ICSI

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Guideline:
Management of Labor

Third Edition
May 2009

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;
- health care teaching institutions;
- health care information technology departments;
- 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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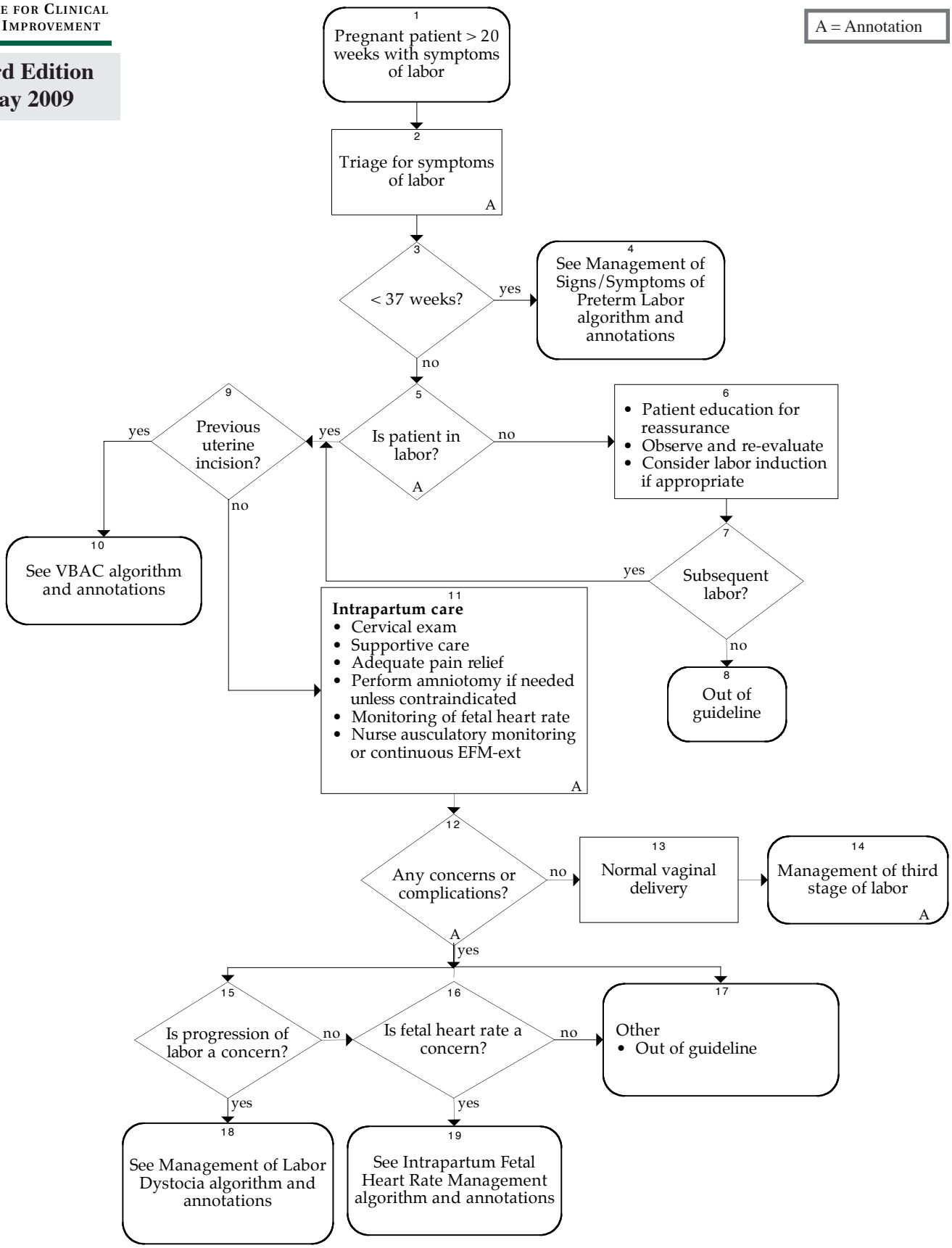

Management of Signs/Symptoms of Preterm Labor (PTL) Algorithm

This algorithm applies to singleton pregnancies only.

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Assessment includes:
- Sterile speculum exam
  - Fetal fibronectin testing
  - Consider GBS, wet prep for bacterial vaginosis
  - GC, chlamydia
- Digital cervical exam
- Transvaginal ultrasound for cervical length (if available)
- Ultrasound for growth, fluid, placenta
- Assess contraction patterns
- Assess fetal well-being
- Urinalysis and urine culture

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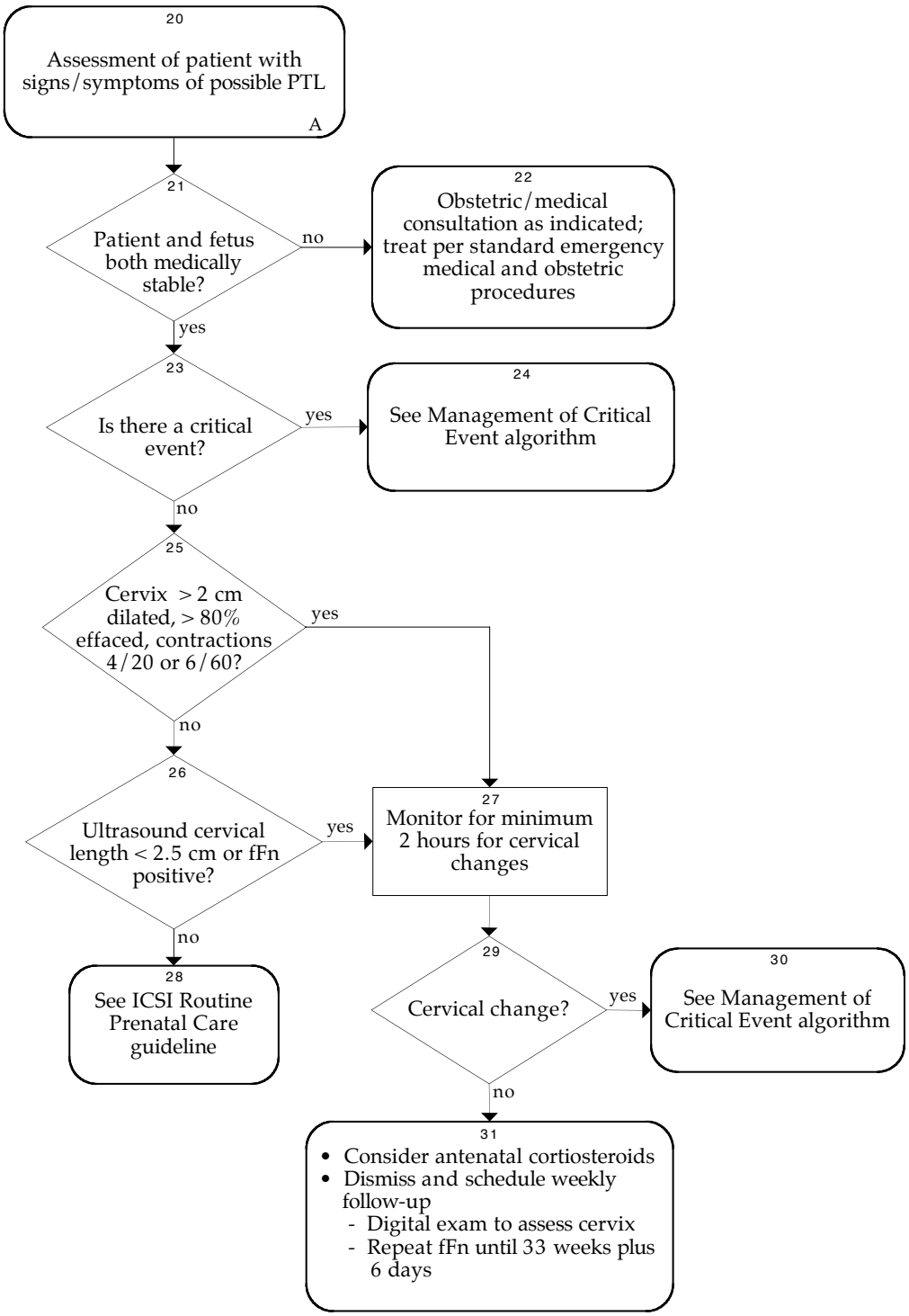
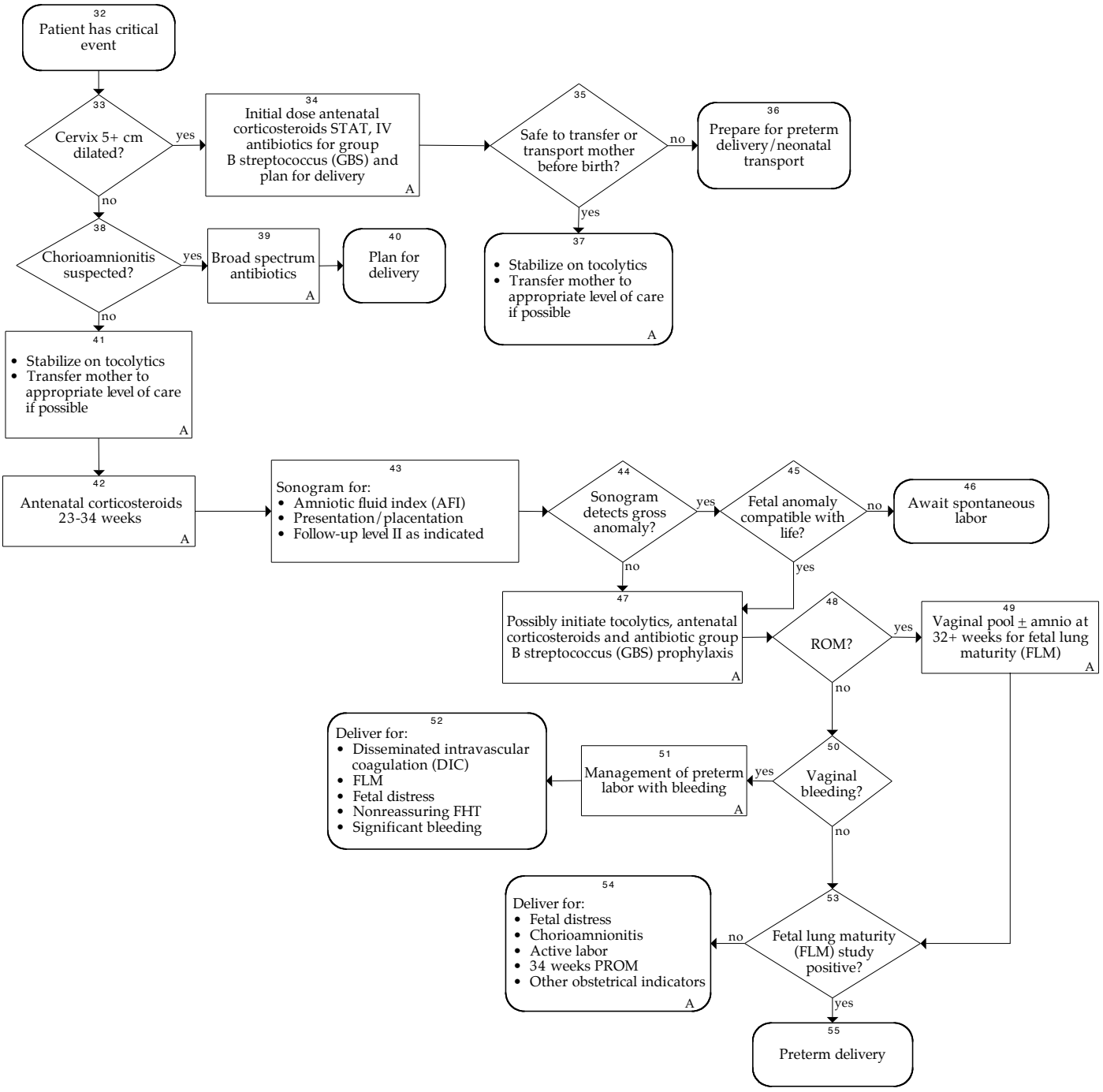
Critical events:
- Cervix 5+ cm dilated
- pPROM
- Vaginal bleeding
- Chorioamnionitis suspected

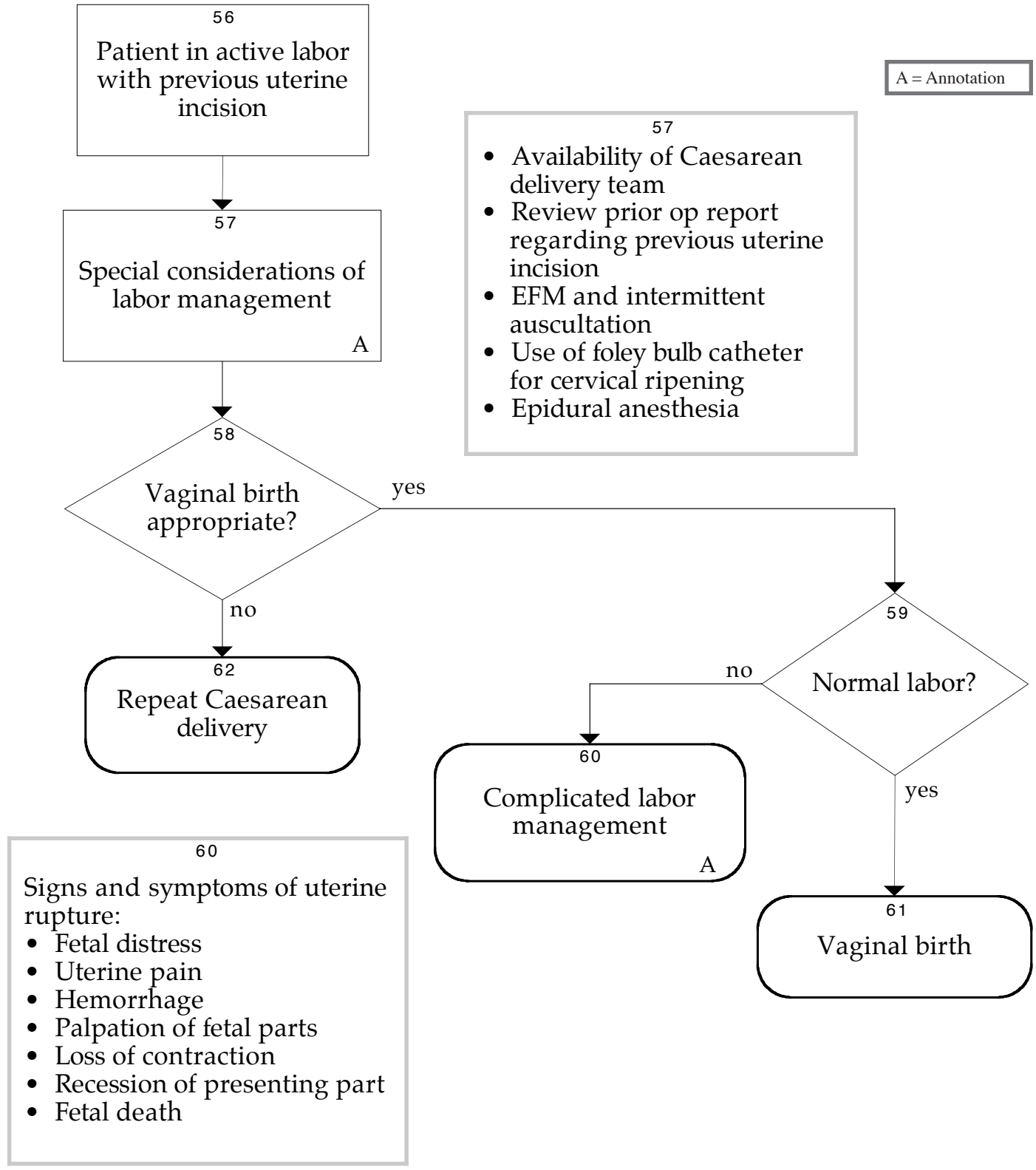


Management of Critical Event Algorithm

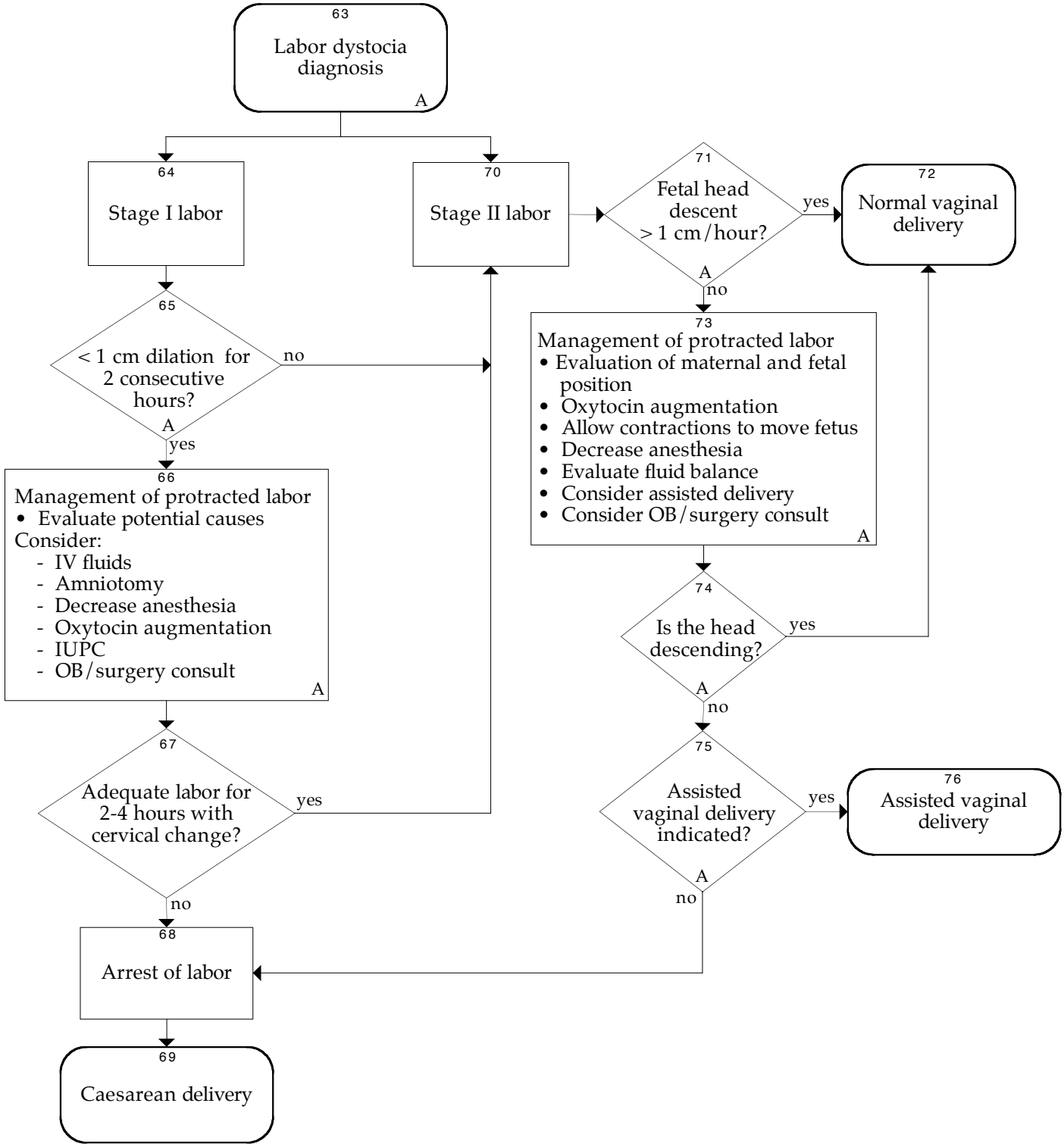


A = Annotation

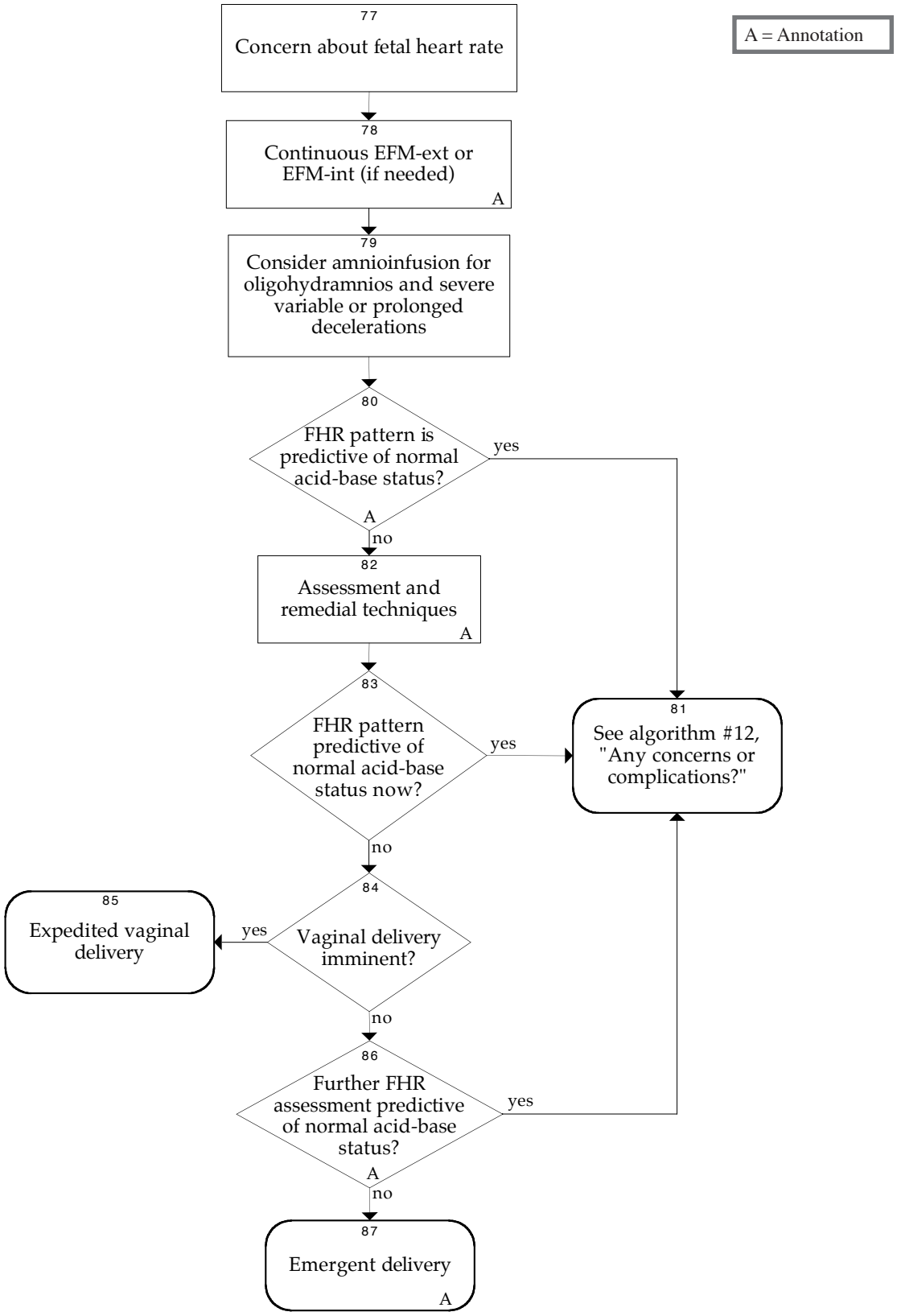
Vaginal Birth After Caesarean (VBAC) Algorithm



Management of Labor Dystocia Algorithm



Intrapartum Fetal Heart Rate (FHR) Management Algorithm



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Foreword

Scope and Target Population

All women who present in labor.

Clinical Highlights and Recommendations

- Confirm active labor before admitting to facility evidenced by:
  - Spontaneous contractions at least 2 per 15 minutes, and two or more of the following:
    - Complete effacement of cervix
    - Cervical dilation greater than or equal to 3 cm
    - Spontaneous rupturing of membranes (SROM)

  (Annotation #5)
- Perform amniotomy early in labor if indicated as discussed in the guideline. *(Annotation #11)*
- Assure fetal well-being with either intermittent auscultation or continuous electronic fetal heart rate monitoring. *(Annotation #11)*
- Patient's level of risk should be assessed on presentation of active labor.
  - Oligohydramnios
  - Chronic and acute medical conditions of mother and/or fetus

  (Annotation #12; Aim #4)
- Start appropriate treatment for the type of preterm labor involved as soon as possible after preterm labor is identified. Treatment should be based on specific symptoms, as well as gestational age and condition of the mother and fetus. *(Annotation #20; Aim #1)*
- Women with preterm labor at appropriate gestational age should receive a single course of antepartum steroids to promote fetal lung maturity. *(Annotations #34, 42, 47; Aim #1)*
- Conduct frequent cervical checks (cervical checks afford best opportunity to detect labor progress and prevent failure to progress). *(Annotation #65)*
- Augment with oxytocin to achieve adequate labor for two to four hours. *(Annotation #66)*
- If patient is in Stage II labor and is not making progress, initiate management of protraction disorders (positioning, fluid balance, oxytocin augmentation, OB/surgical consult). *(Annotation #73; Aim #2)*
- When necessary, initiate remedial techniques such as maternal position, cervical exam for cord prolapse, monitoring maternal blood pressure, assessment for uterine hyperstimulation, discontinuing oxytocics and amnioinfusion. *(Annotation #82; Aim #5)*
- Recognize and manage fetal heart rate abnormal patterns. *(Annotation #80; Aim #6)*

Priority Aims

1. Increase the percentage of women with PTL and/or PTB who receive antenatal corticosteroids appropriately.
2. Prevent unnecessary protracted labor with use of Management of Labor Dystocia algorithm and annotations and its methods.
3. Increase the use of procedures that assist in progress to vaginal birth.
4. Increase the percentage of women who are assessed for risk status on entry to labor and delivery.
5. Increase the use of remedial techniques that resolve temporary abnormal fetal heart tracing in labor.
6. Perform an appropriate evaluation for persistent abnormal fetal heart rate tracing in labor before Caesarean.

Related ICSI Scientific Documents

Guidelines

- Routine Prenatal Care

Disclosure of Potential Conflict of Interest

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee and Respiratory Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

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

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining input from and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at http://www.icsi.org.

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

Citations are listed in the guideline utilizing the format of *(Author, YYYY [report class])*. A full explanation of ICSI's Evidence Grading System can be found at http://www.icsi.org.

Abbreviations Used in This Guideline

fFN	fetal fibronectin
FHR	fetal heart rate
FHT	fetal heart tracing
FLM	fetal lung maturity
GBS	group B streptococcus
N, P, F	nitrazine, pooling and ferning
PROM	premature rupture of membranes
pPROM	preterm premature rupture of membranes
PTL	preterm labor
ROM	rupture of membranes
VBAC	vaginal birth after Caesarean

Algorithm Annotations

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 delivery. It is unsafe to blind care providers to whether a woman has had a previous Caesarean delivery or not or previous labor and delivery complications. It is also unsafe to blind providers to whether persistent non-reassuring heart rate tracings have occurred. 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 published by the American College of Obstetricians and Gynecologists.

Management of Labor Main Algorithm Annotations

2. Triage for Symptoms of Labor

Hospital and/or clinic triage for the labor patient will include these questions. Triage staff will assess general questions from OB experience. Some questions may require more details for assessment. Generally, the patient is encouraged to remain home as long as possible. The caregiver will manage any/all medical concerns according to accepted standards.

General Questions:

- Are you having contractions?
- Is this your first baby?
- Was your cervix dilated at least 2-3 cm on your last office visit?
- Did you have medical complications during your pregnancy? Get specifics.
- Are you at term? (What is your estimated date of conception?)

Specific Questions:

- Is your baby moving as usual?
  - If no, advise go to hospital.
- Has your water broken?
  - If yes, advise go to hospital.
- Are you bleeding?
  - If yes, advise go to hospital.
- Are you having unbearable contractions?
  - If yes, advise go to hospital.

When a patient presents to hospital and assessment shows the patient is NOT in labor: Patient education will include signs to look for, changes to assess, and reassurance that she can come back to the hospital when changes occur. When the caregiver prefers to hold and observe the patient, a reassessment must be conducted prior to release from the hospital.

5. Is Patient in Labor?

Labor is defined as:

Spontaneous contractions at least 2 per 15 minutes and at least two of the following:

- Complete effacement of cervix
- Cervical dilation 3 cm or greater (cervical exam #1)
- Spontaneous rupturing of membrane (SROM)

Only patients who meet this definition of labor should be admitted for careful management of labor. Careful assessment of presenting patients is critical.

Patients who are not in labor should receive education that includes signs to look for, changes to assess, and reassurance that they can come back to the hospital when changes occur. (See Appendix A, "Patient Education Handout.") A patient may be placed on "hold" status for observation. Hold patients require medical reassessment before leaving the hospital.

If the patient's cervix is dilated less than 3 cm and oxytocin is started, this should be considered induction of labor, NOT augmentation of labor *(American College of Obstetricians and Gynecologists, The, Practice Bulletin, 2003 [R])*.

11. Intrapartum Care

See ICSI Admission for Routine Labor Order Set.

Characteristics of care for a patient at time of admission to labor and delivery include:

- Chart evaluation
- Cervical exam #2
- Appropriate supportive care/comfort measures as per individual provider. May include, but are not limited to PO fluids, fluid balance maintenance, position changes, back rubs, music, ambulation, and tub bath/shower. Management of labor using patient care measures and comfort measures is supported. Documentation of progress of labor using a graphic medium is helpful to patient and staff *(McNiven, 1992 [D]; Radin, 1993 [C])*.
- Adequate pain relief. This includes parenteral analgesics, e.g., nalbuphine hydrochloride (such as Nubain), butorphanol tartrate (such as Stadol) or hydroxyzine hydrochloride (such as Vistaril) or epidural or intrathecal narcotics for patients in active progressing labor (continued dilation of the cervix) *(Clark, 1998 [A]; Halpern, 1998 [M]; Rogers, 1999 [C])*.
- Documentation of progress of labor using a graphic medium (partogram) is started on admission.
- Monitoring of fetal heart rate. (See Intrapartum Fetal Heart Rate [FHR] Management algorithm and annotations).
- Amniotomy unless contraindicated. Amniotomy should be done early in labor unless spontaneous rupture has occurred or contraindications are present. Early amniotomy has been shown to be associated with a decrease in duration of labor and is part of the failure to progress protocol *(Brisson-Carroll, 1996 [M]; Fraser, 1993 [A]; Fraser, 2000a [M]; Garite, 1993 [A])*.

Contraindications for amniotomy include:

- Presentation unknown, floating or unstable
- Cervix dilated less than 3 cm
- Patient refuses

Continuous Electronic Fetal Heart Rate Monitoring or Intermittent Auscultation

The established purpose of fetal heart rate (FHR) monitoring is to identify fetal hypoxemia and acidemia so timely intervention can prevent fetal morbidity and mortality. This is based on the rationale that FHR patterns are indirect markers for hypoxemia and acidemia since the central nervous system controls heart rate. Virtually all obstetrical organizations advise monitoring the FHR during labor, although no trials have compared FHR monitoring versus no monitoring *(Freeman, 2002 [R])*. The most common methods of FHR monitoring are continuous electronic FHR monitoring (EFM) and intermittent auscultation. EFM can be done with an external cardiotocography monitor or an internal (scalp) lead and can provide a continuous assessment of FHR variability and any changes from the baseline heart rate (see table of interpreting FHR monitoring). Intermittent auscultation consists of auscultating FHR with either a DeLee stethoscope or a Doppler probe for 30 seconds immediately following a contraction. This monitoring must be performed every 30 minutes during Stage I of labor and every 15 minutes during Stage II *(American College of Obestetrics and Gynetcolgists, The, 2005 [R])*.

Analysis of data from randomized trials comparing these two techniques shows:

- No difference in the rate of intrapartum fetal death rate (approximately 0.5 per 1,000 births with either approach)
- No difference in APGAR scores and NICU admissions
- Neither approach has resulted in a reduction in cerebral palsy or incidence of infant neurologic impairment

Several advantages to EFM have been demonstrated, including a reduction in neonatal seizures *(Alfirevic, 2006 [M])* and better prediction of fetal acidemia at birth *(Vintzileos, 1993 [A]; Vintzileos, 1995 [M])*. One disadvantage to EFM is that it leads to higher assisted deliveries and Caesarean birth without an associated neonatal benefit *(Alfirevic, 2006 [M])*. Compared to intermittent auscultation, EFM is associated with a twofold increase in Caesarean delivery rate for non-reassuring FHR patterns.

12. Any Concerns or Complications?

Risk assessment should be performed on all patients in active labor and is the responsibility of all members of the health care team. This includes, but is not limited to nurses, midwives and physicians. Patient is in active labor. (See Annotation #5, "Is Patient in Labor?" for specific definition.)

Initial assessments on entry into labor and delivery area:

- Fetal heart rate assessment *(Cheyne, 2003 [A]; Impey, 2003 [A])*
- Patient assessment
- Prenatal risk review
- Risk in labor assessment

High-risk situations may include any of the following conditions:

- Abnormal fetal heart rate (see Intrapartum Fetal Heart Rate [FHR] Monitoring algorithm and annotations)
- Situations that involve arrest or protraction disorders (see Management of Labor Dystocia algorithm and annotations)
- Bleeding
- Breech presentation
- Dysfunctional labor
- Fetal congenital heart disease
- Intrauterine growth retardation
- Maternal congenital heart disease
- Maternal diabetes or gestational diabetes
- Maternal hypertension
- Maternal lupus
- Multiple gestation
- Oligohydramnios
- Other serious chronic and acute medical conditions of mother and/or fetus
- Oxytocin use
- Postdate pregnancy (greater than or equal to 42 weeks, per physician discretion)
- Thick meconium

For the evaluation of fetal heart rate in high-risk labor see *(Haverkamp, 1976 [A]; Renou, 1976 [A]; Vintzileos, 1993 [A]; Vintzileos, 1995 [M])*.

14. Management of Third Stage of Labor

Active Management of the third stage of labor should be offered to women since it reduces the incidence of postpartum hemorrhage due to uterine atony. Active management of the third stage of labor consists of interventions designed to facilitate the delivery of the placenta by increasing uterine contractions and to prevent postpartum hemorrhage by averting uterine atony. The usual components include:

- administration of uterotonic agents,
- controlled cord traction, and
- uterine massage after delivery of the placenta, as appropriate.

(Elbourne, 2003 [M]; International Confederation of Midwives [ICM], 2004 [R])

Management of Signs/Symptoms of Preterm Labor (PTL) Algorithm Annotations

20. Assessment of Patient with Signs/Symptoms of Possible Preterm Labor

Be certain intervention is appropriate, including certainty of gestational age. A sonogram should be considered if one has not been done.

A thorough medical evaluation should include the following:

- Perform a sterile speculum exam to visualize the cervix to:
  - identify any source of bleeding or cervical or vaginal pathology or trauma
  - estimate dilation and effacement of the cervix and look for pooling of amniotic fluid as a sign of ruptured membranes
  - obtain samples for fetal fibronectin testing (fFN)*, consider samples for gonorrhea, chlamydia, *(Andrews, 2000 [C])* wet prep for bacterial vaginosis**, group B streptococcus (GBS), and a sample for detecting amniotic fluid with either ferning, nitrazine paper, or Amnisure

  * Perform fetal fibronectin testing (fFN), if patient is between 24 and 34 weeks gestation, and cervix less than 3 cm dilated. Patients with a negative test can expect pregnancy to continue for 7-14 days.

  ** Consider screening high-risk women with a history of at least one preterm delivery for bacterial vaginosis. If positive, treatment should include oral metronidazole. Treatment of bacterial vaginosis infection in pregnant women at high risk for preterm delivery by traditional seven-day courses of therapy early in pregnancy appears to reduce preterm delivery. *[Conclusion Grade II: See Conclusion Grading Worksheet A – Annotation #20 (Bacterial Vaginosis)]* The evidence regarding treatment of low-risk, pregnant women with asymptomatic bacterial vaginosis is limited by use of inadequate therapy in the available studies. *[Conclusion Grade Not Assignable: See Conclusion Grading Worksheet A – Annotation #20 (Bacterial Vaginosis)]*

(Carey, 2000 [A]; Leitich, 2003 [M]; McDonald, 1997 [A]; McGregor, 1995 [C]; Morales, 1994 [A]; Tebes, 2003 [R])

- Perform digital cervical exam if membranes are intact and there is no vaginal bleeding. If ruptured, digital exams increase the risk of infection.
- Obtain transvaginal sonogram (TVS) for cervical length for monitoring of patients with sign/symptoms of preterm labor and early cervical change. Cervical length of less than or equal to 25 mm or a rapidly thinning cervix correlate with increased preterm birth rates *(Vendittelli, 2000 [R])*.
- Perform bedside ultrasound (if feasible) to assess:
  - Presentation
  - Amniotic fluid index
  - Biophysical profile
  - Estimated fetal weight
- Assess contraction pattern

- Assess fetal heart rate pattern and fetal well-being
- Obtain urinalysis, urine culture and urine drug screen (if appropriate)

Consider non-intervention near-term if gestational age is well documented. Do not inhibit labor where there is fetal or maternal jeopardy, fetal malformation or death.

Evidence indicates prophylaxis with progesterone may decrease the reoccurrence of preterm labor in women with a history of one or more preterm births *(da Fonseca, 2003 [A]; Meis, 2003 [A])*. See ICSI Routine Prenatal guideline.

Fish oil supplementation has not been found to be helpful in preventing preterm labor. One analysis of six clinical trials found an increase in intracranial hemorrhage among infants whose mothers took fish oil supplements during pregnancy compared to those who took olive oil *(Olsen, 2000 [A])*.

Definition of Preterm Labor:

- Labor occurring after 20 and before 37 completed weeks **plus**
- Clinically documented uterine contractions (4/20 minutes or 6/60 minutes) **plus**
- Ruptured membranes **or**
- Intact membranes and cervical dilation greater than 2 cm **or**
- Intact membranes and cervical effacement greater than 80% **or**
- Intact membranes and cervical change during observation. These can be measured by changes in dilation or effacement, or by changes in cervical length measured clinically or by ultrasound.

Management of Critical Event Algorithm Annotations

34. Initial Dose Antenatal Corticosteroids STAT, IV Antibiotics for Group B Streptococcus (GBS), and Plan for Delivery

Please refer to Annotation #47, "Possibly Initiate Tocolytics, Antenatal Corticosteroids and Antibiotic Group B Strepcoccus (GBS) Prophylaxis," for information on dosing of other corticosteroids.

37. Stabilize on Tocolytics/Transfer Mother to Appropriate Level of Care if Possible

Several medications are available for the inhibition of preterm labor (tocolysis). These drugs have different routes of administration, dose schedules, safety profiles, contraindications, and fetal and maternal side effects *(Simhan, 2007 [R])*. Although several medications can prevent delivery for 24-48 hours (allowing time for the administration and beneficial effects of corticosteroid therapy), the longer-term efficacy of all tocolytics is poor *(Gyetvai, 1999 [M])*.

Magnesium sulfate

Review of the literature does not support the efficacy of magnesium sulfate as a tocolytic. The largest randomized, placebo-controlled trial showed no benefit over placebo *(Cox, 1990 [A])*. A more recent meta-analysis of 11 studies showed no benefit regarding the risk of preterm birth (less than 37 weeks) or very preterm birth (less than 34 weeks). Moreover, in seven of the trials analyzed, the risk of perinatal mortality was increased for infants exposed to magnesium sulfate *(Crowther, 2002 [M]; Grimes, 2006 [R]; Mittendorf, 2002 [R])*. The work group does not recommend the use of this medication for this indication.

A series of recent randomized controlled trials *(Doyle, 2009 [M]; Marret, 2008 [A]; Rouse, 2008 [A])* evaluated the administration of magnesium sulfate in clinical situations when preterm delivery is regarded as imminent. Review of these trials has suggested magnesium sulfate does not work well as a tocolytic, but does provide a reduction in both the frequency and severity of cerebral palsy for those infants surviving the immediate intrapartum time frame. The following points from these studies are important to note:

- Very preterm birth (less than 34 weeks) and very low birth weight (less than 1,500 g) are principal risk factors for cerebral palsy, making up between 17% to 32% of all cases of cerebral palsy.
- Evidence from population-based registries shows the prevalence of cerebral palsy is rising in very low birth weight infants.
- Recent retrospective studies confirm that the increasing prevalence of cerebral palsy is from higher rates in preterm, not term, infants.

The term neuroprotection is used to describe the possible indication for magnesium sulfate in these clinical situations. Although the results from the relevant studies are intriguing, one of the principal researchers for two of these studies suggests it is not yet time to recommend the routine use of magnesium sulfate for neuroprotective benefits in any circumstance of preterm labor *(Crowther, 2002 [M])*:

A meta-analysis involving individual patient data from the various trials might help to answer these questions, better guide clinical-practice recommendations, and frame future research. Information from long-term follow-up of children whose mothers received antenatal magnesium sulfate also is needed to clarify the neuroprotective role of this therapy before preterm birth *(Stanley, 2008 [R])*.

Calcium channel blockers

Nifedipine is the drug most commonly employed from this class of medications for tocolysis. No placebo-controlled trials have evaluated the drug for this indication, but comparative trials have demonstrated the efficacy and safety of the drug *(King, 2003 [M]; Papatsonis, 1997 [A])*.

Beta-adrenergic-receptor agonists

Terbutaline is one of the commonly employed drugs from this class of medications for tocolysis. Available studies show a prolongation of pregnancy similar to the results of calcium channel blockers, but no significant reduction in perinatal morbidity or mortality *(Anotayanouth, 2004 [M])*. However, the absence of such findings may be a result of the sample size in some of the trials analyzed.

Cyclooxygenase inhibitors

Indomethacin is the drug most commonly employed from this class of medications for tocolysis. A meta-analysis of three comparative trials with other classes of tocolytics showed a reduction of preterm births (< 37 week) *(King, 2005 [M])*. Indomethacin should only be used at less than 32 weeks gestation and only for 48 hours maximum to allow for the administration of antenatal corticosteroids *(Doyle, 2005 [M]; Loe, 2005 [M])*.

Maternal transfer to prevent the need for premature neonatal transfer reduces preterm neonatal morbidity and mortality. Very low birthweight infants (less than 1,500 grams) inborn to Level III perinatal centers have lower mortality, reduced incidence of Grade III and Grade IV intraventricular hemorrhage, and lower sensorineural disability rates than outborn infants *(Menard, 1998 [C]; Towers, 2000 [C]; Yeast, 1998 [C])*.

39. Broad Spectrum Antibiotics

Broad-spectrum antibiotic coverage appears to lengthen the latency from preterm premature rupture of membranes (pPROM) until delivery and/or chorioamnionitis. Antibiotic therapy reduces maternal and neonatal morbidity in women with pPROM. There is no consensus on the choice of antibiotic or dose. A

combination of ampicillin and erythromycin appears promising *(Bar, 2000 [C]; Edwards, 2000 [C]; Kenyon, 2000 [M]; Mercer, 1997 [A])*.

41. Stabilize on Tocolytics/Transfer Mother to Appropriate Level of Care if Possible

See Annotation #37, "Stabilize on Tocolytics/Transfer Mother to Appropriate Level of Care if Possible," for a discussion about tocolytics.

42. Antenatal Corticosteroids 23-34 Weeks

Please refer to annotation #47, "Possibly Initiate Tocolytics, Antenatal Corticosteroids and Antibiotic Group B Streptococcus (GBS) Prophylaxis," for dosing of betamethasone and other corticosteroids.

47. Possibly Initiate Tocolytics, Antenatal Corticosteroids and Antibiotic Group B Streptococcus (GBS) Prophylaxis

Agents to be considered for tocolytic therapy include terbutaline sulfate (including pump), indomethacin and nifedipine. In February 1997, the FDA alerted practitioners to use caution in the continuous subcutaneous administration of terbutaline sulfate.

Other considerations for initial management of preterm labor include the following:

- Initiate antenatal corticosteroids if 23-34 weeks gestation. Please refer below to "Pharmacologic Management of Preterm Labor" for more information on administration of betamethasone and other corticosteroids.
- Administer IV antibiotic effective against group B streptococcus (GBS) until GBS results are back or if patient is known to be positive for GBS *(Thorp, 2002 [M])*.
- Activity limitation as indicated.
- Order additional laboratory analysis pertinent to tocolytic being used.

Pharmacologic Management of Preterm Labor

A. Tocolysis and betamethasone

Management of preterm labor should include parenteral tocolysis for 48 hours with administration of two doses of betamethasone.

The usual dosage regimen is betamethasone 12 mg IM STAT, then repeat in 24 hours.

An alternative medication is dexamethasone for a total of 24 mg (usual dosing regimen is 6 mg IM every 12 hours times four doses).

Treatment should be initiated in women with any symptoms or signs that might herald the onset of preterm delivery or a potential need for elective birth, rather than waiting until the diagnosis is in no doubt. While a single complete course of antenatal steroids provides significant multiple benefits to the preterm neonate, multiple courses should not be used. Please refer to the NIH Consensus Statement *(Guinn, 2001 [A]; National Institutes of Health, 2000 [A]; Thorp, 2001 [A])*.

Treatment should not be withheld because delivery appears to be imminent.

Antenatal corticosteroid therapy for fetal lung maturation reduces mortality, respiratory distress syndrome and intraventricular hemorrhage in preterm infants. These benefits extend to a broad range

of gestational ages and are not limited by gender or race *(Crowley, 2002 [M])*. New data indicate that the benefits of postnatal surfactant are enhanced by antenatal corticosteroid administration. No adverse consequences to a policy of administration of antenatal steroids to women in preterm labor have been identified *(American College of Clinical Pharmacy, 2000 [R]; American College of Obestricians and Gynecologists, The, 2002a [R])*.

The beneficial effects of corticosteroids are greatest more than 24 hours after beginning treatment. However, treatment less than 24 hours in duration may improve outcome. Every effort should be made to treat women before spontaneous or elective preterm delivery.

Aggressive Management with Tocolysis

Tocolysis should be continued if necessary until fetal lung maturity is documented or maternal or fetal complications arise for which preterm delivery is indicated.

The etiology of preterm labor remains obscure. Consequently, patients who continue to have regular uterine activity and/or gradual cervical changes on parenteral tocolysis must be managed with clinical judgment, balancing the risks to the mother of ongoing tocolysis against the risks of preterm birth for the neonate.

For additional information regarding tocolytic therapy, please refer to the following: *(American College of Obstetricians and Gynecologists, The, 1989 [R]; National Institutes of Health Consensus Development Conference Statement, 1995 [R]; Ogburn, 1990 [R]; Sanchez-Ramos, 1999 [M])*.

Terbutaline Pump

Several well-designed studies have concluded that terbutaline administered by infusion pump may be a safe and effective treatment option for the prolongation of pregnancy. However, there continues to be debate in the medical literature concerning the safety and efficacy of the pump *(Allbert, 1994 [C]; Elliott, 1997 [D]; Perry, 1995 [D])*.

Another study *(Elliott, 2004 [B])*, concludes that continuous subcutaneous terbutaline infusion was associated with an exremely low incidence of serious events.

B. Administer antibiotics for group B streptococcus (GBS) prophylaxis until GBS results are back. Please refer to the GBS prophylaxis guidelines at your institution *(Hager, 2000 [R])*.

The Agency for HealthCare Research and Quality reviewed literature on the use of antibiotics in preterm labor *(Agency for HealthCare Research and Quality, 2000 [M])*.

(Centers for Disease Control and Prevention, 2002 [R])

49. Vaginal Pool ± Amnio at 32+ Weeks for Fetal Lung Maturity (FLM)

Phosphatidyl glycerol (PG) is a reliable indicator of FLM if present in vaginal pool specimens. L/S ratio is unreliable if blood and/or meconium are present in the fluid. Certain assays of PG may be influenced by the presence of heavy growth of gardnerella vaginalis. Please consult with your local hospital clinical laboratory *(Beazley, 1996 [R])*.

Maternal chorioamnionitis and hospital length of stay were lessened with induction of labor in preterm premature rupture of membranes (pPROM) with mature fetal lung maturity studies after 32 weeks, with no difference in neonatal outcomes compared with expectant management *(Mercer, 1993 [R])*.

51. Management of Preterm Labor with Bleeding

In the presence of preterm labor with bleeding, IV access is essential.

- The patient should be on strict bedrest.
- Blood should be typed and crossmatched.
- Complete blood counts (CBCs) with platelets, prothrombin time (PT), partial thromboplastin time (PTT) and fibrinogen.
- Continue fetal monitoring while bleeding.

54. Deliver for Fetal Distress/Chorioamnionitis/Active Labor/34 Weeks PROM/Other Obstetrical Indicators

Under these conditions, we recommend delivery *(Hauth, 2006 [M])*.

A "break point" in neonatal morbidity was observed at 34 weeks gestation, which supports induction of labor at this gestional age *(Neerhof, 1999 [B]*.

Vaginal Birth After Caesarean (VBAC) Algorithm Annotations

57. Special Considerations of Labor Management

- Availability of a team capable of performing a Caesarean delivery within a short time *(American College of Obstetricians and Gynecologists, The Practice Bulletin, 2004 [R])*.
- Review the prior operative report(s) to ensure that the uterine incision did not involve the contractile portion of the uterus such as a classical incision. A VBAC after a Caesarean with classical incision carries a tenfold higher risk of uterine rupture compared to a low transverse uterine incision.
- Intermittent auscultation or continuous electronic fetal heart rate monitoring should be done. See Intrapartum Fetal Heart Rate (FHR) Management algorithm and annotations.
- Augmentation or induction of labor with oxytocin increases the risk of uterine rupture *(Blanchette, 2001 [C])* though the risk is still low (1%-2.4%). Oxytocin and prostaglandin were not individually associated with uterine rupture except when sequential prostaglandin-oxytocin was used *(Macones, 2005 [R])*. A meta-analysis *(Dodd, 2006 [R])* found sufficient evidence to help in choosing planned induction in VBAC versus elective repeat Caesarean delivery.
- The ACOG Committee on Obstetric Practice recommends that misoprostol not be used for induction of labor in women with prior Caesareans or major uterine surgery *(American College of Obstetricians and Gynecologists, The, 2006 [R])*.
- Use of the Foley bulb catheter has a uterine rupture rate close to that of women laboring spontaneously and has a VBAC success rate similar to that of women who have induced labor *(Ravasia, 2000 [B])*. The intracervical catheter ripening method does not stimulate uterine contractions, which is an advantage for women with previous Caesareans *(Bujold, 2004 [B])*. The Society of Obstetricians and Gynecologists of Canada has endorsed the use of the Foley bulb catheter for cervical ripening for women with a low transverse uterine scar. ACOG has no statement either endorsing or discouraging mechanical dilators for cervical ripening in women attempting VBAC *(SOGC Clinical Practice Guidelines, 2005 [R])*.

60. Complicated Labor Management

The same considerations for intervention in labor apply to VBACs as for other attempted deliveries.

Complicated labor can be manifested in several categories:

- Failure to progress – the same considerations for intervention – including amniotomy, oxytocin, epidural anesthesia/analgesia – apply to VBACs. If indication for primary Caesarean was dystocia, percentage successful VBACs was 77%. Women who required oxytocin for induction had 58% successful vaginal delivery versus 88% who required oxytocin for augmentation *(Sakala, 1990 [C]; Silver, 1987 [D]; Stovall, 1987 [D])*.
- Fetal distress – see Intrapartum Fetal Heart Rate (FHR) Management algorithm and annotations.
- Maternal complications – pre-eclampsia and exacerbation of pre-existing maternal illness are managed similarly in complicated VBAC versus a complicated vaginal labor patient.
- Uterine rupture – the scarred uterus has an increased potential to rupture. Uterine rupture occurs in between 1/100 and 1/11,000 deliveries, depending on whose data one uses and the clinical presentation. The type of scar makes a difference in frequency of rupture and severity of symptoms, also (LST 0.2-0.8 Classical 4.3-8.8, T4.3-8.8, Low Vertical 0.5-6.5) *(Pridjian, 1992 [R])*.

  Rupture through a low segment transverse scar is much more likely to go undetected or produce maternal hypovolemia or gradual fetal distress. Complete rupture with expulsion of fetus or placenta is a true obstetric emergency and can lead to maternal or hypovolemic complication, even death, as well as fetal hypoxia and death.

Conditions that increase the risk for uterine rupture:

- Previous uterine injury, Caesarean delivery, myomectomy, etc.
- Intrapartum – hyperstimulation, difficult forceps, internal podalic versions, fundal pressure, etc.
- Uterine defects not related to trauma, e.g., congenital defect, invasive mole
- Multiple previous Caesarean deliveries

Signs and symptoms of uterine rupture include:

- Fetal distress – 50%-70% of detected ruptures present with abnormal FH tracings (e.g., variable decelerations that evolve into late decelerations)
- Uterine pain, especially pain over previous incision that continues between contractions
- Hemorrhage – intra-abdominal, vaginal or urinary
- Palpation of fetal parts
- Loss of contractions
- Recession of presenting part
- Fetal death

Uterine scar disruptions can be classified into three types:

- Scar dehiscence – Opening of previous scar, with intact overlying peritoneum (uterine serosa), no expulsion of uterine contents
- Incomplete rupture – Opening of previous scar, but not overlying peritoneum, extraperitoneal extrusion of intrauterine contents

- Complete rupture – Opening of previous scar and overlying peritoneum with extrusion of intrauterine contents into peritoneal cavity

(American College of Obstetrics and Gynecologists, 2006 [R]; Pridjian, 1992 [R])

Management of Labor Dystocia Algorithm Annotations

63. Labor Dystocia Diagnosis

Labor abnormalities are classified as either protraction disorders (slower than normal progress) or arrest disorders (complete cessation of progress). Labor dystocia can only be defined when labor is in the active phase. Management of labor dystocia is especially important in the nulliparous woman to prevent unneeded Caesarean sections *(Gifford, 2000 [D])*.

Friedman provided the definition for "normal labor" in the 1950s. Further observation has shown that the definition of "normal labor" is broader than Friedman's definition. This has lead to more flexibility in the management of abnormal labor. Management strategies assume that mother and baby are doing well (including reassuring fetal monitoring).

65. Less than 1 cm Dilation for Two Consecutive Hours?

Labor progress is measured by checking for cervical change using a digital cervical exam. Cervical exams should indicate at least one centimeter dilation per hour during the active phase. Frequent cervical checks afford the best opportunity to assess the progress of labor and to diagnose labor with abnormal progress.

At least one clinical trial testing the effectiveness of active management of labor in reducing Caesarean deliveries used hourly cervical exams; others studies have used every-two-hour exams. The "two-hour" rule for determining dilatation has been challenged. However, there is not enough supporting evidence to change our recommendation of "one-hour" cervical exams *(American College of Obstetricians and Gynecologists, The Practice Bulletin, 2003a [R]; Frigoletto, 1995 [A]; Lopez-Zeno, 1992 [A]; Zhang, 2002 [C])*.

66. Management of Protracted Labor

Protracted labor is defined as labor which progresses more slowly than usual. "Active" management of labor as defined by O'Driscoll, et al does not reduce the rate of Caesarean delivery but may decrease the length of labor and increase patient satisfaction in nulliparas *[Conclusion Grade II: See Conclusion Grading Worksheet B – Annotation #66 (Management of Protracted Labor)] (DeMott, 1992 [C]; Glantz, 1997 [M]; Harman, 1999 [R]; MN Clinical Comparison and Assessment Project, 1991 [R]; O'Driscoll, 1984 [C])*.

Management of protraction disorders includes *(Frigoletto, 1995 [A]; Lopez-Zeno, 1992 [A]; Sadler, 2000 [A]*:

- Evaluation of the potential causes:
  - Power: hypocontractile uterine activity is the most common cause of first stage of labor abnormalities. Adequate contractions are defined as a minimum of 200 Montevideo units in 10 minutes.
  - Passenger: check for malposition, malpresentation, macrosomia.
  - Passageway: is pelvis adequate? Is there cephalopelvic disproportion?

Consider:

- IV fluids (IV fluids 150 cc/hr may decrease the need for oxytocin augmentation) *(Garite, 2000 [A]*.
- Artificial rupture of membranes if membranes are intact and there are no contraindications. (See Annotation #11, "Intrapartum Care.")

  Amniotomy may be used to enhance progress in active labor (may decrease length of labor and decrease the need for oxytocin augmentation), but may increase the rate of maternal fever. First-stage amniotomy should be reserved for slowly progressing labors *(Fraser, 2000 [M])*.
- Discontinuing or reducing epidural anesthesia, as the use of epidurals has been shown to increase the length of labor. However, there is no increased rate of Caesarean birth for dystocia when epidural anesthesia is in use *(King, 1997 [R]; Rogers, 1999 [C])*.
- Oxytocin augmentation. The use of low-dose or high-dose dosing regimens has been shown to shorten labor by hours *(Hinshaw, 2008 [A]*.

  Contraindications to oxytocin augmentation include:

  - unknown presentation or floating/unstable,
  - patient refusal, and
  - inability to monitor contractions adequately.
- Obtain an obstetrical/surgical consult if necessary. Caesarean delivery is performed when there is an arrest of labor: patient has not made progress for two to four hours after strength of contractions deemed adequate (regardless of oxytocin dosage or duration of oxytocin).

Extending time of observation to four hours before operative treatment has been shown to decrease the Caesarean delivery rate for arrested labor *(Rouse, 2001 [A])*. Although studies of single aspects of "active" management of labor have not demonstrated a decrease in the rate of Caesarean delivery, an analysis of the literature suggests that some combination of active management techniques will lead to an overall decrease in the rate of Caesarean delivery *(Turner, 1988 [C])*.

71. Fetal Head Descent Greater than 1 cm/Hour?

When the patient has reached Stage II labor, a reassessment at least every 30 minutes for two consecutive hours is done to assess descent of the fetus and rotation of the fetus. If the patient is making appropriate progress, the caregiver can anticipate vaginal delivery. Fetal descent should be greater than 1 cm per hour.

If labor is not progressing, consider an internal monitor to measure strength of uterine contractions. After two hours of internal monitoring there should be enough evidence to determine if patient is making progress *(Harbert, 1992 [R])*.

Relative contraindications to direct, invasive monitoring include chorioamnionitis, active maternal genital herpes infection and HIV infection, certain fetal presentations and conditions that preclude vaginal examinations such as placenta previa or undiagnosed vaginal bleeding *(Association of Women's Health Obstetrics and Neonatal Nurses, 2003 [R])*.

73. Management of Protracted Labor

If the patient in Stage II labor is not making progress, management of protraction disorders will include:

- Evaluation of maternal and fetal position. Consider having the patient move into different positions.
- Oxytocin augmentation.
- Allowing fetus to "labor down." Do not start active pushing as soon as patient is fully dilated. Allow contractions to move the baby down *(Fraser, 2000a [A])*.
- Decreasing or stopping epidural anesthesia. Epidural anesthesia is associated with a prolongation of the second stage of labor and an increase in oxytocin use and assisted vaginal delivery *(Shields, 2007 [R])*.
- Evaluation of fluid balance may be beneficial for affecting labor progress *(American College of Obstetricians and Gynecologists, The, 2003 [R])*.
- Consideration of assisted delivery.
- OB/surgical consult if necessary.

(Minnesota Clinical Comparison and Assessment Project, 1991 [R]; Saunders, 1992 [B])

74. Is the Head Descending?

Prolongation of the second stage of labor beyond an arbitrary time limit is no longer an indication for assisted vaginal or Caesarean delivery. As long as progress is being made and fetal monitoring is reassuring, the patient can continue pushing *(Cheng, 2004 [A]; Myles, 2003 [B])*.

75. Assisted Vaginal Delivery Indicated?

If there is no descent for two hours despite optimizing labor, an assisted delivery or surgical consult is suggested. Vacuum extraction or mid/low forceps delivery contraindications include:

- vertex is too high,
- provider is inexperienced,
- fetal distress with inability to do timely operative vaginal delivery, and
- patient refusal.

Note: When using vacuum extraction or forcep application with a suspected macrosomic infant, be aware of the risk of shoulder dystocia.

(O'Driscoll, 1984 [C]; Rouse, 2001 [D]; Shields, 2007 [R])

Intrapartum Fetal Heart Rate (FHR) Monitoring Algorithm Annotations

78. Continuous EFM-ext or EFM-int (if needed)

Electronic fetal monitoring (EFM) is indicated in all high-risk situations and in low-risk situations when the auscultatory pattern is unclear or when 1:1 nursing staff is not available. Internal EFM may allow easier patient positioning and promote patient activity by being less confining than external EFM. Low-risk patients should be encouraged to be as active and mobile as possible.

80. FHR Pattern Is Predictive of Normal Acid-Base Status?

All obstetrical nurses, nurse midwives and physicians must achieve competence and confidence in fetal heart rate monitoring and FHR pattern analysis. Based on careful review of the available options, a three-tier system for the categorization of FHR patterns is recommended. Fetal heart rate tracing patterns can provide information on the current acid-base status of the fetus but cannot predict the development of cerebral palsy. Categorization of the FHR tracing evaluates the fetus at that point in time; tracing patterns can and will change *(Macones, 2008 [R])*.

Category of FHR Pattern Interpretation	**Baseline and Variability**	**Accelerations (15 x 15)**	**Decelerations**	**Interventions**
Category I: strongly predictive of normal fetal acid-base status	• BL 110-160 • Moderate variability	• Present or absent	+/- Early decels • **No** variable or late decelerations	No specific interventions required, ongoing assessment and evaluation.
Category II: Indeterminate. Not predictive of abnormal fetal acid-base status	• BL < 110 without absent variability • BL > 160 • Marked variability • Absent variability without decelerations	• Absence of accelerations after fetal stimulation	• Prolonged decelerations (≥ 2 minutes but < 10 minutes) • Recurrent late decels with moderate variability • Recurrent variable decels with minimal or moderate variability	Requires evaluation and continued surveillance. Review and take into account associated clinical circumstances.
Category III: Predictive of abnormal fetal acid-base status at the time of observation	• Absent variability and any of the following: • Recurrent late decels • Recurrent variable decels, • BL < 110 • Sinusoidal pattern			Prompt evaluation and management indicated. May include: • Maternal position change • Maternal oxygen • Discontinuation of labor stimulus • Treatment of possible underlying condition • Expedited delivery

Developed by the guideline committee.

Source: American College of Obstetricians and Gynecologists, The, 2005 and Macones, 2008

Definitions:

Late decelerations

- Deceleration is delayed in timing, onset-to-nadir if the deceleration is 30 seconds or greater, and there is a gradual decrease and return to baseline.

Early decelerations

- Onset, nadir and recovery mirror the beginning, peak and ending of the contraction.

Variable decelerations

- Abrupt decrease in the FHR with onset to nadir of deceleration reached in less than 30 seconds, decrease in FHR is 15 seconds or greater and less than two minutes in duration.

Variability

- Fluctuations in the FHR baseline over a 10-minute window, accelerations and decelerations are not included in the range.
- Absent - amplitude range is undetectable.
- Minimal - amplitude range is between 2 beats per minutes (bpm) and 5 bpm.
- Moderate - amplitude range is between 6 bpm and 25 bpm.
- Marked - amplitude range is greater than 25 bpm.

Recurrent

- Decelerations that occur with 50% or greater of uterine contractions in any 20-minute window.

Sinusoidal pattern

- Cyclic, smooth, sine wavelike undulating pattern in the FHR baseline frequency cycle of 3-5 per minute that persists for 20 minutes or longer.

(American College of Obstetricians and Gynecologists, The, 2005 [R]; Macones, 2008 [R])

82. Assessment and Remedial Techniques

A persistent Category II or Category III FHR tracing requires evaluation of the possible causes. Initial evaluation and treatment may include:

- discontinuation of any labor stimulating agent;
- cervical examination to assess for umbilical cord prolapse or rapid cervical dilation or descent of the fetal head;
- changing maternal position to the left or right lateral recumbent position, reducing compression of the vena cava and improving uteroplacental blood flow;
- monitoring maternal blood pressure level for evidence of hypotension, especially in those with regional anesthesia (if present, treatment with ephedrine or phenylephrine may be warranted);
- assessment of patient for uterine hyperstimulation by evaluating uterine contraction frequency and duration; and
- amnioinfusion – indications for therapeutic amnioinfusion include repetitive severe variable decelerations and prolonged decelerations *(Fraser, 2005 [A]; Miyazaki, 1985 [A]; Rinehart, 2000 [A])*. Amnioinfusion for thick meconium is no longer recommended.

(American College of Obstetricians and Gynecologists, The Practice Bulletin, 2005 [R])

86. Further FHR Assessment Predictive of Normal Acid-Base Status?

Obtain obstetrical or surgical consultation or referral where needed to plan for operative delivery if the FHR pattern is Category III. Category III tracings are predictive of fetal academia. Consider contacting a neonatology team to plan for possible neonatal intervention.

Scalp stimulation or vibroacoustic testing may be used for further fetal assessment. A 15-beat-per-minute rise in FHR lasting 15 seconds from the beginning to the end of the acceleration in response to scalp stimulation or to vibration or sound is predictive of normal fetal acid-base status. If the scalp stimulation test or vibroacoustic test response is abnormal, immediate delivery is indicated.

Other tests to assess fetal acid-base status may be helpful if available. This includes fetal scalp sampling for PH. A scalp pH greater than 7.19 is a positive result *(Skupski, 2002 [M]; Smith, 1986 [D])*.

However, proper FHR pattern interpretation and the response to scalp stimulation or vibroacoustic stimulation can allow the clinician to detect tracings predictive of abnormal feta acid-base status.

Knowledge of the fetal oxygen saturation is not associated with a reduction in the rate of Caesarean delivery or with improvement in the condition of the newborn *(Bloom, 2006 [A])*.

87. Emergent Delivery

Tracings predictive of abnormal fetal acid-base status (Category III) indicate the need for emergent delivery. Delivery should be affected by appropriate means, depending on the clinical situation. This may include vacuum extraction, forceps or Caesarean delivery, depending upon fetal presentation and the expertise of the attending physician(s).

Caesarean delivery should be performed if vacuum extraction or forceps are inappropriate for use.

If a Caesarean delivery is performed, the suitability of a VBAC in a subsequent pregnancy should be discussed with the patient.

The following are indications for Caesarean birth based on abnormal FHR monitoring, according to the Minnesota Clinical Comparison and Assessment Project:

- Late decelerations that comprise the majority of contractions over a minimum 20-minute period in the absence of adequate beat-to-beat variability and that do not respond to remedial techniques.
- Severe variable decelerations that comprise the majority of contractions over 20-60 minutes and that do not respond to remedial techniques.
- Severe persistent non-remediable bradycardia.
- Scalp pH less than 7.2 or negative FHR acceleration test (confirmation in 15-20 minutes recommended).
- There may be other combinations or non-remediable patterns that may not meet severity criteria listed above that may be indications for preparation for Caesarean birth. A scalp pH or FHR acceleration test (scalp or acoustic) may help clarify the issue. Consultation or second opinion is suggested.
- In the second stage of labor, depending on the judgment and skill of the physician, operative vaginal delivery may be the least hazardous for the mother and child.

If one-minute APGAR is less than three, or five-minute APGAR is less than six, cord pH or gases are recommended. Cord pH is a better indicator than APGAR for fetal compromise. A segment of umbilical cord is isolated with clamps and may be stored up to 60 minutes after delivery with reliable umbilical artery pH determination. The segment does not need to be heparinized or placed on ice *(Duerbeck, 1992 [D]; Johnson, 1993 [D])*.

Appendix A – Patient Education Handout

ACTIVE MANAGEMENT OF LABOR

Is active management of labor for you?

This is for you if you are going to be giving birth for the first time, you are healthy and are within three weeks of your due date, and the baby is in the usual head-down position.

This is not for you if you have delivered a baby before, or if you are having your labor induced (started) in the hospital, or if you are expecting more than one baby.

Why is active management of labor used?

Active management of labor is a method of intervention that prevents labor from lasting too long. Prolonged labor increases a woman's risk of exhaustion, infection, hemorrhage after delivery and need for Caesarean delivery.

Recent studies in both the United States and abroad have demonstrated clear benefits of this intervention. Active management of labor does not cause any increased risks to the baby.

How is active management of labor used?

It begins when you are admitted to the hospital in labor, and you are having regular contractions at least every five to seven minutes. When your cervix is effaced (thinned out) and dilated to 3 centimeters or more, your care provider will check if your membranes have ruptured (water has broken). If not, the membranes will be opened unless the baby's head is too high. This procedure is known as an "amniotomy." The amniotic fluid will then start to leak out. This procedure may be enough to keep your labor progressing and prevent it from lasting a long time.

During your labor, you will need to have a vaginal exam every two hours or so to check your progress. If your cervix continues to dilate at least one centimeter or more per hour, your labor is making normal progress.

If your labor progress stalls and your cervix changes too slowly (less than 1 centimeter in two hours), your labor will be augmented with a medication, oxytocin.

Oxytocin (Pitocin) Augmentation

Pitocin is a synthetic hormone that helps to increase the strength of the contractions and make them more effective. It is given through an intravenous (IV) drip and the amount is carefully monitored.

A fetal monitor will be used to follow the baby's heartbeat and record the contractions.

You will still be able to move around and change positions for your own comfort. You can certainly also receive pain relief as needed.

Failure to Progress

If following this labor management plan does not progress to vaginal delivery, you will need a Caesarean delivery. Active management does not increase your chances of failure to progress; however, it can shorten the time between the beginning of your labor and when the decision is made for a Caesarean delivery. This can help in your recovery from surgery.

The third stage of labor (delivery of placenta)

Following delivery of the baby, oxytocin can be given to help your uterus contract to deliver the placenta and control bleeding. This can be given through your intravenous drip (if you have one) or as a shot. Studies have shown that this management reduces the rate of heavy bleeding after delivery, anemia (low iron in the blood) and the need for blood transfusion.

How do women like active management of labor?

Many women like having an idea of knowing how long their labor will last and knowing that it will not last too long. After delivery, they have more energy to enjoy their baby and to get breast-feeding off to a good start.

This information is meant to enhance but not replace what you learn in childbirth education classes. Childbirth education classes are highly recommended.

Please discuss further questions with your pregnancy care provider during your prenatal visits.

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Original Work Group Members

The Management of Labor guideline is the result of merging the Preterm Birth Prevention (Preterm), Intrapartum Fetal Heart Rate Monitoring (IFHRM), The Prevention, Diagnosis and Treatment of Failure to Progress in Obstetrical Labor (FTP), and Vaginal Birth after Caesarean (VBAC) guidelines.

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Brief Description of Evidence Grading System

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 ø 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 **+**, **–**, **ø**, 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;

ø 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 #20 (Bacterial Vaginosis)

Work Group's Conclusion: Treatment of bacterial vaginosis infection in pregnant women at high risk for preterm delivery by traditional seven-day courses of therapy early in pregnancy appears to reduce preterm delivery.

Conclusion Grade: II

Work Group's Conclusion: The evidence regarding treatment of low-risk, pregnant women with asymptomatic bacterial vaginosis is limited by use of inadequate therapy in the available studies.

Conclusion Grade: Grade Not Assignable

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Morales, Schorr, & Albritton (1994)	RCT	A	0	-Women with a singleton gestation at 13-20 weeks; preterm delivery in preceding pregnancy; positive for BV; no evidence of trichomona infection -Excluded: congenital anomalies; significant maternal complications; documented cocaine use; incompetent cervix likely; prior documented intra-amniotic or urinary tract infection resulting in preterm birth; 2nd trimester bleeding, asymptomatic bacteriuria on initial screen -Randomized to receive 250 mg metronidazole (3X/day for 7 days) or vitamin C tablet -Patients in PTL received IV magnesium sulfate and, if that failed, oral indomethacin (maintained on oral terbutaline)	-94 enrolled: 14 subsequently excluded from analysis (5 lost to follow-up, 6 failed to complete treatment, 3 required treatment for renal or pulmonary disease) -44 of the remaining 80 were treated with metronidazole, 36 with placebo -Groups were similar at baseline in age, parity, race, smoking status, spontaneous abortions, preterm births, outcome of penultimate pregnancy, first trimester bleeding -Metronidazole group had fewer hospital admissions for preterm labor, fewer with >1 hospital admission, fewer with gestational age at delivery of <37 weeks, fewer with birth weight <2500g, and fewer with PROM (all p<0.05)	-In a very high-risk group of patients with a premature delivery in the preceding pregnancy, the treatment of bacterial vaginosis and perhaps elevated vaginal pH in the second trimester would result in a substantial reduction of recurrent preterm births from either idiopathic preterm labor or PROM. NOTES: did sample size estimation – with 40% risk of prematurity, a sample size of 45 per group was needed to detect at least a 40% reduction in prematurity with 80% power at 0.05 level

Author/Year	Design Type	Class	Quality +,–,Ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
McGregor, et al. (1995)	Non Random	C	Ø	-Women initiating prenatal care -Phase I-observation: 7 months, women examined for panel of lower reproductive tract microorganisms & selected vaginal enzymes at 1st prenatal visit, 22-29 wks gestation, after 32 wks gestation; treatment provided for *N. gonorrhea*, *C. trachomatis*, syphilis, & urinary tract infection; no treatment unless complaints or symptoms for BV, *T. vaginalis*, and yeast -Phase II: 8 months; identical screening and sampling, treatment for *N. gonorrhea*, *C. trachomatis*, *T. vaginalis*, BV, yeast & group B streptococcal bacteriuria -Treatment of BV was clindamycin (300 mg orally 2X/day for 7 days)	-614 enrolled in Phase I, 640 in Phase II; analysis based on 559 in Phase I, 579 in Phase II (see NOTES) -Phase I and II groups were similar in age, ethnicity, marital status, medical history, smoking, drug use & antenatal factors; BV was present in 31% of Phase I and 34% of Phase II patients -Spontaneous abortions at <22 wks occurred in 2% of Phase I and 3% of Phase II patients; associated with BV at enrollment (RR=3.1, 95%CI: 1.4-6.9) -Preterm birth in 13% of Phase I and 10% of Phase II patients (NS) but rate of preterm birth after idiopathic preterm labor was reduced in Phase II (RR=0.48; 95%CI: 0.27-0.88) -Birthweights and rates of preterm birth after PROM or for medical complications did not differ -Phase I: BV associated with increased risk of preterm birth (RR=1.9; 95%CI: 1.2-3.0) & preterm PROM (RR=3.5; 95%CI 1.4-8.9) -Phase II patients had reduced rates of preterm birth (vs. Phase I, p=0.02) -In Phase I (risk of preterm birth), with *T. vaginalis* only, RR=1.4; with BV only, RR=2.1; with *T. vaginalis* and BV, RR=3.3 -Treatment of BV (phase II) reduced risks of preterm birth (25%) to rates similar to those among BV-negative women with a prior preterm birth -Multiple logistic regression indicated that BV (OR=1.6; 95%CI: 1.1-2.4) was associated with risk of preterm birth -Oral clindamycin was effective for 93% of women with BV at the 2-4 wk follow-up	-Women with BV had increased occurrences of spontaneous pregnancy loss, preterm PROM, idiopathic preterm birth, and overall preterm birth. Systematic clinical screening and standardized treatment of women with BV were associated with a 50% reduction in both preterm birth and preterm PROM. NOTES: did sample size estimation – with preterm birth rate of 13%, estimated that 564 women would need to be studied in each phase to detect a 50% reduction in the rate of preterm birth with power of 80% at 0.05 level; excluded those with no pregnancy outcome data; also excluded 3 who had therapeutic abortions (Phase I), 1 nonpregnant woman (Phase II), women with multiple gestations (4 Phase I, 13 Phase II); lost or excluded patients differed from those in final analysis in ethnic group, 1st trimester bleeding, report of trauma or injury during pregnancy, earlier enrollment for prenatal care

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
McDonald, et al. (1997)	RCT	A	–	-Screened for BV flora (*G. vaginalis*) and BV at 16-26 weeks at 4 South Australia perinatal centers; asymptomatic women were invited to enroll -Randomized to placebo or oral metronidazole (400 mg, 2X/day for 2 days) -Excluded: multiple pregnancy, < 17 yrs old, *in vitro* fertilization, allergy to metronidazole, symptomatic BV, ruptured membranes, cervical cerclage, insulin-dependent diabetes, placenta praevia, antibiotic tx for vaginitis in past 2 wks, language difficulties, unable to attend clinic after 4 wks of tx	-9,407 were screened; 2,490 were positive; 1,734 were eligible for enrollment; 879 (51%) were enrolled -439 received metronidazole; 440 received placebo -Groups similar at baseline in race, maternal age at enrollment, low socioeconomic status, primigravida, previous preterm birth, gestation; more <20 yrs at enrollment in placebo group ($p<0.01$) -Compliance 81% in treatment group, 83% in placebo group; 189 in treatment group and 236 in placebo group took second course of treatment; 11 in treatment group and 16 in placebo group became symptomatic (& given a 7-day course of treatment) -Cumulative efficacy of metronidazole for treatment of BV was 75% -Preterm birth (<37 wks) in 7.2% of metronidazole group and 7.5% of placebo group; for spontaneous preterm birth, values were 4.7% and 5.6%; for PROM, values were 2.8% and 3.3% -In subset of 480 women with BV only – no difference in preterm birth rate, spontaneous preterm birth rate or PROM rate -In subset of 46 women with previous preterm birth, metronidazole group had lower rate of spontaneous preterm birth (OR=0.14, 95%CI: 0.01-0.84) -No differences in numbers of infants requiring ICU admission or duration of nursery stay -No difference in reporting of side effects	-Metronidazole treatment of women with a heavy growth of *G. vaginalis* or BV did not reduce the preterm birth rate. Among women with previous preterm birth, treatment reduced the risk of spontaneous preterm birth. NOTES: attempted to do screening at 18 wks, enroll at 24 wks, test-of-cure at 28 wks, second course at 29 wks (if needed), and follow-up at 32-36 wks (unless delivery already occurred); did sample size estimation – with expected 38% higher preterm birth rate than overall population, 1,328 women were needed; an interim analysis at 879 women indicated that the difference in preterm birth rate was lower than expected requiring a sample size 10 times larger (not feasible); with 879 enrolled, 26% power to detect a 38% reduction spontaneous preterm birth rate; analysis was by intention to treat *Work Group's Comments: the screening was done later in the pregnancy than recommended and the metronidazole dose was lower than the recommended dose of 250 mg orally, 3X/day, for 7 days*

Author/Year	Design Type	Class	Quality +,−,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Carey, et al. (2000)	RCT	A	0	-Screened women between 8 wks and 22 wks, 6 days of gestation for BV and *T. vaginalis* -Excluded: symptoms of BV; allergy to metronidazole; abuse of ethanol; antibiotic therapy in past 14 days; intention to receive future care at different location; current or planned cervical cerclage or tocolytic therapy; preterm labor before screening; fetal death or life-threatening anomaly; multifetal gestation; medical illness requiring extensive drug therapy -Randomized those with BV only and pregnancies between 16 wks and 23 wks, 6 days -Randomized to 2g metronidazole or placebo (2 doses 48 hrs apart); follow-up at 24 wks to 29 wks, 6 days with second treatment (2 doses) regardless of test results	-21,965 were screened; 6,540 had BV only; 1,953 were randomized -Compliance monitored after 1st 3 doses only – 79% of metronidazole group and 82% of placebo had taken the full dose; 90% returned for follow-up visit -Outcome data available for 98%: no difference in frequency of delivery at <37 wks gestation (or delivery before 35 or 32 wks); no differences with regard to low birth weight, very low birth weight, or preterm delivery attributable to spontaneous labor or spontaneous rupture of the membranes -Of those with follow-up testing, 22% in metronidazole group and 63% in placebo group still had BV -No difference in admissions to hospital for preterm labor or preterm PROM, receipt of tocolytic drugs, vaginal infections requiring treatment, clinical intraamniotic infection or postpartum endometritis -No difference in passage of meconium, fetal death or neonatal death, admission to NICU or presence of neonatal sepsis	-Treatment of asymptomatic BV with metronidazole did not reduce the risk of preterm delivery in women at low risk for preterm delivery or women with a history of preterm delivery. NOTES: short course of treatment was chosen to improve compliance *Work Group's Comments: the screening was done later in the pregnancy than recommended and the metronidazole dose was lower than the recommended dose of 250 mg orally, 3X/day, for 7 days*

Conclusion Grading Worksheet B – Annotation #66 (Management of Protracted Labor)

Work Group's Conclusion: Active management of labor does not reduce the rate of Caesarean delivery but may decrease the length of labor and increase patient satisfaction in nulliparas.

Conclusion Grade: II

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Naiden & Deshpande (2001)	Case Series	D	–	-Delivery statistics for 10-yr period as obtained from birth logbook; prior to data collection period staff agreed with goal of fewer operative deliveries; those with higher rates reviewed literature; each provider given own delivery statistics -Staff also agreed on protocols* for active management of labor -VBAC was encouraged -Nursing staff maintained birth logbook (maternal information and complications, labor information, fetal information); data also collected on Caesarean delivery rate for 5 yrs prior to study -Neonatal morbidity: birth trauma, presence of thick meconium, low APGAR score (<6 at 5 min), perinatal death	-27,780 deliveries in 10 yrs; 3,186 were Caesarean -Risk factors for Caesarean stable throughout study period (% of nulliparous births, age <19 yrs, age >35 yrs, multiple gestations, birth weight <2,500 g, birth weight >4,000 g, gestational age <37 wks, gestational age >41 wks) -% Medicaid deliveries remained at approximately 66%; % of Hispanic-surname patients increased from 35% in 1989 to 50% in 1998 -Caesarean delivery rates: **1989 1998** Total 16.6% 10.9% Primary 9.2% 7.1% Repeat deliveries 7.4% 3.8% Nulliparous 16.4% 11.9% Multiparous 16.8% 10.5% -Significant decrease in rate of Caesarean delivery for cephalopelvic disproportions ($p<0.001$); decreases for other indications were not significant -Significant increases ($p<0.001$): oxytocin use, instrumented vaginal delivery, and epidural anesthesia -No significant changes in neonatal morbidity rate, perinatal and neonatal mortality rates, or number of stillbirths	-In 10-year study period, Caesarean delivery rates were lowered significantly while not adversely increasing indicators of perinatal morbidity or death. Most of the reduction was due to increasing the active management of labor and to encouraging VBAC deliveries. NOTES: *protocol called for oxytocin infusion only under supervision of attending physician; only allowed nurses with experience in labor and delivery and assessment of fetal heart rate patterns and initial management of abnormal patterns to practice the protocol

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Sadler, Davison, & McCowan (2000)	RCT	A	0	-Included: nulliparous; singleton pregnancy, no severe cardiac disease, no uterine scar, no proven contracted pelvis -Excluded: induced labor; noncephalic presentation; gestation <37 wks, abnormal cardiotocography or thick meconium, elective Caesarean; intrauterine death, multiparity -Randomized to active or routine mgmt of labor -Active mgmt group encouraged to have amniotomy at diagnosis of labor; cervical assessment every 2 hrs; oxytocin if progress delayed; no protocol for routine mgmt -Did meta-analysis of 4 studies of active vs. routine mgmt (including present study)	-320 randomized to active mgmt and 331 to routine; no differences at baseline; more women in the active mgmt group had amniotomy (72% vs. 63%; p<0.05) and at lower dilatation (5.1 cm vs. 5.7 cm; p=0.006); oxytocin used more commonly (53% vs. 39%; p<0.05) and at higher doses (p=0.0001) in active mgmt group; no difference in epidural rates or number receiving one-to-one midwifery -Labor reduced by 50 min in active mgmt group (for vaginal deliveries); reduction in first stage of labor only; 5% of active mgmt group had prolonged labor (vs. 12% of routine mgmt; p<0.05) -Caesarean delivery rates did not differ (9% active mgmt, 10% routine mgmt); adjustment for age, ethnicity, gestational age, birth weight, epidural use, and dilatation at randomization did not alter odds of Caesarean delivery (unadjusted & adjusted ORs=0.97) -Newborn outcomes did not differ -Maternal satisfaction with labor care did not differ -40% of active mgmt patients did not adhere to ≥1 aspect of protocol -Meta-analysis showed no reduction in Caesarean rate with active mgmt (OR=0.93; 95%CI:0.8-1.08)	-Active management of labor reduced the duration of the first stage of labor without affecting the rate of Caesarean section, maternal satisfaction, or other maternal or newborn morbidity. NOTES: labor was defined as contractions occurring at least once every 5 mins; lasting ≥40 sec, with spontaneous rupture of membranes or full effacement of cervix and dilatation of ≥2 cm; did sample size estimation – 320 per arm of study to detect reduction in Caesarean rate from 18% to 10% with power=80%; alpha=0.05

Author/Year	Design Type	Class	Quality +,−,Ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Fraser, Turcot, Krauss, Brisson-Carrol (2000)	Systematic Review	M	**N/A**	-Included: 9 randomized trials comparing routine amniotomy to an attempt to conserve the membranes; categorical data available on major indicators of maternal & neonatal morbidity; acceptable methodological quality, no evidence of systematic error in randomization or follow-up processes; women in spontaneous labor	-5 trials were nulliparous women only; 4 were mix of nulliparous and multiparous -Use of oxytocin varied in studies (heterogeneity) -Early use of amniotomy leads to an average reduction of labor duration of 60-120 minutes; length of labor (from randomization to delivery) was significantly reduced by 54 minutes in early amniotomy group (NOTE: data from 3 studies) -Incidence of dystocia was reduced in the amniotomy group (OR=0.63) (NOTE: data from 1 study) -Trend toward increased risk of Caesarean with early amniotomy	-Amniotomy is an effective method to shorten labor duration and reduce the frequency of oxytocin administration. There was no evidence of adverse neonatal consequences. It would seem reasonable to reserve amniotomy for labors that are progressing slowly. NOTES: studies were done in centers where a large proportion of mothers received epidural anesthesia; compliance with the conservative approach was low
Rouse, Owen, & Hauth (1999)	Case Series	D	Ø	-Women ≥36 wks gestation with 1) spontaneous active phase labor (dilatation ≥4 cm, at least 2 contractions in 10 minutes) & 2) labor arrest (≤1 cm cervical progress in 2 hrs) -Excluded: nonvertex presentation; previous Caesarean delivery; multiple gestation; nonreassuring FHR tracing, chorioamnionitis, or spontaneous contractions ≥250 Montevideo units at time of labor arrest -Oxytocin administered at diagnosis of active-phase labor arrest; Caesarean delivery for labor arrest done after 4 hrs of oxytocin with sustained contraction pattern >200 Montevideo units or 6 hrs oxytocin regardless of contraction pattern	-542 eligible: 288 (53%) nulliparous, 254 (47%) parous; groups were similar demographically -Vaginal delivery rate 92% overall (97% for parous group, 88% for nulliparous) -Vaginal delivery rates among those with no progress after 2 hrs of oxytocin: 91% for parous group, 74% for nulliparous group -Vaginal delivery rates among those with no progress after 4 hrs of oxytocin: 88% for parous group, 56% for nulliparous group -No uterine rupture or hysterectomy; rates of chorioamnionitis (10%) and endometritis (5%) were higher for nulliparas than parous women (both 2%); labor progress (or lack thereof) correlated with risk of maternal infectious complications -No stillbirths or neonatal deaths; complications did not differ based on whether there was labor progress, no progress, or no examination -42 Caesarean deliveries (24 labor arrest, 10 non-reassuring fetal status, 8 both labor arrest and non-reassuring status)	-The management protocol used in this study resulted in a high rate of vaginal delivery (92%) with no severe adverse maternal, fetal or neonatal outcomes. Extending the minimum period of oxytocin augmentation for active-phase labor from 2 to at least 4 hours was effective and safe. NOTES: oxytocin dose was one mμ/min increased every 15 min over 2 hrs to 30mμ/min; 93% received continuous lumbar epidural analgesia

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Lavender, Alfirevic, & Walkinshaw (1998) Lavender, Wallymahmed, & Walkinshaw (1999)	RCT	A	0	-Primigravidas with uncomplicated pregnancies; spontaneous labor at term; singleton cephalic presentation -Randomized to have progress of labor recorded on a partogram with an action line at 2, 3 or 4 hrs; prolonged labor defined as progress reaching action line; obstetric intervention (amniotomy and oxytocin if membranes intact; oxytocin only if membranes ruptured) triggered by action line -Questionnaire given on second postnatal day to 618 patients randomized in first year of study	**-From 1998 reference:** -928 women randomized -Caesarean delivery rates: 11.1% for 2-hr group, 14.2% for 3-hr group, & 8.4% for 4-hr group; significant difference ($p<0.05$) between 3 and 4 hrs -Women in 2 hour group more satisfied with their labor than ($p<0.00001$ vs. 3 and 4 hours) **-From 1999 reference:** -Data from 519 who returned questionnaire (86.5% response); response rates similar in the 3 groups -No differences in intrapartum outcomes except action line crossed for 50% of 2-hr group and 37% of 4-hr group ($p=0.02$) and intervention occurred in 46% of 2-hr group and 33% of 4-hr group ($p=0.02$); Caesarean delivery rate did not differ in this subgroup	-Women prefer active management of labor. Earlier intervention may be associated with higher Caesarean delivery rates. NOTES: questionnaires were completed and returned at the patient's convenience *Work Group's Comments: randomization was done by care providers in the labor and delivery unit; a commentary by Hannah (Birth 1999;26:97-98) noted non-significant differences between groups in % with dilatation <3 cm at randomization and epidural analgesic use*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Frigoletto, Lieberman, Lang, et al. (1995)	RCT	A	0	-3,028 nulliparous women eligible; 1934 (64%) agreed to participate and were randomized to active mgmt (n=1017) or usual care (n=917); data missing from 19 -Randomization before 30 wks gestation; eligible patients had no conditions associated with increased risk of preterm or Caesarean delivery -Both groups: fetal heart rate monitoring; access to pain relief -Active mgmt group: cared for in a separate unit by different staff; included 1-to-1 nursing care, standardized diagnosis of labor, and mgmt of labor (amniotomy within 1 hr of diagnosis, cervical exams at least every 2 hrs, oxytocin during either stage 1 or stage 2 of labor); in final protocol failure to progress was failure of normal progress of cervical dilatation or second stage of >2 hrs (>3 hrs if epidural catheter) -Usual Care Group: no constraints on physicians	-Intention-to-treat (ITT) analysis: all randomized -Protocol-eligible subgroup analysis: those medically eligible to receive treatment according to protocol at time of onset of labor -ITT analysis: data from 1915 patients; Caesarean rate was 19.5% in active mgmt group and 19.4% in usual care group; results unchanged when adjusted for baseline characteristics or epidural anesthesia use; Caesarean rates due to failure to progress were 7% in active mgmt and 8% in usual care groups -Subgroup analysis: a. 33% of the active mgmt group and 35% of the usual care group developed medical complications or had labor induced and were ineligible; the protocol-eligible subgroup included 678 in active mgmt and 585 in usual care; 633 in active mgmt group were treated according to protocol b. Groups did not differ at baseline c. Active mgmt group had more frequent vaginal exams, had membranes ruptured artificially more often (and earlier), were more likely to receive oxytocin, had higher maximal dose of oxytocin, requested epidural anesthesia less often ($p<0.05$) d. Overall rates of Caesarean delivery were similar: 10.9% in active mgmt group and 11.5% in usual care group (RR=0.9); for both groups, rate of Caesarean because of fetal distress was low (2.2% in active mgmt group and 1.2% in usual care group); shorter labor in active mgmt group (6.2 hrs vs. 8.9 hrs) e. Lower incidence of maternal fever in active mgmt group (RR=0.6); other complications were same for both groups; no differences in infants' outcomes	-The safety of an active management protocol was confirmed. No substantial decrease in the rate of Caesarean delivery was observed. NOTES: included all components of protocol for active mgmt of labor; implemented active mgmt with separate staff in a physically separate delivery unit; Hawthorne effect may have accounted for results (study focused on rates of Caesarean delivery so rate in usual care group may have been lowered)

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López-Zeno, Peaceman, Adashek, & Socol (1992)	RCT	A	0	-705 nulliparous women in spontaneous labor at ≥37 wks, excluded multiple gestation, noncephalic presentation and previous uterine surgery -Randomly assigned to either active or traditional management -Both groups: fetal heart rate monitored, freq. and intensity of contractions assessed by tokodynamometry; umbilical-cord arterial and venous blood obtained at delivery -Active mgmt group: amniotomy within 1 hr of diagnosis of labor (if membranes intact); cervical exams every hr for the first 3 hrs and then every 2 hrs; oxytocin if rate of dilation was <1 cm/hr in 1st stage of labor or if descent of head was arrested for 1 hr in 2nd stage -Trad. mgmt group: amniotomy, freq. of cervical exams, and criteria for inadequate progress were left to the physician; oxytocin was used for arrest of progress	-351 in active mgmt and 354 in traditional mgmt (control group); no differences in baseline characteristics; only difference in characteristics of labor was maximal dose of oxytocin (higher in active mgmt group, p<0.0001) -Outcomes: Active Mgmt Traditional Mgmt Caesarean Delivery 37 (11%) 50 (14%)* Vaginal Delivery 314 (90%) 304 (86%) *Difference was significant (p<0.05) after adjustment for potential confounding variables -Difference in Caesarean delivery rate was due primarily to a decrease in the frequency of arrest disorders -Difference was greater for patients of private physicians than for clinic patients (11% vs. 16%) -Only 4.6% of patients in active mgmt group had not delivered by 12 hours after admission compared to 18.9% in the traditional mgmt group (p<0.001) -No increase in complications of labor in active mgmt group; active management had greater percent of patients with oxytocin decreased or stopped (p<0.05) and lower percent of patients with chorioamnionitis (p<0.01) -No differences in neonatal outcomes based on arterial pH and other blood gas indexes, birth weight, APGAR score, NICU admissions, seizures, days in hospital; no increased morbidity in active mgmt cases	-Active management of labor in nulliparous patients was associated with a significant decrease in rate of Caesarean delivery with no detectable increase in maternal or fetal morbidity. NOTES: study only tested 3 components of active mgmt (early amniotomy, early diagnosis of inadequate progress, and use of oxytocin at higher doses than usual); study was unblended, which may have contributed to lower Caesarean rate in traditional mgmt group; study differs from other studies of active management in that prenatal patient education was not included, nurse-midwives were not used to manage labor, and use of conduction anesthesia was common *Work Group's Comments: did sample size estimation to determine that 700 patients would need to be studied to achieve a power of 80% for detecting a decrease in the rate of Caesarean delivery from 18% (expected with traditional management) to 11% (with active management)*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Boylan, Frankowski, Rountree, Selwyn, & Parrish (1991)	Non-Random/ Historical Controls	C	0	-3,900 births to nulliparous women; before and after introduction of AML program (two 6-month periods in each phase) -Eligible patients had vertex presentation, singleton pregnancy, and no evidence of fetal distress -Definitive diagnosis of labor within 1 hr of presentation -Attending MDs could exclude patients from AML but all patients were included in analysis -If membranes had not ruptured within 2 hrs of diagnosis, artificial rupture was done -Oxytocin was given if cervix failed to dilate at >1 cm/hr -Electronic fetal heart rate monitoring in all cases -If no delivery imminent within 12 hrs of admission considered doing CS; epidural anesthesia freely available -During control period, management was with existing methods	-Defined CS as due to dystocia when indication was failure to progress or cephalopelvic disproportion; also defined CS for fetal distress, breech presentation and "other" -Outcomes: Control Period (1,843 births) 1 2 Tot. % Caesarean 23 24 24 % Dystocia 57 58 % Forceps 36 % Spont. Vaginal 40 NOTE: 1 and 2 refer to 1st 6 mos and 2nd 6 mos -5.5% drop during AML period in incidence ($p<0.05$) of CS; 10% reduction in incidence of dystocia as an indication for CS ($p<0.05$) -33% of those with CS for dystocia were due to non-compliance with AML protocol; 32% were associated with induction of labor -No differences between control and AML periods for gestation and birth weight -Control: 1 intrapartum death, 1 neonatal death, 36 admitted to NICU, 8 neonatal seizure (4.3 per 1000) -AML: no intrapartum deaths, 1 neonatal death, 37 admitted to NICU, 4 neonatal seizure (1.9 per 1000) -Greater decrease among patients of University faculty than patients from HMO or private practice AML Period (2,057 births) 1 2 Tot. 20 18 19 48 46 30 51	-The incidence of CS for indication of dystocia in nulliparous women may be reduced by AML. NOTES: before-after design cannot isolate the effects of specific components of an AML policy *Work Group's Comments: did sample size analysis to detect at least a 20% relative decrease in incidence of CS between control and initial AML period with 90% power at p=0.05*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Turner, Brassil, & Gordon (1988)	Non-Random/ Historical Controls	C	–	-1000 consecutive nulliparous women in labor after 32 wks gestation with a cephalic presentation and a single, live fetus; labor confirmed -Progress of labor monitored by vaginal assessment every 2 hrs; progress in 1st stage measured by cervical dilatation; progress in 2nd stage measured by descent of head; failure to progress treated with oxytocin -Labor induced if necessary -Electronic fetal heart rate monitoring used routinely -Duration of labor was from time of admission to delivery suite in labor	-Mode of Delivery: Spontaneous Labor (n=614) Induced Labor (n=386) Total (n=1000) Normal 81% 71% 77% Low Cavity Forc. 13% 18% 15% Rotational Forc. 3% 3% 3% Caesarean 3% 9% 6% -2.5% had CS for dystocia; 3% for fetal distress; 0.3% for cephalopelvic disproportion; 0.2% for cord prolapse -There were no CS for dystocia after spontaneous onset of labor; 13 after induced labor -Oxytocin used during 1st stage for 31% and during 2nd stage for 13% -4% were in labor for >12 hrs -No intrapartum fetal deaths; 1 neonatal death due to congenital heart lesion; 1 death 11 days postpartum due to perinatal asphyxia (related to use of oxytocin despite fetal distress); no neonatal seizures -Compared to data from previous 4 years: fewer CS ($p<0.05$); fewer CS for dystocia ($p<0.05$); no increases in perinatal mortality	-Introduction of active management was associated with a 4 to 5% reduction in CS in nulliparous women with no evidence of increased perinatal mortality or morbidity. NOTES: compared data from the study period to data from previous 4 years – the data from the study period included data from patients who were not actively managed (68% of the deliveries during the study period were to women in active mgmt protocol)
Akoury, Brodie, Caddick, McLaughlin, & Pugh (1988)	Non-Random/ Historical Controls	C	–	-552 consecutive nulliparous women in spontaneous labor at ≥37 wks with no fetal distress on admission; labor was confirmed by objective findings -Progress of labor monitored by pelvic exam every 2 hrs -Oxytocin augmentation if cervix failed to dilate ≥1 cm/hr -Descent of head monitored in 2nd stage of labor -Continuous electronic fetal heart rate monitoring -Duration of labor was from when patient admitted herself to the labor suite	-Historical controls were 533 nulliparous patients admitted to the same facility in a similar time period prior to the study period; charts were reviewed with same inclusion/exclusion criteria as the study group -Outcomes (all $p<0.005$): Study Group Control Group Caesarean 24 (4%) 67 (13%) Forceps delivery 107 (19%) 155 (29%) Labor >12 hrs 37 (7%) 109 (20%) -Perinatal outcomes (APGAR score, NICU admission for >24 hrs, hyperbilirubinemia, meconium aspiration, cephalhematoma, seizures and mortality) were comparable in both groups; use of epidural analgesia was comparable (24% in study group and 26% in control group); only difference was in use of oxytocin (41% of study group and 16% of control group; $p<0.005$)	-Active management of labor in nulliparous women reduced the duration of labor, the use of forceps, and the rate of Caesarean deliveries (CS) with no increase in perinatal morbidity and mortality.

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 women with PTL and/or PTB who receive antenatal corticosteroids appropriately.

   Possible measures of accomplishing this aim:

   a. Percentage of mothers with PTL who were given appropriate antenatal corticosteroids during labor.

   b. Percentage of mothers with PTB who were given appropriate antenatal corticosteroids during labor.

2. Prevent unnecessary protracted labor with use of Management of Labor Dystocia algorithm and annotations and its methods.

   Possible measure of accomplishing this aim:

   a. Percent of women whose time from admission with active labor to evaluation of labor's progress is less than two hours.

3. Increase the use of procedures that assist in progress to vaginal birth.

   Possible measures of accomplishing this aim:

   a. Percent of women in the guideline population who have SROM or early amniotomy.

   b. Percent of women in the guideline population with failure to progress diagnosis who have oxytocin.

4. Increase the percentage of women who are assessed for risk status on entry to labor and delivery.

   Possible measure of accomplishing this aim:

   a. Percentage of women who are assessed for risk status on entry to labor and delivery.

5. Increase the use of remedial techniques that resolve temporary abnormal fetal heart tracing in labor.

   Possible measures of accomplishing this aim:

   a. Among those who had begun oxytocin and with abnormal FHR tracing, the percentage of births with discontinuance of oxytocin.

   b. Percentage of births with amnioinfusion when any of the following is present: thick meconium, repetitive severe variable decelerations or oligohydramnios.

6. Perform an appropriate evaluation for persistent abnormal heart rate tracing in labor before Caesarean.

   Possible measures of accomplishing this aim:

   a. Percentage of births with either scalp stimulation, scalp pH or vibroacoustic stimulation of those births with intervention for abnormal FHR tracing.

   b. Percentage of Caesarean deliveries.

Measurement Specifications

Possible Success Measure # 3a

Percent of women in the guideline population who have SROM or early amniotomy.

Population Definition

All women giving birth who are:

- full term (36 completed weeks),
- nullipara,
- without concomitant medical problems,
- having contractions,
- singleton fetus,
- cephalic presentation,
- no evidence of fetal distress, and
- expected to have a normal spontaneous vaginal delivery.

Data of Interest

$$\frac{\text{\# among the denominator with either SROM or early amniotomy}}{\text{\# of women giving birth included in the population definition above}}$$

Numerator/Denominator Definitions

Numerator: All births among denominator with no intact membrane at beginning of active labor. This is accomplished either by either SROM or amniotomy.

Denominator: All births by women who are covered in the guideline as described by: nullipara female, without concomitant medical problems, at term pregnancy (36 completed weeks), having contractions, singleton fetus, cephalic presentation, no evidence of fetal distress, expected normal spontaneous vaginal delivery.

Method/Source of Data Collection

Any one of several possible data collection methods may be used by the medical group to capture data for this particular population.

1. Data may be obtained retrospectively by a chart audit (using a minimum sample of 20 charts per month).
2. Data may be obtained through discharge abstract coding or other data base from the hospital.
3. The hospital may send the medical group a copy of the labor and delivery summary sheet for deliveries.
4. A copy of the nursing checklist form is sent to the medical group for data collection.

Data are reviewed to determine if the delivery fits the inclusion criteria for the measure. If no, the birth is not reviewed. If yes, the birth data are reviewed to assess if amniotomy or SROM occurred and whether oxytocin was used.

Time Frame Pertaining to Data Collection

It is suggested that these data are collected monthly.

Notes

This is the rate where the membrane is not present in active labor. The absence of membranes at the beginning of labor helps progress to vaginal birth. This rate should increase.

Possible Success Measure #3b

Percent of women in the guideline population with failure to progress diagnosis who have oxytocin.

Population Definition

All women giving birth who are:

- full term (36 completed weeks),
- nullipara,
- without concomitant medical problems,
- having contractions,
- singleton fetus,
- cephalic presentation,
- no evidence of fetal distress, and
- expected to have a normal spontaneous vaginal delivery.

Data of Interest

$$\frac{\text{\# of births with oxytocin among the denominator}}{\text{\# of births to guideline women with failure to progress diagnosis}}$$

Numerator/Denominator Definitions

Numerator: # of births of denominator where oxytocin is used.

Denominator: # of births to women covered in the guideline as described by: nullipara female, without concomitant medical problems, at term pregnancy (36 completed), having contractions, singleton fetus, cephalic presentation, no evidence of fetal distress, expected normal spontaneous vaginal delivery and diagnosis of failure to progress.

Method/Source of Data Collection

Any one of several possible data collection methods may be used by the medical group to capture data for this particular population.

1. Data may be obtained retrospectively by a chart audit (using a minimum sample of 20 charts per month).
2. Data may be obtained through discharge abstract coding or other data base from the hospital. Then the hospital can relay data for a medical group's deliveries.
3. The hospital may send the medical group a copy of the labor and delivery summary sheet for deliveries.
4. A copy of the nursing checklist form is sent to the medical group for data collection.

Data are reviewed to determine if the delivery fits the inclusion criteria for the measure. If no, the birth is not reviewed. If yes, the birth data are reviewed to assess if amniotomy or SROM occurred and whether oxytocin was used.

Time Frame Pertaining to Data Collection

It is suggested that these data are collected monthly.

Possible Success Measure #4a

Percentage of women who are assessed for risk status on entry to labor and delivery.

Population Definition

All women who present in labor.

Data of Interest

$$\frac{\text{\# of women who are assessed for risk status on entry to labor and delivery}}{\text{total \# of women whose medical records are reviewed}}$$

Numerator/Denominator Definitions

Numerator: # of women with evidence of assessment for risk status on entry to labor and delivery to include:

- 20-minute fetal heart rate (FHR) assessment,
- patient assessment,
- prenatal risk review, and
- risk in labor assessment.

Denominator: # of women who present in labor.

Method/Source of Data Collection

Any one of several possible data collection methods may be used by the medical group to capture data for this population.

1. Data may be obtained retrospectively by a chart audit (using a minimum sample of 20 charts per month) of all women presenting in labor.
2. Data may be obtained through discharge abstract coding or other data base from the hospital.
3. The hospital may send the medical group a copy of the labor and delivery summary sheet.

Time Frame Pertaining to Data Collection

Suggested time frame for data collection is monthly.

Notes

Risk assessment should be performed on all patients in active labor and is the responsibility of all members of the health care team. That includes, but is not limited to nurses, midwives and physicians.

Possible Success Measure #5b

Percentage of births with amnioinfusion when either of the following is present: thick meconium or repetitive severe variable decelerations or oligohydramnios.

Data of Interest

$$\frac{\text{\# of women who have amnioinfusion}}{\text{\# of women giving birth who have one or more of the following present: thick meconium and repetitive severe variable decelerations and/or prolonged decelerations}}$$

Numerator/Denominator Definitions

Numerator: # of eligible births with amnioinfusion.

Denominator: # of births having one or more of the following present: thick meconium, repetitive severe variable decelerations or oligohydramnios. In the case of multiple births at a delivery, the birth event is counted once.

Method/Source of Data Collection

Any one of several possible data collection methods may be used by the medical group to capture data for this population.

1. Data may be obtained retrospectively by a chart audit (using a minimum sample of 20 charts per month as defined by denominator above.)
2. Data may be obtained through discharge abstract coding or other data base from the hospital.
3. The hospital may send the medical group a copy of the labor and delivery summary sheet.
4. A copy of the nursing checklist form is send to the medical group for data collection.

Data are reviewed to determine if the delivery fits the inclusion criteria for the measure. If no, the birth is not reviewed. If yes, the birth data are reviewed to assess whether an amnioinfusion was performed.

Time Frame Pertaining to Data Collection

These data will be collected monthly.

Notes

Amnioinfusion for fetal stress may be performed if operative delivery is contemplated. It is expected that the amnioinfusion rate will increase.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Management of Labor 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/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

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

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American College of Obstetricians & Gynecologists (ACOG)	Preterm Labor (pamphlet 1999)	Public	1-800-762-2264 AP087
	American College of Obstetricians & Gynecologists (ACOG)	OB/GYN topics	Professionals	http://www.acog.org
	American College of Obstetricians & Gynecologists (ACOG)	Vaginal Birth After Caesarean (pamphlet)	Public	1-800-762-2264 #AP070
	American College of Obstetricians & Gynecologists (ACOG)	Fetal Heart Rate Monitoring During Labor (pamphlet)	Public	1-800-762-2264 x830; #18015
	March of Dimes	Includes downloadable fact sheets on a wide variety of topics related to healthy pregnancy and delivery of healthy babies. Fact sheets include prenatal nutrition, healthy lifestyle before, during and after pregnancy, and prevention of birth defects. Q & A option.	Public & Professionals	http://www.marchofdimes.com Toll-free number also available for direct contact with the March of Dimes: 1-888-MODIMES (663-4637)
	March of Dimes	Preventing Preterm Labor	Public	1-800-367-6630 #09-754-00
	March of Dimes	Premature Labor: A Teaching Guide	Public	1-800-367-6630 English #33-205-03 Spanish #33-205-04
	March of Dimes	Learn the Signs of Preterm Labor (flyer)	Public	1-800-367-6630 English #09-1099-98; Spanish #09-1100-98
	Mayo Clinic	Includes alphabetical listings of conditions as well as search capabilities for information on specific areas of health care including many aspects of prenatal care.	Public	http://www.mayoclinic.com
	National Women's Health Information Center/Office of Women's Health, U.S. Dept. of Health and Human Services	Provides information on many pregnancy-related topics including nutrition and fitness, prevention of birth defects and complications of pregnancy, and financial assistance. Also provides information on preparing for childbirth and tips on caring for a newborn. In English and Spanish.	Public	http://www.womanshealth.gov/pregnancy Call 1-800-994-Woman (1-800-994-9662) or 1-888-220-5546 for the hearing impaired.

* Available to ICSI members only.