disorders unrelated to pregnancy. The onset of hypertensive disorders in either category are nearly always asymptomatic. For this reason, only universal screening maneuvers can reliably detect these disorders early in the disease process *(Chesley, 1984 [Low Quality Evidence])*.

The National High Blood Pressure Working Group defines hypertension in pregnancy as either a diastolic pressure above 90 mmHg or a systolic blood pressure above 140 mmHg in a woman 20 weeks or greater with a previously normal blood pressure. Preeclampsia is defined as gestational hypertension combined with proteinuria after 20 weeks gestation. Proteinuria is defined as 300 mg of protein or more in a 24-hour urine specimen *(Bujold, 2010 [Systematic Review])*.

The conventional urine dipstick test is unreliable in quantifying urine protein excretion. The threshold for a positive urine dipstick (1+ on the scale) roughly corresponds to 300 mg per 24 hours (the upper limit of normal protein excretion) if the urine volume for that 24-hour collection is one liter. A systematic review concluded a 1+ dipstick reading had no clinical value, since a negative dipstick did not necessarily exclude significant proteinuria, while many women with positive tests did not have it *(Waugh, 2004 [Systematic Review])*.

The 24-hour urine collection allows a direct determination of total urine protein and is a common means for accurately quantifying urine protein excretion. The creatinine excretion can also be measured, allowing an estimation of the creatinine clearance, and by extension, the glomerular filtration rate (GFR). However, the 24-hour urine collection is cumbersome and delays making a diagnosis. Additionally, studies have shown many ambulatory patient urine collections are incomplete *(Côté, 2008 [Low Quality Evidence])*.

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The risks of untreated preeclampsia and coincident hypertension in pregnancy are manifold. Potential maternal complications include 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 *(Cunningham, 1992 [Low Quality Evidence])*.

Therefore, the best screening strategy for hypertension in pregnancy appears to be early detection of an abnormal blood pressure trend over time. 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 patients, screening is indicated on an empirical basis *(U.S. Preventive Services Task Force, 2007 [Guideline])*.

Patients who may be at a higher risk for developing preeclampsia include, but are not limited to, those with a history of preeclampsia, chronic hypertension, lupus, preexisting diabetes mellitus, antiphospholipid syndrome, morbid obesity (BMI > 30) and renal disease. Baseline laboratory testing including hemoglobin, platelet count, liver function tests and 24-hour urine during an early prenatal visit may be helpful in establishing an accurate diagnosis should signs or symptoms of preeclampsia be present later in the pregnancy *(Seed, 2011 [Low Quality Evidence]; Duckitt, 2005 [Systematic Review])*.

There is evidence to suggest some efficacy for low-dose aspirin (50 to 150 mg daily) to prevent preeclampsia in higher risk patients. A systematic review of 34 randomized controlled trials using such regimens concluded that the therapy was effective in reducing the incidence of preeclampsia only if started before 16 weeks gestation. Possible low-dose aspirin side effects – including bleeding ulcers, allergic reactions including asthma, hemorrhagic stroke, and interactions with other medications – should be discussed with patients before starting the medication *(Bujold, 2010 [Systematic Review])*.

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7. History and Physical

An age-appropriate periodic health assessment as described in the ICSI Preventive Services guidelines should be performed. The Preventive Services guidelines should be consulted regarding the indicated frequency of screening, counseling and immunization maneuvers. Ensure patient is up to date on tetanus and Hepatitis B vaccinations. Abdominal and pelvic examination to evaluate gynecologic pathology should be done at the preconception visit and the first prenatal visit.

Most of the major textbooks suggest a general history be obtained at the onset of prenatal care. The best summation regarding the extent of the history is given in Williams Obstetrics and Gynecology, which states that the history "must be sufficiently penetrating to uncover any current abnormalities and any prior ones that could have a bearing in the course of pregnancy" *(Pritchard, 1985 [Low Quality Evidence])*.

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8. Rubella/Rubeola Status

Screening for rubella susceptibility by history of vaccination or by serology is recommended for all women of childbearing age at their first preconception encounter to reduce incidence of congenital rubella syndrome (CRS). All susceptible non-pregnant women of childbearing age should be offered vaccination. Susceptible pregnant women should be vaccinated in the immediate postpartum period.

Due to concerns about possible teratogenicity, MMR or measles vaccination is not recommended during pregnancy. There are no known adverse consequences to vaccination postpartum while breastfeeding *(Krogh, 1989 [Low Quality Evidence])*.

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Burden of Suffering

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. The lifetime costs of treating a patient with CRS in 1985 exceeded $220,000. In 1993 the incidence rate was 0.1 in 100,000 (92 cases).

Adults accounted for 25% of the measles cases reported in 1994. Complications of measles, including pneumonia and encephalitis, are more common among adults than among school-aged children. Outbreaks have been known to occur in locations such as schools or barracks where young adults congregate. Measles was reported in 232 (0.1 in 100,000) American adults (age 20 or older) in 1994 *(Centers for Disease Control, 1994 [Guideline])*.

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9. Varicella Status

The CDC recommends that all adults be immunized if seronegative. However, administration of the varicella vaccine during pregnancy is contraindicated. Immunity status should be elicited during the preconception counseling session. Testing and immunization should then be offered to the appropriate individuals *(Jumaan, 2002 [R])*.

Maternal varicella 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 *(Enders, 1994 [Low Quality Evidence]; Jones, 1994 [Low Quality Evidence])*.

Among adults having a negative or uncertain history of varicella, approximately 75% will be immune *(Nordin, 1998 [Guideline])*. Generally, it is felt that a patient with a positive history of varicella infection before 1995 should be considered immune. Patients 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, 1998b [Cost-Effectiveness Analysis])*.

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10. Domestic Violence

Domestic violence is a serious public health problem for many Americans. In accordance with the ICSI Preventive Services guideline, screening for domestic violence should be done at a preconception visit. See Appendix A,"Preconception Risk Assessment Form."

Due to the substantial potential benefit to families in which the cycle of abuse can be interrupted, clinicians should maintain a high index of suspicion for domestic violence when caring for pregnant women. Likewise, clinicians should have a clear plan for referring victims and perpetrators of domestic violence to other professionals and community services.

Violence during pregnancy has been associated with miscarriage, late entry into prenatal care, stillbirth, premature labor and birth, fetal injury and low birth weight *(Krug, 2002 [Low Quality Evidence])*.

Pregnant women do experience domestic violence, and some studies suggest pregnancy as a risk factor. In surveys (primarily from urban, public clinics), 7-18% of women reported physical abuse during the current pregnancy. Women of all ethnic, educational and socioeconomic backgrounds have reported abuse. Studies have also reported associations between partner abuse and unhealthy prenatal behaviors and poor perinatal outcomes *(Webster, 1996 [Low Quality Evidence])*.

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In a survey study of urgent care OB/GYN patients, 46% of pregnant women reported a history of abuse, and 10% of pregnant women reported recent abuse. Young age was significantly associated with recent abuse independent of pregnancy status. In this study, young age was defined as under 20 years of age *(McGrath, 1998 [Low Quality Evidence])*.

Some studies have described an increase in the reporting of domestic violence during pregnancy when a systemic screening approach is implemented. There is also some evidence to suggest that repeated screening for domestic violence during pregnancy may increase reporting of domestic violence. Direct interview screening resulted in a higher rate of reporting prenatal domestic abuse than a written, self-report questionnaire method *(Wiist, 1999 [Low Quality Evidence]; McFarlane, 1992 [Low Quality Evidence])*.

Pregnant women who reported abuse and were offered intervention and resources increased their safety behaviors both during and after pregnancy. One study reported increased moderate or severe violence during the postpartum period. Identification of prenatal abuse and immediate intervention with safety information may prevent future abuse *(Gielen, 1994 [Low Quality Evidence])*.

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11. Depression

The prevalence of depression in pregnant women and new mothers is estimated from 5 to 25% and is considered a major public health problem *(Gaynes, 2005 [Meta-analysis])*. Untreated depression has been associated with unfavorable health behaviors in pregnancy such as poor attendance at prenatal clinics, substance misuse, decrease in appetite resulting in poor weight gain and subsequent fetal growth restriction, preterm delivery, placenta abruption, and newborn irritability *(Evans, 2001 [Low Quality Evidence]; Zuckerman, 1989 [Low Quality Evidence])*.

Factors associated with a greater likelihood of antepartum depressive symptoms in bivariate analyses were maternal anxiety, life stress, history of depression, lack of social support, unintended pregnancy, Medicaid insurance, domestic violence, lower income, lower education, smoking, single status and poor relationship quality *(Lancaster, 2010 [Systematic Review])*.

Given the significant morbidity for both mother and infant, antenatal screening and intervention for those women who are at greatest risk of antenatal and postnatal depression and anxiety are potentially important strategies. During pregnancy and the early postpartum period provide opportunities through regular prenatal and postpartum clinician contacts to screen for depression *(Gavin, 2005 [Systematic Review])*. The American College of Obstetricians and Gynecologist, The Committee Opinion recommendation is to perform psychosocial screening at least once per trimester to increase the likelihood of identifying important issues and reducing poor birth outcomes *(American College of Obstetricians and Gynecologists, 2006a [Low Quality Evidence])*. The United States Preventive Services Task Force (USPSTF) recommends routine depression screening for all patients in clinical practices that have systems in place to assure effective diagnosis, treatment and follow-up *(U.S. Preventive Services Task Force, 2009 [Systematic Review])*.

There is not, however, good evidence to distinguish between the different screening instruments for depression. There is also little evidence of large-scale screening programs to date. The work group suggests using the following two questions to screen for depression to be as effective as lengthier tools and an appropriate place to start.

1. Over the past two weeks, have you ever felt down, depressed or hopeless?
2. Over the past two weeks, have you felt little interest or pleasure in doing things?

(Pignone, 2002 [Systematic Review])

If a patient has an active diagnosis of depression or screens positive anytime during the perinatal period, refer to the ICSI Major Depression in Adults in Primary Care guideline for treatment options for patients with depression during the perinatal phase.

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12. Preterm Labor Education

Advise the patient of the importance of communication with health care clinician as soon as pregnancy is suspected.

At-risk patients should be assessed and given educational information about risk factors by 16-20 weeks or anytime thereafter when a risk factor is identified.

If patients have identifiable risk factors, intervene as appropriate in your health care setting. See Annotation #4, "Risk Profile Screening."

Is Patient Willing to Change Modifiable Risks?

- Provide information about problems caused by specific behaviors in pregnancy, and offer help when ready to change.
- Offer support, interventions and/or referrals as referred to in the ICSI Preventive Services for Adults guideline.
- Ask to set a quit or change date, provide educational aids, offer counseling or classes, arrange for follow-up (at least a phone call) soon after the quit or change date.

Modifiable risk factors:

- Family stress

  Psychosocial situation – referrals as appropriate, include patient's "support system" in visits and education

  Stress/anxiety – educate about and assist with sources of stress such as medical limitations for work, day care, home help
- Depression
- Domestic violence
- Tobacco use
- Drug and alcohol use – urine testing where indicated

  For clinicians' legal obligations in testing for chemical use during pregnancy, see the 2002 Minnesota Statutes 626.5561 (Reporting of Prenatal Exposure to Controlled Substances) and 626.5562 (Toxicology Tests Required). Minnesota statutes may be accessed at http://www.leg.state.mn.us.
- Nutritional concerns

  Dietary inadequacy – educate, assist with referral for food supplement program
- Sexually transmitted diseases
- Low preconception BMI/slow prenatal weight gain (see Annotation #5, "Height and Weight/Body Mass Index [BMI]")

Educate Patient to Monitor Risk Factors

Contractions

Menstrual cramps

Intestinal cramps

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Constant backache

Constant pelvic pressure

Vaginal discharge amount and color

Bleeding or spotting

Urinary frequency

(Andersen, 1989 [Low Quality Evidence]; Nagey, 1985 [Low Quality Evidence])

Also see the Implementation Tools and Resources Table, "March of Dimes," section of this guideline.

Home Health Visits/Case Management

Home health visits and case management are additional methods for monitoring patients at risk *(Bryce, 1991 [High Quality Evidence])*.

Also see the Implementation Tools and Resources Table, "March of Dimes," section of this guideline.

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13. List of Medications, Herbal Supplements and Vitamins

(See also Annotation #25, "Nutritional Supplements.")

Use of all prescription and nonprescription drugs, herbal supplements, and vitamins should be reviewed and documented with every woman at a preconception visit. A complete inventory of drug usage immediately prior to and during pregnancy should be performed at the first prenatal visit. All pregnant women should be counseled about the potential reproductive effects of medications. A Web site that provides patients with a review of the pregnancy implications for the most common herbal supplements is http://www.american-pregnancy.org/pregnancyhealth/naturalherbsvitamins.html.

With rare exceptions, any drug that exerts a systemic effect in the mother will cross the placenta to reach the embryo and fetus. The effects on the embryo and fetus cannot be predicted accurately either from the effects or lack of effects in the mother. Similarly, widespread use of a medication during pregnancy without recognized effects on the fetus does not guarantee the safety of the medication. The work group recommends accessing resources such as Drugs in Pregnancy and Lactation *(Briggs, 2008 [Low Quality Evidence])*.

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14. Accurate Recording of Menstrual Dates

The most accurate determination of an estimated due date is the last menstrual period in women with regular menstrual cycles. This requires careful history taking, because many women erroneously determine this date. Some women can say with certainty exactly which day they became pregnant. In vitro fertilization and related reproductive technologies allow exact determination of due date from time of fertilization of the ovum in the laboratory.

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15. Folic Acid Supplement

The U.S. Preventive Services Task Force (USPSTF) and Centers for Disease Prevention and Control (CDC) recommend that all women of childbearing age take a daily vitamin supplement containing 400 to 800 micrograms of folic acid from at least one month before conception through the first three months of pregnancy. The CDC recommends that women planning pregnancy who have previously had a pregnancy affected by a neural tube defect (NTD) consult their clinician about taking an increased daily dose of folic acid *(Wolff, 2009 [Low Quality Evidence])*. Patients who previously have a pregnancy affected by a neural tube defect

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should have 4 mg daily. Other patient groups who may be considered for higher doses of folic acid include black, Hispanic, or Asian/Pacific Islander race/ethnicity, younger patients or overweight or obese patients *(Lawrence, 2006 [Low Quality Evidence])*.

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16. Complete Blood Count (CBC)

A CBC is recommended for screening of hemoglobinopathies.

Hemoglobin Assessment

A hemoglobin assessment is recommended for all pregnant women at their first prenatal visit.

If hemoglobin is less than 11 g/dL in the first or third trimester or less than 10.5 g/dL in the second trimester, a course of at least 30 mg oral elemental iron daily should be administered. If a repeat hemoglobin assessment one month after oral iron therapy remains low, a serum ferritin should be drawn. If the serum ferritin level is less than 12 mcg/L, one can still make the diagnosis of iron deficiency anemia. If daily doses of more than 30 mg elemental iron are administered, consideration should be given to replacement of copper and zinc.

Supplemental iron is available in two forms: ferrous and ferric. Ferrous iron salts (ferrous fumarate, ferrous sulfate, and ferrous gluconate) are the best-absorbed forms of iron supplements *(Hoffman, 2000 [Low Quality Evidence])*.

Elemental iron is the amount of iron in a supplement that is available for absorption.

Ferrous gluconate	12% elemental iron
Ferrous sulfate	20% elemental iron
Ferrous fumarate	33% elemental iron

The amount of iron absorbed decreases with increasing doses. For this reason, it is recommended that most people take their prescribed daily iron supplement in two or three equally spaced doses *(Centers for Disease Control, 2002 [Guideline])*.

Pregnant women should be encouraged to drink water or orange juice and to eat foods high in available iron. Women should be counseled that drinking milk, coffee or tea with meals lowers iron absorption. The value of breastfeeding as primary protection against iron deficiency anemia in infants should also be reviewed with all pregnant women *(Centers for Disease Control, 1989 [Guideline]; Pizarro, 1991 [Low Quality Evidence])*.

Iron deficiency anemia may be related to preterm birth and low birth weight, though other studies failed to demonstrate this correlation *(Rasmussen, 2001 [Low Quality Evidence])*.

A randomized clinical trial concluded that intravenous iron treatment for iron deficiency anemia in pregnancy replaced iron stores faster and more effectively than oral iron with no serious adverse reaction *(Al, 2005 [High Quality Evidence])*.

Dietary counseling to promote iron absorption from foods should be given to all pregnant women.

Because hemoglobin measurement is a non-specific test for iron deficiency, further evaluation should be performed to identify the etiology of anemia detected by screening. Serum ferritin appears to have the best sensitivity and specificity for diagnosing deficiency in anemic patients *(Guyatt, 1992 [Systematic Review])*.

There is insufficient evidence to support universal iron supplementation in pregnancy *(Hemminki, 1995[High Quality Evidence])*.

Excess supplementation may not be benign. Mineral imbalances, including zinc and copper, may result. Placental infarctions, a common cause of fetal death, are non-existent with hemoglobin levels less than or equal to 8 g/dL. No benefit from supplementation can be demonstrated for non-anemic women in the prevention of international growth restriction, pregnancy-induced hypertension, primary pulmonary hypertension or fatigue *(Simmer, 1987 [Low Quality Evidence])*.

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17. ABO/Rh/Ab (RhoGAM)

D (Rh) Incompatibility

D (formerly Rh) blood typing and antibody screening is recommended for all pregnant women at their first prenatal visit. For purposes of chemoprophylaxis, D-negative and DU blood types are equivalent. As a consequence of the current laboratory testing procedure, ABO typing will also be determined through such screening. Repeat D antibody testing is recommended for all unsensitized D-negative women at 28 weeks gestation, followed by D immunoglobulin (RhoGAM) if the woman is antibody-negative. A similar dose of D immunoglobulin is recommended for all unsensitized D-negative women after amniocentesis. There is currently insufficient evidence to recommend for or against the administration of RhoGAM after chorionic villus sampling, cordocentesis, external version, or antepartum placental hemorrhage (*U.S. Preventive Services Task Force, 1966b [Systematic Review]*).

D incompatibility (D-negative woman pregnant with D-positive fetus) occurs in up to 10% of pregnancies. If no preventive measures are taken, 0.7-1.8% of these women will be isoimmunized antenatally, 8-17% at delivery, 3-6% after elective or spontaneous abortion, and 2-5% after amniocentesis *(Mollison, 1987 [Low Quality Evidence])*.

In subsequent D-positive pregnancies in such isoimmunized women, maternal D antibody will cross the placenta into the fetal circulation and cause hemolysis (erythroblastosis fetalis). Without treatment, 25-30% of such fetuses will develop detectable hemolytic anemia and hyperbilirubinemia, and another 20-25% will develop severe enough hydrops fetalis to die in utero or in the neonatal period *(Bowman, 1985 [Low Quality Evidence])*.

A series of controlled clinical trials in the 1960s demonstrated the efficacy of D immunoglobulin in preventing maternal isoimmunization of most unsensitized D-negative women after delivery of a D-positive fetus *(Pollack, 1968 [High Quality Evidence])*.

The most frequent cause of failure of postpartum chemoprophylaxis is antenatal isoimmunization, which happens in 0.7-1.8% of pregnant women at risk. Non-randomized trials have shown a reduction in the incidence of isoimmunization to less than 2.0% when D immunoglobulin is also administered to unsensitized pregnant women at risk at 28 weeks gestation *(Trolle, 1989 [Low Quality Evidence])*.

There is similar evidence for the efficacy of such chemoprophylaxis after amniocentesis *(Tabsh, 1984 [Low Quality Evidence])*.

Studies documenting the effectiveness of D immunoglobulin prophylaxis are not available for chorionic villus sampling, cordocentesis, external version, or antepartum placental hemorrhage *(U.S. Preventive Services Task Force, 1996b [Systematic Reivew])*.

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18. Syphilis

All pregnant women at the first prenatal visit and all high-risk women at a preconception visit should undergo routine serologic testing (RPR or VDRL) for syphilis *(U.S. Preventive Services Task Force, 2009 [Systematic Reivew])*. There is insufficient evidence to recommend screening all women at the preconception visit. However, early detection of syphilis at the preconception visit allows antibiotic therapy to prevent clinical disease and to prevent transmission to sexual contacts. Maternal antibiotic therapy prevents nearly all congenital syphilis.

Because of the decline in cases of syphilis in women during the years 1992-2002 and in certain areas of the country syphilis has nearly disappeared, universal screening may no longer be justified. Yet certain areas of the U.S. (urban areas and the South) have had syphilis outbreaks, and due to the devastating effects of congenital syphilis, prenatal screening is still universally recommended by the CDC *(Centers for Disease Control, 2006 [Guideline]; Centers for Disease Control, 2008 [Guideline]; Kiss, 2004 [Low Quality Evidence])*.

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Premature birth occurs in 20% of cases of maternal syphilis, and a wide variety of severe abnormalities result from congenital syphilis. The vertical transmission rate is estimated at 70-100% *(Dorfman, 1990 [Low Quality Evidence])*.

Serologic tests have a sensitivity of 62-76% and near 100% in primary and secondary syphilis, respectively. Specific treponemal tests, such as fluorescent treponemal antibody absorption (FTA), have a specificity of 96%. Treponemal tests should not be used as initial screening tests in asymptomatic patients due to the increased expense and the persistent positive test in patients with previous, treated infection *(Hart, 1986 [Low Quality Evidence])*.

A high-risk profile for women likely to have asymptomatic syphilis can be devised. A growing number of cases occur in prostitutes and IV drug users. A number of demographic and behavioral variables have been associated with higher rates of *T. palladium* infection: large urban areas or Southern states, history of sexually transmitted diseases or other current STIs, low socioeconomic status, and Black race or Hispanic heritage.

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19. Urine Culture

Screening for asymptomatic bacteriuria (ASB) by urine culture is recommended for all pregnant women at the first prenatal visit. There are inadequate data to determine the optimal frequency of subsequent urine testing during pregnancy.

A urine culture obtained at 12-16 weeks of pregnancy will identify 80% of women who will ultimately have ASB in pregnancy, with an additional 1-2% identified by repeated monthly screening *(Bachman, 1993 [Low Quality Evidence])*.

Among pregnant women, a sensitivity of only 50% for dipstick testing compared to culture has been reported. In pregnant women, microscopic analysis, with either bacteriuria or pyuria indicating a positive test, had a sensitivity of 83% but a specificity of only 59%. Positive predictive value of dipstick tests is 13% for pregnant women.

Predictive value of bacteriuria found on microscopic urinalysis among pregnant women is 4.2-4.5%.

Early detection of ASB in pregnant women is of value because bacteriuria is an established risk factor for serious complications, including acute pyelonephritis, preterm delivery and low birth weight. Randomized controlled trials (RCTs), cohort studies and a meta-analysis of eight RCTs have shown that treatment of ASB can reduce the incidence of such complications *(Pastore, 1999 [Low Quality Evidence]; Romero, 1989 [Meta-analysis]; Stenqvist, 1989 [Low Quality Evidence])*.

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20. HIV

As the incidence of HIV infection has increased among women of childbearing age, increasing numbers of children have become infected through perinatal transmission *(Centers for Disease Control, 1995b [Guideline])*.

All pregnant women should receive education and counseling about HIV testing as part of their routine prenatal care. HIV testing should be recommended at the first prenatal visit for all pregnant women with their consent. In the event of a refusal of testing, the refusal should be documented.

Pregnant women found to be at higher risk for HIV on the basis of a screening instrument for infectious disease risks should receive continued education about the health benefits of HIV testing and should be considered for repeat HIV testing later in pregnancy.

A study involving mothers with mildly symptomatic HIV infection (CD4 greater than 200 mcg/L) showed that zidovudine has had a low incidence of severe side effects in the mothers and infants studied *(Connor,*

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1994 [High Quality Evidence]). Anti-retroviral medications given to pregnant women with HIV and to their newborns in the first few weeks of life reduces the vertical transmission rate from 25% to 2% or less *(American College of Obstetricians and Gynecologists, 2008a [Guideline])*. It does transmit to the fetus and is associated in animal studies with early pregnancy failure, but it does not appear to cause fetal abnormality. The current guidelines on interventions to reduce perinatal HIV transmission recommend combination antiretroviral therapy to be started from the second trimester until delivery, using zidovudine as the cornerstone. Despite the fact that evidence so far does not suggest zidovudine causes any significant fetal malformation in either human and animals when given in first trimester, this work group is still cautious in recommending the use of zidovudine in the first trimester *(Siu, 2005 [Low Quality Evidence])*. Detailed protocols of drug therapy do change and the work group recommends that this be developed in conjunction with infectious disease specialists who have detailed knowledge of current recommendations for both maternal and newborn treatment.

There is evidence to suggest that pregnant women in high-risk categories or from communities with a higher prevalence of seropositive newborns (greater than 0.1%) should be counseled about the benefits of early intervention for HIV. Repeat testing in the third trimester may also be indicated for this group *(Tookey, 1998 [Low Quality Evidence])*.

Several studies have indicated that counseling and testing strategies that offer testing only to those women who report risk factors fail to identify up to 50-70% of HIV-infected women *(Centers for Disease Control, 1995b [Guideline])*.

A policy of universal screening for all pregnant women with their consent is recommended on grounds of easier implementation and greater sensitivity than risk-profile screening alone *(American College of Obstetricians and Gynecologists, 2008 [Guideline])*.

Identifying seropositive women may have other important benefits, including:

- some women may be candidates for Pneumocystis carinii chemoprophylaxis,
- male partners can be counseled about coitus and the use of condoms,
- newborns can be monitored for signs of infection,
- mothers can be counseled about breastfeeding, and
- parents may elect to terminate the pregnancy.

It may be possible to increase patient acceptance of HIV testing by informing women about the opportunity to reduce vertical transmission to their baby with treatment *(Carusi, 1998 [Low Quality Evidence])*.

A meta-analysis of cohort studies suggested that breastfeeding increased the vertical transmission rate by 14% *(Dunn, 1992 [Low Quality Evidence])*.

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21. Blood Lead Screening

The Minnesota Department of Health recommends blood lead screening for pregnant women felt to be at risk for lead exposure. Patients should be assessed for lead exposure using the Blood Lead Screening Risk Questionnaire for Pregnant Women in Minnesota. (See Appendix F, "Blood Lead Screening Guidelines for Pregnant Women in Minnesota.")

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22. Vaginal Birth After Caesarean (VBAC)

The recommendations in this guideline are supported by large controlled studies. The guideline work group would prefer to refer to double-blind studies, but it is not feasible to blind a woman to whether she is having labor or a Caesarean delivery, and it is unsafe to blind care clinicians to whether or not a woman has had a previous Caesarean delivery. Given these limitations, the work group feels confident of the literature support for the recommendations within this guideline. Furthermore, these recommendations are consistent with the latest practice patterns for VBAC published by the American College of Obstetricians and Gynecologists *(American College of Obstetrics and Gynecologists, 2010 [Guideline])*.

At the first office visit:

- obtain previous operative reports stating type of uterine incision,
- perform thorough history and physical, and
- obtain necessary consultations from other specialists.

The operative report(s) of previous Caesarean deliveries or other uterine surgery should clearly state the type of uterine incision. A previous low segment transverse uterine incision carries the lowest risk of complications when attempting a VBAC. Certain cardiac, neurological, orthopedic or other medical conditions may be present that could jeopardize maternal and/or fetal safety if vaginal birth is attempted. Consultations and a copy of the recommendations should be obtained early in the prenatal period. Physical examination may detect pelvic masses or other conditions undetected by previous medical care that may be a barrier to VBAC *(Pridjian, 1992 [Low Quality Evidence]; Lilford, 1990 [Low Quality Evidence])*.

Discuss Risks/Benefits with Patient and Document

Provide patient education, including a discussion of the risks and benefits associated with VBAC. Encourage VBAC in appropriate patients. Document this discussion *(NIH Conference Statement, 2010 [Guideline]; American College of Obstetrics and Gynecologists, 2010 [Low Quality Evidence])*. Also see Appendix H, "ICSI Shared Decision-Making Model."

A. Contraindications to VBAC

The overall rate of maternal complications has not been found to differ significantly between women who choose a trial of labor and women who elect to have a Caesarean delivery *(Guise, 2004 [Systematic Review]; Mozurkewich, 2000 [Meta-analysis])*.

The study "Comparison of a Trial of Labor with an Elective Caesarean Section" reconfirms that, for both vaginal delivery and Caesarean section, the baby's risk for major complications is fairly equal and the safest route for the mother is vaginal delivery. While the mother's risk of major complications (hysterectomy, uterine rupture, operative injury) with trial of labor is slightly higher (0.7%) than a scheduled repeat Caesarean delivery (0.2%), these risks are still quite low *(Al-Zirqi, 2010 [Low Quality Evidence])*.

The work group recommends that after consideration of the individual situation of the patient, VBAC is still a viable option for the majority, due to the high probability of successful vaginal delivery and the low rate of complications after trial of labor. This data should be discussed when counseling a patient.

Symptomatic rupture of the gravid uterus carries a 45.8% perinatal mortality and a 4.2% maternal mortality and occurs in 4.3-8.8% of women with a high vertical uterine scar *(Pridjian, 1992 [Low Quality Evidence]; Eden, 1986 [Low Quality Evidence])*.

Incisions penetrating the muscular layer of the uterus may weaken this area and increase the risk of uterine rupture *(O'Brien-Abel, 2003 [Low Quality Evidence]; Caughey, 1999 [Low Quality Evidence])*.

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(Shipp, 2003 [Low Quality Evidence]; Shipp, 2002 [Low Quality Evidence]; Mozurkewich, 2000 [Meta-analysis]; Gabbe, 1986 [Low Quality Evidence])

A history of previous uterine dehiscence or rupture has a rate of repeat separation of 6.4% if previous uterine incision was in the lower segment and 32.1% if the scar is in the upper segment, with complication rates assumed to be similar to those of the primary uterine rupture *(Ritchie, 1971 [Low Quality Evidence])*. However, there was no significant association found with the presence of an unknown uterine scar type *(American College of Obstetricians and Gynecologists, 2010 [Guideline])*.

A patient with a history of arrest of dilation or descent in labor has a 74% success rate for a VBAC, slightly lower than those without that diagnosis *(Eden, 2010 [Low Quality Evidence]; Guise, 2004 [Systematic Review]; Duff, 1988 [Low Quality Evidence]; Suonio, 1986 [Low Quality Evidence])*.

Various maternal/fetal medical conditions may make a Caesarean delivery the appropriate method of birth to decrease the risk of specific complications.

The risk of rupture is low in the laboring patient with an unknown type of uterine scar, since most of these are probably the low segment transverse type. If the indication for Caesarean delivery would require a low segment transverse incision, VBAC should be considered. If the indication for the Caesarean delivery requires a vertical incision, repeat Caesarean delivery may be safer *(Beall, 1984 [Low Quality Evidence]; Pruett, 1988 [Low Quality Evidence])*.

There may be occasionally present certain rare social, geographic or past obstetrical complications that may justify the patient's electing to have a repeat Caesarean delivery *(American College of Obstetricians and Gynecologists, 2010 [Guideline])*.

Misoprostol should not be used for either cervical ripening or labor inductions due to an increased risk of uterine rupture.

Conditions that are not contraindications but that may increase risk

- Two large studies have shown a minimal increase in risk for uterine rupture for women attempting VBAC after two previous low segment transverse Caesarean sections. This risk may be as low as 0.7% and as high as 1.8%. Since this risk is quite low, attempting VBAC after two such Caesarean sections is not contraindicated. Women with a previous vaginal delivery followed by a Caesarean delivery were only approximately one-fourth as likely to sustain uterine rupture during a trial of labor *(American College of Obstetricians and Gynecologists Practice Bulletin, 2010 [Guideline])*.
- There is evidence that a short interval between pregnancies increases risk *(Esposito, 2000 [Low Quality Evidence]; Shipp, 2001 [Low Quality Evidence])*.
- The risk of uterine rupture is increased with induction of labor, regardless of gestational age *(Delaney, 2003 [Low Quality Evidence]; Zelop, 2001 [Low Quality Evidence])*.
- The risk of uterine rupture may be greater if the previous uterine incision was repaired with a single-layer uterine closure than if it was repaired with a two-layer technique *(Bujold, 2002 [Low Quality Evidence])*.

While there appears to be no accurate rating system to determine which patients are likely to be successful at a trial of labor, there are general trends supported in the literature. Greater success is noted in gestational age less than 40 weeks, absence of fetal macrosomia, and spontaneous labor. A lower rate of success is noted with previous low vertical incision, unknown type of incision, twin gestation, external cephalic version, and having an epidural *(Bujold, 2001 [Low Quality Evidence]; Flamm, 1991 [Low Quality Evidence]; Nielson, 1989 [Low Quality Evidence]; Strong, 1989 [Low Quality Evidence]; Phelan, 1984 [Low Quality Evidence])*.

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23. Prenatal and Lifestyle Education

Prenatal education is the primary tool used to transmit information to women about their pregnancies. Prenatal education serves to help reduce modifiable risk factors and to add to women's satisfaction by increasing their knowledge about pregnancy changes, fetal development, etc. Women who did not receive complete prenatal health behavior advice were 1.5 times more likely to deliver very-low-birth-weight (VLBW) infants *(Sable, 1997 [Low Quality Evidence])*.

A study done in an inner city showed that when obstetrical personnel are actively involved in counseling women about breastfeeding, more women will initiate breastfeeding and continue for a longer duration. Adequately trained health care staff can reinforce the counseling women have received in prenatal education sessions at each prenatal visit *(Russell, 1999 [Low Quality Evidence])*.

Visit 1

Education also provides information on the positive and negative impacts of the choices a woman makes. Identify which modifiable risk factors the patient is willing to address.

Counseling and education

- **Course of care**

  Review with the patient the nature of her visit schedule and upcoming assessments/interventions.

- **Discuss fetal aneuploidy screening (see Annotation #24)**

- **Nausea and vomiting**

  Nausea and vomiting in pregnancy is a common condition that affects 70-85% of pregnant women, with hyperemesis gravidarum representing the extreme end of the spectrum in 0.5-2% of pregnancies. Early treatment of nausea and vomiting in pregnancy is the goal to prevent progression to hyperemesis gravidarum.

  Symptoms of nausea and vomiting in pregnancy manifest before nine weeks gestation in virtually all affected women. If a patient experiences nausea and vomiting for the first time after nine weeks gestation, careful investigation of other causes should be considered.

  Few non-pharmacologic therapies have proven effective in preventing nausea and vomiting of pregnancy. Studies have shown women who were taking a multivitamin at time of conception were less likely to need medical attention for nausea and vomiting. Consuming different regimens of ginger also have shown significant benefit for some women.

  (American College of Obstetricians and Gynecologists Practice Bulletin, 2004 [Guideline])

  Pharmacologic therapies have proven beneficial in treating nausea and vomiting of pregnancy. Initial monotherapy recognized is vitamin B6 alone or with doxylamine added. Other medications including many of the antihistamine H1 receptor blockers, phenothiazines and benzamides have proven to be safe and efficacious in pregnancy. In refractory cases or in hyperemesis gravidarum, ondansetron (Zofran®) may be considered, as well as corticosteroids. However, corticosteroids continue to be used with caution as there is a known increased risk of oral clefts in the first 10 weeks of gestation *(American College of Obstetricians and Gynecologists Practice Bulletin, 2004 [Guideline])*. Currently available data does not demonstrate convincing evidence of benefit *(Yost, 2003 [High Quality Evidence])*.

- **Nutrition/environmental risks**

  Subject matter might include providing adequate nutrition for the growing fetus or the effects of toxins in the woman's environment.

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- **Physical activity**

  For the active woman, education on exercise helps her to understand what she can safely continue to do and what modifications need to occur *(Bungum, 2000 [Low Quality Evidence]); Kramer, 2006 [Systematic Review]; Lewis, 2008 [Low Quality Evidence])*. There is no evidence from randomized controlled trials demonstrating that exercise during pregnancy results altered outcomes; however, many other health benefits have been clearly demonstrated with a regular exercise program. (See the ICSI Preventive Services for Adults guideline.)

- **Physiology of pregnancy**

  Prenatal education gives a woman information about how her body is changing and why, thus helping her to adjust to changes as they occur. Education during clinical visits, as well as community and worksite prenatal programs, provide an opportunity for her to learn about the early hormonal changes and the growing fetus as the changes occur, and provide information on labor, birth and care after birth, at appropriate times *(Zib, 1999 [Low Quality Evidence])*.

- **Warning signs**

  Discuss signs and symptoms of miscarriage and ectopic pregnancy.

Visit 2

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Breastfeeding

  Most parents make the decision about infant feeding during pregnancy. Prenatal education offers an excellent and well-timed opportunity to provide information to expectant parents about the benefits of breastfeeding. Those benefits include complete infant nutrition and fewer infant allergies and illnesses.

- Fetal growth
- Nausea and vomiting (see visit 1 above)
- Physiology of pregnancy
- Review lab tests obtained at visit 1

Visit 3

Follow-up on any modifiable risk factors patient is addressing.

Counseling and education

- 2nd-trimester growth
- Physiology of pregnancy
- Quickening

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Visit 4

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Family issues

  Discuss with the patient her plans for assistance after delivery.
- Gestational diabetes mellitus (GDM)
- Hospital length of stay
- Prenatal classes

  Discuss with the patient the value of prenatal education.
- RhoGam

Visit 5

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Awareness of fetal movement (see Annotation #33)
- Fetal growth and development
- Physiology of pregnancy
- Preregistration
- Work

Visit 6

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Contraception
- Episiotomy
- Labor and delivery issues
- Pediatric care
- Sexuality
- Travel

Visit 7

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Contraception

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- Discussion of postpartum depression

  A discussion about postpartum depression and available resources should be disseminated to women in late pregnancy. Those at high risk for postpartum depression should be identified and counseled. Also see Annotation #11, "Depression."

- Management of late pregnancy symptoms
- Postpartum care
- When to call the clinician

Visits 8-11

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Infant CPR
- Labor and delivery issues
- Post-term management
- Postpartum vaccination

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24. Fetal Aneuploidy Screening

The work group is aware of the recent availability of circulating cell-free DNA testing for aneuploidy screening, as well as broader screening for other birth defects. The professional associations involved in determining the proper role of DNA testing in such screening, as well as in developing algorithms for the use of this type of testing in various clinical situations, have not achieved any measure of consensus. The work group wishes to alert clinicians to the possible availability of such testing for their own organizations. The applications for circulating cell-free DNA testing will be reviewed in the next revision of this guideline.

Counseling

See Appendix H, "ICSI Shared Decision-Making Model."

Comprehensive counseling should be offered to all pregnant women regarding the different screening options and the benefits and limitations of each of the screening and diagnostic tests. Clinicians counseling patients need to take into consideration a variety of factors, including attitudes toward early first trimester detection, miscarriage, elective termination and having a child with Down syndrome or other birth defects *(Légaré, 2010 [Low Quality Evidence]; Berkowitz, 2006 [Low Quality Evidence]; Kupperman, 1999 [Low Quality Evidence])*. The estimated risk of miscarriage following amniocentesis or chorionic villus sampling (CVS) has decreased over time. From 1998 to 2003 the adjusted amniocentesis loss rate was 1 in 370. This compares to a previous loss rate of 1 in 200. The decrease in loss rate from CVS has been greater, and there is no longer a statistically significant difference between the two *(Caughey, 2006 [Low Quality Evidence])*. Patients should be counseled that the rate of miscarriage is low with either amniocentesis or CVS, and there is no preference for one or the other.

It is preferable to provide patients with their numerical risk determined by the screening test, rather than a positive versus negative screening result using an arbitrary cutoff. It is often useful to contrast this risk with the general population risk and their age-related risk before screening (*American College of Obstetricians and Gynecologists, 2007 [Guideline]*). It is suggested that the patient's clinician make a concerted effort while counseling to convey the information in as simple terms as possible, and use a translator if needed. Additionally, meeting with a genetic counselor may be beneficial.

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Although maternal serum alpha-fetoprotein (AFP) can be used in the second trimester to screen for fetal spina bifida, reported detection rates typically fall in the 80% range. However, an ultrasound at 18-20 weeks gestation when screening for fetal neural tube defects may be technically superior to serum testing detecting 96% of fetal neural tube defects in one series *(Kooper, 2007 [Low Quality Evidence])*.

Screening for Trisomy 21

The last decade has seen major shifts in the tests available and recommendations for screening for Down syndrome (Trisomy 21). Driving these changes has been a desire to shift invasive testing from the second trimester (amniocentesis) to the first trimester (chorionic villus sampling). Targeting high-risk individuals can also increase rates of detection while simultaneously decreasing rates of invasive testing in the overall population *(American College of Obstetricians and Gynecologists, 2007 [Guideline])*.

Using maternal age of 35 as a sole indicator for testing will detect only 30% of Trisomy 21. Approximately 80% of Down syndrome babies are born to mothers under the age of 35 *(Berkowitz, 2006 [Low Quality Evidence])*.

The most widely available and used screening for Trisomy 21 is serum testing in the second trimester (15-18 weeks). Triple screen (AFP, hCG, Estriol) and quadruple screen (triple screen plus inhibin-A) are combined with maternal age to compute a pregnancy-specific risk for Trisomy 21. The quadruple screen improves the detection rates by 5-7% over triple screen alone.

More recently available is first-trimester screening. First-trimester testing techniques of ultrasound nuchal translucency (NT) between 10 and 13 weeks or a combined test (NT, hCG, and PAPP-A) enhance the detection of Down syndrome compared with second-trimester testing with the triple or quadruple screen while reducing false-positives. *[Conclusion Grade I: See Conclusion Grading Worksheet A – Annotation #24 (Fetal Aneuploidy Screening)] (Malone, 2005 [Low Quality Evidence])*

Other first-trimester sonographic markers, such as hypoplasia/absence of the nasal bone and tricuspid regurgitation, are being evaluated for their potential as screening tests for Down syndrome, but their clinical usefulness currently remains uncertain. If the nuchal translucency (NT) measurement equals or exceeds 3.0 mm, consideration should be given to immediate counseling of parents regarding invasive prenatal diagnosis as above this threshold, only 8% of patients will have negative screening results *(Comstock, 2006 [Low Quality Evidence])*. Also, if an NT measurement exceeds the 99% for gestational age or 2.5 mm, regardless of screening results consideration should be given to a "specialized/targeted" fetal anatomic evaluation due to an elevated risk of congenital heart defects *(Simpson, 2007 [Low Quality Evidence])*. PAPP-A levels that fall below the 5% expected for gestational age may also indicate a higher risk for subsequent fetal intrauterine growth restriction (IUGR) and preterm delivery, but no surveillance protocols have yet been validated *(Spencer, 2008 [Low Quality Evidence])*.

For each test individually, the detection rate calculated for Down syndrome, with a fixed screen-positive rate (similar to false-positive) of 5%, is *(American College of Obstetricians and Gynecologists, 2007 [Guideline]):*

- triple screen 69%;
- quadruple screen 81%;
- PAPP-A and free B-hCG at 10 weeks 58%, at 12 weeks 53%; and
- NT 64-70%.

Combining these tests produces higher detection rates while keeping a fixed screen-positive rate; combining NT with PAPP-A and free B-hCG yields 84-87% detection rates *(Berkowitz, 2006 [Low Quality Evidence]; Malone, 2005 [Low Quality Evidence])*.

There are many different aneuploidy screening protocols currently available *(Wenstrom, 2005 [Low Quality Evidence])*. Sensitive and specific first- and second-trimester screening protocols are now widely available, and different health care organizations and individual clinicians use elements from various strategies

to screen their patients for Down syndrome and other fetal abnormalities. Algorithms that incorporate the elements of the three principal aneuploidy screening strategies have been constructed. The work group is also cognizant that all strategies may not be available at all institutions.

First-trimester Down syndrome screening protocols can detect the majority of cases of other chromosomal aneuploidies. Addition of a Trisomy 18-specific risk algorithm in the second trimester achieves high detection rates for aneuploidies other than Down syndrome *(Breathnach, 2007 [Low Quality Evidence])*.

Several methods for combining first- and second-trimester screening reach higher detection rates for Trisomy 21 than either first- or second-trimester screening alone:

- Integrated (94-96% detection)
- Serum integrated (85-88% detection)
- Stepwise sequential (95% detection)
- Contingency (88-94% detection)

Integrated screening: The patient is scanned for nuchal translucency determination and has a serum PAPP-A analysis performed between 10 and 13 weeks. The results of these tests are held, and the patient then has a quadruple screen test performed between 15 and 19 weeks. At that time, the results of all the studies, combined with risk assessment due to the patient's age, are used to present a single-risk figure. A variation in which the first-trimester PAPP-A test result is combined with a second-trimester quad test to provide a single-risk figure is called a serum integrated screening.

Stepwise sequential screening: The patient is scanned for nuchal translucency determination and has a serum PAPP-A analysis performed between 10 and 13 weeks. The results of these studies are combined with the patient's age-associated risk, and the patient is given a risk assessment for aneuploidy. The patient may choose at this time to undergo invasive testing (e.g., amniocentesis or chorionic villas sampling [CVS]), or a triple or quad screen at 15-19 weeks. If the patient has the second-trimester test, a new risk is assessed based on the results of her age and both the first- and second-trimester screening test results.

Contingency screening: The patient has the same first-trimester study described for the stepwise sequential test and is told the results. If the results are above an arbitrary cutoff, such as 1 in 50, she is offered CVS. If her results are below another arbitrary cutoff, such as 1 in 1,000, she is advised that no further testing is necessary. If the patient's risk falls between these two cutoffs, she is offered a quad screen after 15 weeks, and a new risk assessment is determined as in the stepwise sequential test.

As noted by Berkowitz, there is obviously no "right thing" for every woman to do. Patients and their caregivers have to decide what an individual patient desires *(Berkowitz, 2006 [Low Quality Evidence])*. The work group has provided the information on aneuploidy screening strategies to provide each clinician and health care organization with information on the range of options currently available.

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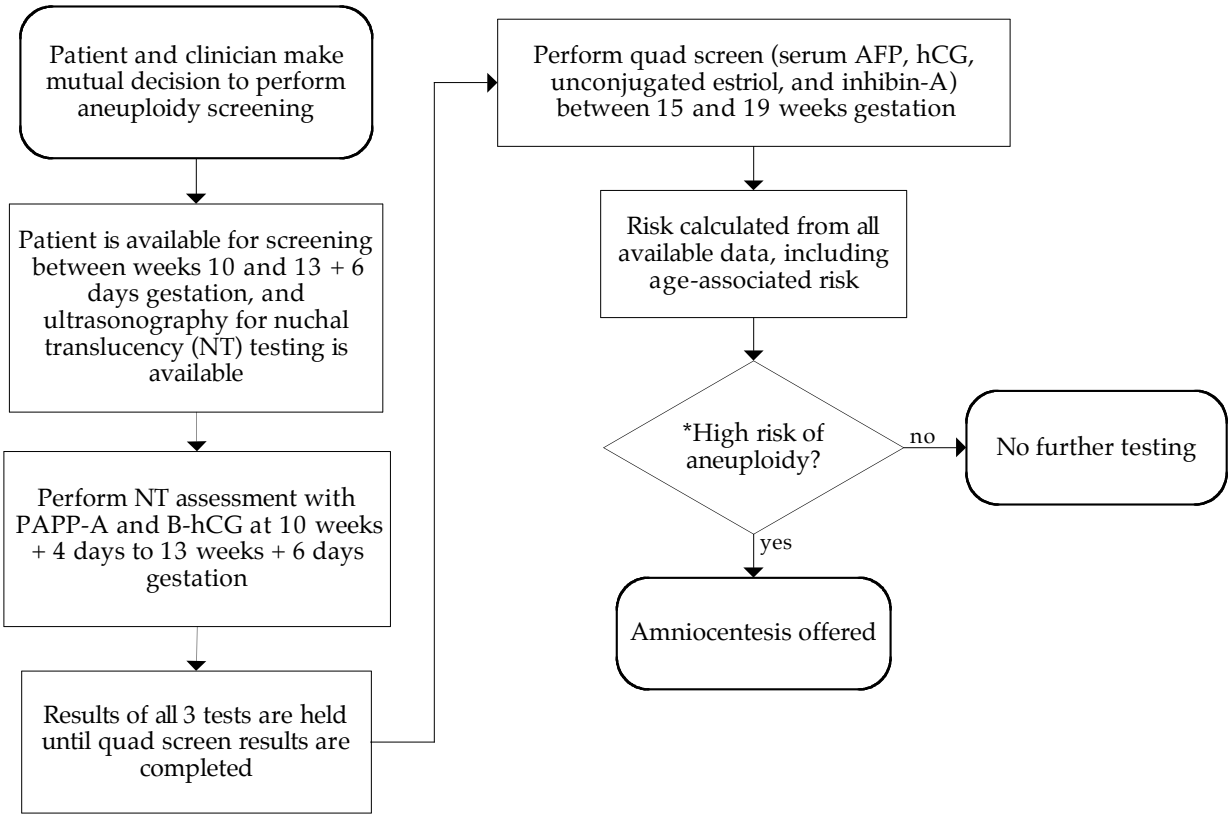
Name of Test	Week Test Used	Detection Rate (5% screen positive rate)	Screening Strategy
PAPP-A and free beta-hCG with NT	10-13	82-87%	Combined test
AFP, hCG and unconjugated estriol (triple screen)	15-19	69%	Single test
AFP, hCG, unconjugated estriol and inhibin-A (quad screen)	15-19	81%	Single test

(American College of Obstetricians and Gynecologists, 2007 [Guideline]; Simpson, 2007 [Low Quality Evidence]; Berkowitz, 2006 [Low Quality Evidence]; Cuckle, 2005 [Meta-analysis]; Malone, 2005 [Low Quality Evidence])

Aneuploidy Testing Integrated Screening Tool



* Each clinician/health care organization will establish cutoff values for low and high risk based on laboratory and patient particulars. One system used 1 in 200 as the cutoff.

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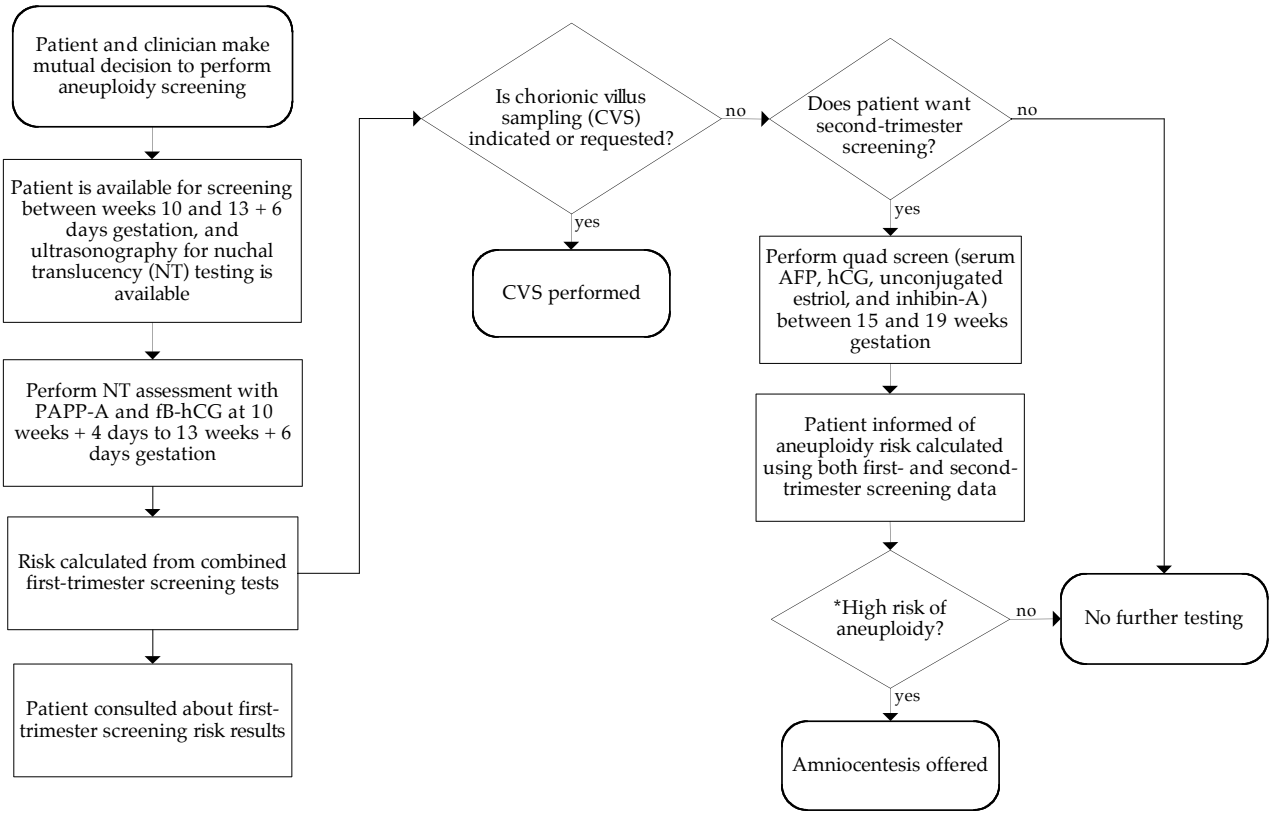
Aneuploidy Testing Stepwise Sequential Screening Tool



* Each clinician/health care organization will establish cutoff values for low and high risk based on laboratory and patient particulars. One system used 1 in 200 as the cutoff.

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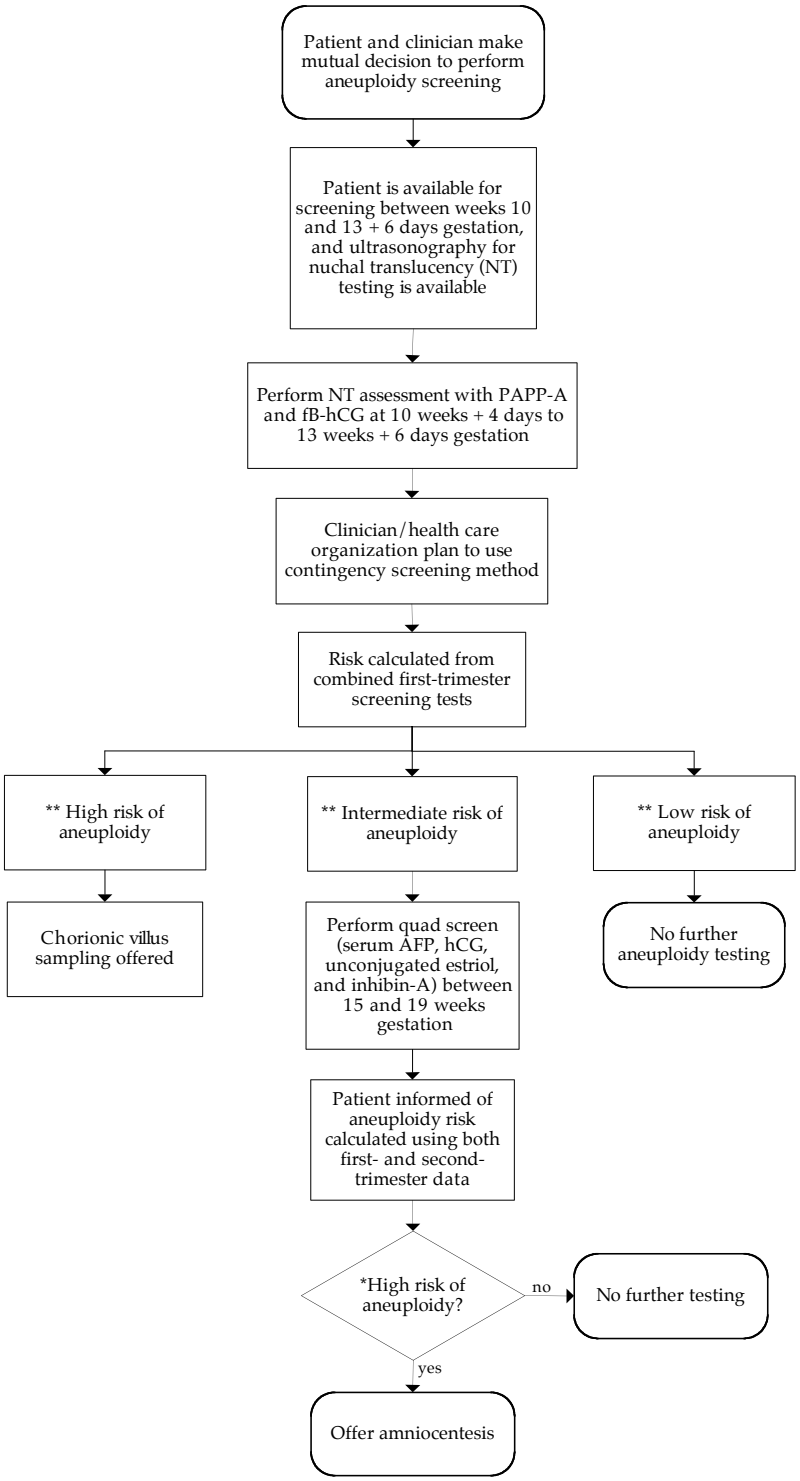
Aneuploidy Testing Contingency Screening Tool



* Each clinician/health care organization will establish cutoff values for low and high risk based on laboratory and patient particulars. One system used 1 in 200 as the cutoff.

** Each clinician/health care organization will establish cutoff values for low, intermediate and high risk based on laboratory and patient particulars. One system uses 1 in 1,000 as the cutoff between low and intermediate risk, 1 in 50 as the cutoff between intermediate and high risk.

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25. Nutritional Supplements

Preconception

There is no clinical evidence that universal supplementation with a multivitamin in the preconception period is beneficial. As noted in Annotation #15, "Folic Acid Supplement," there is evidence to support a folate supplement of 400 to 800 micrograms daily beginning at least one month prior to conception. Several case control studies have also reported a reduced risk of NTD in women without a prior affected pregnancy who took daily multivitamins during the preconception period. The study analyzed the amount of folic acid in most of the multivitamins as greater than or equal to 0.4 mg *(Werler, 1993 [Low Quality Evidence])*. Another study concluded that since the advent of routine dietary fortification of folate, the magnitude of this benefit has likely been diminished *(Mosley, 2009 [Low Quality Evidence])*.

The Institute of Medicine (IOM) and CDC have issued recommendations on folic acid intake for women of childbearing age and women planning pregnancy who have previously had a pregnancy affected by a neural tube defect *(Institute of Medicine, 2000 [Low Quality Evidence])*. (See Annotation #15, "Folic Acid Supplement.")

Pregnancy

There is no clinical evidence that universal supplementation with a multivitamin in pregnancy is beneficial. Multivitamins are designed with the daily recommended doses of vitamins and occasionally minerals for a healthy adult. While multivitamins are beneficial for adults, they are not recommended for pregnant women because they contain insufficient amounts of some nutrients and higher than recommended amounts of others.

There is also no clinical evidence that universal supplementation with a prenatal vitamin in pregnancy is beneficial. Prenatal vitamin supplementation is recommended for multiple gestations, tobacco or chemical use, complete vegetarians and for women with inadequate diets despite counseling.

Randomized placebo-controlled trials and non-randomized controlled trials in pregnant women with a prior pregnancy affected by an NTD have demonstrated that folic acid supplements substantially reduce the risk of recurrent NTD *(Kirke, 1992 [High Quality Evidence])*.

A randomized trial concluded that supplementation with vitamins C and E during pregnancy does not reduce the risk of preeclampsia in nulliparous women, the risk of intrauterine growth restriction, or the risk of death or other serious outcomes in their infants *(Rumbold, 2006 [High Quality Evidence])*. Another study concluded combined vitamin C and E supplementation during pregnancy does not reduce the risk of preeclampsia, fetal or neonatal loss, small-for-gestational-aged infant, or preterm birth *(Polyzos, 2007 [Systematic Review])*.

Women who have undergone bariatric surgery or who are vegans may have deficiencies in iron, vitamin B12, folate and calcium. Patients should be evaluated for nutritional deficiencies and vitamin supplementation where indicated *(American College of Obstetricians and Gynecologists – Committee Opinion, 2005a [Low Quality Evidence])*.

Omega-3 fatty acids are essential and can be obtained from the diet and from supplements. The requirements during pregnancy have not been established but likely exceed that of a non-pregnant state. Omega-3 fatty acids are critical for fetal neurodevelopment and may be important for the timing of gestation and birth weight, as well. Most pregnant women likely do not get enough omega-3 fatty acids because the major dietary source, seafood, is restricted to two servings a week. For pregnant women to obtain adequate omega-3 fatty acids, a variety of sources should be consumed: vegetable oils, two low-mercury fish servings a week, and supplements (fish oil or algae-based docosahexaenoic acid) *(Greenberg, 2008 [Low Quality Evidence])*.

Calcium supplementation is recommended for pregnant women with poor dietary calcium intake, but universal calcium supplementation is not recommended. Current calcium intake recommendations for pregnancy are 1,200-1,500 mg, but one study found median calcium intake in pregnancy at 600-700 mg *(Glenville, 2006*

[Low Quality Evidence]). A meta-analysis of 10 RCTs showed a 45% reduction in gestational hypertension when a 2 g daily calcium supplement was given to patients with low baseline calcium intake *(Imdad, 2011 [Meta-analysis])*. A previous review sponsored by the FDA showed no reduction in gestational hypertension when calcium supplements were given to women with normal baseline calcium intake *(Trumbo, 2007 [Low Quality Evidence])*. A Cochrane review of 21 RCTs has shown no reduction in preterm labor when patients received calcium supplementation *(Buppasiri, 2011 [Systematic Review])*. Although generally well tolerated, calcium supplementation side effects include difficulty swallowing; increase in nephrolithiasis and UTI; and reduced absorption of iron, zinc, and magnesium.

Vitamin D supplementation in pregnancy is recommended for women who are complete vegetarians and others who have a lack of vitamin D-fortified milk in their diet. These women should receive 400 IU or 10 micrograms of vitamin D daily, especially during the winter months. In vulnerable communities (e.g., Southeast Asian women in northern climates), vitamin D supplementation during pregnancy reduces the risk of symptomatic neonatal hypocalcemia *(Maxwell, 1981 [High Quality Evidence])*.

More recently, vitamin D testing and treatment of pregnant women is practiced by some clinicians. There is no clinical evidence that this supplementation affects pregnancy outcomes. However, exclusively breastfed infants whose mothers have low vitamin D stores are frequently vitamin D deficient, and thus at risk of nutritional rickets.

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26. Viral Hepatitis

Hepatitis B

Universal screening for Hepatitis B surface antigen (HbsAg) is advised at the first prenatal visit. Those identified as high risk should be rescreened later in pregnancy. High-risk categories include:

- more than one sex partner in the previous six months,
- evaluation or treatment for sexually transmitted infection(s),
- recent or current injecting drug use, and
- HbsAg-positive sex partner.

(Centers for Disease Control, 2007 [Guideline])

It is estimated that there are 1.25 million people living in the U.S. who are chronically infected with Hepatitis B virus (HBV). Of these individuals, 30% acquired their infection in the perinatal period. In Minnesota, according to the MDH 2006 statistics, there are 15,345 persons living with HBV. There were 1,136 newly reported chronic cases – 434 were babies born to infected mothers.

The American College of Obstetricians and Gynecologists recommends universal screening of all pregnant women for Hepatitis B early in pregnancy. In addition, it recommends that infants of seropositive mothers receive Hepatitis B immune globulin (HBIG) immediately after birth *(American College of Obstetricians and Gynecologists, 2007 [Guideline])*.

The Minnesota Department of Health requires reporting all positive HBV serology tests to the state agency (per online reporting form). (See Appendix G, "Perinatal Hepatitis B Prevention Program.") Each pregnant women who is HBsAg positive should have further evaluation, including additional lab work, to determine viral load. High viral counts increase the risk of prenatal transmission *(Lok, 2007 [Low Quality Evidence])*.

Perinatal transmission of Hepatitis B virus occurs if the mother has acute infection during late pregnancy or the early postpartum period or if the mother is a chronic Hepatitis B antigen carrier *(Levy, 1991 [Low Quality Evidence])*.

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A combination of passive HBIG and active (Hepatitis vaccine) immunization of infants born to Hepatitis B surface-antigen-positive mothers affords very good protection to the infected infants *(Sangfelt, 1995 [Low Quality Evidence])*.

Pregnant women in high-risk categories for acquiring Hepatitis B infection should be offered vaccination. To avoid misinterpreting a transient positive HbsAg result during the 21 days after vaccination, HbsAg testing should be performed before the vaccination.

Hepatitis C

All pregnant women at high risk for Hepatitis C infection should be tested for Hepatitis C antibodies at the first prenatal visit. Women at high risk include those with a history of injecting drug use and those with a history of blood transfusion or organ transplantation prior to 1992.

No treatment is available for Hepatitis C-infected pregnant women apart from supportive care. No vaccine is available to prevent Hepatitis C transmission.

(Conte, 2000 [Low Quality Evidence])

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27. Immunizations

Influenza

It is recommended that all pregnant women receive the influenza vaccination during influenza season *(Saleeby, 2009 [Low Quality Evidence])*. Immune system alterations during pregnancy may increase the likelihood of influenza complications such as pneumonia, particularly in the third trimester. Historical data from the 1918 and 1957 influenza A pandemics described a 50% mortality rate for influenza-induced pneumonia in pregnancy. In addition, the presence of fever, tachycardia and hypoxemia may be harmful to the developing fetus *(Rodrigues, 1992 [Low Quality Evidence])*. Universal vaccination with inactivated trivalent influenza vaccine is cost saving relative to providing supportive care alone in the pregnant population *(Roberts, 2006 [Cost-Effectiveness Analysis])*.

Influenza vaccines made from inactivated/non-infectious viruses are considered safe at any gestational age *(Nichol, 1995 [High Quality Evidence])*. If patient has hypersensitivity to eggs or to vaccine components, preservative-free vaccines are available for use in these populations. However, nasal spray influenza vaccines are made from live attenuated virus; administration of this form of an influenza vaccine is not recommended in pregnancy.

(Centers for Disease Control, 2009a [Guideline]; Centers for Disease Control, 2009b [Guideline]; U.S. Department of Health and Human Services, 2007 [Guideline])

Tetanus/pertussis

If an urgent need for tetanus protection occurs during pregnancy, Td should be administered *(Centers for Disease Control, 2011 [Guideline])*. In special situations in which a pregnant woman has increased risk for tetanus, diphtheria or pertussis, the Advisory Committee on Immunization Practices acknowledges that health care clinicians may choose to administer Tdap instead of Td during pregnancy to add protection against pertussis, after discussing with the woman the theoretical benefits and risks for her, her fetus and the pregnancy outcome, before vaccination. Current recommendation is to administer Tdap after 20 weeks gestation. If not administered during pregnancy, Tdap should be administered immediately postpartum.

Pregnancy provides an excellent time to assess a woman's immunization status. In addition, parents of infants, siblings of newborns, day care providers and others caring for the newborn should all be offered Tdap if they are not up-to-date on their vaccinations. This also pertains to health care professionals who care for newborns and young infants. Vaccination of parents and household contacts of premature infants has been advocated to ensure that such persons receive Tdap *(Shah, 2007 [Low Quality Evidence])*.

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To ensure protection against maternal and neonatal tetanus, pregnant women who have never been vaccinated against tetanus should receive three vaccinations containing tetanus and reduced diphtheria toxoids. The recommended schedule is 0, 4 weeks and 6 to 12 months. Tdap should replace one dose of Td, preferably during the third or late second trimester (after 20 weeks' gestation) of pregnancy *(Centers for Disease Control, 2011 [Guideline])*. (See the ICSI Immunizations guideline.)

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28. Fetal Heart Tones

Fetal heart tones should be identified at 10-12 weeks and thereafter.

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.

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29. Ultrasound (Optional)

Universal screening

The work group acknowledges that prenatal ultrasound examination has become an almost universal feature of prenatal care. The Centers for Disease Control reported an ultrasound examination was performed in 67% of live births in the United States in 2002 *(Martin, 2003 [Low Quality Evidence])*. In the Routine Antenatal Diagnostic Imaging with Ultrasound Study (RADIUS), 85% of the patients had a recognized indication for ultrasound examination *(Crane, 1994 [High Quality Evidence])*. The near-universal access to prenatal ultrasound examinations continues to spur an ongoing controversy regarding the use of routine ultrasound examination in screening low-risk pregnancies.

Several studies have failed to show any consistent benefit to maternal or fetal outcome. Several of these studies show ultrasonography to be beneficial in detecting intrauterine growth retardation. Only one study showed a slight decrease in perinatal death in the routinely scanned group (P=0.11) *(Ringa, 1989 [Low Quality Evidence]; Secher, 1986 [Low Quality Evidence]; Bakketeig, 1984 [High Quality Evidence]; Eik-Nes, 1984 [High Quality Evidence]; Bennett, 1982 [High Quality Evidence])*.

The RADIUS study group concluded that screening ultrasonography did not improve perinatal outcome. This study excluded 40,214 out of 55,744 patients who registered to arrive at a randomized group of 15,530.

More recent literature suggests that first-trimester routine ultrasound leads to a decrease in post-term pregnancy and a better ability to assess gestational age and multiple pregnancy *(Caughey, 2008 [Low Quality Evidence]; Eik-Nes, 2000 [High Quality Evidence]; Neilson, 2000 [Systematic Review])*.

One additional RCT showed a significantly lower perinatal mortality in a screened population that was screened at 16-20 weeks gestation. The decrease in perinatal mortality was mainly due to improved early detection of major malformations that led to induced abortion *(Saari-Kemppainen, 1990 [High Quality Evidence])*. The Eurofetus study of 1999, the largest study of routine ultrasound examinations before 24 weeks gestation in a low-risk population detected 73.7% of major anomalies and 45.7% of minor anomalies for an overall detection rate of 44% *(Grandjean, 1999 [Low Quality Evidence])*.

An overall assessment of the existing evidence does not support the use of routine ultrasound examination in low-risk pregnancies as there currently is no proof of improved perinatal outcome. However, the work group acknowledges ongoing improvement in the detection of congenital anomalies using superior equipment in the hands of more experienced examiners. Indeed, both the Helsinki and RADIUS trials showed improved anomaly detection rates in hospital or tertiary centers. With higher anomaly detection rates, cost-effectiveness studies may soon demonstrate a rationale for routine ultrasound examination in some low-risk

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prenatal populations, though variations in anomaly prevalence rates and the cost of ultrasound examinations may still preclude a universal screening recommendation *(Leivo, 1996 [High Quality Evidence])*.

Timing of ultrasound examination

The work group recognizes that the timing of a single obstetric ultrasound examination during routine prenatal care is also controversial. There are many indications for ultrasound examinations, and the optimal timing for each indication varies. For example, first-trimester ultrasound evaluations are preferable for pregnancy dating, whereas second-trimester examinations are superior for evaluations of fetal anatomy.

With these considerations in mind, the American College of Obstetricians and Gynecologists recommends if one screening ultrasound examination is performed, the optimal timing is at 18-20 weeks of gestation *(American College of Obstetricians and Gynecologists Practice Bulletin, 2009b [Guideline])*. This timing provides satisfactory information for dating the pregnancy, allows good visualization of the fetal anatomy with concomitant detection of anomalies, and is performed at a time in the pregnancy when legal termination of the pregnancy is possible, if desired. There is no evidence to support the use of routine ultrasound examination in low-risk pregnancies after 24 weeks gestation *(Bricker, 2008 [Systematic Review])*.

Consideration should be given to early sonography to confirm dating in cases of uncertain age or antecedent medical complications such as pregestational diabetes mellitus or previous complications *(Caughey, 2008 [Low Quality Evidence]; Eik-Nes, 2000 [High Quality Evidence]; Neilson, 2000 [Systematic Review])*. Shorter cervical length as measured by ultrasound is directly associated with preterm labor. See Annotation #31, "Preterm Labor Prevention."

Although maternal serum AFP can be used in the second trimester to screen for fetal spina bifida, reported detection rates typically fall in the 80% range. In contrast, routine ultrasound at 18-20 weeks gestation was shown in one series to detect 90% of fetal neural tube defects *(Kooper, 2007 [Low Quality Evidence])*.

Type of ultrasound examination

Three-dimensional/four-dimensional (3D/4D) ultrasound is considered investigational and is not routinely recommended at this time. Although there is no evidence of fetal harm from routine prenatal ultrasonography, the American College of Obstetricians and Gynecologists recommends against performance of ultrasound for no medical benefit (i.e., "keepsake videos") to be unjustified *(American College of Obstetricians and Gynecologists – Committee Opinion, 2006b [Low Quality Evidence])*.

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30. Fundal Height

A measurement of the fundal height should be performed at each visit during the second and third trimesters of pregnancy *(Lindhard, 1990 [High Quality Evidence])*.

Fundal height measurement is inexact and subject to inter- and intraobserver errors *(Calvert, 1982 [Low Quality Evidence])*.

However, the screening maneuver is simple, inexpensive and widely used during prenatal care. Furthermore, several studies have shown quite good sensitivity and specificity for predicting low birth weight for gestational age *(Gardosi, 1999 [Low Quality Evidence])*.

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31. Preterm Labor Prevention

Cervical Assessment

Transvaginal sonography of the cervix appears to be an objective and reliable method to assess cervical length and estimate risk of preterm delivery *(Honest, 2003 [Systematic Review])*. A recent report *(American College of Obstetricians and Gynecologists – Committee Opinion, 2012 [Low Quality Evidence])* suggests

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that a cervical length measurement be performed at the time of the 18-22 week fetal anatomy survey scan. This report suggests that a transvaginal ultrasound be performed subsequently to confirm the presence of a short cervical length defined as less than 25 mm at 14-28 weeks gestation. Serial measurements may be considered starting at 16 weeks in high-risk patients *(Spong, 2007 [Low Quality Evidence])*.

Cervical sonography is generally performed every two weeks unless clinical conditions suggest more frequent evaluation *(Airoldi, 2005 [Low Quality Evidence])*. A possible benefit of cerclage for patients with prior preterm birth, current singleton pregnancy and a cervical length of less than 15 mm between 16 and 24 weeks has been suggested by a multicenter randomized trial *(Owen, 2009 [High Quality Evidence])*.

Digital exams should not be eliminated and can be a useful adjunct to transvaginal cervical sonograms findings *(Newman, 2008 [Low Quality Evidence]; Iams, 1996 [Low Quality Evidence])*.

Progesterone

Progesterone use to improve pregnancy outcome has been under consideration for over 50 years. Early trials for reducing the rate of preterm delivery was fraught with small numbers. A randomized controlled trial found that treatment with 17 alpha-hydroxyprogesterone caproate 250 mg weekly from 16 to 36 weeks reduced the rate of recurrent preterm delivery less than 37 weeks in women at high risk from 54.9 to 36.3% *(da Fonseca, 2009 [Low Quality Evidence]; Meis, 2003 [High Quality Evidence])*. In addition, perinatal morbidity – such as rates of IVH, NEC, and need for supplemental oxygen and ventilatory support – was significantly reduced.

Prophylactic progesterone treatment to prevent preterm delivery should be considered in women at high risk for preterm delivery because of a history of a prior spontaneous preterm delivery caused by spontaneous preterm labor or premature rupture of the fetal membranes *(American College of Obstetrics and Gynecology, 2008b [Guideline]; Meis, 2005 [Low Quality Evidence])*. A review of randomized trials *(Mackenzie, 2005 [Systematic Review])* concluded that there was a significant reduction in risk of delivery less than 37 weeks with progestational agents.

Treatment with progesterone for multiple gestations has not shown a reduction in the rate of preterm birth in women with twin gestations *(Rouse, 2007 [High Quality Evidence])*. However, in women with a short cervix, treatment with progesterone may reduce the rate of spontaneous early preterm delivery *(da Fonseca, 2009 [Low Quality Evidence])*.

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32. Gestational Diabetes Mellitus (GDM)

Gestational diabetes is defined as a glucose intolerance occurring during pregnancy. Incidence is usually quoted as 2-3%, with a range of .31-37.4% noted *(Stephenson, 1993 [Low Quality Evidence])*. There is a higher prevalence in American Indian and Hispanic populations and a very low incidence among Caucasian teens *(Garner, 1997 [High Quality Evidence])*.

In a recent randomized clinical trial, treatment of women with gestational diabetes reduced the rate of serious perinatal outcomes (defined as death, shoulder dystocia, bone fracture and nerve palsy) from 4 to 1%. Treatment included dietary advice, blood glucose monitoring and insulin therapy, if needed, for glycemic control. The study concluded that treatment reduced the rate of complications without increasing the rate of Caesarean delivery *(Crowther, 2005 [High Quality Evidence])*.

Screening

Screening for gestational diabetes mellitus is optimally performed at 24 to 28 weeks gestation, due to pregnancy-related hormonal changes *(Jovanovic, 1985 [Low Quality Evidence])*. Most practitioners use a 50 grams oral glucose load followed one hour later by the blood draw. Screening levels should be based on American College of Obstetricians and Gynecologists guidelines as stated in American College of

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Obstetricians and Gynecologists Technical Bulletin Number 200. If the glucose challenge test results fall outside the guideline, a 100 grams load followed by a three-hour glucose tolerance test should be performed *(American College of Obstetricians and Gynecologists, 1994 [Low Quality Evidence])*.

The guideline work group discussed the possibility that if the 140 mg/dL threshold were lowered, sensitivity would improve. Thresholds of 140 yield 90% of gestational diabetes with 15% of all patients screened having a glucose tolerance test (GTT). Lowering the threshold to 130 would identify almost all the gestational diabetes cases but would require 25% of women to have the GTT *(Bonomo, 1998 [Low Quality Evidence])*.

There have been investigations regarding selective rather than universal screening. Criteria for selective screening was fairly consistent, with obesity and family history of diabetes as the main reasons. Age greater than 30 *(American College of Obstetricians and Gynecologists Practice Bulletin, 2001b [Guideline]; American Diabetes Association, 2010 [Low Quality Evidence]),* previous macrosomic baby or baby with anomalies, stillbirth and glycosuria are other criteria for screening. Most studies agree that selective screening fails to detect 43-50% of women with gestational diabetes *(American College of Obstetricians and Gynecologists, 1994 [Low Quality Evidence]*; *Weeks, 1994 [Low Quality Evidence])*. Currently there is a lack of consensus and insufficient evidence to assess the balance between the benefits and harms of screening for gestational diabetes mellitus. Universal screening of obstetrical patients for gestational diabetes is commonplace in the U.S. *(U.S. Preventive Services Task Force, 2008 [Systematic Reivew])*.

High-risk for abnormal glucose tolerance

However, screening for abnormal glucose tolerance should be performed as early as the first prenatal visit if there is significant risk for undiagnosed type 2 diabetes mellitus. Risk factors include marked obesity, personal history of gestational diabetes mellitus (GDM), glycosuria, or strong family history of diabetes mellitus. Women with a history of GDM in a previous pregnancy have a 33-50% risk of recurrence, some of which may represent undiagnosed type 2 diabetes mellitus *(American Diabetes Association, 2010 [Low Quality Evidence]; American College of Obstetricians and Gynecologists Practice Bulletin, 2001b [Guideline])*.

High risk (one or more of the following):

- BMI greater than 30 kg/m^2
- Diabetes in first-degree relative
- History of glucose intolerance
- Previous infant with macrosomia (greater than 4,500 grams)
- Current glycosuria (previous impaired fasting glucose [IFG] with fasting BG 110-125 mg/dL)
- Previous gestational diabetes mellitus

Screening for these patients should occur at the initial antepartum visit or as soon as possible with a repeat screen at 24-28 weeks gestation if the initial screening is negative for gestational diabetes.

(Kjos, 1999 [Low Quality Evidence])

The International Association of Diabetes and Pregnancy Study Groups (IADPSG), an international diabetes consensus group, with agreement from the American Diabetes Association (ADA), has recommended that women found to have diabetes mellitus at their initial prenatal visit by standard criteria, should be diagnosed with type 2 diabetes, not gestational diabetes mellitus *(American Diabetes Association, 2010 [Low Quality Evidence])*.

There is no consensus on the method for gestational diabetes screening for pregnant bariatric surgery patients. There is concern of a risk for triggering significant hypoglycemia in such patients using current screening

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methods. Consultation with a perinatologist and a bariatric surgeon may be warranted before proceeding with such screening.

Hemoglobin A1c screening

A hemoglobin A1c higher than 6.5% suggests type 2 diabetes mellitus, but hemoglobin A1c below 6.5% should not be used as evidence against the diagnosis of gestational diabetes mellitus. Hence, hemoglobin A1c is not a useful screening test for detecting mildly abnormal blood glucose levels. There is some evidence a hemoglobin A1c more than two standard deviations above the mean may identify women at risk for delivering a large for gestational age (LGA) infant *(Radder, 2005 [Low Quality Evidence]; Bevier, 1999 [High Quality Evidence])*.

Diabetes screening with history of GDM

Women with a history of gestational diabetes mellitus are at high risk for development of type 2 diabetes mellitus and should be screened annually *(Smirnakis, 2005 [Low Quality Evidence]; Kim, 2002 [Systematic Review]; Peters, 1996 [Low Quality Evidence])*. See the ICSI Diagnosis and Management of Type 2 Diabetes Mellitus in Adults guideline.

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33. Awareness of Fetal Movement

There is no evidence that a formal program of fetal kick counts reduces the incidence of intrauterine fetal deaths. Patients should be instructed on daily identification of fetal movement at the 28-week visit.

Burden of Suffering

Reduction or cessation of fetal movements may precede death by a day or more *(Sadovsky, 1973 [Low Quality Evidence])*.

Approximately 50% of antepartum late fetal deaths are not associated with any recognizable risk factor, and this is the rationale for screening all pregnancies in late pregnancy.

Accuracy of Screening Tests

There are no set counting criteria nor set values that can be universally applied to all antepartum patients when evaluating fetal movement *(Davis, 1987 [Low Quality Evidence])*.

Variables include activity of an individual fetus, perception of a baby's movements by an individual mother, activity levels of individual fetuses, and perception among different women *(Valentin, 1986 [Low Quality Evidence])*.

Effectiveness of Early Detection

Two randomized control trials have addressed the question of whether clinical actions taken on the basis of fetal movement counting improve fetal outcome, with the largest involving over 68,000 women. These trials collectively provide no evidence that routine formal fetal movement counting reduces the incidence of intrauterine fetal death in late pregnancy *(Grant, 1989 [High Quality Evidence]; Neldam, 1983 [High Quality Evidence])*.

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34. Cervix Exam as Indicated

Cervical examinations at term are useful to diagnose abnormal presentation and to identify cervical dilation. Examinations do not increase the risk of rupture of membranes, rates of induction or Caesarean section, or risk of neonatal or maternal infections.

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Stripping membranes at cervical examinations greater than or equal to 38 weeks reduces the rate of post-term (greater than 42 weeks) deliveries by up to 75%, significantly reduces the risk of induction of labor (8.1% versus 18.8%), and increases the likelihood of a gravida presenting to labor and delivery in the active phase of labor. A meta-analysis of available studies examining the use of membrane stripping among women of undetermined GBS colonization status found no significant increases in overall peripartum or perinatal infection rates among women who underwent this procedure *(Boulvain, 2005 [Systematic Review])*. The greatest benefit is seen with unfavorable cervix in a primigravid patient. No increase in adverse outcomes is evident. The recommended method is digital insertion 2-3 cm above internal os, and sweeping circumferentially twice. Daily membrane sweeping after 41 weeks has been shown to be more effective than the use of prostaglandins in reducing postdate pregnancies *(Magnann, 1999 [High Quality Evidence]; Allott, 1993 [High Quality Evidence])*.

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35. Confirm Fetal Position

Confirm fetal presentation by Leopold's and/or cervical examination at 36 weeks. Ultrasound may be used to confirm a questionable fetal presentation.

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36. Group B Streptococcus Screening

Significance Testing

Proper culture techniques include sampling the lower vagina and rectum. Selective broth media should be used. Sensitivity and specificity of such cultures in the late third trimester are estimated at 70.0% and 90.4%, respectively *(Yancey, 1996 [Low Quality Evidence])*.

DNA probe testing at time of delivery may identify those at highest risk of delivering an infant who may develop GBS sepsis *(Bergeron, 2000 [Low Quality Evidence]; Reisner, 2000 [Low Quality Evidence])*. GBS, or *Streptococcus agalactiae*, is recognized as an important cause of perinatal morbidity and mortality. About 7,600 cases of GBS sepsis occur in newborns in the United States and result in about 300 deaths per year. Invasive GBS disease in the newborn may manifest as sepsis, pneumonia or meningitis *(Centers for Disease Control, 2010 [Guideline]; Weisman, 1992 [Low Quality Evidence]; Zangwill, 1992 [Low Quality Evidence])*.

Vertical transmission of GBS during labor or delivery constitutes about 80% of GBS disease in the newborn *(Weisman, 1992 [Low Quality Evidence])*.

Ten to thirty percent of pregnant women are colonized with GBS in the vaginal or rectal areas *(Edwards, 2002 [Low Quality Evidence]; Spaetgens, 2002 [Low Quality Evidence]; Vergani, 2002 [Low Quality Evidence]; Main, 2000 [Low Quality Evidence]; Regan, 1991 [Low Quality Evidence]; Dillon, 1982 [Low Quality Evidence])*.

GBS is of concern with Caesarean delivery since intact amniotic membranes do not prevent vertical transmission. Although this risk for GBS vertical transmission with intact membranes does exist, for a patient undergoing Caesarean delivery prior to labor the risk is low. Intrapartum prophylaxis in this situation is not recommended.

(Centers for Disease Control, 2010 [Guideline])

Prophylaxis

Some studies have demonstrated a reduction in the incidence of early-onset neonatal GBS disease when antibiotics were administered intrapartum to women with positive GBS colonization from prenatal cultures.

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Care should be used in the selection of antibiotics for intrapartum prophylaxis to minimize the risk of increasing the incidence of antibiotic resistance *(Edwards, 2002 [Low Quality Evidence]; Spaetgens, 2002 [Low Quality Evidence])*.

Management

The following protocol for the management of group B *Streptococcus* (GBS) in pregnancy should be universally applied, based on obtaining cultures at 35-37 weeks gestation:

1. All pregnant women should be screened at 35-37 weeks gestation for anogenital GBS colonization unless patient has a positive urine culture for GBS earlier in pregnancy. All patients with a positive urine culture should be offered intrapartum prophylaxis. If the time from initial screening to delivery is greater than five weeks, the patient should be rescreened.
2. Culture techniques that maximize the recovery of GBS should be used.
3. Cultures from the lower vagina and rectum should be collected without speculum examination.

   At the time of screening, if the patient has a penicillin allergy with anaphylaxis, sensitivities for GBS should be obtained.
4. If the GBS culture is positive, the patient should be offered intrapartum prophylaxis with penicillin G (5 million units IV followed by 2.5 million units every four hours until delivery). Prophylaxis is not efficacious if initiated less than four hours prior to delivery.
5. Women with the following risk factors should receive intrapartum antibiotic prophylaxis regardless of GBS culture results:
   - Previous infant who had invasive GBS disease
   - GBS bacteriuria during this pregnancy
   - Intrapartum maternal temperature more than 38°C (more than 100.4°F) if results of GBS culture are unknown. For patients with suspected chorioamnionitis, broad-spectrum coverage is recommended.
6. In addition to the factors discussed under above, women with unknown GBS status should also receive intrapartum antibiotic prophylaxis when membranes have ruptured greater than 18 hours.
7. Alternative antibiotic recommendations:
   - Ampicillin should be avoided because it has been associated with an increase in resistant *E. coli* sepsis, particularly in premature newborns.
   - For penicillin-allergic women without history of anaphylaxis, a first-generation cephalosporin is the antibiotic of choice.
   - For penicillin-allergic women with a history of anaphylaxis, susceptibility testing is recommended for clindamycin (900 mg IV every eight hours) and erythromycin (500 mg IV every six hours). For organisms resistant to clindamycin or erythromycin, vancomycin should be used.
   - Oral antimicrobial agents should not be used to treat women who are found to be colonized with GBS during prenatal screening.
8. Patients undergoing elective Caesarean section should undergo routine GBS screening at 35-37 weeks for the possible circumstances when either membranes rupture or labor begins prior to the scheduled Caesarean delivery.

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9. Threatened Preterm Delivery

   Preterm delivery is an important risk factor for vertical transmission of GBS, but the uncertain nature of preterm labor and possible delivery makes antibiotic intrapartum prophylaxis decision-making complex.

   The Centers for Disease Control have devised a suggested algorithm for managing this problem as there is insufficient evidence for a single approach in all circumstances. Once a patient has been identified with the onset of labor or with rupture of membranes at less than 37 weeks gestation to be at significant risk for imminent preterm delivery, one of the following three arms of the algorithm should apply:

   - If there is no GBS culture result, the GBS vaginal and rectal culture should be obtained. While waiting for the results, intravenous penicillin therapy as recommended for term prophylaxis should be initiated. This therapy should be continued for at least 48 hours. If the GBS culture results are negative after 48 hours, the antibiotics may be stopped at the clinician's discretion.
   - If the GBS culture is known to be positive at the onset of preterm labor or rupture of membranes, the intravenous penicillin therapy as recommended for term prophylaxis should be continued for at least 48 hours. If the GBS culture is positive and the patient does not immediately deliver, intrapartum antibiotic prophylaxis should be repeated during the subsequent labor.
   - If the GBS culture result is known to be negative, no GBS antibiotic prophylaxis is needed. If the interval from GBS culture to delivery is greater than four weeks, the GBS cultures should be repeated.

(Centers for Disease Control, 2010 [Guideline])

Practices to Consider Discontinuing

Routine Digital Exams

Routine digital examination by itself has been determined to be a poor predictor of future preterm delivery or preterm premature rupture of membranes. However, there may be a role for digital exams in concert with transvaginal cervical sonography (see Annotation #31, "Preterm Labor Prevention," "Cervical Assessment") *(Newman, 2008 [Low Quality Evidence])*.

Pelvimetry

The evaluation of clinical pelvimetry during the prenatal period is of little value in predicting the occurrence of cephalopelvic disproportion (CPD) during delivery. In cases in which a previous Caesarean section had been performed for CPD, or for women who are at high risk for CPD, there may be some usefulness in performing clinical pelvimetry prior to the subsequent delivery *(Hanzal, 1993 [Low Quality Evidence])*.

Routine Urine Dipsticks and Routine Urinalysis

The conventional urine dipstick test is unreliable in detecting the moderate and highly variable elevations in albumin that occur early in the course of preeclampsia. (See the blood pressure discussion, Annotation #6.) Likewise, a "trace positive" urine dipstick for glycosuria has a reported sensitivity of only 23-64% *(Gribble, 1995a [Low Quality Evidence]; Gribble, 1995b [Low Quality Evidence])*.

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Routine Evaluation for Edema

The American College of Obstetricians and Gynecologists defines edema as a "generalized accumulation of fluid represented by greater than 1+ pitting edema after 12 hours of bed rest, or a weight gain of 5 lbs. or more in one week."

Edema has traditionally been an important diagnostic criterion for preeclampsia. However, by itself it is not useful to predict the development of preeclampsia because of the low specificity and sensitivity of this finding *(Smith, 1993 [Low Quality Evidence])*.

Routine Testing for CMV, Parvovirus, Toxoplasmosis

CMV

Selective testing of high-risk groups (day care workers, NICU nurses, adolescents with multiple partners or a history of sexually transmitted diseases) could be considered in order to advise them of their risk. Good hand washing and wearing gloves significantly reduces risk for this virus *(Henderson, 1995 [Low Quality Evidence])*.

Parvovirus

No routine testing is recommended. Affected pregnancies may result in fetal morbidity, but such outcomes are exceedingly rare *(Guidozzi, 1994 [Low Quality Evidence])*.

Toxoplasmosis

Universal screening is not recommended because of the low prevalence of the disease during pregnancy, the uncertain and costly screening, and the possible teratogenicity of treatment. It is recommended that efforts be directed at education of patients in prevention of this disease, which is now more commonly acquired in pregnancy through the handling of contaminated meat than from cat litter boxes *(Tinelli, 1995 [Low Quality Evidence])*.

Routine Nutritional Supplements

There is no demonstrated benefit for universal prenatal supplementation of the following:

Multivitamins (A)*	Magnesium (A)*
Amino acids/protein (A)*	Pyridoxine (vitamin B6) (B)*
Iron (see Annotation #15)	Zinc (A)*

High doses of vitamin A and molybdenum supplements are contraindicated in pregnancy. (A)*

*Letters in parentheses denote the grade of evidence for each nutrient.

There are no well-controlled studies demonstrating the efficacy of universal multivitamin supplements in pregnancy. A randomized control trial (RCT) to evaluate the effects of multivitamin supplements without folate versus placebo from preconception through the first trimester for women at risk for neural tube defect (NTD) demonstrated no decrease in NTD nor other salutary effects *(MRC Vitamin Study Group, 1991 [High Quality Evidence])*.

Recent concern over the possible adverse effects of certain components of multivitamins would suggest against universal supplementation. Secondly, many patients experience significant gastrointestinal distress from such combination supplements. Finally, the cost of multivitamins can be a financial burden for some patients.

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Balanced protein/energy supplementation results in increases in maternal weight gain and fetal growth. These increases do not appear larger in undernourished women, nor do they seem to confer long-term benefits to the child in terms of growth or cognitive development *(Rush, 1980 [High Quality Evidence])*.

There is currently insufficient evidence to justify magnesium supplementation during pregnancy *(Sibai, 1988 [Low Quality Evidence])*.

Pyridoxine supplementation during pregnancy cannot be recommended on the basis of current evidence *(Hillman, 1962 [High Quality Evidence])*.

The available data from controlled trials provide no convincing case for routine zinc supplementation during pregnancy *(Simmer, 1991 [High Quality Evidence])*.

Routine Testing for Bacterial Vaginosis

The USPSTF does not recommend universal screening for bacterial vaginosis. However, women with a history of preterm labor may be advised that such a screening is necessary *(U.S. Preventive Services Task Force, 2008 [Systematic Review])*.

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The Aims and Measures section is intended to provide guideline users with a menu of measures for multiple purposes, which may include the following:

- Population health improvement measures
- Quality improvement measures for delivery systems
- Measures from regulatory organizations such as The Joint Commission
- Measures that are currently required for public reporting
- Measures that are part of Center for Medicare Services Physician Quality Reporting initiative
- Other measures from local and national organizations aimed at measuring population health and improvement of care delivery

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources
- Implementation Tools and Resources Table

Aims and Measures

1. Increase the percentage of patients pregnant or planning a pregnancy who receive timely, comprehensive screens for risk factors. *(Annotation #4)*

   Measures for accomplishing this aim:

   a. Percentage of pregnant patients who have an initial risk assessment completed within two visits of initiation of prenatal care.

   b. Percentage of patients planning pregnancy who have preconception risk assessment/counseling.

2. Increase the percentage of pregnant patients or women planning pregnancy who receive timely prenatal counseling and education as outlined in the guideline. *(Annotations #4, 12)*

   Measures for accomplishing this aim:

   a. Percentage of patients planning pregnancy who receive counseling and education before pregnancy according to the guideline.

   b. Percentage of patients who receive counseling and education at each visit as outlined in the guideline.

3. Increase the percentage of first-trimester pregnant patients who have documentation of counseling about appropriate aneuploidy screening. *(Annotation #24)*

   Measure for accomplishing this aim:

   a. Percentage of pregnant patients who receive counseling about aneuploidy screening in the first trimester.

4. Increase the percentage of VBAC-eligible pregnant patients who have a collaborative conversation with their clinican about the risks and benefits of VBAC. *(Annotation #22)*

   Measure for accomplishing this aim:

   a. Percentage of VBAC-eligible pregnant patients who have a collaborative conversation with their provider about the risks and benefits of VBAC (e.g., the American College of Obstetricians and Gynecologists pamphlet on VBAC).

5. Increase the percentage of pregnant patients who have appropriate interventions for preterm birth (PTB) risk factors. *(Annotations #4, 31)*

   Measure for accomplishing this aim:

   a. Percentage of patients who have identified PTB modifiable risk factors who receive an intervention.

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Measurement Specifications

Measurement #1a

Percentage of pregnant patients who have an initial risk assessment completed within two visits of initiation of prenatal care.

Population Definition

All women in the clinic panel who are in the course of prenatal care.

Data of Interest

$$\frac{\text{\# of women with an initial risk assessment completed}}{\text{\# of women in the clinic panel who are pregnant}}$$

Numerator/Denominator Definitions

Numerator: Number of pregnant patients who have an initial risk assessment completed within two visits of initiation of prenatal care.

Denominator: Number of women in the clinic panel who are pregnant.

Method/Source of Data Collection

Determine from panel data the number of women in the practice that are pregnant. Out of that number, determine the number of women who have had initial risk assessment completed within two visits of initiation of prenatal care.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #1b

Percentage of patients planning pregnancy who have preconception risk assessment/counseling.

Population Definition

All women in the clinic panel who are planning a pregnancy.

Data of Interest

$$\frac{\text{\# of women with preconception risk assessment/counseling}}{\text{\# of women in the clinic panel who are planning a pregnancy}}$$

Numerator/Denominator Definitions

Numerator: Number of women with preconception risk assessment/counseling.

Denominator: Number of women in the clinic panel who are planning a pregnancy.

Method/Source of Data Collection

Determine from panel data the number of women in the practice who are planning a pregnancy. Out of that number, determine the number of women who have had preconception risk assessment/counseling.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #2a

Percentage of patients planning a pregnancy who receive counseling and education before pregnancy according to the guideline.

Population Definition

All women in the clinic panel who are planning a pregnancy.

Data of Interest

$$\frac{\text{\# of women who receive counseling and education before pregnancy}}{\text{\# of women in the clinic panel who are planning a pregnancy}}$$

Numerator/Denominator Definitions

Numerator: Number of women who receive counseling and education before pregnancy according to the guideline.

Denominator: Number of women in the clinic panel who are planning a pregnancy.

Method/Source of Data Collection

Determine from panel data the number of women in the practice who are planning a pregnancy. Out of that number, determine the number of women who have had counseling and education before pregnancy.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #2b

Percentage of pregnant patients who receive counseling and education at each visit as outlined in the guideline.

Population Definition

All women in the clinic panel who are in the course of prenatal care.

Data of Interest

$$\frac{\text{\# of women who receive counseling and education at each visit}}{\text{\# of women in the clinic panel who are pregnant}}$$

Numerator/Denominator Definitions

Numerator: Number of women who receive counseling and education at each visit as outlined in the guideline.

Denominator: Number of women in the clinic panel who are pregnant.

Method/Source of Data Collection

Determine from panel data the number of women in the practice who are pregnant. Out of that number, determine the number of women who have counseling and education at each visit as outlined by the guideline.

Time Frame Pertaining to Data Collection

Monthly and each visit could be tracked separately to determine whether counseling and education were done at that particular visit.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #3a

Percentage of pregnant patients who receive counseling about aneuploidy screening in the first trimester.

Population Definition

All women in the clinic panel who are in the course of prenatal care.

Data of Interest

$$\frac{\text{\# of women who receive counseling about aneuploidy screening in the first trimester}}{\text{\# of women in the clinic panel who are pregnant}}$$

Numerator/Denominator Definitions

Numerator: Number of women who receive counseling and education about aneuploidy screening in the first trimester.

Denominator: Number of women in the clinic panel who are pregnant.

Method/Source of Data Collection

Determine from panel data the number of women in the practice who are pregnant. Out of that number, determine the number of women who have counseling about aneuploidy screening the first trimester.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #4a

Percentage of VBAC-eligible pregnant patients who have a collaborative conversation with their clinician about the risks and benefits of VBAC.

Population Definition

Women in the course of prenatal care with a prenatal visit who are VBAC-eligible.

Data of Interest

$$\frac{\text{\# of VBAC-eligible women who had a collaborative conversation with their clinician about the risks and benefits of VBAC}}{\text{\# of of VBAC-eligible women}}$$

Numerator/Denominator Definitions

Numerator: Number of VBAC-eligible woman who have had collaborative conversations with their clinician about the risks and benefits of VBAC.

Denominator: Number of pregnant women who are VBAC eligible. VBAC eligible would include women without any of the following contraindications to VBAC:

- Previous classic Caesarean delivery
- Some uterine surgery, e.g., hysterotomy, deep myomectomy, cornual resection, and metroplasty
- Previous uterine rupture or dehiscence
- Some maternal/fetal medical conditions, such as open neural tube defect and complete placenta previa
- Unknown uterine scar if there is a high likelihood of classical scar
- Rare psychological or social conditions that indicate the patient may not be a good candidate

Method/Source of Data Collection

Determine from panel data the number of women in the practice who are pregnant and are VBAC eligible. Out of that number, determine the number of women who have had collaborative conversations with their provider about the risks and benefits of VBAC.

Time Frame Pertaining to Data Collection

Suggested time frame for data collection is monthly.

Notes

It is recommended that VBAC is discussed for appropriate patients. Patient education, including a discussion of the risks and benefits associated with VBAC, should be documented. The American College of Obstetricians and Gynecologists pamphlet on VBAC could be used to help with the conversation with the patient and her clinician.

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #5a

Percentage of patients who have had identified preterm birth (PTB) modifiable risk factors who receive an intervention.

Population Definition

All women in the clinic panel who are in the course of prenatal care with preterm birth risk factors identified.

Data of Interest

$$\frac{\text{\# of women who receive intervention for modifiable risk factors}}{\text{\# of women in the clinic panel who are pregnant and have identifiable preterm risk factors}}$$

Numerator/Denominator Definitions

Numerator: Number of women with modifiable preterm birth risk factors who have an intervention. An intervention can be:

- referral,
- education,
- home health nurse visits,
- ultrasound,
- advice, or
- any documented plan for action/follow-up.

Denominator: Number of women in the clinic panel who are pregnant and have identified preterm birth risk factors.

Method/Source of Data Collection

Determine the number of pregnant women in the clinic panel who have modifiable risk factors for preterm birth. Determine whether an intervention was documented for each identified modifiable risk factor.

A chart abstraction is conducted to determine which risk factors have been identified and addressed. The positive risk factor has an intervention if any of the following are documented: referral, education, home health nurse visits, ultrasound, advice or any documented plan or discussion referring to the positive risk factor.

Time Frame Pertaining to Data Collection

Monthly. Since this is a chart abstraction measure, recommended sample size would be 20 per month or 5 per week.

Notes

The guideline recommends prompt intervention for modifiable risk factors identified in early pregnancy. This measure assesses if all positive risk factors have received appropriate follow-up. The definition of intervention and appropriate follow-up is deliberately broad and may be refined by a medical group to fit its improvement aims.

This is a process measure, and improvement is noted as an increase in the rate.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization.

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline:

- Use of simple prenatal forms and checklists can provide an inexpensive and effective means of improving implementation of periodic health maintenance and increase the likelihood that clinicians will put clinical evidence into practice.
- Use of electronic medical records with electronic interfaces allowing transfer of pertinent patient information between clinicians can significantly improve clinician acceptance and implementation of these recommendations.

(Kirkham, 2005a [Low Quality Evidence]; Cheney, 1987 [High Quality Evidence])

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Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the guideline were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content is included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

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Implementation Tools and Resources Table

Author/Organization	Title/Description	Audience	Web Sites/Order Information
American Congress of Gynecologists and Obstetricians	Tobacco, Alcohol, Drugs and Pregnancy	Public and professionals	http://www.acog.org/Search?Keyword=tobacco%2c+alcohol%2c+Drugs%2c+in+pregnancy
American Congress of Gynecologists and Obstetricians	Preterm Labor	Public and professionals	http://www.acog.org/Search?Keyword=Preterm+Labor
American Congress of Gynecologists and Obstetricians	Vaginal Birth After Caesarean	Public and professionals	http://www.acog.org/Search?Keyword=VBAC
American Congress of Nurse-Midwives	Information on midwifery, health during pregnancy and caring for baby.	Public	http://www.mymidwife.org
American Congress of Obstetricians and Gynecologists (2000)	Screening tests for Birth Defects	Public and professionals	http://www.acog.org/ Search?Keyword=Screening+for+birth+defects
American Congress of Obstetricians and Gynecologists	The patient educator pamphlet on alcohol in women.	Public	http://www.acog.org/About_ACOG/ACOG_Departments/Adolescent_Health_Care/Adolescents_and_Alcohol
American Congress of Obstetricians and Gynecologists	Patient educator pamphlet – Depression	Public	http://www.acog.org/Search?Keyword=AP106
American Congress of Obstetricians and Gynecologists	Patient educator pamphlet – It's Time to Quit Smoking	Public	http://www.acog.org/Search?Keyword=AP065
Center for Disease Control	Pregnancy and Hepatitis B – Frequently Asked Questions	Public and professionals	http://www.cdc.gov/ncidod/diseases/Hepatitis/b/faqb-pregnancy.htm
March of Dimes	Stress and Prematurity	Public and professionals	http://www.marchofdimes.com/pregnancy/pretermlabor_stress.html
March of Dimes	Smoking During Pregnancy	Public and professionals	http://www.marchofdimes.com/pregnancy/alcohol_smoking.html
March of Dimes	Preterm Labor and Birth: A Serious Pregnancy Complication	Public and professionals	https://www.marchofdimes.com/pregnancy/preterm_indepth.html
March of Dimes	Signs and Symptoms of Preterm Labor and What to Do	Public and professionals	http://www.marchofdimes.com/pregnancy/pretermlabor_signs.html
Mayo Clinic	Amniocentesis	Public and professionals	http://www.mayoclinic.com/health/amniocentesis/MY00155
Mayo Clinic	Chorionic Villus Sampling	Public and professionals	http://www.mayoclinic.com/health/chorionic-villus-sampling/MY00154

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Implementation Tools and Resources Table

Author/Organization	Title/Description	Audience	Web Sites/Order Information
Mayo Clinic	Pregnancy After 35: Healthy Moms, Healthy Babies	Public and professionals	http://www.mayoclinic.com/health/pregnancy/PR00115
Minnesota Department of Health	Pregnant? Get Tested for Hepatitis B	Public and professionals	http://www.health.state.mn.us/divs/idepc/diseases/hepb/hepbpreg.pdf
Minnesota Department of Health	Perinatal Group B *Streptococcus* in Pregnant Women and Infants (GBS)	Public and professionals	http://www.health.state.mn.us/macros/search/index.html?q=Perinatal+Group+B+Streptococcus+in+Pregnant+Women+and+Infants+%28GBS%29&cx=001025453661958716519%3Aj2323tveixc&cof=FORID%3A10&ie=UTF-8&submit=Search
National Institute for Health & Clinical Excellence	Antenatal care, Routine Care for the Healthy Pregnant Woman	Public and professionals	http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11947

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The subdivisions of this section are:

- Conclusion Grading Worksheet Summary
  - Conclusion Grading Worksheets
- References
- Appendices

Conclusion Grading Worksheet Summary

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

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Conclusion Grading Worksheet A – Annotation #24 (Fetal Aneuploidy Screening)

Work Group's Conclusion: First-trimester testing techniques of ultrasound nuchal translucency (NT) between 10 and 13 weeks or a combined test (NT, hCG, and PAPP-A) enhance the detection of Down syndrome compared with second-trimester testing with the triple or quadruple test while reducing false-positives.

Conclusion Grade: I

Author/Year	Design Type	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Snijders et al., 1998 (NT)	Sens/ Spec	-96,127 women with singleton pregnancies at 22 centers were tested for NT -Median maternal age of population: 31 years -Median gestational age of fetuses: 12 weeks (range 10-14 weeks)	-234 of 326 (71.8%) cases of Down syndrome detected with a 4.4% (4209/94,476) false-positive rate using NT thickness > 95th percentile -268 of 326 (82.2%) cases detected with an 8.3% (7907/95,476) false-positive rate using an estimated risk cutoff of 1 in 300; PPV and NPV were 3.2% and 99.9% respectively -306 sonographers certified by the Fetal Medicine Foundation (FMF)	-Selection of the high-risk group for invasive testing by this method allows the detection of about 80% of affected pregnancies. However, even this method of risk assessment requires about 30 invasive tests for identification of one affected fetus.
Thilaganathan et al., 1999 (NT)	Sens/ spec	-11,398 women with a crown rump length between 38mm-84mm were scanned for nuchal translucency in a district general hospital from 1994-1998 -Mean age of the tested population was 28.6 years	-16 of 21 (76%) fetuses with Down syndrome were detected using a 1 in 200 risk cutoff; 4.7% false-positive rate; PPV and NPV were 3.3% and 99.9% respectively -Sonographers certified by the FMF	-First-trimester nuchal translucency measurement is an effective screening test for Down syndrome in a routine obstetric population. -With minimal additional training and resources, routine ultrasound staff are able to achieve good NT screening results.
Wald et al., 1997 (NT and combined test)	Meta-analysis	-Results of three published datasets were combined: NT in 86 cases of Down syndrome, fbhCG and PAPP-A in 77 cases and 385 unaffected pregnancies, and 561 unaffected pregnancies with NT measurements	-For the combined test, a detection rate of 80% with a false-positive rate of 5% was estimated by combining the results of all three data sets -For NT alone, a sensitivity of 64%, 5.4% false-positive rate and a 1.5% PPV with a 1 in 250 risk cutoff was estimated	-It appears using the combined test is better than second-trimester serum testing, though these estimates do not allow for an association between the markers and spontaneous fetal loss, an issue that needs to be clarified by further research. -These results are a reasonable working estimate of the performance of testing using the combined test in the first trimester. It is only as a combined test that first trimester testing appears to be potentially more effective than second trimester testing.

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Author/Year	Design Type	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Krantz et al., 2000 (combined test)	Sens/ spec	-Blood samples were collected between 9 and 14 weeks gestation for 10,251 women -NT measurement was done between 10 and 14 weeks gestation in 5809 of the women	-At a fixed 5% false-positive rate, a 91% detection rate was obtained for all women using the combined test. -For women under 35 years of age the combined test offered an 87.5% detection rate and 4.5% false-positive rate -For women 35 years of age or older the combined test offered a 92% detection rate and 14.3% false-positive rate -Sonographers certified by the FMF	-First trimester testing using a combination of biochemistry and NT is feasible, results in improved detection compared with currently used second trimester protocols, and provides substantial advantages to clinicians and patients.
Orlandi et al., 1997 (combined test)	Sens/ spec	-Serum was collected prospectively in 2,010 singleton pregnancies and 744 of these women underwent NT measurement -Median maternal age was 32 years in unaffected pregnancies and 41.5 years in all 18 affected aneuploidy cases (11 Down syndrome)	-An 87% detection rate of Down syndrome with a 5% false-positive rate was shown using modelling with the age distribution of live births -With same method, a 73% detection rate for NT alone with a 5% false-positive rate -Sonographers certified by the FMF	-The data in this study demonstrate that combined biochemical and ultrasound evaluation for Down syndrome in the first trimester of pregnancy yields a detection capability that may exceed that of current second trimester prenatal screening protocols. The potential for enhanced detection coupled to an earlier alert of fetal complications could represent a substantial advantage to both clinician and patient.
Wapner et al., 2003 (NT and combined test)	Sens/ spec	-8,816 singleton pregnancies in women of any age; days of gestation between 74 and 97 (approximately 10.5 to 14 weeks) -Blood samples for free β human chorionic gonadotropin (β-hCG) and pregnancy-associated plasma protein A (PAPP-A) -NT measurement	-8,205 patients in analysis; 61 had a fetus with trisomy 21 (prevalence of 1 in 135 pregnancies) -*Rates:* Detection (at 1:270) False-Pos (at 1:270) Detection (at 5% false pos) Age only 80.3% 48.0% 32.8% Age+biochem 85.2% 23.2% 67.2% Age+NT 82.0% 11.9% 68.8% Age+biochem +NT 85.2% 9.4% 78.7% Age<35 yrs 66.7% 3.7% 66.7% Age≥35 yrs 89.8% 15.2% 77.6% -Based on ROC curves, combined test better than biochemical component alone ($p<0.01$) but not better than NT alone -Sonographers certified by the FMF	-First trimester screening for trisomy 21 on the basis of maternal age, maternal levels of free β human chorionic gonadotropin and pregnancy-associated plasma protein A, and measurement of fetal nuchal translucency has good sensitivity at an acceptable false-positive rate. NOTES: 40% of patients were 35-39 years; 10% were ≥40 yrs

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Author/Year	Design Type	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Wald et al., 2003 (NT and/or other tests)	Sens/ spec	-Women at 25 maternity centers for antenatal care between 8 and 14 weeks of pregnancy -At booking visit: ultrasound, crown-rump length, ≥3 NT measurements -Serum and urine samples from booking visit and time of second trimester screening test (not analyzed until outcome of pregnancy was known) -Diagnosis of Down syndrome based on second trimester double, triple, or quadruple test (policy was to avoid early intervention based on NT) -Each pregnancy with Down syndrome (case) matched with 5 singleton unaffected pregnancies (controls); analyzed serum and urine (see NOTES)	-Analysis based on 102 Down syndrome pregnancies out of 42,712 singleton pregnancies recruited at 10-13 weeks gestation *-Overall detection rate=63% (with 5% false positive rate and based on NT and maternal age)*; observed false positive rate for 85% detection rate=19% *-Detection rates at 10 completed weeks (5% false positive rate) for independent variables*: age=34%, NT=51%, PAPP-A=58% (all others <20%) *-Detection rates at 10 completed weeks (5% false positive rate) for combinations of tests*: PAPP-A+free-β-hCG+inhibin-A+AFP+uE_3+NT=86%, PAPP-A+free-β-hCG+NT=83% ("combined test"); best detection rate (5% false positive) without NT was 78% *-False positive rates for 85% detection rate (all include maternal age)* *1st trimester:* combined test=6.1% NT (at 12-13 wks)=25.1% *2nd trimester:* integrated test*=1.2% quadruple test=6.2% triple test=9.3% double test=13.1% *includes NT+PAPP-A (1st trimester) AND quadruple test (2nd trimester) -Urinary markers were "useless" in 1st trimester; ITA was the most effective 2nd trimester marker but added little to screening performance	-Screening performance in the 1st trimester of pregnancy was virtually the same as that in the 2nd trimester but both were less effective than integrating screening results from both trimesters into a single test. There is no evidence to support retaining the double test, the triple test, or NT alone. The most effective and safe screening tests were: 1) integrated test 2) serum integrated test if no NT 3) quadruple test if no antenatal care until 2nd trimester 4) combined test if choice is to have screening in 1st trimester NOTES: designed to compare 1st and 2nd trimester screening tests without bias caused by diagnosis and termination of some pregnancies and miscarriage of others; serum analyzed for AFT, free β-hCG, total hCG, uE_3, PAPP-A, dimeric inhibin-A; urine analyzed for ITA and β-core fragment, total hCG, free β-hCG, and creatinine; no NT measurement in 9% of pregnancies – greater failure rate before 10 weeks and after 14 weeks; sonographer experience and ultrasound make and model also influenced ability to obtain NT measurement

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Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – Preconception Risk Assessment Form

(to be completed by patient)

Patient's name:_____ Date:_____

Because of the nature of your visit today, we ask that you answer the following brief questions so we may help you:

1.	Will you be trying to get pregnant within the next year?	❑ Y*	❑ N	❑ Unsure*
2.	Do you think you are underweight or overweight?	❑ Y*	❑ N	❑ Unsure*
3.	Do you eat fewer than three meals per day or have fewer than five vegetables or fruit servings per day?	❑ Y*	❑ N	❑ Unsure*
4.	Are you on a special diet (e.g., vegetarian, weight loss, lactose-free)?	❑ Y*	❑ N	❑ Unsure*
5.	Do you use caffeinated supplements or beverages? (Three cups of coffee per day is the maximum recommended intake for pregnant women.)	❑ Y*	❑ N	
6.	Do you use tobacco?	❑ Y*	❑ N	
7.	Do you sometimes drink beer, wine or other alcoholic beverages?	❑ Y**	❑ N	
8.	Do you use street or recreational drugs (i.e., cocaine, speed, marijuana, etc.)?	❑ Y*	❑ N	
9.	Do you use any prescription or over-the-counter medications?	❑ Y*	❑ N	❑ Unsure*
10.	Have you had a urine/bladder/kidney infection in the last three years?	❑ Y*	❑ N	❑ Unsure*
11.	Have you had chicken pox?	❑ Y	❑ N*	❑ Unsure*
12.	Are you aware of toxoplasmosis and how this organism is transmitted (i.e., cat litter cleanup or food preparation)?	❑ Y	❑ N*	❑ Unsure*
13.	Are you exposed to chemicals or infections in your work?	❑ Y*	❑ N	❑ Unsure*
14.	Are you currently taking folic acid supplements? (Any woman attempting pregnancy should take a folic acid supplement of 0.4 mg daily. This vitamin reduces the risk of birth defects.)	❑ Y	❑ N*	❑ Unsure*
15.	Within the past year – or since you have been pregnant – have you been hit, slapped, kicked or otherwise physically hurt by someone?	❑ Y*	❑ N	❑ Unsure*
16.	Are you in a relationship with a person who threatens or physically hurts you?	❑ Y*	❑ N	❑ Unsure*
17.	Has anyone forced you to have sexual activities that made you feel uncomfortable?	❑ Y*	❑ N	❑ Unsure*
18.	Do you have a family history of birth defects or hereditary disorders?	❑ Y*	❑ N	❑ Unsure*
19.	Have you had three or more lost pregnancies before 14 weeks due to miscarriage or abortion?	❑ Y*	❑ N	❑ Unsure*
20.	Have you ever had a pregnancy loss after 14 weeks for genetic or unknown reasons?	❑ Y*	❑ N	❑ Unsure*
21.	Have you ever been screened (tested) for HIV?	❑ Y*	❑ N	❑ Unsure*
22.	Have you had periodontal disease?	❑ Y*	❑ N	❑ Unsure*
23.	Do you have a history of genital or oral herpes simplex virus (HSV)?	❑ Y*	❑ N	❑ Unsure*
24.	Have you been vaccinated for hepatitis?	❑ Y*	❑ N	❑ Unsure*

If you answered "no" to question #21, HIV testing is recommended if you are considering pregnancy.

If you answered "yes" to question #21, what was the date of your last HIV test? _____

* Answers with asterisks may have health implications. If you need additional information, we recommend scheduling an appointment with your health care provider.

** If yes, see Appendix I, "T-ACE Screening Tool."

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Appendix B – Workplace Environment/Lifestyle Risk Assessment Form (to be completed by patient)

Patient's name:_____ Date:_____

Occupation

What is your occupation? _____

Does your employer accommodate flexible work hours?	Y N Unsure
Is there a health professional available at work?	Y N Unsure
(If so, can your blood pressure be checked as needed?)	Y N Unsure
(If so, is there a place where you may rest?)	Y N Unsure

Workplace Exposure

Are you exposed to lead or chemicals (handling or airborne)?	Y N Unsure
Are you exposed to radiation?	Y N Unsure
Are you exposed to infections (hospital, lab work, day care, etc.)?	Y N Unsure
Is there a high level of stress at work?	Y N Unsure
Is overtime required?	Y N Unsure

Physical Requirements of Occupation

Do you:

stand for prolonged periods of time?	Y N Unsure
(If so, # of hours per day)	_____hr.
sit for prolonged periods of time?	Y N Unsure
(If so, # of hours per day)	_____hr.
lift heavy objects repeatedly?	Y N Unsure
(If so, # of pounds at a time)	_____lb.

Nutrition

Are you on a special diet?	Y N Unsure
Do you have a history of an eating disorder?	Y N Unsure
Do you often skip meals?	Y N Unsure
Have you had a significant weight change in the past year?	Y N Unsure
Do you drink caffeinated coffee, pop or tea?	Y N Unsure
Do you eat fewer than five servings of fruits or vegetables per day?	Y N Unsure
Are you currently taking folic acid supplements?	Y N Unsure
Are you aware of toxoplasmosis and how this organism is transmitted (i.e., food preparation or cat litter cleanup)?	Y N Unsure

At Home

Do you have home remodeling plans? Y N Unsure

Please list your hobbies: _____

_____

Describe your usual form of exercise: _____

How many times a week do you exercise? _____

How long do your exercise sessions usually last? _____

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Appendix C – Infectious Diseases in Pregnancy Screening Form

Patient's name: _____ Date: _____

History *Letters refer to the interventions listed below.*

1.	Does the patient have a record of rubella immunity?		Yes	No[B]
2.	Has the patient been vaccinated for or had chicken pox?		Yes	No[A]
3.	Does the patient have a history of oral or genital HSV?		Yes	No
4.	Is the patient known to be HIV positive?		Yes[CDEF]	No
5.	Has the patient been in close contact with persons with known or suspected tuberculosis?		Yes[C]	No
6.	Is the patient an immigrant from Africa, Asia or Latin America?		Yes[C]	No
7.	Has the patient been treated for IV drug use?		Yes[CGH]	No
8.	Has the patient been treated for alcoholism?		Yes	No
9.	Is the patient a member of a medically underserved, low-income population?		Yes[CDE]	No
10.	Is the patient under 25 years old?		Yes[DE]	No
11.	Does the patient (or her partner) have a history of STIs?		Yes[DEF]	No
12.	Does the patient have a new sexual partner?		Yes[D]	No
13.	Does the patient (or her partner) have multiple sexual partners?		Yes[DE]	No
14.	Is the patient married?		Yes	No[D]
15.	Is the patient seen today for STI screening?		Yes[DEFGH]	No
16.	Has the patient had sex for money?	Unknown	Yes[DEFG]	No
17.	Is the patient's partner(s) HIV positive?	Unknown	Yes[G]	No

Physical Examination

18.	Is there cervical ectopy?		Yes[D]	No
19.	Is there cervical friability?		Yes[DE]	No
20.	Is there cervical erythema?		Yes[DE]	No
21.	Is there a mucopurulent discharge?		Yes[DE]	No

Interventions

A.	Test for varicella immune status	_____
B.	Test for rubella immune status	_____
C.	Screen for tuberculosis	_____
D.	Screen for chlamydia	_____
E.	Screen for gonorrhea	_____
F.	Screen for syphilis	_____
G.	Screen for HIV	_____
H.	Screen for Hepatitis B	_____

Recommended interventions are per United States Preventive Services Task Force interpretive report of 1996 Centers for Disease Control guidelines.

Form completed by:_____(Init.) _____

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Appendix D – Prenatal Genetic Risk Assessment Form (to be completed by medical staff)

Patient's name: _____ Date: _____

1. Are you or the baby's father of the following ethnic backgrounds?
   a. Jewish (Eastern European or Mediterranean background) or French Canadian? ❑ Y ❑ N
      If yes, have you ever been tested for Tay-Sachs? ❑ Y ❑ N
   b. Italian, Greek or Mediterranean? ❑ Y ❑ N
      If yes, have you ever been tested for beta-thalassemia? ❑ Y ❑ N
   c. Southeast Asian or Philippine? ❑ Y ❑ N
      If yes, have you ever been tested for alpha-/beta-thalassemia? ❑ Y ❑ N
   d. African American? ❑ Y ❑ N
      If yes, have you ever been tested for sickle cell trait? ❑ Y ❑ N
   e. Have you ever been tested for cystic fibrosis? ❑ Y ❑ N
2. Will you be 35 years old or older when your baby is born? ❑ Y ❑ N
   Will the baby's father be 50 or older when the baby is born? ❑ Y ❑ N
3. Have you had three or more unplanned pregnancy losses? ❑ Y ❑ N
4. Have you used any street drugs (including marijuana and cocaine) or chemicals in the past six months or during this pregnancy? ❑ Y ❑ N
5. If any close relatives have these hereditary medical problems, check "Y"; check "N" if a condition does not apply. For the following questions, "close" relatives are considered to include the grandparents, parents, aunts, uncles, first cousins, brothers, sisters, or children of yours or the baby's father.
   a. Child with a known birth defect* or stillborn (* e.g., heart defect, cleft lip/palate, club foot) ❑ Y ❑ N
   b. Chromosome abnormalities (e.g., Down syndrome, Turner syndrome, Klinefelter syndrome) ❑ Y ❑ N
   c. Abnormalities of the brain or spinal column (e.g., hydrocephalus, spina bifida, meningomyelocele, microcephalus, mental retardation) ❑ Y ❑ N
   d. Abnormalities of the bones or skeleton (e.g., osteogenesis imperfecta, achondroplasia, limb deformities, dwarfism) ❑ Y ❑ N
   e. Inherited disorders of the blood (e.g., hemophilia, sickle cell trait or disease, thalessemia) ❑ Y ❑ N
   f. Neuromuscular disorders (e.g., muscular dystrophy, myotonic dystrophy) ❑ Y ❑ N
   g. Metabolic or chemical disorders (e.g., Tay-Sachs disease, cystic fibrosis, glycogen storage diseases, Hurler's and Hunter's syndromes) ❑ Y ❑ N
   h. Skin disorders (e.g., neurofibromatosis, ichthyosis, tuberous sclerosis) ❑ Y ❑ N
   i. Hereditary visual or hearing defects ❑ Y ❑ N
   j. Unusual reactions to anesthetic agents ❑ Y ❑ N
   k. Other inherited genetic diseases not listed above (e.g., Huntington's chorea, polycystic kidney disease, congenital adrenal hyperplasia) ❑ Y ❑ N
6. Do you have any serious health problems such as diabetes or epilepsy? ❑ Y ❑ N
7. Were you ever on a special diet as a child or do you know of a family member with PKU (phenylketonuria)? ❑ Y ❑ N
8. Do you or the father of the baby have a family history of psychiatric disease or mood disorders (e.g., manic depression, depression, anxiety disorder, schizophrenia)? ❑ Y ❑ N
9. Do you or the father of the baby have any concerns about conditions that may be inherited? ❑ Y ❑ N

Patient's Signature:_____ Date: _____

[ ] No known increased risk.
[ ] Positives reviewed; formal counseling not indicated.
[ ] Genetic counseling and/or amniocentesis have been offered and refused.
[ ] Genetic counseling and/or amniocentesis scheduled and/or referral done.
[ ] Undecided at this time.

Form completed by: _____ (Init.) _____

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Appendix E – Prenatal Record

Logo Area

Chart No.	Service
Name	Provided at:
D.O.B.	Med. Grp._____ Provider_____

Patient Name	Age/DOB:	Marital Status: M S W D Sep Part
Phone Number H: W:	Emergency Contact: Phone:	
Address:	Patient Occupation:	
Birthplace (City, State, Country)	Interpreter Need? Y N Primary Language:	
Husband/Partner's name	Occupation	
Current Involvement	Phone Number H: W:	
Hospital of Delivery:	Plans for Newborn: keep adopt unsure	
Provider: MD DO CNM	Newborn's Physician:	

Gestational Age Assessment
Menses: Interval: _____ Regularity: _____ LNMP: Certain?
Conception date:
Use of BC: Yes_____ No_____ Type: _____ If OCP – last taken _____
Pregnancy tests: Type: Date: Result:
Quickening date:
Ultrasound: Date: Size: Sonar EDD:
Physical Assessment Factors Considered (circle): Initial uterine size Uterus at umbilicus FHR by doptone FHR by fetoscope
EDD revision based on:

Past Obstetrical History

Total Preg	Full-term	Premature	Ab./Induced		Abortions Spont.		Ectopics	Multiple Births	Living
Date of Del./Ab.	Sex	Name	Wt.	Hrs. in Labor	Type of Delivery	Weeks Gestation	Comments/Complications		

Medical History	Pt (+/-)	Fam (+/-)	Notes
Allergic rhinitis/sinusitis			
Cardiac murmur			
Congenital heart disease, valve(s) affected:			
Rheumatic heart disease			
Needs SBE prophylaxis			
Hypertension			
Asthma			
Other pulmonary disease			
Diabetes mellitus			
Thyroid disease			
Cystitis			
Pyelonephritis			
Anemia			
Blood transfusion(s)			
Psych. Disorder, type: year:			
Thrombophlebitis, deep/DVT year:			
Embolism, year:			
Epilepsy/seizure disorder			
Migraine headache			
Collagen disorder, specify:			
Chronic back pain			
Ulcer/gastritis			
Gall bladder disorder			
Inflammatory bowel disease			
Hepatitis, specify:			

Medical History	Pt (+/-)	Fam (+/-)	Notes
Malignancy, specify:			
Treatment for substance abuse			
Other:			
Surgical History			
ENT, year:			
Cardiac, year:			
GI, specify: year:			
Gynecologic, specify: year:			
Other:			
Other:			
Anesthetic complications			
Gynecologic History			
Infertility			
Clomiphene			
Supra ovulation medications			
In vitro fertilization			
Pelvic trauma, year:			
PID, year:			
Uterine anomaly/DES exposure			
Cervical incompetence			
Repetitive pregnancy loss			
Abnormal Pap smear year:			
Cervical carcinoma in situ			
Conization/LEEP/cryo year:			

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Appendix E – Prenatal Record

Logo Area

Chart No.	Service
Name	Provided at:
D.O.B.	Med. Grp._____ Provider_____

Laboratory

Initial Labs	Date	Result	Reviewed by
Blood Type		A B AB O	
D (Rh) Type		neg pos	
Antibody Screen		neg pos	
CBC & platelets			
Rubella		immune not immune	
RPR		Non-reactive reactive	
GC/Chlamydia			
Hepatitis BsAg		neg pos	
HIV (with consent)		Non-reactive reactive	
Urine Culture		no growth pos_____	
Pap Smear		normal abnorm____	
Immunizations & Chemoprophylaxis:	**Date**		
•Td Booster IM		Lot #_____ Init._____	
•Influenza IM (must be ≥ 14 weeks EGA)		Lot #_____ Init._____	
16-18 Week Labs (when indicated)	**Date**	**Result**	**Reviewed**
Maternal Serum Screen		normal abnorm____	
Amnio/CVS			
Karyotype Fetal Anomaly Screening			
Amniotic Fluid (AFP)			
RhoGAM IM (for amnio) 22 weeks		Lot #_____ Init._____	
24-28 Week Labs (when indicated)	**Date**	Result	**Reviewed**
Diabetes Screen		1 Hr. _____	
GTT (if screen abnormal)		FBS___ 1 Hr. ___ 2 Hr. ___ 3 Hr. ___	
D (Rh) Antibody Screen		neg pos	
RhoGAM IM		Lot #_____ Init._____	
32-36 Week Labs (when indicated)	**Date**	**Result**	**Reviewed**
		1 Hr. _____	
GTT (if screen abnormal)		FBS___ 1 Hr. ___ 2 Hr. ___ 3 Hr. ___	
Group B Strep **Date**	**Date**	neg pos	
Other Labs	**Date**	**Result**	**Reviewed**

Sono Date	Sono EDD	Comments

Fetal Testing	**Date**										
	NST										
	BPP/AFI										

Education/Counseling

Educational Topics	Date	Init
Visit at 6-8 Weeks		
Lifestyle		
Warning Signs		
Course of Care		
Physiology of Pregnancy		
Nutrition and Supplements		
Referral PTL Education Class		
HIV Counseling		
Risk Profile Form Completion:		
- Risk Assessment (preterm labor)		
- Infectious Disease (ID) screening		
- Genetic Screening		
- Workplace Envir./Lifestyle Screening		
Visit at 10-12 Weeks		
Fetal Growth		
Future Lab Testing		
Breast-Feeding		
Influenza IM for due date 11/1-5/31		
Body Mechanics		
Visit at 16-18 Weeks		
Second Trimester Growth		
Quickening		
Lifestyle		
Physiology of Pregnancy		
Visit at 22 Weeks		
PTL Signs		
Labor Class		
Family Issues		
Length of stay		
Gestational DM		
Rh Status		
Visit at 28 Weeks		
Continuing Work		
Physiology of Pregnancy		
Fetal Growth/Movement		
Screen for Domestic Abuse		
PTL Risk Assessment		
Optional Reassess for ID risk		
Postpartum Depression		
Birth Control Plans		
Visit at 32 Weeks		
Travel		
Sexuality		
Pediatric Care		
Episiotomy		
Labor and Delivery Issues		
Warning Signs/PIH		
Postpartum Care		
Birth Control Plans		
Visit at 36 Weeks		
Attended/Attending Prenatal Classes		
Mgmt. of Late Preg. Signs & Symptoms		
Visits at 38-41 Weeks		
Postpartum Vaccinations		
Infant CPR		
Post-term Mgmt.		
Labor and Delivery Update		

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Appendix E – Prenatal Record

Logo Area

Chart No.	Service
Name	Provided at:
D.O.B.	Med. Grp._____ Provider_____

Substance Use

Substance			Amt/Day PrePreg	Amt/Day Preg	Spouse/ Partner Use
Tobacco	Y	N			
Alcohol	Y	N			
Street Drugs Specify:	Y	N			

Allergies

	NKDA
	Latex allergy, specify reaction:
	Med. allergy: _____ Specify reaction:
	Med. allergy: _____ Specify reaction:
	Med. allergy: _____ Specify reaction:

Medication

Medication (Rx and OTC)	Present Dosage	Date Began	Date Discontinued

For VBAC Only (Init._____) Date _____

	Y	N
Record of previous lower segment incision attached to prenatal chart?		
Record of low segment incision confirmed?		
Patient counseled regarding VBAC risks?		
Patient received written information about VBAC?		
Patient given informed consent for trial of labor after Cesarean section?		

Initial Physical Exam Performed by: _____ (Init.)
Date _____ PrePreg Wt: _____ Ht: _____ BMI: _____ BP: R: _____ or L: _____

	Normal	Abnormal, specify
HEENT		
Thyroid		
Breast		
Lungs		
Heart		
Abdomen		
Extremities		
Skin		

Gyn Exam

	Normal		+		+
Vulva		Condylomata		Lesions	
Vagina		Inflamed		Discharge	
Cervix		Inflamed		Lesions	
Uterus, weeks _____		Myoma(s)			
Adnexa		Mass			
Rectum		Hemorrhoids			

Postpartum Issues

Breastfeeding: Y N Unsure If yes, attending classes? Y N	Circumcision: Y N Unsure Postpartum birth control:	Desires sterilization (tubal): Y N Unsure __ Tubal literature given Risks, failure, and alternatives discussed by:_____(Init.) Date consent signed:

Logo Area

Chart No. Service

Name Provided at:

D.O.B. Med. Grp._____ Provider_____

Prenatal Record

LMP: EDD: Revised EDD (see p.4): ADD:

Hospital_____

Problem List w/Plans

Problems			Date	Plans
1. Preterm Labor Risk	Yes	No		1.
2. Rh Neg	Yes	No		2.
3.				3.
4.				4.
5.				5.
6.				6.
7.				7.
8.				8.
9.				9.
10.				10.

Visit Flow Sheet

Date	Wks	BP	Pre Preg wt. _____		FHR	Fundal Height	FM*	Posi-tion	Cerv Exam	Patient Concerns**	Other**	See PN+	Return Visit	Init
			Wt	Total Gain										

If more visits are necessary, use supplemental flow sheet

*Fetal Movement

**If more space is needed, use progress notes on next page

+Progress Notes

Initial Identification (Providers)

Init	Name	Init	Name
1.		6.	
2.		7.	
3.		8.	
4.		9.	
5.		10.	

Routing Record

Initial chart copied & sent to hospital:
❑ Copy ❑ Fax
Date_____ Init._____
Updated chart sent to hospital:
❑ Copy ❑ Fax
Date_____ Init._____
Updated chart sent to hospital:
❑ Copy ❑ Fax
Date_____ Init.
❑ EMR

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Logo Area

Chart No. Service

Name Provided at:

D.O.B. Med. Grp._____ Provider_____

Supplemental Flow Sheet

Date	Wks	BP	Wt.	Total Gain	FHR	Fundal Height	FM*	Posi-tion	Cerv Exam	Patient Concerns**	Other**	See PN+	Return Visit	Init

*Fetal movement **If more space is needed, use progress notes on next page +Progress Notes

Logo Area

Chart No. Service

Name Provided at:

D.O.B. Med. Grp._____ Provider_____

Progress Notes (entries to be dated)

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Appendix F – Blood Lead Screening Guidelines for Pregnant Women in Minnesota

Blood Lead Screening Guidelines for Pregnant Women in Minnesota

Prenatal lead exposure is of concern because it may have an effect on cognitive development and may increase delinquent and antisocial behaviors when the child gets older. Prenatal lead exposure may also reduce neonatal weight gain. In addition to fetal risk, lead may be a risk to the mother by causing an increase in blood pressure.

Lead is transferred from the mother to the fetus because the placenta is a weak barrier to the passage of lead. Therefore, it may be assumed that fetal blood contains the same concentration of lead as maternal blood. The Centers for Disease Control and Prevention (CDC) and the Minnesota Department of Health (MDH) consider 10 micrograms per deciliter (µg/dL) and above to be an elevated blood lead level for children.

In many cases, high levels of lead in pregnant women arise from maternal occupational exposure. However, other lead exposures may occur, such as: remodeling a home containing lead paint that allows lead dust to become airborne and inhaled; a family member's occupation or hobby resulting in "take-home" lead; using non-commercial home remedies or cosmetics that contain lead; using non-commercial glazed pottery for cooking; and pica behavior of the mother, such as eating soil or pieces of clay pots. There may also be exposure of the fetus to lead coming out of the mother's bones. This may arise from long-term previous exposures of the mother even though lead exposure is not happening during the pregnancy. Lead may come out of maternal bones faster during pregnancy and lactation because of the mother's and fetus's need for calcium. A diet rich in iron and calcium may help reduce absorption of lead during pregnancy.

Not every woman is at risk for lead exposure, so a risk screening questionnaire should be used to decide when to test a pregnant, or potentially pregnant, woman for lead.

Blood Lead Screening Risk Questionnaire for Pregnant Women in Minnesota

Health-care providers should **use a blood lead test** to screen pregnant women if they answer, "yes" or "don't know" to any of the following questions, or if they have moved to Minnesota from a major metropolitan area or another country within the last twelve months:

1. Do you or others in your household have an occupation that involves lead exposure?
2. Sometimes pregnant women have the urge to eat things that are not food, such as clay, soil, plaster, or paint chips. Do you ever eat any of these things—even accidentally?
3. Do you live in a house built before 1978 with ongoing renovations that generate a lot of dust (for example, sanding and scraping)?
4. To your knowledge, has your home been tested for lead in the water, and if so, were you told that the level was high?
5. Do you use any traditional folk remedies or cosmetics that are not sold in a regular drug store or are homemade? (See list on back.)
6. Do you or others in your household have any hobbies or activities likely to cause lead exposure? (See list on back.)
7. Do you use non-commercially prepared pottery or leaded crystal?

MINNESOTA MDH DEPARTMENT OF HEALTH

Environmental Health Division
Environmental Surveillance and Assessment Section
Environmental Impacts Analysis Unit – Lead Program
P.O. Box 64975
St. Paul, Minnesota 55164-0975

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These guidelines have been reviewed and approved by the Minnesota Chapter of the American College of Obstetricians and Gynocologists (ACOG)

The guidelines were based on the New York State Department of Health, *Lead Poisoning Prevention Guidelines for Prenatal Care Providers*.

Sources of Lead

The most common sources of lead are paint, dust, soil, and water. Other sources include:

Traditional Remedies/Cosmetics

IN ASIAN, AFRICAN, & MIDDLE EASTERN COMMUNITIES:
As a cosmetic or a treatment for skin infections or umbilical stump.
- alkohl, kajal, kohl, or surma (black powder)

IN ASIAN COMMUNITIES:
For intestinal disorders.
- bali goli (round flat black bean)
- ghasard/ghazard (brown powder)
- kandu (red powder)

IN HMONG COMMUNITIES:
For fever or rash.
- pay-loo-ah (orange/red powder)

IN LATINO COMMUNITIES:
- Some salt-based candies made in Mexico

For abdominal pain/empacho.
- azarcon (yellow/orange powder), also known as: alarcon, cora, coral, liga, maria luisa, and rueda
- greta (yellow/orange powder)

IN SOUTH ASIAN (EAST INDIAN) COMMUNITIES:
For bindi dots.
- sindoor (red powder)

As a dietary supplement.
- Ayurvedic herbal medicine products

Hobbies

May also include some of the occupations listed in the right column.
- Bronze Casting
- Collecting, Painting or Playing Games with Lead Figurines
- Copper Enameling
- Electronics with Lead Solder
- Hunting and Target Shooting
- Jewelry Making with Lead Solder
- Liquor Distillation
- Making Pottery and Ceramic Ware with Lead Glazes and Paints
- Making Stained Glass and Painting on Stained Glass
- Melting Lead for Fishing Sinkers or Bullets or Lead Figurines
- Painting/Stripping Cars, Boats, and Bicycles
- Print Making and Other Fine Arts (When Lead White, Flake White and Chrome Yellow Pigments are Involved)
- Remodeling, Repairing, and Renovating Homes

Occupations/Industries

- Ammunition/Explosives Maker
- Auto Repair/Auto Body Work
- Battery Manufacturing and Repair
- Bridge, Tunnel and Elevated Highway Construction
- Building or Repairing Ships
- Cable/Wire Stripping, Splicing or Production
- Ceramics Worker (Pottery, Tiles)
- Construction
- Firing Range Work
- Glass Recycling, Stained Glass and Glass Work
- Jewelry Maker or Repair
- Lead Abatement
- Lead Miner
- Leaded Glass Factory Worker
- Manufacturing and Installation of Plumbing Components
- Manufacturing of Industrial Machinery and Equipment
- Melting Metal (Smelting)
- Metal Scrap Yards and Other Recycling Operations
- Motor Vehicle Parts and Accessories
- Occupations Using Firearms
- Paint/Pigment Manufacturing
- Pottery Making
- Production and Use of Chemical Preparations
- Radiator Repair
- Remodeling/Repainting/Renovating Houses or Buildings
- Removing Paint (Sandblasting, Scraping, Sanding, Heat Gun or Torch)
- Steel Metalwork
- Tearing Down Buildings/Metal Structures
- Welding, Burning, Cutting or Torching

Miscellaneous

- Antique/Imported Toys
- Chalk (Particularly for Snooker/Billiards)
- Imported Candy
- Imported Pottery
- Non-Commercially Prepared Pottery
- Non-Commercially Prepared Leaded Crystal
- Some Children's Jewelry

www.health.state.mn.us/divs/eh/lead

For more information about lead, contact the **Lead Program at (651) 201-4620**
If you require this document in another format, such as large print, Braille, or cassette tape, call:
(651) 201-5000 ♦ 1-800-657-3908 ♦ MDH TTY (651) 201-5797

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IC #141-1508

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Appendix G – Perinatal Hepatitis B Prevention Program

Program Guidelines

Minnesota Department of Health

Perinatal Hepatitis B Prevention Program

What is perinatal transmission of hepatitis B?

Perinatal transmission of the hepatitis B virus (HBV) from mother to infant at birth is very efficient. The risk of infection may be as high as 70-90%. The HBV virus is transmitted by blood exposures. Up to 90% of perinatally infected babies who are not treated will develop a chronic hepatitis B infection. An estimated 15-25% of these individuals will ultimately die of liver failure secondary to chronic hepatitis, liver cirrhosis, or primary liver cancer. Treatment initiated within 12 hours after birth is up to 90% effective at preventing this serious infection.

Approximately 100,000 new hepatitis B cases are diagnosed in the U.S. each year. One third of the chronic infections are acquired perinatally or in early childhood through close household contact. The disease is largely preventable through treatment of infants born to infected mothers, as well as vaccination of individuals at risk for infection.

Since 1988, the Centers for Disease Control's Immunization Practices Advisory Committee (ACIP) has recommended that all pregnant women be screened for hepatitis B infection. Testing should be performed with each pregnancy, regardless of patient history or previous testing results. The cost effectiveness of universal hepatitis B screening of pregnant women compares with other prenatal and neonatal screening programs (including hypothyroidism and phenylketonuria).

What is the perinatal hepatitis B prevention program in Minnesota?

The Minnesota Department of Health (MDH) implemented a perinatal hepatitis B prevention program in 1990. **The goal of the MDH Perinatal Hepatitis B Prevention Program is to identify and treat infants born to HBV-infected mothers in an effort to prevent perinatally acquired infection.** The benefits of this cost-effective strategy are:

- preventing potential long-term health consequences for the child, and
- eliminating a potential source of infection to others in the future.

To prevent perinatal transmission:

1. Obstetric patients are evaluated and screened for HBV infection **early** in ***each*** **pregnancy** regardless of past test results and/or immunization status. **HBsAg(surface antigen)** serology testing is used for screening. If the patient is high risk, screening tests are repeated later in the pregnancy.
2. HBV-infected women receive further medical evaluation and follow-up.
3. Hepatitis B serology results are documented in the patient's prenatal record. A copy of the original HBsAg lab is forwarded to the hospital to be placed prominently in the patient's chart.
4. Pregnancies in HBV-infected women are reported to MDH within one working day of knowledge of the pregnancy.
5. Local public health nurses receive referrals from MDH and follow up with the expectant mother to educate her about her infection, and the implications and recommended preventive treatment for her baby.
6. Infants born to HBV-infected mothers receive:
   a. Hepatitis B immune globulin (HBIG) and HBV vaccine within 12 hours of birth,
   b. Additional doses of HBV vaccine to complete the series in accordance with the recommended schedule, and
   c. Post-vaccination serology

   All treatment is documented in the infant's medical record and reported to local or state health departments.
7. Infants who do not demonstrate an immune response in post-vaccination serologic testing receive a second vaccine series.
8. HBV-infected infants are referred for further medical evaluation and follow-up.
9. Household members and other close contacts of the mother and infant are screened; HBV-susceptible individuals are vaccinated; and infected individuals receive further medical evaluation and follow-up.

MINNESOTA MDH DEPARTMENT OF HEALTH
Immunization Program
P.O. Box 64975
St. Paul, MN 55164-0975
651-201-5503 or 1-800-657-3970
www.health.state.mn.us/immunize

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MDH Use Only
Record Number

Perinatal Hepatitis B Birth Report

Hospitals should use this form to report perinatal hepatitis B births to the Minnesota Department of Health.

Fax to: **(651) 201-5502**
Perinatal Hepatitis B Coordinator
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975

Person Completing: _____

Phone: (_____) _____

Date Faxed:_____ / _____ / _____

Phone: (651) 201-5557 - if questions

For women known to be HBsAg Positive:	For women whose HBsAg status is unknown:
☐ Administer **hepatitis B immune globulin (HBIG)** and **hepatitis B** vaccine, within **12 hours** of birth, to all infants born to hepatitis B positive mothers. ☐ If your hospital is having difficulty obtaining HBIG, please call MDH at (651) 201-5414. ☐ **FAX completed form to MDH at (651) 201-5502**	☐ Perform a stat HBsAg screening test for all women admitted for delivery whose hepatitis status is **unknown.** ☐ While test results are pending, the infant should receive **hepatitis B vaccine within 12 hours of birth**. If the mother's HBsAg test is positive or unknown at discharge, the infant should receive HBIG before leaving the hospital. *(Please check individual hospital orders/policies for your Institution's guidelines as they may vary from MDH recommendations)* ☐ **FAX completed form to MDH at (651) 201-5502**

Name of hospital: _____ City of hospital: _____

Date sent: _____/_____/_____ **Mother's hospital record no:** _____

*Note: Report if mother is **HBsAg(+)or status unknown at time of admission***

Mother's information		HBsAg(+) Test date: / /
Last name:		First name:
Address:		Phone: ( )
City:	Zip code:	Alternate phone (i.e. relative): ( )
Physician's name:		Clinic name:
Mother's date of birth: / /		Clinic phone: ( )
Race: ☐ Asian/Pacific Islander ☐ Unknown ☐ American Indian ☐ White ☐ Black ☐ Other _____		Ethnicity: ☐ Hmong ☐ Vietnamese ☐ Hispanic ☐ Other (specify): ☐ Somali _____
Infant's Information		**Infant's hospital record no.**
Last name:		First: (If known)
Date of birth: / / Time of birth: AM PM	Birthweight:	Sex: M F
Date of HBV1: / / Time of HBV1: AM PM	Date of HBIG: / /	Time of HBIG: AM PM
Brand: ☐ Engerix ☐ Recombivax		
Important! Clinic where infant will receive HBV2:		City of Clinic:
Infant's physician (Include phone if known):		

MINNESOTA MDH DEPARTMENT OF HEALTH

Perinatal Hepatitis B Prevention Program
P.O. Box 64975
St. Paul, MN 55164-0975
www.health.state.mn.us/hepatitis

(1/08)

Appendix H – ICSI Shared Decision-Making Model

ICSI Institute for Clinical Systems Improvement

The technical aspects of Shared Decision-Making are widely discussed and understood.

- **Decisional conflict** occurs when a patient is presented with options where no single option satisfies all the patient's objectives, where there is an inherent difficulty in making a decision, or where external influencers act to make the choice more difficult.
- **Decision support** clarifies the decision that needs to be made, clarifies the patient's values and preferences, provides facts and probabilities, guides the deliberation and communication and monitors the progress.
- **Decision aids** are evidence-based tools that outline the benefits, harms, probabilities and scientific uncertainties of specific health care options available to the patient.

However, before decision support and decision aids can be most advantageously utilized, a Collaborative Conversation™ should be undertaken between the provider and the patient to provide a supportive framework for Shared Decision-Making.

Collaborative Conversation™

A collaborative approach toward decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an inter-professional approach that nurtures relationships, enhances patients' knowledge, skills and confidence as vital participants in their health, and encourages them to manage their health care.

Within a Collaborative Conversation™ , the perspective is that both the patient and the provider play key roles in the decision-making process. The patient knows which course of action is most consistent with his/her values and preferences, and the provider contributes knowledge of medical evidence and best practices. Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care provider and team relationships when patients and families are dealing with high stakes or highly charged issues, such as diagnosis of a life-limiting illness.

The overall framework for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences. A rote script or a completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects involved in making a decision: cognitive, affective, social and spiritual.

Key communication skills help build the Collaborative Conversation™ approach. These skills include many elements, but in this appendix only the questioning skills will be described. (For complete instruction, see O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007], and Bunn H, O'Connor AM, Jacobsen MJ "Analyzing decision support and related communication" [1998, 2003].)

1. **Listening skills:**

   Encourage patient to talk by providing prompts to continue such as "*go on, and then?, uh huh,*" or by repeating the last thing a person said, "*It's confusing*."

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Paraphrase content of messages shared by patient to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The provider should use his/her own words rather than just parroting what he/she heard.

Reflection of feelings usually can be done effectively once trust has been established. Until the provider feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the provider understands the patient's feelings and may work as a catalyst for further problem solving. For example, the provider identifies what the person is feeling and responds back in his/her own words like this: "*So, you're unsure which choice is the best for you*."

Summarize the person's key comments and reflect them back to the patient. The provider should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situations rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is, "*You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks*."

Perception checks ensure that the provider accurately understands a patient or family member, and may be used as a summary or reflection. They are used to verify that the provider is interpreting the message correctly. The provider can say "*So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?*"

2. **Questioning Skills**

Open and closed questions are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be "*What else would influence you to choose this?*" Closed questions are appropriate if specific information is required such as "*Does your daughter support your decision?*"

Other skills such as summarizing, paraphrasing and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the provider saying, "*You mentioned earlier…*"

3. **Information-Giving Skills**

Providing information and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a provider to supplement the patient's knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the provider.

Providing information can be sharing facts or responding to questions. An example is "*If we look at the evidence, the risk is…*" Providing feedback gives the patient the provider's view of the patient's reaction. For instance, the provider can say, "*You seem to understand the facts and value your daughter's advice*."

Additional Communication Components

Other elements that can impact the effectiveness of a Collaborative Conversation™ include:

- Eye contact
- Body language consistent with message
- Respect

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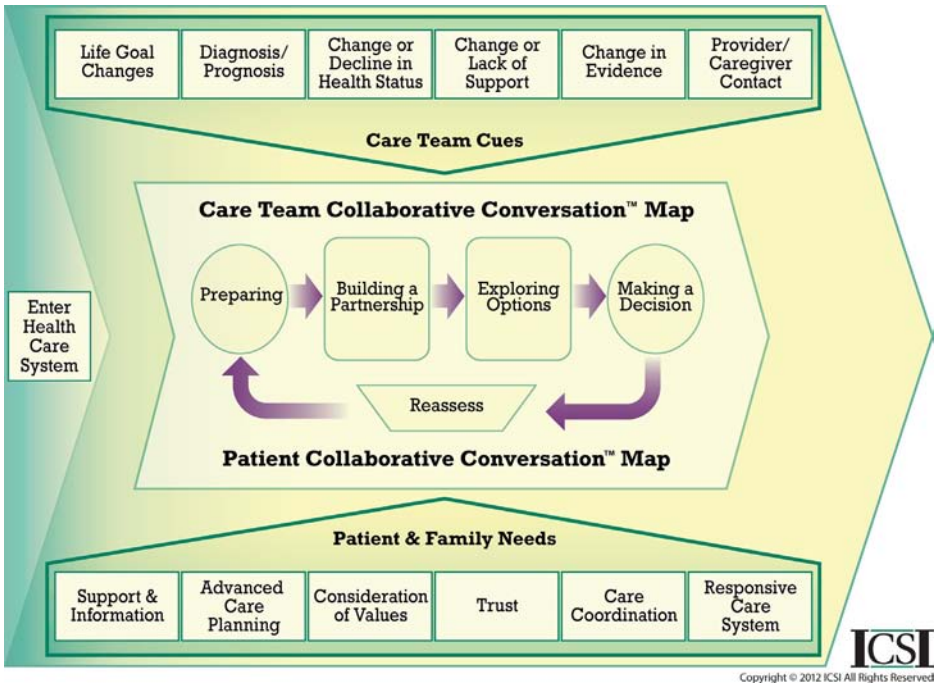
- Empathy
- Partnerships

Self-examination by the provider involved in the Collaborative Conversation™ can be instructive. Some questions to ask oneself include:

- Do I have a clear understanding of the likely outcomes?
- Do I fully understand the patient's values?
- Have I framed the options in comprehensible ways?
- Have I helped the decision-makers recognize that preferences may change over time?
- Am I willing and able to assist the patient in reaching a decision based on his/her values, even when his/her values and ultimate decision may differ from my values and decisions in similar circumstances?

When to Initiate a Collaborative Conversation™

A Collaborative Conversation™ can support decisions that vary widely in complexity. It can range from a straightforward discussion concerning routine immunizations to the morass of navigating care for a life-limiting illness. Table 1 represents one health care event. This event can be simple like a 12 year-old coming to the clinic for routine immunizations, or something much more complex like an individual receiving a diagnosis of congestive heart failure. In either case, the event is the catalyst that starts the process represented in this table. There are cues for providers and patient needs that exert influence on this process. They are described below. The heart of the process is the Collaborative Conversation™. The time the patient spends within this health care event will vary according to the decision complexity and the patient's readiness to make a decision.



Regardless of the decision complexity there are cues applicable to all situations that indicate an opportune time for a Collaborative Conversation™. These cues can occur singularly or in conjunction with other cues.

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Cues for the Care Team to Initiate a Collaborative Conversation™

- **Life goal changes:** Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.
- **Diagnosis/prognosis changes:** Additional diagnoses, improved or worsening prognosis.
- **Change or decline in health status:** Improving or worsening symptoms, change in performance status or psychological distress.
- **Change or lack of support:** Increase or decrease in caregiver support, change in caregiver, or caregiver status, change in financial standing, difference between patient and family wishes.
- **Change in medical evidence or interpretation of medical evidence:** Providers can clarify the change and help the patient understand its impact.
- **Provider/caregiver contact:** Each contact between the provider/caregiver and the patient presents an opportunity to reaffirm with the patient that his/her care plan and the care the patient is receiving are consistent with his/her values.

Patients and families have a role to play as decision-making partners, as well. The needs and influencers brought to the process by patients and families impact the decision-making process. These are described below.

Patient and Family Needs within a Collaborative Conversation™

- **Request for support and information:** Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values and/or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Generational and cultural influencers may act to inhibit the patient from actively participating in care discussions, often patients need to be given "permission" to participate as partners in making decisions about his/her care.

  Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When the patient expresses a need for information regarding options and his/her potential outcomes, the patient should understand the key facts about options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.
- **Advance Care Planning:** With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis.
- **Consideration of Values:** The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize the preferences, value clarification can be achieved through a Collaborative Conversation™ and by the use of decision aids that detail the benefits and harms of potential outcomes in terms the patient can understand.
- **Trust:** The patient must feel confident that his/her preferences will be communicated and respected by all caregivers.
- **Care Coordination:** Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Furthermore, the care delivery system must be able to provide coordinated care throughout the continuum of care.

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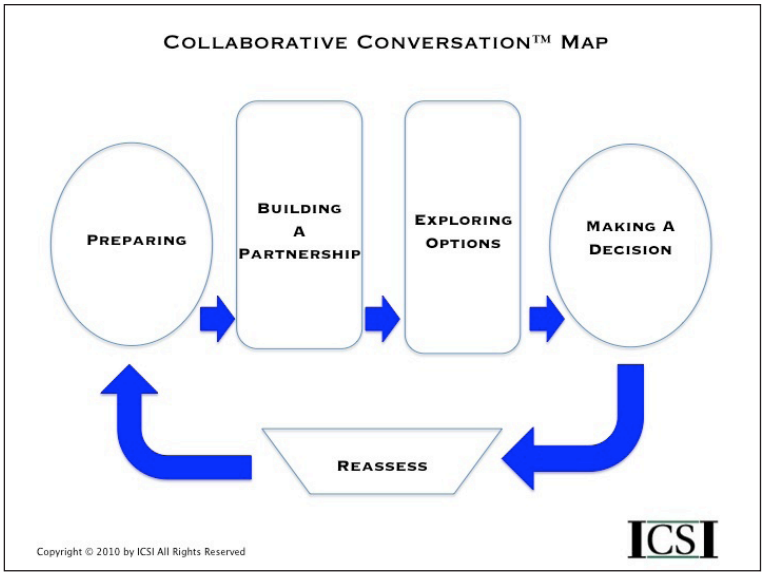
- **Responsive Care System:** The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he/she receives throughout the care continuum.

The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation™ Map can be used as a stand-alone tool that is equally applicable to providers and patients as shown in Table 2. Providers use the map as a clinical workflow. It helps get the Shared Decision-Making process initiated and provides navigation for the process. Care teams can used the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.



Evaluating the Decision Quality

Adapted from O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007].

When the patient and family understand the key facts about the condition and his/her options, a good decision can be made. Additionally, the patient should have realistic expectations about the probable benefits and harms. A good indicator of the decision quality is whether or not the patient follows through with his/her chosen option. There may be implications of the decision on patient's emotional state such as regret or blame, and there may be utilization consequences.

Decision quality can be determined by the extent to which the patient's chosen option best matches his/her values and preferences as revealed through the Collaborative Conversation™ process.

Support for this project was provided in part by a grant from the Robert Wood Johnson Foundation.

ICSI Institute for Clinical Systems Improvement

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Appendix I – T-ACE Screening Tool

T-ACE is a measurement tool of four questions that are significant identifiers of risk drinking (i.e., alcohol intake sufficient to potentially damage the embryo/fetus).

The T-ACE is completed at intake. The T-ACE score has a range of 0-5. The value of each answer to the four questions is totaled to determine the final T-ACE score.

Note:
1 Drink
= 12 oz beer
= 12 oz cooler
= 5 oz wine
= 1 mixed drink (1.5 oz. hard liquor)

Binge (drinking) = consuming 5 or more alcoholic drinks on an occasion

A total score of 2 or greater indicates potential risk for the purposes of Pregnancy Outreach Program identification of prenatal risk.

1. How many drinks does it take to make you feel high? 0. less than or equal to 2 drinks 1. more than 2 drinks	**Tolerance**
2. Have people annoyed you by criticizing your drinking? 0. No 1. Yes	**Annoyance**
3. Have you felt you ought to cut down on your drinking? 0. No 1. Yes	**Cut Down**
4. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover? 0. No 1. Yes	**Eye Opener**
Total Score = _____	

Sokol, Robert J., "Finding the Risk Drinker in Your Clinical Practice" in G. Robinson and R. Armstrong (eds), Alcohol and Child/Family Health: Proceedings of a Conference with Particular Reference to the Prevention of Alcohol-Related Birth Defects. Vancouver, BC., December, 1988.

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ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

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ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

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Routine Prenatal Care

All ICSI documents are available for review during the revision process by member medical groups and sponsors. In addition, all members commit to reviewing specific documents each year. This comprehensive review provides information to the work group for such issues as content update, improving clarity of recommendations, implementation suggestions and more. The specific reviewer comments and the work group responses are available to ICSI members at http:bit.ly/Prenatal0712.

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

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Acknowledgements

ICSI Patient Advisory Council

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Routine Prenatal Care guideline and thank them for their suggestion to improve the care of women during the pregnancy period.

Invited Reviewers

During this revision, the following groups reviewed this document. The work group would like to thank them for their comments and feedback.

HealthPartners Medical Group and Regions Hospital, Minneapolis, MN
Marshfield Clinic, Marshfield, WI
Mayo Clinic, Rochester, MN
Medica, Minnetonka, MN

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The next scheduled revision will occur within 24 months.

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group midcycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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