



INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

Health Care Guideline: Routine Prenatal Care

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The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and the following expert audiences:

- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in your 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. An ICSI Health Care Guideline rarely will establish the only approach to a problem.

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- copies may be provided to patients and the clinicians who manage their care, if the ICSI Health Care Guideline is incorporated into the medical group's clinical guideline program.

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 Cholesterol & HDL 2 Cervical cancer screening 2 Rubella/rubeola 8 Varicella 9 Domestic abuse 10	Risk profiles 4 GC/Chlamydia 4 Height and weight/BMI 5 Blood pressure 6 History and physical 7* Rubella 8 Varicella 9 Domestic abuse 10 Hemoglobin 15 ABO/Rh/Ab 16 Syphilis 17 Urine culture 18 HIV 19 [Blood lead screening 20] [VBAC 21] Hepatitis B S Ag 25	Weight 5 Blood pressure 6 Fetal heart tones 27 Fetal aneuploidy screening 23	Weight 5 Blood pressure 6 Fetal heart tones 27 Fetal aneuploidy screening 23 OB Ultrasound (optional) 28 Fundal height 29 [Cervical assessment 30]	Weight 5 Blood pressure 6 Fetal heart tones 27 Fundal height 29 [Cervical assessment 30]
Counseling Education Intervention	Preterm labor education and prevention 11 Substance use 2 Nutrition & weight 2 Domestic abuse 10 List of medications, herbal supplements, vitamins 12 Accurate recording of menstrual dates 13	Preterm labor education and prevention 11 Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Physical activity Nutrition Follow-up of modifiable risk factors Warning signs Course of care Physiology of pregnancy Discuss fetal aneuploidy screening 23	Preterm labor education and prevention 11 Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Fetal growth Review labs from visit 1 Breast-feeding Physiology of pregnancy Follow-up of modifiable risk factors 	Preterm labor education and prevention 11 Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Follow-up of modifiable risk factors Physiology of pregnancy Second trimester growth Quickening 	Preterm labor education and prevention 11 Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Follow-up of modifiable risk factors Classes Family issues Length of stay Gestational diabetes mellitus 32 (GDM) [RhoGam 16]
Immunization & Chemoprophylaxis	Tetanus booster 7 Rubella/MMR 4 [Varicella/VZIG 9] Hepatitis B Vaccine 7,25 Folic acid supplement 14	Tetanus booster 7 Nutritional supplements 24 Influenza 26 [Varicella/VZIG 9]		[Progesterone 31]	

Event	Visit 5 28 weeks	Visit 6 32 weeks	Visit 7 36 weeks	Visit 8-11 38-41 weeks
Screening Maneuvers	Preterm labor risk 4 Weight 5 Blood pressure 6 Fetal heart tones 27 Fundal height 29 [Cervical assessment 30] Gestational diabetes mellitus (GDM) 32 Domestic abuse 10 [Rh antibody status 16] [Hepatitis B Ag 25] [GC/Chlamydia 4]	Weight 5 Blood pressure 6 Fetal heart tones 27 Fundal height 29	Weight 5 Blood pressure 6 Fetal heart tones 27 Fundal height 29 Cervix exam 34 Confirm fetal position 35 Culture for group B streptococcus 36	Weight 5 Blood pressure 6 Fetal heart tones 27 Fundal height 29 Cervix exam 34
Counseling Education Intervention	Preterm labor education and prevention 11 Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Follow-up modifiable risk factors Work Physiology of pregnancy Preregistration Fetal growth Awareness of fetal movement 33	Preterm labor education and prevention 11 Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Follow-up of modifiable risk factors Travel Sexuality Pediatric care Episiotomy Labor & Delivery issues Warning signs/pregnancy-induced hypertension [VBAC 21]	Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Follow-up of modifiable risk factors Postpartum care Management of late pregnancy symptoms Contraception When to call provider Discussion of postpartum depression 	Prenatal & lifestyle education 22 <ul style="list-style-type: none"> Follow-up of modifiable risk factors Postpartum vaccinations Infant CPR Post-term management Labor & delivery update
Immunization & Chemoprophylaxis	[ABO/Rh/Ab 16] [RhoGAM 16]			

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 provider.

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

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Foreword

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.)

Clinical Highlights and Recommendations

- Identify patients with greater potential for high-risk for pregnancy and provide appropriate preconception counseling. (*Annotation #4*)
- Each pregnant patient should receive visit-specific screening tests, education, immunizations and chemoprophylaxis as described in the prenatal care table.
- 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*)
- For patients with previous Caesarean section, provide education of risks and benefits associated with VBAC. Assess and document patients' desire and appropriateness for VBAC (*Annotation #21*).
- Counseling for appropriate aneuploidy testing (screening) should be offered to all pregnant women regarding the different screening options and the limitations and benefits of each of the screening and diagnostic tests. (*Annotation #23*)

Priority Aims

1. Increase the percentage of pregnant women who receive timely, comprehensive screens for risk factors.
2. Increase the percentage of pregnant women who receive timely prenatal counseling and education as outlined in the guideline.
3. Increase the rate of appropriate interventions for identified change in status in women with preterm birth (PTB) risk factors.
4. Increase the percentage of VBAC-eligible women who receive documented education describing risks and benefits of VBAC.
5. Increase the number of first trimester patients who have documentation of counseling about appropriate aneuploidy screening.

Related ICSI Scientific Documents

Related Guidelines

- Domestic Violence
- Preventive Services for Adults
- Management of Labor Guidelines
 - Intrapartum Fetal Heart Rate Monitoring
 - Failure to Progress in Obstetrical Labor
 - Vaginal Birth After Caesarean Section
 - Preterm Birth
- Immunizations
- Prevention and Management of Obesity

Technology Assessment Reports

- First Trimester Prenatal Testing for Down syndrome Using Nuchal Translucency (#61, 2002)
- Prenatal Ultrasound as a Screening Test (#16, 2002)
- Genetic Carrier Testing for Cystic Fibrosis (#69, 2003)
- Fetal Fibronectin for the Prediction of Preterm Labor (#47, 2000)
- Home Uterine Activity Monitoring for Detection of Preterm Labor (#15, 2002)
- Ultrasound Cervical Length for the Prediction of Preterm Labor (#74, 2003)
- Genetic Carrier Testing for Cystic Fibrosis (#69, 2003)
- Tocolytic Therapy for Preterm Labor (#49, 2000)

Order Set

- Admission for Labor Order Set

Patient and Family Guidelines

- Routine Prenatal Care

Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's Web site at <http://www.icsi.org>.

Introduction to ICSI Document Development

Each guideline, order set and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists and other health care professionals relevant to the topic, along with an ICSI staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, one or two members may be recruited from medical groups or hospitals outside of ICSI.

Prospective work group members are asked to disclose any potential conflicts of interest relevant to the topic of the document; disclosure forms are reviewed for unacceptable conflicts. At the beginning of each work group meeting, the potential conflicts of interest that have been disclosed are reviewed by the work group.

The work group meets for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

Critical Review Process

The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set or protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health and Preventive Services. The Committee for Evidence-Based Practice approves guidelines, order sets and protocols not associated with a particular category. The steering committees reviews and approves each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- To the extent of the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets and protocols are reviewed regularly and revised, if warranted.

Document Revision Process

ICSI scientific documents are revised every 12-36 months as indicated by changes in clinical practice and literature. Every six months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis and systematic reviews is performed and reviewed by the work group. The work group meets for one to two three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Evidence Grading System

A. Primary Reports of New Data Collection:

- Class A: Randomized, controlled trial
- Class B: Cohort study
- Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study
- Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

- Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis
- Class R: Consensus statement
Consensus report
Narrative review
- Class X: Medical opinion

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.

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*).

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 Obstetrics and Gynecologists, 1989; Public Health Service Expert Panel, 1989*).

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 (*Clement, 1999; Ward, 1999*).

Supporting evidence is of classes: A, C, R

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 provider 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.

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, with the exception of cholesterol and high-density lipoprotein (HDL).

Preconception discussion should include information about proper nutrition, including preconceptual use of folic acid, ideal body weight and substance abuse in the preconception period.

3. Pregnancy Confirmation Evaluation

Early confirmation of pregnancy is important because it allows for early intervention of risk factors. Consensus of the guideline work group is that confirmation as soon as possible within the first two weeks of provider 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, physician or midwife. This may include a pregnancy test, examination or ultrasound for ectopic pregnancy or miscarriage.

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.")

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
- Tobacco use
- Substance abuse
- Behavioral health concerns

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. Providers should focus on modifiable risk factors, particularly factors that have been shown to be responsive to provider counseling or intervention.

Evidence-based recommendations support provider counseling for tobacco cessation, alcohol use and nutrition. No strong evidence exists against comprehensive counseling and education (*Chang, 1998; Fenster, 1991; Mullen, 1999*).

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 (*Dolan-Mullen, 1994*).

Intervention early in pregnancy – through written materials, education, counseling and a message from physician 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*).

If a pregnant patient is clearly not going to stop smoking without the use of nicotine replacement and/or bupropion (Zyban®), 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 (*U.S. Department of Health and Human Services, 1996*).

Domestic abuse 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*).

Supporting evidence is of classes: A, C, M, R

Risk Scoring

The guideline work group acknowledges that not all risk factors listed on the Minnesota Pregnancy Assessment Form (MPAF) are associated with preterm labor or preterm birth (e.g., gestational diabetes). The MPAF was developed by the Minnesota Council of Health Plans to assess a broad range of risk factors that contribute to unfavorable pregnancy outcomes. In the course of evaluating feedback about the MPAF, the task force discovered that attention became focused on scoring or weighting the risk factors instead of on education and intervention for identified risk factors. Since then, risk assessment has evolved from the use of weighted scoring to an emphasis on education and intervention (*Berkowitz, 1993; Dijkstra, 1999; Holbrook, 1989; Knox, 1993; Lockwood, 1999; Norwitz, 1999; Ross, 1986*).

Supporting evidence is of classes: C, D, R

B. At risk for preterm birth? (See Appendix B, "Minnesota Pregnancy Assessment Form")

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 than others of risk for preterm birth. For example, a history of prior preterm birth or myomectomy or multiple gestation this pregnancy are of particular concern. Risk factors associated with preterm birth may include, but are not limited to, the following:

Algorithm Annotations

Risk factors for preterm birth

History and Demographics	Activated Hypothalamic-Pituitary Adrenal Axis	Inflammation	Decidual Hemorrhage	Pathologic Distention of the Uterus
Unmarried	Family or life stress	Bacterial vaginosis with history of preterm labor	Domestic abuse	Polyhydramnios
Less than 12 th grade education	Fetal stress, e.g., intra-uterine growth retardation	Group B strep	Abdominal surgery this pregnancy	Multiple gestation
Under age 18 or over age 35	Cocaine, marijuana, benzodiazapene or other street drug use	Sexually transmitted disease	Trauma, e.g., motor vehicle accident	Uterine anomalies
Prior cone biopsy or LEEP	Tobacco use	Pyelonephritis or UTI	Vaginal bleeding after 12 wks this pregnancy	Uterine fibroids
3 or more 1 st trimester losses		Periodontal disease		
Any 2 nd trimester loss		Other systemic infection or febrile illness		
Prior preterm delivery				
Prior myomectomy				
Cervical cerclage				
Cervix dilated				
More than 1 cm at 32 wks gestation				
Uterine irritability				

Supporting evidence is of classes: C, D, R

Broad experience within medical groups

The following references present examples of success in the use of screening and education to prevent preterm birth.

Fangman JJ, Mark PM, Pratt L, et al. Prematurity prevention programs: an analysis of success and failures. *Am J Obstet Gynecol* 1994;170:744-50. (Class C)

Hobel CJ, Ross MG, Bemis RL. The West Los Angeles Preterm Birth Prevention Project: I. Program impact on high-risk women. *Am J Obstet Gynecol* 1994;170:54-62. (Class A)

Mark PM, Eggen D, Barosso G, et al. Reduction of preterm birth in an HMO. *HMO Prac* 1989;3:199-204. (Class D)

Oswald JW, Mark PM. Assessing the costs of HMO services: a preterm birth prevention program. *HMO Prac* 1996;10:83-87. (Class M)

Ross MG, Sandhu M, Bemis R, et al. The West Los Angeles Preterm Birth Prevention Project: II. Cost effectiveness analysis of high-risk pregnancy interventions. *Obstet Gynecol* 1994;83:506-11. (Class C)

Algorithm Annotations

Yawn BP, Yawn RA. Preterm birth prevention in a rural practice. *JAMA* 1989;262:230-33. (Class C)

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

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

- Work-related risks for preterm labor
- Work-related exposure to chemicals or infectious agents
- 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 G, "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*).

Certain working conditions have been associated with increased adverse outcomes of pregnancy, including preterm birth, low birth weight, and pregnancy-induced hypertension. These factors include:

- Working more than 36 hours per week or 10 hours per day
- Prolonged standing (more than 6 hours per shift)
- Heavy lifting
- Excessive noise
- High fatigue score (more than four hours standing per shift, mental stress, cold work environment, and loud noise)

(*Klebanoff, 1990; Luke, 1995; Peoples-Sheps, 1991*)

Occupational exposure to toxic chemicals – including anesthetic agents, solvents and pesticides – can increase the risk of miscarriage, malformations and other adverse pregnancy outcomes.

The Council on Scientific Affairs has established guidelines for work in pregnancy (*Council on Scientific Affairs, 1984*).

Supporting evidence is of classes: B, C, D, R

D. Infectious disease risks (see Appendix D, "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

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. In addition, all women under the age of 26 should be screened for *N. gonorrhoeae* and *C. trachomatis*, regardless of risk status, in keeping with the USPSTF recommendation (*U.S. Preventive Services Task Force, 2001*).

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 gonorrhea or chlamydia (*Andrews, 2000*).

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 has the potential to reduce morbidity from obstetric complications.

A high-risk profile for women likely to have asymptomatic gonococcal and chlamydial infection can be devised. Over 60% of cases occur to persons under age 25, according to the Centers for Disease Control (CDC) reports. A number of demographic and behavioral variables have been associated with higher rates of infection: unmarried, urban residence, multiple sexual contacts, early sexual activity, low socioeconomic status and black race. Numerous clinical algorithms have been devised to aid the provider in identifying high-risk groups for screening (*Rice, 1991*).

Gonorrhea

The CDC reports that there are about 1 million new cases of gonorrhea each year, and up to 80% of women infected with gonorrhea are asymptomatic. The reported prevalence among pregnant women varies from 0.4% to 7.5% (*Centers for Disease Control, 1997*).

Pregnant women with gonococcal infections are at increased risk for obstetric complications (still-birth, preterm delivery, chorioamnionitis, low birth weight, and intrauterine growth restriction) (*Elliott, 1990*).

Concerns remain about the frequency of antibiotic-resistant *N. gonorrhoeae* in the U.S. Current data estimate 32% of gonococcal isolates are resistant to penicillin or tetracycline. These organisms are currently sensitive to broad-spectrum cephalosporins, but the potential emergence of new resistance is a concern (*Gorwitz, 1988*).

Chlamydia

The CDC reports that there are about 4 million new cases of chlamydia each year, and up to 75% of women infected with chlamydia are asymptomatic. The reported prevalence among pregnant women varies from 2 to 37%. Evidence of cervical ectopy, friability or erythema, as well as mucopurulent discharge on pelvic examination, is suggestive of chlamydial infection.

Chlamydia infection in early pregnancy increases the risk for preterm labor. Infection during pregnancy increases the risk of postpartum and postabortal endometritis. Each year more than 155,000 infants are born to chlamydia-infected mothers, with a vertical transmission rate greater than 50%, as noted by the CDC. Neonatal infection can result in ophthalmia neonatorum and pneumonia (*Blackwell, 1993*).

Supporting evidence is of classes: C, D, R

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.

Reported cases of tuberculosis in the U.S. increased 20% from 1985 to 1992, with a 44% increase in those aged 25 to 44. The incidence of tuberculosis complicating pregnancy is rising in some cities.

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 can result in mortality of 30%-40%.

Active tuberculosis can be treated during pregnancy. Inactive tuberculosis could be treated prior to conception if detected (*Weinberger, 1995*).

Periodontal disease

Any infection during pregnancy can be a problem, and an assessment of oral health should be considered as a part of prenatal care. Women who have periodontal disease are seven times more likely to have preterm low-birth-weight babies than women who were not affected by the disease (*Offenbacher, 1996*).

Supporting evidence is of classes: C, D, R

Rubella/Rubeola (see Annotation #8)

Varicella (see Annotation #9)

Syphilis (see Annotation #17)

HIV (see Annotation #19)

Hepatitis B (see Annotation #25)

Influenza (see Annotation #26)

E. Genetic risks (see Appendix E, "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*).

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*).

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 1/3300 live male births. 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 2,000 births. All identified mutations account for about 90% of mutations in most populations. The effectiveness of testing in other than Caucasians is not clear. The American College of Obstetricians and Gynecologists (ACOG) recommends that all patients be asked about genetic risks for CF. Genetic testing and counseling should be offered if risk factors are present (*Institute for Clinical Systems Improvement, 2003; Langfelder-Schwind, 2005; Mennuti, 1999; Schwind, 1999; American College of Obstetricians and Gynecologists, 2005*).

Severe mental retardation has a definable etiology in 50% of cases. Thirty percent of all severe mental retardation is caused by Down syndrome. Other chromosomal abnormalities account for 1%-4%. Fragile X syndrome and inborn errors of metabolism account for 20% and 3%-7% of severe mental retardation, respectively (*Moser, 1990*).

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 Obstetrics and Gynecologists, 2005*).

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 3,600 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 Jewish patients. Pregnancy and oral contraceptives diminish serum

levels of hexosaminidase, so leukocyte hexosaminidase A levels should be checked (*American College of Obstetricians and Gynecologists, 2005*).

Hemoglobinopathies

A complete blood count and hemoglobin electrophoresis are the appropriate laboratory tests for screening for hemoglobinopathies. Solubility tests alone are inadequate for screening because they fail to identify important transmissible hemoglobin gene abnormalities affecting fetal outcome (*American College of Obstetricians and Gynecologists, 2005*).

Individuals of African, Southeast Asian, and Mediterranean descent are at increased risk for being carriers of hemoglobinopathies and should be offered carrier screening. If both parents are determined to be carriers, genetic counseling should be offered (*American College of Obstetrics and Gynecologists, 2005*).

Sickle hemoglobin is due to a single base-pair change in the beta coding region. One of every 600 African Americans is born with sickle cell disease, and one in twelve is a heterozygote for the genetic alteration, i.e., is a carrier or has sickle cell trait.

Thalassemias are an imbalance in globin-chain synthesis. Collectively, thalassemias are the most common single-gene disorder. Alpha-thalassemia affects formation of both fetal and adult hemoglobins, causing intrauterine disease. The deletion leading to hydrops fetalis is largely restricted to Southeast Asian populations. Southeast Asian patients and the father of the fetus should be screened for microcytic anemia as a clue to carrier status.

Beta-thalassemia is important only in postnatal life, so the affected fetus has no intrauterine problems. Beta-thalassemia is common in Mediterranean populations. Carriers are detected by microcytic anemia and an elevation of HbA₂ (*Fischel-Ghodsian, 1990*).

Fetal aneuploidy screening

A discussion of the rationale and screening for Down syndrome and neural tube defects can be found in Annotation #23, "Fetal Aneuploidy Screening."

Folate chemoprophylaxis against neural tube defects is discussed in Annotation #14, "Folic Acid Supplement."

Supporting evidence is of classes: C, D, R

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

Patients whose prepregnancy BMI puts them in an overweight (BMI 25 and above) or underweight (BMI below 19) category have specific risks associated with pregnancy (*Robinson, 2005*).

Women with prepregnancy high BMI:

- a. Are at increased risk for gestational diabetes, hypertension, preeclampsia, dystocia, primary Caesarean section, labor induction, increased wound infection, antepartum venous thromboembolism, and anesthesia complications.
- b. Have better outcomes with lower total weight gain.

Women with prepregnancy low BMI:

- a. Are at increased risk for low birth weight and preterm labor (*Spinillo, 1998*).
- b. Have better outcomes with higher total weight gain.

Weight gain during pregnancy should be monitored at each prenatal visit. There is no association between the amount of weight gained, either week to week or over the course of the entire pregnancy, and pregnancy-induced hypertension (Abrams, 2000; Schieve, 2000). For patients with a BMI greater than 30, consider earlier screening for gestational diabetes.

Supporting evidence is of classes: B, C, R

6. Blood Pressure

Blood pressure screening is recommended at the preconception visit and at all prenatal visits throughout the pregnancy.

Hypertension occurs in 6%-8% of all pregnancies. Hypertension in pregnancy is variously subdivided into disorders related to the pregnancy (preeclampsia) and disorders unrelated, but coincident, to the pregnancy. Both subdivisions of hypertension in pregnancy are nearly always asymptomatic at first; hence, only screening maneuvers can detect these disorders early in the disease process (Chesley, 1984).

Hypertension in pregnancy can be defined as either a diastolic pressure above a defined cutoff point or a rise from a woman's preexisting blood pressure level. Common, but not universal, definitions describe preeclampsia as an acute rise in blood pressure greater than 140 mmHg systolic or 90 mmHg diastolic, or a rise of 30 mmHg or 15 mmHg above the usual systolic and diastolic pressures, respectively. The collection of meaningful blood pressure data requires consistent use of correct technique and a cuff of appropriate size. The patient should be in the sitting 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, 1990). Hypertension coincident with pregnancy, as with hypertension outside of pregnancy, is defined elsewhere. See the ICSI Hypertension Diagnosis and Treatment guideline.

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. Twenty-four-hour urine protein collection and angiotensin II infusion are impractical screening tests for preeclampsia. The supine "rollover" test and elevation of edema lack adequate screening sensitivity and specificity as screening tests (Conde-Agudelo, 2004).

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).

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, 1996a).

Supporting evidence is of class: R

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 Danforth's *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).

Supporting evidence is of class: R

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 nonpregnant women of childbearing age should be offered vaccination. Susceptible pregnant women should be vaccinated in the immediate postpartum period.

Administration of the measles-mumps-rubella (MMR) or measles vaccine during pregnancy is not recommended. Susceptible pregnant women should be vaccinated in the immediate postpartum period.

Measles-mumps-rubella (MMR) vaccine should be administered to all persons born after 1956 who lack evidence of immunity to measles (receipt of live vaccine on or after the first birthday, laboratory evidence of immunity, or a history of provider-diagnosed measles). A second measles vaccination is recommended for adolescents and young adults in settings in which such individuals congregate, if they have not previously received a second dose.

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*).

Accuracy of Screening Tests

Hemagglutination-inhibition (HI) tests, associated with both false-positive and false-negative results, have been replaced by enzyme immunoassay and latex agglutination with sensitivities of 92%-100% and specificities of 71%-100% (Steece, 1985).

A person with a history of rubella vaccination is more likely to be seropositive than those without such a history. In determining a person's rubella immune status, a history of vaccination is preferred over a history of infection (Robinson, 1982).

Efficacy of Early Detection

A single dose of measles vaccine is 95% effective in producing long-term immunity. Seropositivity rates remain high at least 10-15 years following vaccination (Horstmann, 1985; Markowitz, 1990).

Measles outbreaks among young adults are much less common when two doses of vaccine are required (Baughman, 1994).

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 breast-feeding (Krogh, 1989).

Supporting evidence is of classes: C, D, R

9. Varicella Status

The CDC recommends that all adults be immunized if seronegative. However, administration of the varicella vaccine during pregnancy is not recommended. Immunity status should be elicited during the preconception counseling session. Testing and immunization should then be offered to the appropriate individuals.

Among U.S. women of childbearing age, the mean incidence of varicella is 2.16 in 1,000 per year. After household exposure, approximately 90% of susceptible contacts will develop varicella. Varicella is an uncommon infection during pregnancy; its incidence is estimated at 1 in 7,500 based on 8 cases occurring in 60,000 pregnancies prospectively studied. Maternal infection in the first half of the pregnancy has been associated with congenital varicella syndrome. Also, varicella infections during pregnancy may result in higher rates of complications from the infection, such as varicella pneumonia and death.

Among adults having a negative or uncertain history of varicella, approximately 85%-90% will be immune. Generally it is felt that a patient with a positive history of varicella infection 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, 1998).

Varicella-Zoster Immune Globulin decreased maternal complications, but there was no proof of improved fetal outcome (Enders, 1994; Jones, 1994).

Supporting evidence is of classes: C, D, M

10. Domestic Abuse

Domestic violence is a serious public health problem for many Americans. In accordance with the ICSI Preventive Services and Domestic Violence guidelines, screening for domestic violence should be done at a preconception visit and the first and fifth prenatal visits. See the ICSI Domestic Violence guideline for screening and intervention techniques.

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

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).

In a survey study of urgent care OB/GYN patients, 40% of pregnant women reported a history of abuse and 8% 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).

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 (*McFarlane, 1992; Wilst, 1999*).

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*).

Supporting evidence is of classes: B, C, D

11. Preterm Labor Education and Prevention

The Minnesota Council of Health Plans developed the Minnesota Pregnancy Assessment Form (MPAF), as an initial assessment and update at 28 weeks. (See Appendix B.)

Advise the patient of the importance of an early communication with health care provider as soon as pregnancy is suspected.

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

If patients have identifiable risk factors, intervene as appropriate in your health care setting. (Refer to WIC, smoking cessation classes, etc.) Articles relating to the discussion of education include the following:

Herron MA, Katz M, Creasy RK. Evaluation of a preterm birth prevention program: preliminary report. *Obstet Gynecol* 1982;59:452-56. (Class C)

Katz M, Goodyear K, Creasy RK. Early signs and symptoms of preterm labor. *Am J Obstet Gynecol* 1990;162:1150-53. (Class C)

Morrison JC. Preterm birth: a puzzle worth solving. *Obstet Gynecol* 1990;76(Supplement): 5S-11S. (Class R)

St. Pierre A, Mark PM, Michelson R, et al. Alcohol and other drugs of abuse in pregnancy. *HMO Prac* 1996;10:114-18. (Class D)

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 Domestic Violence, Preventive Services for Adults, and Tobacco Cessation guidelines.
- 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

Algorithm Annotations

Stress/anxiety – educate about and assist with sources of stress such as medical limitations for work, day care, home help

- Domestic abuse
- Tobacco use
- Drug and alcohol use – urine testing where indicated

For physicians' 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

In a recent literature review of the relationship of prenatal weight gain and the risk of preterm birth, most of the studies reported a significant association between inadequate weight gain and preterm birth. A slower weight gain during the third trimester might also be a risk factor of preterm birth. A retrospective analysis of 7,259 deliveries found either a rapid or slow weight gain during later pregnancy was associated with preterm birth (*Carmichael, 1997a; Carmichael, 1997b; Siega-Riz, 1996*).

A low BMI prior to conception has also been associated with an increased risk of preterm birth. In one study of 7,589 pregnant women, a prepregnant BMI of less than 19.8 kg/m had an assumption of risk of 1.98 (*Spinillo, 1998*).

Supporting evidence is of classes: B, C, R

Educate Patient to Monitor Risk Factors

Contractions

Menstrual cramps

Intestinal cramps

Constant backache

Constant pelvic pressure

Vaginal discharge amount and color

Urinary frequency

(Alexander, 1991; Andersen, 1989; Green, 2002; Nagey, 1985; Yawn, 1989)

Supporting evidence is of classes: C, D, R

Home Health Visits/Case Management

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

Home Uterine Monitoring

The ICSI Technology Assessment Committee (Home Uterine Activity Monitoring for Detection of Preterm Labor #15, 2002) has reviewed the evidence on home uterine activity monitoring (HUAM) for the detection

of preterm labor. Although HUAM is safe and approved by the FDA, its effectiveness in improving clinical outcome remains in question. It may be useful for patients with multiple gestations, patients with a history of preterm birth, and patients diagnosed with preterm labor in their current pregnancy (in lieu of hospitalization). It has not been determined how to identify risk group(s) most likely to benefit from monitoring.

Supporting evidence is of classes: A, R

12. List of Medications, Herbal Supplements and Vitamins

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.

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 (*Pritchard, 1985*).

The average patient has been reported to consume four to five different prescribed drugs during pregnancy. Excluding vitamins and iron preparations, drugs are prescribed to 82% of all pregnant women, and 65% of all pregnant women take drugs not prescribed by a physician (*Forfar, 1973; Hepner, 2002*).

Supporting evidence is of classes: A, D, R

13. 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.

14. Folic Acid Supplement

The Institute of Medicine (IOM) and Centers for Disease Prevention and Control (CDC) recommend that all women of childbearing age take 400 micrograms of folic acid daily from fortified foods (such as commercial breads and cereals), supplements or both in addition to consuming folate in food from a varied diet. During pregnancy, women should take 600 micrograms of folic acid from these sources. A 1991 guideline from the CDC recommends that women planning pregnancy who have previously had a pregnancy affected by a neural tube defect (NTD) consult their physician about taking a 4.0 mg daily dose of folic acid from at least one month before conception, through the first three months of pregnancy.

15. 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.

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 breast-feeding as primary protection against iron deficiency anemia in infants should also be reviewed with all pregnant women (*Centers for Disease Control, 1989; Pizarro, 1991*).

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

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*).

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

As hemoglobin measurement is a nonspecific 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*).

There is insufficient evidence to support universal iron supplementation in pregnancy (*Hemminki, 1995*).

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

Supporting evidence is of classes: A, C, M, R

16. 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.

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*).

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*).

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*).

The most frequent cause of failure of postpartum chemoprophylaxis is antenatal isoimmunization, which happens in 0.7%-1.8% of pregnant women at risk. Nonrandomized 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*).

There is similar evidence for the efficacy of such chemoprophylaxis after amniocentesis (*Tabsh, 1984*).

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, 1996*).

Supporting evidence is of classes: A, C, R

17. 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. As the annual incidence of syphilis is 3.3 cases per 100,000 women or less, 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, 2004; Kiss, 2004*).

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*).

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*).

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.

Supporting evidence is of classes: C, D

18. Urine Culture

Screening for asymptomatic bacteriuria (ASB) by urine culture is recommended for all pregnant women at the first prenatal visit. 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*).

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

Algorithm Annotations

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; Romero, 1989; Stenqvist, 1989*).

There are inadequate data to determine the optimal frequency of subsequent urine testing during pregnancy.

Supporting evidence is of classes: B, C, M

19. HIV

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.

During the past decade, HIV infection has become a leading cause of morbidity and mortality among women. As the incidence of HIV infection has increased among women of childbearing age, increasing numbers of children have become infected through perinatal transmission (*Centers for Disease Control, 1995*).

A randomized placebo-controlled trial demonstrated that a regimen of zidovudine started by 14 to 34 weeks gestation and continued through six weeks postpartum reduced vertical transmission of HIV from 25.5% to 8.3%. The study involved mothers with mildly symptomatic HIV infection (CD4 greater than 200 mcg/L). Zidovudine has had a low incidence of severe side effects in the mothers and infants studied (*Connor, 1994*). 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 backbone. 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 first trimester (*Siu, 2005*).

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 (*Tooke, 1998*).

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, 1995*).

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 Academy of Pediatrics, American College of Obstetricians and Gynecologists, 1995*).

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 breast-feeding, and
- parents may elect to terminate the pregnancy.

Algorithm Annotations

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*).

A meta-analysis of cohort studies suggested that breast-feeding increased the vertical transmission rate by 14% (*Dunn, 1998*).

Supporting evidence is of classes: A, B, D, R

20. 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 G, "Blood Lead Screening Guidelines for Pregnant Women in Minnesota.")

21. 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 providers 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, 2004*).

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 (*Lilford, 1990; Pridjian, 1992*).

Supporting evidence is of classes: C, R

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 (*American College of Obstetrics and Gynecologists, 2004*).

Supporting evidence is of class: R

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; Mozurkewich, 2000*).

Algorithm Annotations

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 (1.6%) than a scheduled repeat Caesarean delivery (0.8%), these risks are still quite low (*McMahon, 1996*).

After reviewing this study, the guideline work group and the ICSI Eleventh Edition/August 2007 feel that, due to the high probability of successful vaginal delivery and the low rate of complications after trial of labor, VBAC is still the best option. The guideline work group and the ICSI Eleventh Edition/August 2007 feel that this data should be discussed when counseling the 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 (*Eden, 1986; Pridjian, 1992*).

Incisions penetrating the muscular layer of the uterus may weaken this area and increase the risk of uterine rupture.

(*Caughey, 1999; Gabbe, 1986; Mozurkewich, 2000; OBrien-Abel, 2003; Shipp, 2003; Shipp, 2002*)

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*).

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; Pruett, 1988*).

There may be 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, 1997*).

Supporting evidence is of classes: B, C, D, M, R

Conditions that are not contraindications but may increase risk

- 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. Therefore, for women with two prior Caesarean deliveries, only those with a prior vaginal delivery should be considered candidates for a spontaneous trial of labor (*American College of Obstetricians and Gynecologists, 2004; Caughey, 1999; Roberts, 1999; Zelop, 2000*).
- A patient with a history of failure to progress in labor or a borderline pelvis on clinical pelvimetry has a 61%-79% success rate for a VBAC, slightly lower than those without that diagnosis (*Duff, 1988; Herlicoviez, 1992; Suonio, 1986*).
- There is evidence that a short interval between pregnancies increases risk (*Eposite, 2000; Shipp, 2001*).
- The risk of uterine rupture is increased with induction of labor, regardless of gestational age (*Delaney, 2003; Zelop, 2001*).

Algorithm Annotations

- 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*).

Supporting evidence is of classes: B, C, D, R, X

Conditions that have no documented increased risk

- A history of post Caesarean section infection is unrelated to the incidence of uterine rupture (*Nielsen, 1989*)
- Known overdistended uterus, e.g., twins, macrosomia, hydramnios (*Bujold, 2001; Phelan, 1984; Strong, 1989*)
- Attempt at external version is not contraindicated after previous Caesarean delivery (*Flamm, 1991*)

Supporting evidence is of classes: C, D

22. 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*).

A study done in the innercity showed that when obstetrical personnel are actively involved in counseling women about breast-feeding, more women will initiate breast-feeding 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*).

Supporting evidence is of class: C

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

- **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. Education about the benefits of exercise, including possible reduced rates of Caesarean section with regular exercise during pregnancy, should be emphasized (*Bungum, 2000*).

- **Nutrition/environmental risks**

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

- **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*).

Algorithm Annotations

- **Warning signs**

Discuss signs and symptoms of miscarriage and ectopic pregnancy.

- **Course of care**

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

Supporting evidence is of classes: B, C

Visit 2

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

Counseling and education

- Fetal growth
- Review lab tests obtained at visit 1
- Breast-feeding

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 breast-feeding. Those benefits include complete infant nutrition and fewer infant allergies and illnesses.

- Physiology of pregnancy

Visit 3

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Physiology of pregnancy
- 2nd trimester growth
- Quickening

Visit 4

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Prenatal classes
Discuss with the patient the value of prenatal education
- Family issues
Discuss with the patient her plans for assistance after delivery
- Length of stay
- Gestational diabetes mellitus (GDM)
- RhoGam

Algorithm Annotations

Visit 5

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Work
- Physiology of pregnancy
- Preregistration
- Fetal growth and development

Visit 6

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

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

Visit 7

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

- Postpartum care
- Management of late pregnancy symptoms
- Contraception
- When to call the provider
- 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.

Visits 8-11

Follow up on any modifiable risk factors patient is addressing.

Counseling and education

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

23. Fetal Aneuploidy Screening

Counseling

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. Providers 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 (*Kupperman, 1999; Berkowitz, 2006*). 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, 2007*). 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*). It is suggested that the patient's physician make a concerted effort while counseling to convey the information in as simple terms as possible, and use a translator if needed.

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, 2001*).

Using maternal age of 35 as a sole indicator for testing will detect only 30% of Trisomy 21. Eighty percent of Down syndrome babies are born to mothers under the age of 35 (*Berkowitz, 2006*).

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 (plus Inhibin A) are combined with maternal age to compute a pregnancy-specific risk for Trisomy 21. 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 test while reducing false-positives. [*Conclusion Grade I: See Conclusion Grading Worksheet A – Annotation #23 (Fetal Aneuploidy Screening)*] (*Malone, 2005*).

Other first trimester ultrasound graphic markers, such as nonvisualization of the nasal bone and tricuspid regurgitation, are being evaluated for their potential as screening test for Down syndrome, but their clinical usefulness remains uncertain.

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*):

- Triple screen 69%
- Quad screen 81%
- PAPP-A and fBHCG at 10 weeks 58%, at 12 weeks 53%
- NT 64%-70%

Algorithm Annotations

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

There are many different aneuploidy screening protocols currently available (*Wenstrom, 2005*). 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. (See Appendix H, "Aneuploidy Testing.") The work group is also mindful that all strategies may not be available at all institutions.

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 quad 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. See Appendix H, "Aneuploidy Screening" for a tool to assist in the decision-making process.

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 villus sampling [CVS]), or may undergo a triple or quad screen at 15 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. See Appendix H, "Aneuploidy Testing" for a tool to assist in the decision-making process.

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. See Appendix H, "Aneuploidy Testing" for a tool to assist in the decision-making process.

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*). 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.

Algorithm Annotations

Name of Test	Week Test Used	Detection Rate (5% screen positive rate)	Screening Strategy
PAPP-A and free beta-hCG	10	58%	single test
PAPP-A and free beta-hCG	12	53%	single test
Nuchal Translucency (NT)	11-14	64%-70%	single test
PAPP-A and free beta-hCG followed by NT	10/11*	82%-87%	combined test
PAPP-A and free beta-hCG followed by NT	12/13**	84%	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

*The PAPP-A and free beta-hCG are drawn during week 10; the ultrasound study to assess nuchal translucency (NT) is performed during week 11. This allows the results of the PAPP-A and free beta-hCG to be available for risk calculation at the time of the NT assessment.

**The PAPP-A and free beta-hCG are drawn during week 12; the ultrasound study to assess nuchal translucency (NT) is performed during week 13. This allows the results of the PAPP-A and free beta-hCG to be available for risk calculation at the time of the NT assessment.

(Berkowitz, 2006; Cuckle, 2005; Malone, 2005; American College of Obstetricians and Gynecologists, 2007)

Supporting evidence is of classes: B, C, M, R

24. Nutritional Supplements

There is no clinical evidence that universal supplementation with a multivitamin in the preconception period is beneficial. Multivitamin supplementation is recommended for multiple gestations, tobacco or chemical use, complete vegetarians and for women with inadequate diets despite counseling.

Women who have undergone bariatric surgery 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, 2005).

Calcium supplementation is recommended for pregnant women with poor dietary calcium intake. Although current calcium intake recommendations for pregnancy are 1,200-1,500 mg per day, the median intake is 600 to 700 mg. There is evidence that those with lowest calcium intake (i.e., teenagers and African Americans) are also at highest risk for pregnancy-induced hypertension (Bucher, 1996). Also, low intake may lead to decreased bone mass for the mother but does not appear to affect the fetus.

Calcium supplementation for selected populations and age categories is in accordance with recommendations from national groups (NIH, 1994).

Iodine supplementation in pregnancy may be necessary in certain communities with an increased incidence of childhood iodine deficiency (endemic cretinism). Iodine supplementation in a population with high levels of endemic cretinism reduces the incidence of that condition without apparent adverse effects (Pharaoh, 1971).

Algorithm Annotations

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*).

The average daily consumption of dietary folate by women aged 19 to 34 years in the United States is 0.2 mg/day (*Subar, 1989*). A randomized double-blind controlled trial of the efficacy of daily preconception multivitamin-multimineral supplements containing 0.8 mg of folic acid in preventing first occurrences of neural tube defect (NTD) was conducted in Hungary, enrolling 4,753 women planning pregnancy. Full supplementation was defined as taking them from 28 days before conception to at least the second missed menstrual period. The supplemented group experienced a significantly decreased prevalence of NTDs, congenital malformations as a whole, and genetic syndromes diagnosed by eight months of age (*Czeizel, 1992*).

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*).

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*). Randomized placebo-controlled trials and nonrandomized 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*).

A randomized trial concluded that supplementation with vitamin 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*).

Supporting evidence is of classes: A, C, M, R

25. Hepatitis B Surface Antigen

Universal screening for Hepatitis B surface antigen is advised at the first prenatal visit. Those identified as high risk based upon exposure to hepatitis or injection drug usage should be rescreened later in pregnancy.

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.

ACOG 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, 1993*).

The Minnesota Department of Health requires reporting all positive HBV serology tests to the state agency (per online reporting form). See Appendix I, "Perinatal Hepatitis B Prevention Program." Each pregnant woman 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*).

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*).

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*).

Supporting evidence is of classes: C, R

26. Influenza Vaccination

Influenza vaccines are made from inactivated/noninfectious viruses and are considered safe at any stage of pregnancy (*Nichol, 1995*).

All pregnant women should be offered influenza vaccination during the influenza season. Vaccination is contraindicated for women with a history of hypersensitivity to chicken eggs or to vaccine components such as the preservatives.

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*).

Universal vaccination with inactivated trivalent influenza vaccine is cost saving relative to providing supportive care alone in the pregnant population (*Roberts, 2006*).

Supporting evidence is of classes: A, M, R

27. 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.

28. Ultrasound (Optional)

This work group acknowledges that ultrasounds have become an almost universal feature of prenatal care. There is no scientific data available to support improved fetal outcome as a result of routine ultrasound. The ready availability of real-time ultrasonography has generated an ongoing controversy regarding its routine use in screening low-risk pregnancies.

The work group recognizes that the timing of a single obstetric ultrasound examination during routine prenatal care is controversial. There are many indications for such ultrasound examinations, and the optimal timing for each indication varies. For example, first trimester ultrasound evaluations are preferable for pregnancy dating, whereas ultrasound evaluations for fetal anatomy are better after 22 weeks gestation.

As a compromise, the work group recommends performing an ultrasound at 16-18 weeks gestation. Although this is suboptimal for both dating and anatomy evaluations, the timing is satisfactory for both indications and serves as an evaluation for genetic abnormalities at a time in the pregnancy when the patient can consider termination if significant abnormalities are present.

Six randomized control studies have failed to show any consistent benefit to maternal or fetal outcome. Several of these studies showed ultrasonography to be beneficial in detecting intrauterine growth retardation. Only one study showed a slight decrease in perinatal death in the routinely scanned group ($P = 0.11$) (*American College of Obstetricians and Gynecologists, 1997; Bakketeg, 1984; Bennett, 1982; Eik-Nes, 1984; Neilson, 1984; Secher, 1986; Waldenstrom, 1988*).

The Routine Antenatal Diagnostic Imaging with Ultrasound Study (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 (*Ringa, 1989*).

Most of the studies, randomized or otherwise, have suffered from deficiencies in statistical power to answer whether or not routine ultrasound screening affects perinatal outcome (*Ewigman, 1993*).

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*).

More recent literature suggests that routine ultrasound leads to a decrease in postterm pregnancy and a better ability to assess gestational age and multiple pregnancy (*Eik-Nes, 2000; Neilson, 2000*).

A recent large retrospective study suggested that second trimester ultrasound is more likely to detect NTDs than is biochemical screening (*Norem, 2005*).

Supporting evidence is of classes: A, C, M, R

29. Fundal Height

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

Fundal height measurement is inexact and subject to inter- and intraobserver errors (*Calvert, 1982*).

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*).

Supporting evidence is of classes: A, C

30. Cervical Assessment

Pregnant women at high risk for preterm delivery should be considered for digital examination at 28 weeks gestation. High-risk conditions include a history of preterm delivery, premature rupture of membranes, uterine anomaly, DES exposure or cervical cone biopsy or LEEP.

Cervical sonogram has become an objective and reliable method to assess cervical length in high-risk patients. It approximates cervical effacement and is a more objective assessment than digital examination. Serial cervical sonography should be considered starting at 16 weeks in assessing the risk of preterm delivery in high-risk patients. Digital exams should not be eliminated and can be a useful adjunct to cervical sonography (*Iams, 1996*).

Transvaginal sonogram of the cervix appears to be helpful to predict increased risk for preterm delivery. There is no agreement on what is a sonographic short cervix (*Honest, 2003*). A recent study suggested 25 mm cutoff for twin gestation and 15 mm for singleton pregnancies (*Kagan, 2006*). Sonographic cervical length is a method for risk assessment for spontaneous preterm delivery and is not a screening test. It can be useful in modifying the a priori risk based on other factors (*Romero, 2006*). Cervical sonography is generally assessed on a biweekly basis unless clinical conditions suggest more frequent evaluation (*Airoidi, 2005*).

Supporting evidence is of classes: B, C, R, X

31. 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 recent 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% (Meis, 2003). 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 (Meis, 2005). Treatment with progesterone for other high-risk conditions, such as multiple gestations or short cervix, should not be encouraged outside of randomized trials.

Supporting evidence is of classes: A, R

32. Gestational Diabetes Mellitus (GDM)

Although there is a lack of consensus in medical literature regarding universal screening, it is recommended at this time that all pregnant women be screened for gestational diabetes mellitus at 28 weeks gestation.

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. There is a higher prevalence in American Indian and Hispanic populations and a very low incidence among Caucasian teens (Garner, 1997; Stephenson, 1993).

Universal screening of pregnant women for GDM at 28 weeks gestation is current practice.

There is a lack of prospective studies to determine whether universal screening or selective screening based on high risk criteria is better. There is also a lack of consensus among practitioners. ACOG recommends selective screening, while the Third International Workshop-Conference on Gestational Diabetes sponsored by the American Diabetes Association recommends universal screening.

Recent evaluation by the USPSTF also concluded there is insufficient evidence for or against routine screening for gestational diabetes. Studies reviewed universal screening versus risk-based screening. All concluded that a small but significant number of patients with GDM would be missed by selective screening, and 90% of patients would still need to be screened. All studies recommended continued universal screening of all pregnant patients (Brody, 2003; Danilenko-Dixon, 1999; Griffin, 2000; U.S. Preventive Services Task Force, 2003).

Screening is agreed to be most beneficial if done at 24-28 weeks gestation. Most practitioners use a 50 grams oral glucose load followed one hour later by the blood draw. Screening levels should be based on ACOG guidelines as stated in ACOG 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).

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).

Criteria for selective screening was fairly consistent, with obesity and family history of diabetes as the main reasons. Age greater than 30, 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; Weeks, 1994).

Weeks, et al. studied whether risk factors for gestational diabetes influenced perinatal outcome. This study showed little to no difference in macrosomic infants, Caesarean deliveries and shoulder dystocia between women with gestational diabetes who had one or more risk factors when compared with those who had no risk factors. A control group of nondiabetic women who delivered in the same months as the study group

Algorithm Annotations

was included. Caesarean section rate was higher in the study group, but shoulder dystocia rates did not reach statistical significance (*Weeks, 1994*).

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) 4%-1% (*Crowther, 2005*).

Cochrane states, "It is likely that glucose intolerance is simply a marker for other underlying conditions that adversely influence perinatal outcome." Is the gestational diabetes the cause of adverse outcomes, or are the risk factors? An excellent article reviews the controversies and opinions regarding gestational diabetes mellitus (*Khandewal, 1999; Walkinshaw, 2000*).

The Canadian Task Force reviewed the literature on validity and potential effectiveness of the different screening methods. They concluded from the quality of evidence available that universal screening for gestational diabetes is not supported, and that a decision to screen needs to be made on other grounds. (*Canadian Task Force on the Periodic Health Examination, 1992; Wen, 2000*).

Santini studied two populations of women in New York over a five-month period in 1980. Depending on the practice of the clinic the women attended, some were screened and some were not.

The screening and treatment process was found not to decrease the rate of large infants or to improve pregnancy outcomes and was associated with more intense surveillance during pregnancy and a higher rate of Caesarean deliveries. Santini acknowledged the increased risk for women with gestational diabetes developing overt diabetes later in life and the possible long-term effects on the baby (e.g., diabetes, obesity) (*Santini, 1990*).

Postpartum surveillance

Women with a history of gestational diabetes mellitus are at high risk for development of diabetes mellitus and should be appropriately followed (*Kim, 2002; Peters, 1996; Smirnakis, 2005*).

Supporting evidence is of classes: A, C, M, R

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*).

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*).

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*).

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; Neldam, 1983*).

Supporting evidence is of classes: A, D, R

34. Cervix Exam

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.

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, 2001*). 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 (*Allott, 1993; Magnann, 1999*).

Supporting evidence is of classes: A, R

35. Confirm Fetal Position

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

36. Group B Streptococcus Screening

Testing

Proper culture techniques include sampling the introitus (lower vagina) and the perianal area. 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*).

DNA probe testing at time of delivery may identify those at highest risk of delivering an infant who may develop GBS sepsis (*Bergeron, 2000; Reisner, 2000*).

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.

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; Spaetgens, 2002*).

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.
2. Culture techniques that maximize the recovery of GBS should be used.

Algorithm Annotations

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). Optimal timing of prophylaxis is 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
 - Delivery at less than 37 weeks gestation
 - Intrapartum maternal temperature more than 38°C (more than 100.4°F). 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 every eight hours) and erythromycin (500 mg every six hours). For resistant organisms, 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 do not require GBS screening.

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, 2002; Weisman, 1992; Zangwill, 1992*).

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

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

Supporting evidence is of classes: B, C, D, R

Practices to Consider Discontinuing

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*).

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 blood pressure discussion, Annotation #6.) Likewise, a "trace positive" urine dipstick for glycosuria has a reported sensitivity of only 23%-64% (Gribble, 1995a; Gribble, 1995b).

Routine Evaluation for Edema

The American College of Obstetricians and Gynecologists (ACOG) 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).

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).

Parvovirus

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

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).

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 Vit Study Group, 1991).

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.

Algorithm Annotations

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*).

There is currently insufficient evidence to justify magnesium supplementation during pregnancy (*Sibai, 1989*).

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

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

Supporting evidence is of classes: A, C, D, R

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, 2001*).

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 use alcohol? ----- 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? ----- Y N* Unsure*
(Any woman attempting pregnancy should take a folic acid supplement of 0.4 mg daily. This vitamin reduces the risk of birth defects.)
15. Have you ever been physically, emotionally or sexually abused, or do you live with someone who is abusive?----- Y* N Unsure*
16. Do you have a family history of birth defects or hereditary disorders?----- Y* N Unsure*
17. Have you had three or more lost pregnancies before 14 weeks due to miscarriage or abortion?----- Y* N Unsure*
18. Have you ever had a pregnancy loss after 14 weeks for genetic or unknown reasons?----- Y* N Unsure*
19. Have you ever been screened (tested) for HIV?----- Y* N Unsure*

If you answered "no" to question #19, HIV testing is recommended if you are considering pregnancy.

If you answered "yes" to question #19, 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.

Appendix B – Minnesota Pregnancy Assessment Form

(Note: No longer required in state of Minnesota)

DHS-3294-ENG (10-03)

Patient's Name		DOB	Patient's County of Residence		Please return to health plan (see training manual for address) or, if patient not enrolled in a health plan, to: Minnesota Medical Assistance Department of Human Services PO Box 64893 St. Paul, MN 55164
Patient's Address			Patient's MHC ID # or Insurance #	Patient's Phone #	
Patient's Health Plan Name	MHCP Provider ID #	Provider's Name/Clinic Name		Provider's Phone #	

Does this patient consider herself (check all that apply - optional):

Caucasian / White African American / Black
 Hispanic / Latino Asian/Pacific Islander
 Native American Other: (please list) _____

Due Date / / **1ST VISIT** **2ND SCREEN**

Gestational Age weeks weeks

Date Screened / / / /

1ST VISIT

- Less than a 12th grade education..... Y N
- Currently unmarried..... Y N
- Age is < 18 or > 35 yrs..... Y N
- 1st trimester pregnancy loss, any cause (3 or more)..... Y N
- 2nd trimester pregnancy loss, any cause (2 or more)..... Y N
- Previous preterm labor with term delivery..... Y N
- Previous preterm delivery or low birthweight baby..... Y N
- Previous stillbirth..... Y N
- History of cone biopsy (laser or cold knife cone)..... Y N
- DES exposure..... Y N
- Any history of cervical cerclage or myomectomy..... Y N
- Last birth within 1 year..... Y N
- Significantly underweight or over weight during prepregnant period..... Y N
- During the last year prior to pregnancy has had gynecological infection (bacterial vaginosis, trichomonas, chlamydia, herpes, gonorrhea, syphilis)..... Y N

ENHANCED SERVICES: Check all that apply, and indicate person(s)/agencies that will be providing services.

At Risk Antepartum Mgmt. (Primary Provider: MD, CNM, DO)

Care Coordination _____

Prenatal Health Education I _____

Prenatal Health Education II _____

Prenatal Nutrition Education _____

Postpartum Follow-up Home Visit _____

	1ST VISIT	2ND SCREEN (24-28 WKS)
15. Cervix dilated > 1 cm < 34 weeks this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
16. Cervical shortening < 1 cm < 34 weeks this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
17. Drank any beer, wine, wine coolers, or liquor since last menstrual period ¹	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
18. Multiple gestation this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
19. Diabetes mellitus.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
20. Uterine anomaly.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
21. Uterine irritability requiring medication, bed rest, hydration.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
22. Abdominal surgery during this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
23. Cocaine, marijuana, benzodiazepines, or street drug use this pregnancy ¹	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
24. Poly/oligohydramnios this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
25. Has been physically, sexually, or emotionally hurt by someone ¹	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
26. Ever been or is currently being treated for an emotional disturbance.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
27. Felt sad or down for more than 2 weeks in the past year ¹	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
28. Initial prenatal visit 20 weeks.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
29. Febrile illness during this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
30. Bleeding > 12 wks this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
31. History of pyelonephritis.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
32. Smoking more than 10 cigarettes per day this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
33. Hypertension/preeclampsia.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
34. Work: standing more than 4 hours/shift or heavy physical exertion.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
35. Anemia (> 10 mg/dl) this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
36. Inappropriate weight gain or loss this pregnancy.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
37. Inadequate prenatal care (< 2 visits 2nd or 3rd trimester).....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
38. During this pregnancy has had gynecological infection (bacterial vaginosis, trichomonas, chlamydia, herpes, gonorrhea, or syphilis).....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
39. Has tested HIV positive.....	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N

¹ Additional questions are recommended if yes

Other risks:

At Risk Pregnancy..... Y N Y N

Signature of Primary Provider 1st Visit	Date
Signature of Primary Provider 2nd Screen	Date

REMINDER — Refer to WIC Services 1-800-657-3942

Copy 1 — Patient Chart Copy 2 — Payer (2nd Screen) Copy 3 — Payer (1st Visit)

HOW TO COMPLETE THIS FORM

This pregnancy assessment form is recommended for use with all pregnant women in Minnesota. This form is required for all persons who receive benefits from Minnesota Health Care Programs (MHCP), which include Medical Assistance (MA), General Assistance Medical Care (GAMC), MinnesotaCare, and MHCP patients enrolled in health plans (Prepaid Medical Assistance Program [PMAP], or MinnesotaCare enrollees). The **first screening** will be done at the **first prenatal visit**, and the **second screening** will be done at a prenatal visit **around 24–28 weeks**.

Identifying information:

1. Label or write in the identifying information. **Include patient's:** name, date of birth, county of residence, address, MHCP ID # or insurance #, phone #, and patient's health plan name (if applicable). **Include provider's:** name and/or clinic name, MHCP Provider ID #, and phone #. If using a label, place a label on each of the three copies of the form.
2. Submit directly to the health plan for persons with PMAP or MinnesotaCare enrollees. Listed in the manual are the appropriate addresses/fax numbers for the Minnesota Department of Human Services and the participating health plans.

Completion of items:

1. Indicate the race/ethnic categories. Ask the patient with which group(s) she identifies (optional).
2. Complete the EDC using two digits for month, day, and year. **The estimated date of confinement (EDC) is the estimated date of delivery.**
3. Report the number of weeks of gestational age at the **first visit** and at the **second screening** between 24–28 weeks.
4. List the actual dates of the screening visit using two digits for month, day and year.

Complete items 1–39 by marking an X in the appropriate box.

Other Risks: If you identify other risks, please write them in this box.

Is this an at risk pregnancy? Check "yes" if you determine this pregnancy to be at risk regardless of the number or type of risk factors.

Enhanced services for MHCP enrollees: Please document the services to be provided to MHCP enrollees to address identified risk factors. Check the boxes that apply, and list who will provide these services.

Signatures: Please sign and date the appropriate provider box for **each screening**.

WIC referral: Pregnant women who are on Medical Assistance and/or who are working and meet federal income guidelines can receive free nutritious food and additional nutrition counseling during their pregnancy. Please refer to WIC (1–800–657–3942).

What to do with the completed form: Retain two copies of the completed form for your patient's record. Send one copy to the payer (health plan or DHS) for the first screen. Some health plans encourage providers to fax a copy to expedite payment and/or begin case management. After the second screen, send the second copy to the payer. If you are referring this patient to a community health service (CHS) agency, it may be appropriate to send a copy of the form with the referral.

RISK FACTOR DEFINITIONS

Preterm	Less than 37 completed weeks gestation.	AB 2nd trimester	Spontaneous or induced abortion between 12–19 weeks gestation.
Pregnancy loss	Stillbirth, fetal demise.	Alcohol use	Any use of alcohol during current pregnancy.
Hx preterm labor	Spontaneous preterm labor after 20 weeks and before 37 completed weeks, with documented uterine contractions (4/20 or 8/60 minutes); plus ruptured membranes or intact membranes with cervical dilation of > 2 cm or intact membranes > 80% effacement; or intact membranes and cervical change during observation. Preterm labor or preterm delivery during any previous pregnancies whether or not it resulted in preterm or term birth.	Underweight/overweight	Prepregnancy weight < 90% or > 120% of Metropolitan Life Insurance Co. standards.
DES exposure	Exposure to DES (diethylstilbestrol) in utero.	Late prenatal care	First prenatal visit at or after 20 weeks gestation.
Uterine anomaly	Bicornate, T-shaped, septate uterus, etc.	Febrile illness	Systemic illness with temperature of 101°F or greater such as influenza determined by thermometer reading on two or more occasions.
Uterine irritability	Uterine contractions of five contractions in one hour perceived by patient or documented by provider without cervical change at < 34 weeks.	Bleeding after 12th week	Vaginal bleeding or spotting after 12 weeks gestation of any amount, duration, or frequency which is not obviously due to cervical contact.
Surgery	Any abdominal surgery performed at 18 weeks or more gestation or cervical cerclage at any time in this pregnancy.	Pyelonephritis	One or more diagnosed episodes in past or current medical history.
Dilation (internal os)	Cervical dilation of the internal os of 1 cm or more at less than 34 weeks gestation.	Work	Work (paid or unpaid) which involves standing more than four hours per shift or heavy physical exertion. Examples: nurses, cleaning staff, sales staff, babysitters, cashiers, laborers, etc.
Drug use	Any street drug use during this pregnancy, e.g. speed, marijuana, cocaine, heroin (includes methadone), benzodiazepines.	Anemia	Hematocrit 31% or hemoglobin 10 mg/dl.
AB 1st trimester	More than three spontaneous or induced abortions at < 13 weeks gestation. Does not include ectopics.	Inappropriate weight gain	Weight gain < 7 pounds at 22 weeks and/or weight loss > 5 pounds at any time in this pregnancy.
		Inadequate prenatal care	Less than two visits per trimester in 2nd and 3rd trimester.

EXAMPLES OF ADDITIONAL RISK FACTORS

Medical	OB History	Poor Social Situation
Thyroid disease	Infertility	Poverty
Type I diabetes	C-section	Personal or family history of abuse
Type II diabetes	Grand multipara	Incarceration
Renal disease	Perinatal loss	Homelessness
Heart disease	Assisted reproductive technology	Exposure to hazardous/toxic agents
Blood borne disease	Previa	Inadequate support system
Autoimmune disease	Abruption	Mental illness of family member
Seizure disorder		Child custody loss
Cervical cancer		Housing instability
Gestational diabetes		Violence or substance abuse in the house or neighborhood
Psychiatric disorder		
Exposure to chicken pox, rubella	Nutrition	Barriers to Care
History of DVT/pulmonary embolus	Diet deficient in one or more food groups	Child care problems
Breast cancer	Excessive use of supplements	Cultural practices or beliefs about pregnancy
TORCH syndrome	Hyperemesis	Language different than the provider
	Food faddism	Scheduling issues
	Pica	Transportation problems
	Eating disorder	Ambivalent, denying, or rejecting this pregnancy
	Total vegetarianism	Developmental disability
		Number of children under five years of age in the home

Definition for Enhanced Services (See training manual for more complete definitions.)

Enhanced Services are a package of prenatal health services for MHCP enrollees who are determined to be **at risk** by this assessment.

At Risk Antepartum Management: Provider who is primarily responsible for care of patient.

Care Coordination: Development, implementation, and ongoing evaluation of plan of care.

Prenatal Health Education I: Instruction on general information about pregnancy, warning signs of early labor, and education about other medical conditions.

Prenatal Health Education II: Education for patient who requires additional education related to **at risk** behaviors.

Prenatal Nutrition Education: Information and support for appropriate nutritional intake.

Postpartum Follow-up Home Visit: Visit planned within the first two weeks postpartum for assessment and education.

Appendix C – 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? _____

Appendix D – 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. | Is the patient known to be HIV positive?..... | Yes ^{CDEF} | No |
| 4. | Has the patient been in close contact with persons with known
or suspected tuberculosis? | Yes ^C | No |
| 5. | Is the patient an immigrant from Africa, Asia or Latin America?..... | Yes ^C | No |
| 6. | Has the patient been treated for IV drug use? | Yes ^{CGH} | No |
| 7. | Has the patient been treated for alcoholism? | Yes ^C | No |
| 8. | Is the patient a member of a medically underserved, low-income population? | Yes ^{CDE} | No |
| 9. | Is the patient under 25 years old?..... | Yes ^{DE} | No |
| 10. | Does the patient have a history of STIs?..... | Yes ^{DEF} | No |
| 11. | Does the patient have a new sexual partner? | Yes ^D | No |
| 12. | Does the patient have multiple sexual partners?..... | Yes ^{DE} | No |
| 13. | Is the patient married? | Yes | No ^D |
| 14. | Is the patient seen today for STD screening?..... | Yes ^{DEFGH} | No |
| 15. | Has the patient had sex for money? | Unknown | Yes ^{DEFG} No |
| 16. | Is the patient's partner(s) HIV positive?..... | Unknown | Yes ^G No |

Physical Examination

- | | | | |
|-----|--|-------------------|----|
| 17. | Is there cervical ectopy?..... | Yes ^D | No |
| 18. | Is there cervical friability?..... | Yes ^{DE} | No |
| 19. | Is there cervical erythema?..... | Yes ^{DE} | No |
| 20. | 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.)

Appendix E – 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. Are you or the baby's father Caucasian? ----- Y N
If yes, 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 you and 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, thalassemia) ----- 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.) _____

Appendix F – 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
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: _____ LNMP: _____	Regularity: _____ 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	Medical History	Pt (+/-)	Fam (+/-)	Notes
Allergic rhinitis/sinusitis				Malignancy, specify:			
Cardiac murmur				Treatment for substance abuse			
Congenital heart disease, valve(s) affected:				Other:			
Rheumatic heart disease				Surgical History			
Needs SBE prophylaxis				ENT, year:			
Hypertension				Cardiac, year:			
Asthma				GI, specify: _____ year:			
Other pulmonary disease				Gynecologic, specify: _____ year:			
Diabetes mellitus				Other:			
Thyroid disease				Other:			
Cystitis				Anesthetic complications			
Pyelonephritis				Gynecologic History			
Anemia				Infertility			
Blood transfusion(s)				Clomiphene			
Psych. Disorder, type: _____ year:				Pergonal/Metrodin			
Thrombophlebitis, deep/DVT _____ year:				In vitro fertilization			
Thrombophlebitis, superficial							
Embolism, year:				Pelvic trauma, year:			
Epilepsy/Seizure disorder				PID, year:			
Migraine headache				Uterine anomaly/DES exposure			
Collagen disorder, specify:			Cervical incompetence				
Chronic back pain			Repetitive pregnancy loss				
Ulcer/gastritis			Abnormal Pap Smear _____ year:				
Gall bladder disorder			Cervical carcinoma in situ				
Inflammatory bowel disease			Conization/LEEP/cryo _____ year:				
Hepatitis, specify:							

Appendix F – 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							
Hgb									
Rubella		immune not immune							
RPR		nonreactive reactive							
Hepatitis BsAg		neg pos							
HIV (with consent)		nonreactive 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. _____ Lot # _____ Init. _____							
16-18 Week Labs (when indicated)	Date	Result	Reviewed						
Triple Screen		normal abnorm _____							
Amnio/CVS									
Karyotype Fetal Anomaly Screening									
Amniotic Fluid (AFP)									
Rhogam IM (for amnio) 22 weeks		Lot # _____ Init. _____							
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						
Repeat Diabetes		1 Hr. _____							
GTT (if screen abnormal)		FBS _____ 1 Hr. _____ 2 Hr. _____ 3 Hr. _____							
Group B Strep		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:		
- MPAF (preterm labor)		
- Infectious Disease (ID) screening		
- Genetic Screening		
- Workplace Envir./Lifestyle Screening		
Visit at 10-12 Weeks		
Fetal Growth		
Future Lab Testing		
Breastfeeding		
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 re-assess for ID risk		
Visit at 32 Weeks		
Travel		
Sexuality		
Pediatric Care		
Episiotomy		
Labor and Delivery Issues		
Warning Signs/PIH		
Visit at 36 Weeks		
Attended/Attending Prenatal Classes		
Postpartum Care		
Birth Control Plans		
Mgmt. of Late Preg. Signs & Symptoms		
Visits at 38-41 Weeks		
Postpartum Vaccinations		
Infant CPR		
Post-term Mgmt.		
Labor and Delivery Update		

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 Y N Specify:			

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. _____)

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

Appendix F – Prenatal Record

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*	Position	Cerv Exam	Patient Concerns**	Other**	See PN+	Return Visit	Init
			Wt	total gain										

If more visits are necessary, use supplemental flow sheet (p.1a.)

*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. _____

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*	Position	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)

Appendix G – 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 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 CDC and MDH consider 10 $\mu\text{g}/\text{dL}$ 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 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?



Environmental Health Division
Environmental Surveillance and Assessment Section
Environmental Impact Analysis Unit – Lead Program

Sources of Lead

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

Other sources include:

Cosmetics/Traditional Remedies

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:

(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:

(bindi dot)

sindoor (red powder)

(dietary supplement)

Ayurvedic herbal medicine products (HMPs)

Hobbies

(may include occupations listed in the column on the right)

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

Miscellaneous

Antique/Imported Toys

Chalk (Particularly for Snooker/Billiards)

Imported Candy

Imported Pottery

Non-Commercially Prepared Pottery

Non-Commercially Prepared Leaded Crystal

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

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

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

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

For more information about lead screening, contact the Minnesota Department of Health, Environmental Surveillance and Assessment Section, Environmental Impact Analysis Unit at (651) 215-0890; or 1-800-657-3908; or TTY (651) 215-0707.

If you require this document in another format, such as large print, Braille, or cassette tape, call (651) 215-0700.



Minnesota Department of Health
Environmental Health Division
121 East Seventh Place, P.O. Box 64975
St. Paul, Minnesota 55164-0975

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

6/2004 (Last Updated 12/2004) -- IC #141-1508

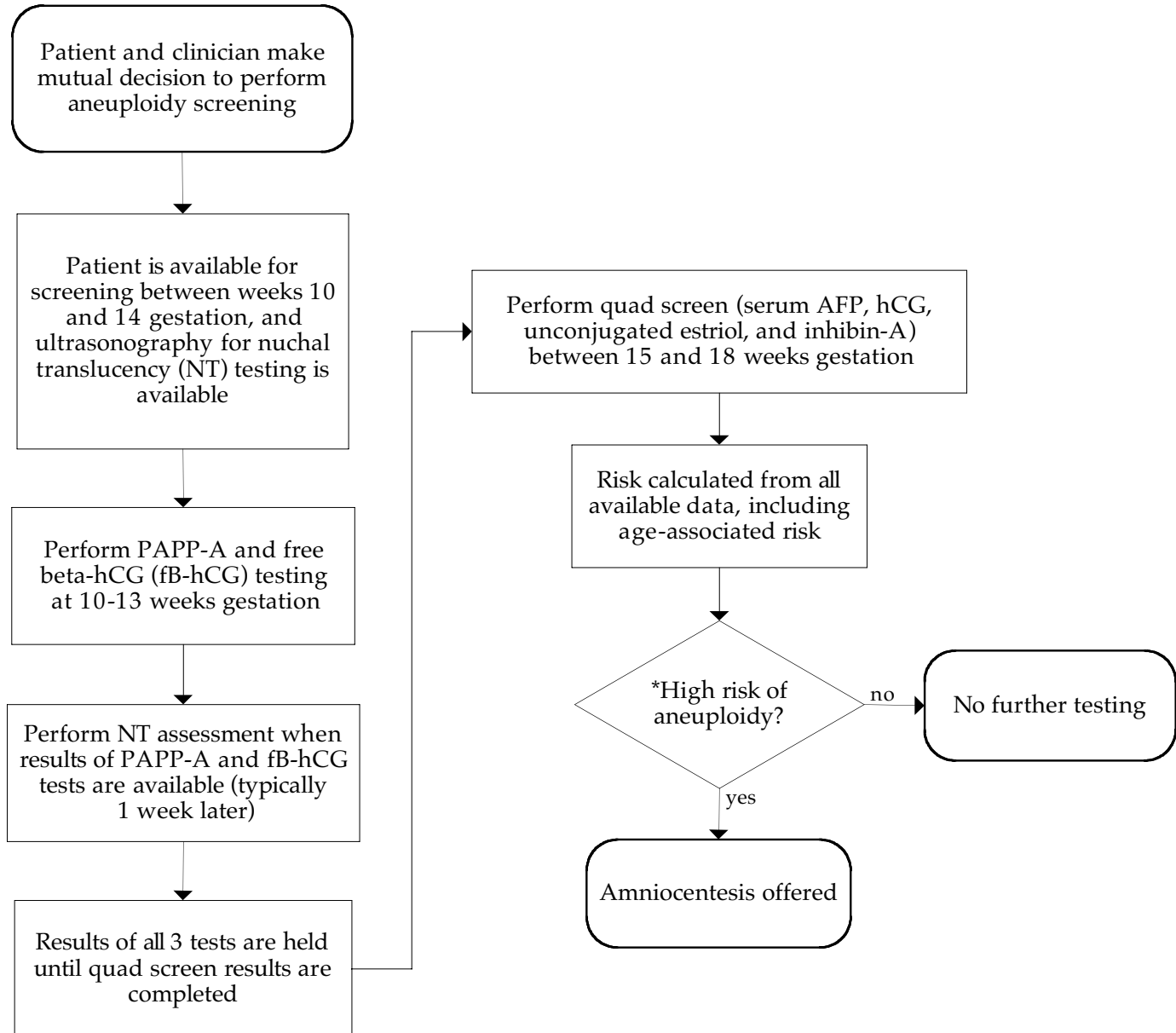
Printed on Recycled Paper

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Appendix H – Aneuploidy Testing

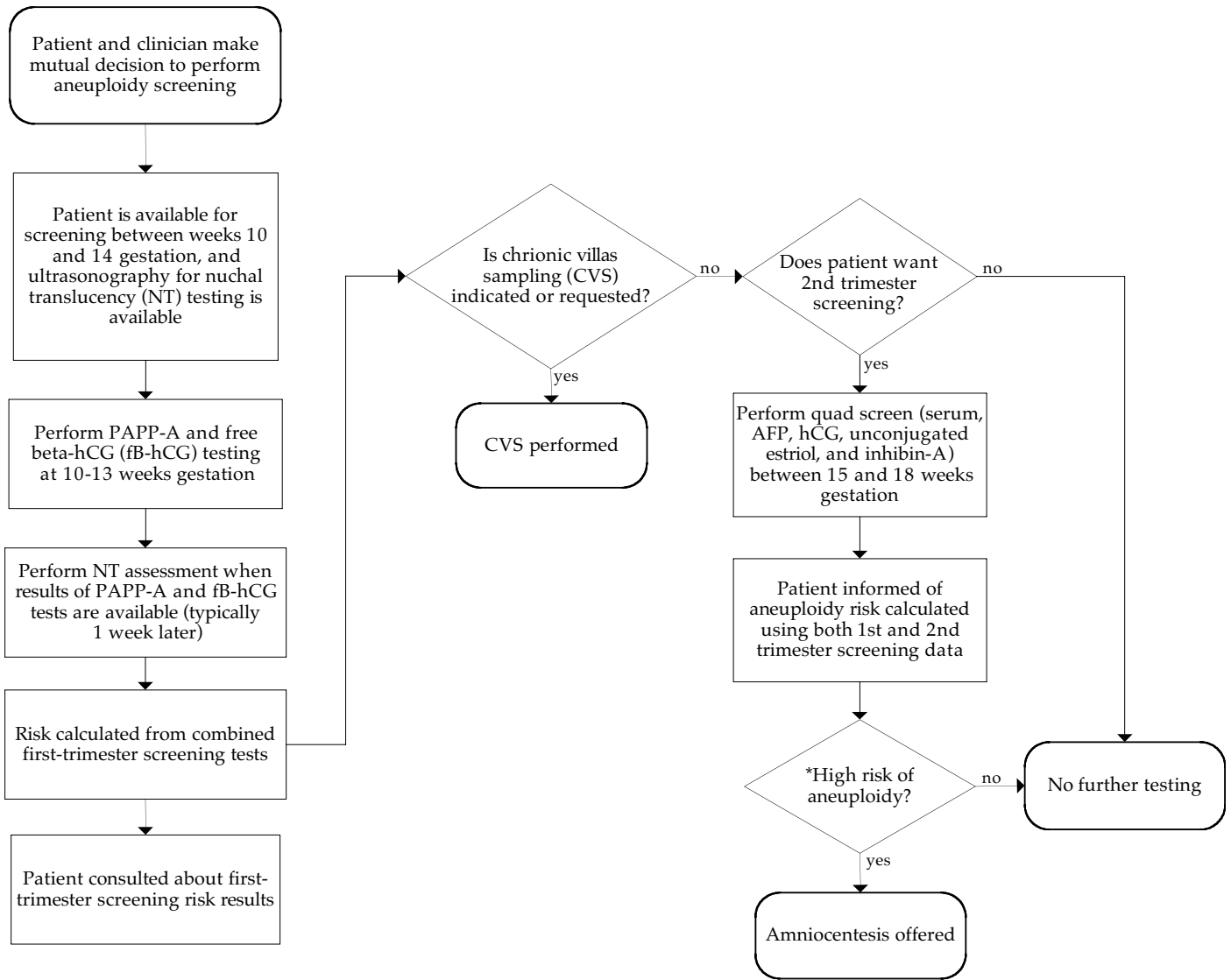
Aneuploidy Testing Integrated Screening Tool



* 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.

Appendix H – Aneuploidy Testing

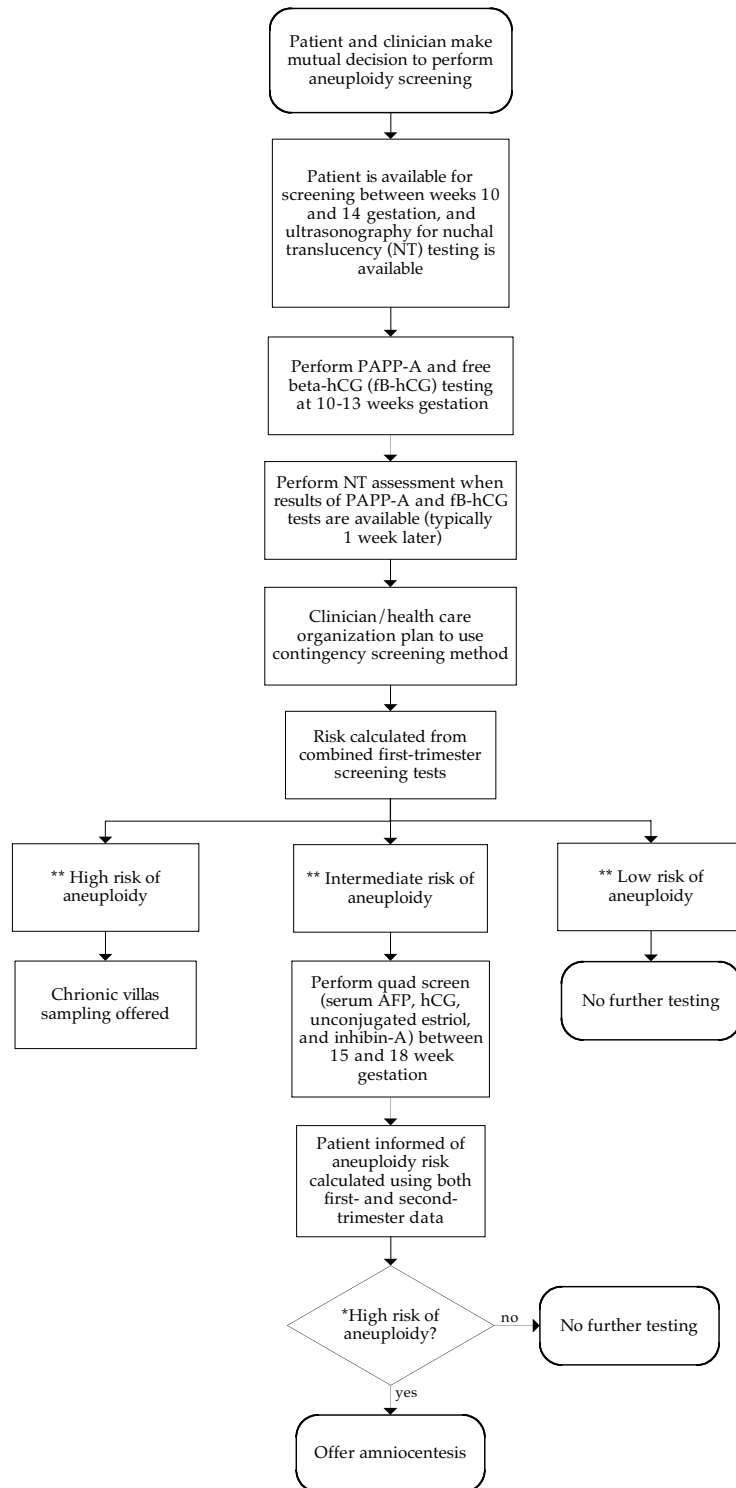
Aneuploidy Testing Stepwise Sequential Screening Tool



* 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.

Appendix H – Aneuploidy Testing

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.

Appendix I – 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.



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

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 serologyAll 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.

10/06



PERINATAL HEPATITIS B HOSPITAL REPORT

MDH USE ONLY RECORD NUMBER

Please complete the information that applies and **FAX** to: Perinatal Hepatitis B Coordinator
 FAX: **(651) 201-5502**
 If questions call **(651) 201-5557**

<p>FOR WOMEN KNOWN TO BE HBsAg POSITIVE:</p> <p><input type="checkbox"/> Administer hepatitis B immune globulin (HBIG) and hepatitis B vaccine, within 12 hours of birth, to all infants born to hepatitis B positive mothers.</p> <p><input type="checkbox"/> If your hospital is having difficulty obtaining HBIG, please call MDH at (651) 201-5414.</p>	<p>FOR WOMEN WHOSE HBsAg STATUS IS UNKNOWN:</p> <p><input type="checkbox"/> Perform a stat HBsAg screening test for all women admitted for delivery whose hepatitis status is unknown.</p> <p><input type="checkbox"/> While test results are pending, the infant should receive hepatitis B vaccine within 12 hours of birth. If the mother is later found to be positive, her infant should receive the additional protection of HBIG as soon as possible and before infant is discharged. HBIG needs to be given within 7 days of birth.</p>
---	--

NAME OF HOSPITAL: _____ CITY OF HOSPITAL: _____

DATE SENT: ____/____/____ MOTHER'S HOSPITAL RECORD NO. _____

Note: only report if mother is **HBsAg(+)**

MOTHER'S INFORMATION	HBsAg(+) Test date: / /
LAST NAME:	FIRST NAME:
ADDRESS:	
CITY / ZIP CODE:	PHONE: ()
DATE OF BIRTH: / /	ALTERNATE PHONE # (i.e. relative): ()
PHYSICIAN'S NAME:	CLINIC NAME:
RACE: <input type="checkbox"/> ASIAN/PACIFIC ISLANDER <input type="checkbox"/> AMERICAN INDIAN <input type="checkbox"/> BLACK <input type="checkbox"/> UNKNOWN <input type="checkbox"/> WHITE <input type="checkbox"/> OTHER	ETHNICITY: <input type="checkbox"/> HMONG <input type="checkbox"/> HISPANIC <input type="checkbox"/> SOMALI <input type="checkbox"/> OTHER <input type="checkbox"/> VIETNAMESE

INFANT'S HOSPITAL RECORD NO. _____

INFANT'S INFORMATION	
LAST NAME:	FIRST: (If known)
DATE OF BIRTH: / /	BIRTHWT: Sex: M F
DATE OF HBIG: / /	DATE OF HBVI: / /
<p>IMPORTANT – CLINIC WHERE INFANT WILL RECEIVE HBV2: _____</p> <p> INFANT'S PHYSICIAN (Include phone # if known): _____</p>	

Minnesota Department of Health / Immunization, Tuberculosis and International Health
 625 Robert St N. / P.O. Box 64975 / St. Paul, MN 55164-0975
www.health.state.mn.us/immunize

For more information, please call (651) 201-5557

Perinatal Hepatitis B Program
 HE# 01666-02 (MDH, 11/2005)

www.health.state.mn.us

FAX: 651-201-5502

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Availability of references

References cited are available to ICSI participating member groups on request from the ICSI office. Please fill out the reference request sheet included with your guideline and send it to ICSI.

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The next scheduled revision will occur within 24 months.

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Online at <http://www.ICSI.org>

Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in the Foreword and are assigned a designator of +, -, or \emptyset to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

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.

The symbols +, -, \emptyset , and N/A found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

- indicates that these issues have not been adequately addressed;

\emptyset indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

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Conclusion Grading Worksheet A – Annotation #23 (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	Class	Quality	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/ <i>Work Group's Comments (italicized)</i>
Snijders et al., 1998 (NT)	Sens/Spec	C	+	-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 > 95 th 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	C	0	-11,398 women with a crown lump 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	M	N/A	-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.

**Conclusion Grading Worksheet A – Annotation #23
(Fetal Aneuploidy Screening)**

Author/Year	Design Type	Class	Quality	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/ <i>Work Group's Comments (italicized)</i>
Krantz et al., 2000 (combined test)	Sens/spec	C	+	-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	C	0	-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	C	0	-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 False-Pos Detection (at 1:270) (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 \geq 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 \geq 40 yrs

**Conclusion Grading Worksheet A – Annotation #23
(Fetal Aneuploidy Screening)**

Author/Year	Design Type	Class	Quality	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/ <i>Work Group's Comments (italicized)</i>
Wald et al., 2003 (NT and/or other tests)	Sens/spec	C	+	<p>-Women at 25 maternity centers for antenatal care between 8 and 14 weeks of pregnancy</p> <p>-At booking visit: ultrasound, crown-rump length, ≥ 3 NT measurements</p> <p>-Serum and urine samples from booking visit and time of second-trimester screening test (not analyzed until outcome of pregnancy was known)</p> <p>-Diagnosis of Down syndrome based on second-trimester double, triple or quadruple test (polycy was to avoid early intervention based on NT)</p> <p>-Each pregnancy with Down syndrome (case) matched with 5 singleton unaffected pregnancies (controls); analyzed serum and urine (see NOTES)</p>	<p>-Analysis based on 102 Down syndrome pregnancies out of 42,712 singleton pregnancies recruited at 10-13 weeks gestation</p> <p>-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%</p> <p>-Detection rates at 10 completed weeks (5% false-positive rate) for independent variables: age=34%, NT=51%, PAPP-A=58% (all others <20%)</p> <p>-Detection rates at 10 completed weeks (5% false-positive rate) for combinations of tests: PAPP-A+free-β-hCG+inhibin-A+AFP+uE₃+NT=86%, PAPP-A+free-β-hCG+NT=83% ("combined test"); best detection rate (5% false-positive) without NT was 78%</p> <p>-False-positive rates for 85% detection rate (all include maternal age)</p> <p>1st trimester: combined test=6.1% NT (at 12-13 wks)=25.1%</p> <p>2nd trimester: integrated test*=1.2% quadruple test=6.2% triple test=9.3% double test=13.1%</p> <p>*includes NT+PAPP-A (1st trimester) AND quadruple test (2nd trimester)</p> <p>-Urinary markers were "useless" in 1st trimester; ITA was the most effective 2nd trimester marker but added little to screening performance</p>	<p>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:</p> <ol style="list-style-type: none"> 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 <p>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, uE₃, 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</p>

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

The subdivisions of this section are:

- Priority Aims and Suggested Measures
 - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

1. Increase the percentage of pregnant women who receive timely prenatal counseling and education as outlined in the guideline.

Possible measures of accomplishing this aim:

- a. Percentage of pregnant women who receive counseling and education before pregnancy.
 - b. Percentage of pregnant women who receive counseling and education at each visit as outlined in the guideline.
 - c. Percentage of pregnant women who receive counseling and education by the 28th week visit.
2. Increase the percentage of pregnant women who receive timely, comprehensive screens for testing risk factors.

Possible measures of accomplishing this aim:

- a. Percentage of initial risk assessment forms completed within two visits of initiation of prenatal care.
 - b. Percentage of pregnant women with interventions documented for identified risk factors.
 - c. Percentage of pregnant women with documented preconception risk assessment/counseling.
3. Increase the rate of interventions for identified preterm birth (PTB) risk factors.

Possible measures of accomplishing this aim:

- a. Percentage of all identified PTB modifiable risk factors assessed that receive an intervention.
 - b. Percentage of all identified modifiable and non-modifiable PTB risk factors that receive appropriate follow-up.
4. Increase the percentage of VBAC eligible women who receive documented education describing risk and benefits of VBAC.

Possible measures of accomplishing this aim:

- a. Percentage of VBAC eligible women who receive general education describing the risks and benefits of VBAC (e.g., the ACOG pamphlet on VBAC).
 - b. Percentage of VBAC eligible women who receive documented education describing the personal risks and benefits of VBAC (e.g., two or more previous Caesarean deliveries).
 - c. Percentage of VBAC eligible women who can describe the personal risks and benefits of VBAC.
5. Increase the number of first trimester patients who have documentation of counseling about appropriate aneuploidy screening.

Possible measure of accomplishing this aim:

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

Measurement Specifications

Possible Success Measure #1c

Percentage of pregnant women who received counseling and education by the 28th week visit.

Population Definition

All women who are in the course of prenatal care and who are present for the 28th week visit.

Data of Interest

of yes answers on the survey

total # of questions having either a "yes" or a "no" answer indicated on returned surveys

Numerator/Denominator Definitions

Numerator: The survey questions are:

1. Has your provider or someone from the clinic, community health program or worksite explained the benefits of breast-feeding? Yes No
2. Has your provider or someone from the clinic, community health program, or worksite told you to report vaginal bleeding during your pregnancy? Yes No
3. Has your provider or someone from the clinic, community health program, or worksite discussed attending or availability of childbirth classes with you? Yes No

Denominator: All returned survey forms

Method/Source of Data Collection

These data can be collected by a patient survey at the 28th week visit. Since that visit uses a glucose tolerance test and there is a waiting time for completion of the test, this survey can be completed during that waiting time. The patient completes the survey by herself.

This may be collected on everybody, or a sample. If a sample is done, it is suggested that the data be collected on specific days (or times) to create a regular pattern for data collection. This pattern will allow for more consistent and regular data collection. The minimum sample size is 15 per month or 40 per quarter.

Time Frame Pertaining to Data Collection

These data can be collected monthly.

Priority Aims and Suggested Measures

Possible Success Measure #3a

Percentage of all identified PTB modifiable risk factors assessed that receive an intervention.

Population Definition

Women at a prenatal visit.

Data of Interest

$$\frac{\text{\# of modifiable risk factors in the denominator with documented intervention}}{\text{\# of modifiable risk factors identified through screening and documentation in patient chart}}$$

Numerator/Denominator Definitions

Numerator: Of factors in the denominator, those factors with a documented intervention at the visit. An intervention can be:

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

Denominator: The number of risk factors assessed as present during the screening

Method/Source of Data Collection

Obtain risk factors identified that are documented in patient chart. 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. A sample chart abstraction form is included. The positive risk factor has an intervention if any of the following are documented: referral, education, home health nurse visits, case management, ultrasound, advice or any documented plan or discussion referring to the positive risk factor.

Time Frame Pertaining to Data Collection

These data may be collected weekly or monthly.

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.

Priority Aims and Suggested Measures

Possible Success Measure #4a

Percentage of VBAC eligible women who receive general education describing risks and benefits of VBAC (e.g., the ACOG pamphlet on VBAC).

Population Definition

Women at a prenatal visit who are VBAC eligible.

Data of Interest

$$\frac{\text{\# of VBAC eligible women with documentation of education of the risks and benefits of VBAC}}{\text{total \# of VBAC eligible women whose medical records are reviewed}}$$

Numerator/Denominator Definitions

Numerator: Documented is defined as any evidence in the medical record that a clinician provided education to the VBAC eligible woman of the risks and benefits of VBAC.

Denominator: The number of 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

Each month a minimum sample of prenatal visits is identified. This may be accomplished either by administrative search (CPT-4 codes 59510, 59400, or ICD-9 code V22.0), or by other case identification at the medical group.

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.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Routine Prenatal Care guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are only available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to <http://www.icsi.org/knowledge>. To access these materials on the Web site you must be logged in as an ICSI member.

The Knowledge Resources list in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Title/Description	Audience	Author/Organization	Web Sites/Order Information
	Drugs and Pregnancy	Public and professionals	American College of Gynecologists and Obstetricians	http://www.acog.com AP104
	Preterm Labor	Public and professionals	American College of Gynecologists and Obstetricians	http://www.acog.com
	Vaginal Birth After Caesarean	Public and professionals	American College of Gynecologists and Obstetricians	http://www.acog.com
	Screening tests for Birth Defects	Public and professionals	American College of Obstetricians and Gynecologists (2000)	AP 165 http://www.acog.com
	Chorionic Villus Sampling	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Preterm Labor; pamphlet	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Folic Acid; "What You Need to Know"	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Rh Disease	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Drugs and Herbal Preparations	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Cocaine Use During Pregnancy; Pregnancy risk	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Stress and Pregnancy; Pregnancy risk	Public and professionals	March of Dimes	http://www.marchofdimes.com
	The Facts about Smoking & Pregnancy	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Preventing Preterm Labor; prevention	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Premature Labor: A Teaching Guide	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Learn the Signs of Preterm Labor	Public and professionals	March of Dimes	http://www.marchofdimes.com
	Pregnant? Get Tested for Hepatitis B	Public and professionals	Minnesota Department of Health	http://www.health.state.mn.us
	Perinatal Group B <i>Streptococcus</i> in Pregnant Women and Infants (GBS)	Public and professionals	Minnesota Department of Health	http://www.health.state.mn.us

* Available to ICSI members only.

Resources Available

*	Title/Description	Audience	Author/Organization	Web Sites/Order Information
	Post Partum Depression When Caring for Your Baby Is Not What You Expected	Public	Minnesota Department of Health	http://www.health.state.mn.us/divs/fh/mch/fhv/strategies/ppd/ppdfactsheet.pdf
	Amniocentesis: Answers to Common Questions	Public and professionals	Mayo Clinic	http://www.mayoclinic.com PR00144
	Chorionic Villus Sampling: Answers to Common Questions	Public and professionals	Mayo Clinic	http://www.mayoclinic.com PR00145
	Pregnancy After 35: Healthy Moms, Healthy Babies	Public and professionals	Mayo Clinic	http://www.mayoclinic.com PR00115
	Prenatal Testing: Common Prenatal Tests	Public and professionals	Mayo Clinic	http://www.mayoclinic.com PR00095
	Pregnancy and Hepatitis B – Frequently Asked Questions	Public and professionals	Center for Disease Control	http://www.cdc.gov/ncidod/diseases/hepatitis/b/faqb-pregnancy.htm

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