

Optimizing Protocols in Obstetrics

OXYTOCIN FOR INDUCTION



SERIES 1

ACOG

THE AMERICAN CONGRESS
OF OBSTETRICIANS
AND GYNECOLOGISTS

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Oxytocin for Induction

Dear ACOG District II Member:

This past January, the American Congress of Obstetricians and Gynecologists (ACOG), District II asked for you to submit your hospital's protocol for use of oxytocin for labor augmentation. First and foremost, we thank you for your submission; since then, ACOG has received over 90 hospital protocols. In addition to oxytocin use, the Committee has collected protocols on managing massive obstetrical hemorrhage, hypertensive crisis and shoulder dystocia. The Committee has since divided into four subgroups and while still in the review phase with some of the protocols, it is now in a position to begin offering effective tools and resources on completed and reviewed protocols.

We are pleased to update you on our Patient Safety and Quality Improvement (PSQI) Committee's progress thus far and hope your hospital will partner to improve safety as it relates to the use of oxytocin for labor augmentation. Rather than create a sample protocol, the PSQI Committee's goal was to identify existing protocols that hospitals could adapt to meet their specific needs and resources. Additionally, the committee identified a number of key elements that all oxytocin protocols should include and/or consider. By providing educational materials such as key elements, assessment tools and fundamental criteria, together we can help improve quality to further reduce adverse maternal and neonatal outcomes.

Although many of the protocols received were well written and met the needs of their institution, three protocols were particularly meritorious. The Committee has chosen and enclosed the oxytocin protocols from Community General Hospital, University of Rochester School of Medicine and Nathan Littauer Hospital. In addition to the three selected protocols, enclosed you will find:

- Oxytocin Executive Summary
- Key Elements for the Use of Oxytocin
- Induction of Labor Scheduling Form & Checklist
- ACOG Practice Bulletin # 107
- HCA Checklist

The PSQI Committee strongly encourages you to utilize the enclosed materials and work with your medical team to review your existing oxytocin policies and procedures, and modify them if necessary to fit your hospital environment.

The District II PSQI Committee will continue developing assessment tools for each of the topic areas mentioned above. If you have any questions regarding the enclosed materials, please contact Donna Montalto, ACOG District II Executive Director, at 518-436-3461 or at dmontalto@ny.acog.org.

Sincerely,



Richard L. Berkowitz, MD, FACOG
Co-Chair, PSQI Committee
ACOG District II



Peter Bernstein, MD, FACOG
Co-Chair, PSQI Committee
ACOG District II

RB/PB/kg

Enclosures

Executive Summary

Twenty three hospitals throughout New York State responded to a request from ACOG District II to submit their protocols regarding the use of oxytocin for induction and augmentation of labor. Although many were well written and met the needs of their institution, three protocols were particularly meritorious. We are submitting these documents as examples that any hospital may want to consider for their own use.

The Committee used several criteria to select those protocols that were considered “best practice” in the use of oxytocin. Two key criteria were: 1) the protocols should reflect the current understanding of the safe use of oxytocin for induction and augmentation of labor, and must be consistent with ACOG Practice Bulletin 107 (August 2009); and 2) the protocols should utilize recognized electronic fetal monitoring (EFM) nomenclature and describe appropriate interventions for the management of abnormal fetal heart rate tracings, as described in ACOG Practice Bulletin 116 (November 2010).

The committee also recommends that each hospital consider the use of a checklist when administering oxytocin. Checklists provide prerequisites at the point of patient care to safely initiate oxytocin, and help to identify situations that require its discontinuation. We identified several examples of checklists currently in use that could be incorporated into an institution’s oxytocin protocol.

The committee did not identify a single protocol that meets the needs of all hospitals in New York State. Each hospital must take into account the resources available within its own institution and community to design a protocol that will assist them in the safe use of oxytocin. We encourage each institution to review its existing oxytocin policy and protocols, and modify them if necessary to provide safe patient care.

ACOG District II Patient Safety and Quality Improvement Committee

Sample Oxytocin Protocols

Community General Hospital



NATHAN LITTAUER
Hospital & Nursing Home



UNIVERSITY of ROCHESTER
MEDICAL CENTER

Community General Hospital

4900 Broad Road, Syracuse, New York 13215
(315) 492- 5011

Nathan Littauer Hospital

Gloversville, New York
(518) 725-8621

University of Rochester Medical Center

Rochester, New York
(585) 275-9306

Sample Oxytocin Checklists

Hospital Corporation of America (HCA)
Institute for Healthcare Improvement (IHI)

November 8, 2011

Key Elements for the Use of Oxytocin

Purpose

This document reflects emerging clinical, scientific and patient safety advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. While the components of a particular protocol and/or checklist may be adapted to local resources, standardization of protocols and checklists within an institution is strongly encouraged.

Fundamental Criteria

- The protocol should reflect current understanding of the safe use of oxytocin for induction and augmentation of labor, and must be consistent with ACOG Practice Bulletin #107 (August 2009).
 - The protocol should utilize recognized electronic fetal monitoring (EFM) nomenclature and describe appropriate interventions for the management of abnormal fetal heart rate tracings, as described in ACOG Practice Bulletin #116 (November 2010).
-

Core Elements

- Use National Institute of Child Health and Human Development (NICHD) terminology throughout the protocol
 - Clearly explain the purpose of the protocol
 - Describe pre-induction assessment of the patient
 - (strongly recommend incorporating pre-induction checklist)
 - State any pre-induction documentation requirements
 - List the contraindications to labor induction
 - Describe the intrapartum physician and/or nursing assessment and documentation that may be required.
 - (strongly recommend utilizing a checklist as part of the ongoing assessment)
 - List the parameters for discontinuation of the induction agent
 - Describe in detail any interventions that may be used if tachysystole, fetal heart rate abnormalities or other complications occur
 - Outline the notification process of providers should the induction agents be discontinued or when nursing interventions do not readily resolve tachysystole, fetal heart rate abnormalities or other complications
-

Checklists

The use of a checklist is highly recommended when administering oxytocin. Checklists provide prerequisites at the point of patient care to safely initiate oxytocin and help to identify situations that require its discontinuation. The Hospital Corporation of America (HCA) and the Institute of Health-care Improvement (IHI) have developed oxytocin checklists that could be incorporated into your institution's protocol.

Hospital Protocols

The below listed hospital oxytocin protocols are enclosed to be used as models. Variations in practice may be warranted based on the needs of the individual hospital, resources, patient, and limitations unique to the institution. Each institution is encouraged to review its existing oxytocin policy and protocols, and modify them as necessary to provide safe patient care.

Community General
Nathan Littauer
University of Rochester Medical Center

Med: Oxytocin for Induction or Augmentation of Labor - Policy

Community General Hospital

The Jim & Dede
Walsh Family Birth
Center

This policy is applicable to the Jim and DeDe Walsh Family Birth Center

I. PURPOSE:

To outline the nursing management of a patient undergoing an induction or augmentation of labor

II. POLICY:

Labor is induced when the benefits to either the woman or the fetus outweigh those of continuing the pregnancy. Induction of labor is considered after evaluation of the maternal-fetal status, cervical status, gestational age at 39 completed weeks minimum for best outcomes and other relevant factors. Augmentation for hypocontractility is considered after evaluation of the maternal pelvis and fetal presentation. A physician with privileges to perform cesarean delivery should be readily available. Note: Oxytocin infusion may be ordered by a CNM only after consulting with the attending or covering OB/GYN physician.

III. SCOPE:

Affects Registered Nurses who have completed core competencies including administering and monitoring women having oxytocin for induction and/or augmentation of labor, midwives, and physicians caring for these obstetrical patients at Community General Hospital.

IV. SUPPORTIVE DATA:

The state of the cervix is clearly related to the success of labor induction. The duration of labor induction is affected by parity and cervical status and predicted only to a minor degree by baseline uterine activity and sensitivity to oxytocin. In 1964, Bishop designed a scoring system for multiparous patients in which 0-3 points are given for each of five factors (Table 1). He determined that when the total cervical score exceeded 8, the likelihood of vaginal delivery subsequent to labor induction was similar to that observed after spontaneous labor. Induction of labor with a poor cervical score has been associated with failure of induction, prolonged labor, and a high cesarean birth rate. Oxytocin does not cross the placenta, so no direct effects on the fetus have been observed.

TABLE 1. BISHOP SCORING SYSTEM

FACTOR					
Score	Dilatation (cm)	Effacement (%)	Station	Consistency	Position of Cervix
0	Closed	0-30	-3	Firm	Posterior
1	1-2	40-50	-2	Medium	Midposition
2	3-4	60-70	-1,0	Soft	Anterior
3	Greater than or equal to 5	Greater than or equal to 80	+1,+2		

Oxytocin for Induction

V. **INDICATIONS:**

Conditions that necessitate labor induction include, but are not limited to, hypertensive disorders of pregnancy, preeclampsia or eclampsia, chorioamnionitis, maternal medical condition such as diabetes mellitus or chronic hypertension, premature spontaneous rupture of membranes with the absence of contractions within twelve hours, severe intrauterine fetal growth retardation, and pregnancy that has exceeded 41 weeks.

VI. **CONTRAINDICATIONS:**

Conditions that may contraindicate induction with oxytocin include, but are not limited to less than 39 completed weeks gestation without medical indication, fetal macrosomia, > 4500 grams, placenta previa, transverse lie or other malpresentation, umbilical cord prolapse, prior classical uterine incision or previous transfundal uterine surgery, active genital herpes infection, pelvic structural deformities, and invasive cervical carcinoma.

VII. **DEFINITIONS:**

- A. **AUGMENTATION**—Stimulation of uterine contractions when spontaneous contractions have failed to result in progressive cervical dilation or descent of the fetus.
 - B. **INDUCTION**—Stimulation of labor by artificial methods. Oxytocin is a drug used in the medical induction of labor and is also used to augment existing contraction patterns that may not be adequate for progression of labor.
-

VIII. **COMPLICATIONS:**

- A. Uterine hypertonus
 - B. Uterine tachysystole
 - C. Uterine rupture
 - D. Fetal hypoxia
 - E. Prolapsed cord
 - F. Precipitous labor
-

IX. **REQUIRED PROVIDER DATA:**

- A. Verification of the requirement for 39 completed weeks gestation documented before elective labor induction is started by one of the following:
 - 1. An ultrasound measurement of the crown-rump length, obtained at 6 to 12 weeks, supports a gestational age of at least 39 weeks.
 - 2. An ultrasound obtained at 13 to 20 weeks confirms the gestational age of at least 39 weeks determined by clinical history and physical examination.
 - 3. It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test was performed by a reliable laboratory.
 - 4. Fetal heart tones have been documented for 30 weeks by Doppler.
 - B. Verify discussing the indications and potential risks and benefits of induction or augmentation of labor with the pregnant woman.
 - C. Verify the indication for induction is documented in the medical record.
 - D. Perform and document vaginal examination to evaluate cervical status and fetal station and presentation within 2 hours prior to the initiation of the oxytocin infusion.
 - E. The provider may fax dated and signed orders prior to admission of the patient or use computer physician order entry (CPOE).
-

X. **EQUIPMENT:**

- A. Oxytocin concentration of 30 units in 500 mL of Lactated Ringers solution properly labeled
 - B. Infusion Pump
 - C. Appropriate intravenous tubing
 - D. 18 or 20 gauge IV catheter
 - E. Electronic Fetal Monitor (EFM) for continuous fetal monitoring
-

Oxytocin for Induction

XI. **PROCEDURE:**

A. **BASELINE ASSESSMENT**

1. **Fetal Assessment:** Initiate external continuous electronic fetal monitoring (EFM) and confirm a reactive fetal heart rate tracing over 30 minutes. If EFM not reactive, contact provider. An attempt should be made to maintain external tracing during procedures (e.g. epidural catheter placement). *Continuous electronic fetal monitoring must be maintained when oxytocin is used.*
2. **Maternal Assessment:** Record patient's baseline vital signs

B. **PERIPHERAL IV**

1. A primary line for infusion of Lactated Ringers solution is established using an 18 or 20 gauge intravenous catheter. A primary line is necessary to maintain intravenous access should intravenous oxytocin (Pitocin) be discontinued.
2. Obtain from Pyxis pre-mixed IV solution of 30 units oxytocin (Pitocin) in 500 mL Lactated Ringers solution (1 milliunit per minute [mU/min] = 1 milliliter per hour [mL/hr]) and verify correct set-up of infusion per physician order.
3. Place oxytocin (Pitocin) on an infusion pump to insure accurate flow rate. Piggyback oxytocin into primary line nearest the venipuncture site.

C. **TREATMENT**

1. Explain all procedures, equipment, and nursing care to patient and significant others.
2. Assess patient's level of understanding, acceptance, and tolerance of procedure.
 - a. Individualized patient teaching is necessary to meet the needs of the patient and family for information and emotional support.
 - b. Ensure that the patient understands that oxytocin will stimulate or augment contractions and that she will experience contractions at some point after initiation of the drug. Each patient's response is unique.
 - c. Support the patient through her labor at the bedside.

D. **INDUCTION/AUGMENTATION of LABOR**

1. Begin infusion at 1 milliunit/minute or 2 milliunits/minute per physician orders, as long as a provider is available within 10 minutes of the L&D area.
2. Increase oxytocin dosage in increments of 1 to 2 milliunits/minute no sooner than every 30 to 60 minutes as physician orders until uterine contractions are 2-3 minutes apart and of moderate quality by palpation or 50-60 mmHg above baseline with IUPC. Labor progress may be 0.5 to 1 centimeters of cervical dilation per hour during labor induction, particularly for nulliparous women.
3. Increase infusion rate until adequate uterine activity is achieved to a maximum dose of 20 milliunits/minute of oxytocin. ***A physician order is needed to increase oxytocin beyond 20 milliunits/minute.***
4. Adequate uterine activity is defined as:
 - a. 3-5 contractions in a 10 minute period with a maximum, not to exceed, 5 contractions in a 10 minute period.
 - b. Contraction duration of 40 to 90 seconds.
 - c. Moderate-to-strong contraction intensity by palpation and patient perception
5. **Assessment of maternal-fetal status described below occurs every 15 minutes during oxytocin administration.** The following documentation in the medical record is required each time oxytocin dosage rate is increased or decreased (or at least every 30 minutes if the dosage is unchanged).
 - a. **Fetal Heart Rate:** baseline rate, baseline variability, presence or absence of FHR accelerations, presence or absence of FHR decelerations and nursing interventions as appropriate.
 - b. **Uterine Activity:** contraction frequency, duration, intensity and uterine resting tone by palpation or Intrauterine pressure catheter (IUPC).
 - c. **Maternal Response to Labor:** the woman's response to the contractions, i.e., not feeling contractions, using breathing techniques with contractions, requires intense labor coaching with contractions, comfortable with contractions with epidural analgesia, etc. *If a registered nurse is not available to clinically evaluate the effects of the oxytocin infusion at least every 15 minutes, the infusion will be discontinued until that level of nursing care is available. The attending physician will be notified.*
6. Assess and document maternal pulse, respirations, and blood pressure every hour.
7. Assess maternal temperature every 4 hours if membranes are intact or every 2 hours if membranes are ruptured.
8. Assess intake and output as ordered by provider.
9. Attempt to maintain external fetal monitoring during epidural catheter placement.

Oxytocin for Induction

10. **Decrease Oxytocin for:**
 - a. Uterine “Tachysystole” as defined by ACOG Practice Bulletin #106, July 2009: “more than five contractions in 10 minutes, averaged over a 30-minute window.”
 - b. Contractions lasting 2 minutes or more
 - c. Contractions of normal duration occurring within 1 minute of each other
 - d. Insufficient return of uterine resting tone between contractions via palpation, or
 - e. Intraamniotic pressure above 25 mm Hg between contractions via IUPC

Note: Decreasing the oxytocin dose by half rather than stopping it may correct the abnormal contraction pattern yet prevent an unwarranted delay in delivery. Additional measures may include changing the patient’s position to right or left lateral, giving an IV fluid bolus of 500 mL of lactated Ringer’s solution and administering oxygen at 10 liters/minute per non-rebreather face mask.
11. **Discontinue oxytocin, and notify provider for:**
 - a. Uterine Tachysystole that does not resolve after decreasing oxytocin immediately by half.
 - b. Nonreassuring fetal heart rate pattern:
 - recurrent variable decelerations
 - fetal tachycardia or bradycardia
 - minimal to absent baseline FHR variability
 - late decelerations
 - c. Maternal hypotension—Bolus of at least 500 mL of Lactated Ringers solution. If not resolved after bolus, notify obstetrician or, if epidural in place anesthesia, for ephedrine order.
 - d. Signs and symptoms of uterine rupture—increased uterine resting tone/hyper tonus, uterine tachysystole, abdominal rigidity and pain or “tearing” type pain reported by patient, hypotension, tachycardia, and/or vaginal bleeding.
12. Anticipate emergency preparations if surgical intervention becomes necessary for prolapsed cord or abnormal fetal heart rate responses.
 13. **Oxytocin infusion may be restarted only with a physician’s order**, not more than half the dose if it had been discontinued for <20 to 30 minutes. If oxytocin is discontinued for > 30 to 40 minutes, it may be resumed at the initial dose ordered.

E. DOCUMENTATION ON L&D FLOW RECORD

1. Oxytocin (Pitocin) dosage in milliunits per minute, including initial and subsequent dosages, as well as times of dosage changes.
2. Reassuring FHR pattern assessed before induction/augmentation is initiated
3. FHR assessment before each increase in Pitocin and at least every 15 minutes
4. Uterine assessment before each increase in Pitocin and at least every 15 minutes
5. Maternal response to labor: not feeling contractions, using breathing techniques with contractions, comfortable with contractions with epidural analgesia, etc.
6. Patient pain scale report and interventions with response to intervention(s).
7. All nursing and medical interventions and patient’s responses
8. All patient education.

~ end ~

Approved by OB/GYN Department: 6/20/10
Date

Approved by P&T Committee:
(Previously approved 10/27/03) 8/30/10
Date

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mgd, afd, kl, JW
8/92
Revised: 5/94, 5/95, 5/98, 8/00, 9/03, 7/05, 1/07, 12/08, 9/09, 9/10

Medication: Oxytocin Protocol (Intrapartum Use Of)



Department of
Nursing

Purpose To outline the nursing management and responsibility for Oxytocin usage in augmentation and induction of labor.

Level Interdependent (* = requires a practitioner's order [LIP = Licensed Independent Practitioner] for dependent functions – this includes physician, or nurse midwife.)

Supportive Data

- Exogenous oxytocin is a powerful uterine stimulant dependent on uterine receptor uptake.
- The circulatory half-life of oxytocin is approximately 10-12 minutes, although uterine effects may persist as long as 20-40 minutes.
- It takes 3-4 half-lives to reach a steady state plasma concentration.
- Oxytocin for augmentation/induction of labor is used to initiate or improve uterine contractions by direct action on the myometrium.
- The patient will be monitored by a RN who is trained and competent in both the monitoring of the fetal heart rate and uterine contractions and the interpretation of such monitoring.
- The attending, **or** another LIP who has assumed responsibility for the patient's care, or the appropriately trained and credentialed Obstetrics Registered Nurse shall initiate the infusion of the oxytocin agent, or other substance used to induce or augment labor, and remain with the woman for a period of time sufficient to insure that the drug is well tolerated and has caused no adverse reactions.
- During the infusion of the oxytocin, the attending or another LIP who has assumed responsibility for the patient's care shall be available within 30 minutes to manage any complications that may arise.
- With any deviation from the protocol, an order must be obtained.

Nurse: Patient Ratio 1:2 during induction/augmentation with oxytocin (AAP and ACOG Guidelines for Perinatal Care, 2007)
1:1 with high risk and active management

Examples of clinical situation requiring 1:1 nurse/patient ratio including, but not limited to, women in labor with severe pre-eclampsia, during the active phase of the first stage of labor and during the second stage of labor. A nurse must be able to clinically evaluate the effects of oxytocin at least every 15 minutes (AAP & ACOG, 2007). The oxytocin infusion should be discontinued if this level of nursing care cannot be provided. A LIP who has privileges to perform a cesarean birth should be readily available (AAP & ACOG, 2007).

Oxytocin for Induction

Scheduling Non-Emergent Inductions

Two non-emergent inductions may be scheduled per day. The LIP will call the charge nurse to schedule induction (**stating indication**). The charge nurse will record on desk calendar. In the case of more than two requests for inductions, the Chief of OB/Gyn and Nurse Manager (or her designee) will make final decision based on the nature and intensity of the indication and staffing resources.

Initial Assessment

- *1) Verify that:
 - a. the H&P (performed within 72 hours prior to the beginning of oxytocin) is completed and on medical record;
 - b. a signed informed consent for procedure is completed and on the medical record;
 - c. signed orders are completed and on the medical record; d. fetal position/presentation (via ultrasound) if necessary and cervical exam are documented.
 - 2) Obtain vital signs (BP, P, R, T).
 - 3) Assess presence of vaginal bleeding.
 - 4) Assess cervical status.
 - 5) Obtain a 20-30 minute electronic fetal monitoring strip prior to the initiation of oxytocin. Notify LIP if non-reassuring.
 - 6) Explain nursing actions involved during this procedure and the expected effects of oxytocin on labor to the patient. Document education given.
 - 7) Position the patient to avoid vena cava compression.
-

Initiation and Titration of IV Oxytocin

- *8) Start primary IV line of 1000ml lactated ringers using #18 gauge cathlon (#20 gauge cathlon if necessary) per IV protocol. Run at 150ml per hour.
 - *9) Obtain pre-mixed Oxytocin 30 units in 500 ml of lactated ringers and label.
 - 10) Insert secondary IV line containing oxytocin medication into the most proximal port of the primary IV line (to avoid administering bolus of oxytocin remaining in tubing if primary infusion is run in rapidly).
 - 11) Both primary and secondary IV lines must be on IV controller. **Do not begin oxytocin regimen if uterine contractions are every two minutes or more frequent.**
 - 12) Begin oxytocin administration at 2.0 milliunits per minutes (2.0ml per hour).
 - 13) Increase oxytocin by 2.0 milliunits per minute (2.0ml per hour) every 30 minutes.
 - 14) Titrate oxytocin to maintain contractions of moderate to strong intensity by palpation. For contractions lasting 60-90 seconds and every 2-3 minutes, consider discontinuing the oxytocin.
 - 15) Total infusion rate should **not exceed** 150ml per hour. Decrease main IV rate as oxytocin rate is increased to maintain total rate of 150ml per hour.
 - 16) **Do not exceed** 20 milliunits per minute (20ml per hour) without LIP order.
 - 17) It may be necessary to use a lower dose to avoid uterine hyperstimulation.
 - 18) After spontaneous rupture of membranes (SROM), oxytocin dose may have to be significantly decreased during first stage of labor and every 10 minutes during the second stage of labor.
-

Ongoing Assessment

- 19) Assess and record BP, T, P, R at least every 4 hours and more frequently when risk factors identified. Maternal temperature every 2 hours if membranes ruptured.
 - 20) Assess and document uterine contractions before every dosage increase. If dosage is maintained at the same rate, document uterine activity every 30 minutes. Consider discontinuing oxytocin once labor pattern is established.
 - 21) Evaluate and record the FHR every 15 minutes during the active phase of the first stage of labor, and evaluate every 5 minutes during the second stage of labor.
 - 22) Initiate **Fetal Monitoring Protocol**. Fetal monitoring and uterine contractions can be achieved by intermittent auscultation and palpation or continuous fetal monitoring.
 - 23) Assess and record I&O every shift. Encourage patient to urinate every 2-3 hours during labor .
 - 24) Observe patient for signs/symptoms of water intoxication (such as headache, nausea, vomiting).
 - 25) Assess the woman's emotional status and coping behaviors during labor. Record these assessments, your interventions, and the patient's response to your interventions every hour .
 - 26) In reference to all other labor care and documentation, see ***Standards of Care for Patients With Routine/Uncomplicated Labor.***
-

Oxytocin for Induction

Complication Management

27) Monitor maternal/fetal status for the following complications (complications of oxytocin are primarily dose related):

- ❖ **Tachysystole:** A persistent pattern of more than 5 contractions in 10 minutes, contractions lasting 2 minutes or more, contractions of normal duration occurring within 1 minute of each other or no resting tone between contractions. Contractions occurring six or more times in 10 minutes, lasting longer than 2 minutes, or increasing resting tone is greater than 20mg per Hg with an IUPC.

NURSING INTERVENTIONS

Tachysystole with non-reassuring fetal heart rate pattern

- discontinue oxytocin
- turn patient left lateral position
- IV bolus with 250-300ml lactated ringers (unless contraindicated)
- apply O2 via mask at 8-10 liters per minute
- have 0.25mg terbutaline* readily available
- notify LIP, observe and re-evaluate

Tachysystole with reassuring fetal heart rate pattern

- maternal reposition (left or right lateral position)
- IV bolus with 250-300ml lactated ringers (unless fluid restricted)
- if uterine activity has not returned to normal after 10 minutes, decrease oxytocin rate by half; if uterine activity has not returned to normal after 10 minutes, discontinue oxytocin until uterine activity has returned to normal (≤ 5 contractions in 10 minutes)
- notify LIP
- have terbutaline* (0.25mg) readily available

Non-reassuring fetal heart rate pattern

- a. new onset of bradycardia/tachycardia
- b. less of variability
- c. either of the above with late deceleration

- discontinue oxytocin
- turn patient to left lateral position
- IV bolus with 250-300 ml of lactated ringers (unless fluid restricted)
- apply O2 via face mask at 8-10 liters per minute
- notify LIP, observe and re-evaluate

* terbutaline is given per LIP orders.

- 28) If oxytocin has been discontinued for 20-30 minutes, the FHR is reassuring and no uterine tachysystole present, oxytocin may be restarted at half the rate that caused tachysystole and gradually increased every 30 minutes based on maternal/fetal response.
- 29) If oxytocin has been discontinued for more than 30-40 minutes, exogenous oxytocin is metabolized, therefore, oxytocin must be restarted of the initial dose (2.0 milliunits per minute or 2.0ml per hour).

Termination of Oxytocin

30) Terminate the oxytocin infusion if:

- tachysystole of uterus as defined above
- precipitous labor
- non-reassuring fetal heart rate pattern
- LIP unexpectedly unavailable
- inability to monitor patient's FHR or uterine contraction at recommended intervals
- desired labor pattern

If unable to continuously monitor FHR during an epidural administration, stop Pitocin infusion, and restart infusion at half-strength and increase per protocol once FHR continuous monitoring can be re-established.

Oxytocin for Induction

Reportable Conditions

- 31) Report following to LIP or appropriate resource person:
- tachysystole
 - non-reassuring fetal heart rate pattern
 - vaginal bleeding
 - unusual abdominal pain
 - disappearance of contractions
 - change in uterine contour
 - SROM
 - change of baseline vital signs and fetal heart rate patterns

Documentation

- 32) Document commencement of oxytocin infusion in Labor Assessment.
- 33) Record all maternal/fetal assessments, interventions, and patient's response to interventions in Labor Assessment.
- 34) Document "Oxytocin protocol in effect".
- 35) Document any patient/significant other education.

Oxytocin Titration Table

OXYTOCIN TITRATION TABLE

Using 30 units of Oxytocin in 500ml lactated ringers

1.0	milliunits per min	=	1.0	ml per hour
2.0	milliunits per min	=	2.0	ml per hour
3.0	milliunits per min	=	3.0	ml per hour
4.0	milliunits per min	=	4.0	ml per hour
5.0	milliunits per min	=	5.0	ml per hour
6.0	milliunits per min	=	6.0	ml per hour
7.0	milliunits per min	=	7.0	ml per hour
8.0	milliunits per min	=	8.0	ml per hour
9.0	milliunits per min	=	9.0	ml per hour
10.0	milliunits per min	=	10.0	ml per hour
11.0	milliunits per min	=	11.0	ml per hour
12.0	milliunits per min	=	12.0	ml per hour
13.0	milliunits per min	=	13.0	ml per hour
14.0	milliunits per min	=	14.0	ml per hour
15.0	milliunits per min	=	15.0	ml per hour
16.0	milliunits per min	=	16.0	ml per hour
17.0	milliunits per min	=	17.0	ml per hour
18.0	milliunits per min	=	18.0	ml per hour
19.0	milliunits per min	=	19.0	ml per hour
20.0	milliunits per min	=	20.0	ml per hour

- REFERENCES:** Simpson and Creehan, Perinatal Nursing, 3rd Edition, Lippincott, 2008 (AWHONN, chapter 7, pg. 300-375); NENY Regional Protocol; NYS DOH 405.21; Cervical Ripening and Induction and Augmentation of Labor, 3rd edition, 2008; American Journal of Obstetric and Gynecology 1/09; Maternal Child Nursing Jan/Feb 2009, p. 8-15. Vol. 34(1); ACOG Practice Bulletin, #10, Induction of Labor
- APPROVAL:** OB Nursing Protocol Committee; Department of OB/GYN (4/21/92, 5/20/97, 8/06)
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Standard of Care for the Woman for Induction / Augmentation of Labor



Department of
Obstetrics and Gynecology
OB/GYN Service

General Information

“Induction of labor refers to the iatrogenic stimulation of uterine contractions to accomplish delivery prior to the onset of spontaneous labor” (Wing, 2009). “Augmentation of labor is defines as the use of medical interventions when there is no progression in labor as a result of uterine dystocia or inadequate uterine contractions” (Simpson, 2008).

Prior to induction/augmentation for any indication it is recommended that a riskbenefit analysis and a discussion of the advantages and disadvantages, including the risk of cesarean birth or the possibility of a repeat induction be performed with the patient and her significant other. It is the responsibility of the nurse to ensure that the patient has been fully informed, as outlined above, and has given verbal consent.

Contraindications to induction/augmentation of labor include:

- Prior classical uterine incision
- Prior transmural uterine incision entering the uterine cavity
- Active genital herpes infection
- Placenta or vasa previa
- Umbilical cord prolapse
- Transverse fetal lie (ACOG, 2009)

Oxytocin

Oxytocin is the most commonly used medication for the induction/augmentation of labor. Oxytocin is a synthetic product that is chemically and physiologically identical to the hormone oxytocin that is released by the posterior pituitary gland. Oxytocin is picked up by oxytocin receptors on the myometrium and decidua of the uterus. It is felt that oxytocin facilitates the contraction of smooth muscle cells causing the rhythmic and coordinated contractions of labor. In this way, labor is initiated and coordinated to its ultimate outcome.

IP 4.0

Misoprostol

Misoprostol is a synthetic prostaglandin E1 analog, presently being used in the treatment and prevention of gastric ulcers caused by nonsteroidal antiinflammatory drugs. Because of its prostaglandin properties misoprostol recently has been used obstetrics for cervical ripening and as an induction agent (Simpson & Creehan, 2008). Misoprostol cannot be used in patients who have had previous uterine surgery (includes a low transverse cesarean section). It should also be noted that women with dysfunctional contraction patterns are not candidates for misoprostol. Misoprostol cannot be used augmentation of labor in women whose contractions began spontaneously or were induced by oxytocin. Those patients induced by artificial rupture of membranes may be given misoprostol if their contractions have not started spontaneously.

Oxytocin for Induction

Patient Outcomes

1. The patient will maintain optimal physiological and psychological functioning to include:
 - a. Stable vital signs
 - b. Pain rating at a level acceptable to the patient
 - c. Absence of uterine tachysystole
 - d. Absence of adverse effects to the oxytocin or misoprostol
 - e. Stable emotional status
2. The patient and significant other will demonstrate appropriate knowledge of the induction/augmentation procedure and will have indicated informal consent.
3. The fetus will maintain optimal physiological status as evidenced by:
 - a. FHR 110 – 160 bpm
 - b. Absence of indications of fetal compromise (recurrent decelerations and/or absent or minimal variability)

Interventions

1. Prior to the initiation of the induction/augmentation of labor the nurse will review the record and ensure that the following are present:
 - a. Indications for induction/augmentation of labor.
 - b. If appropriate, documentation of fetal lung maturity
 - c. Appropriate medical and nursing assessment of both maternal and fetal status – includes care provider's statement indicating necessity for induction/augmentation of labor. The faxed induction sheet meets criteria for the care provider's statement.
 - d. Appropriate orders – as per the medication, solution and dosing regimen as outlined below.
 - e. Presence of the attending or appropriate representative (Maternal-Fetal medicine attending may cover) in the hospital.
 - f. Notification of NICU regarding expected preterm or potentially compromised neonate.
 - g. Completion of the Oxytocin Checklist (located in the QS system) ensuring that all areas are complete. The nurse will indicate in the appropriate box that:
 - i. the oxytocin order is present.
 - ii. there is documentation of informed consent.
 - iii. the care provider privileged to do a cesarean section is present.
 - iv. there is documentation for the indication for induction/augmentation of labor.
2. Prior to the start of the induction/augmentation of labor the following will need to be in place:
 - a. Place the patient on continuous electronic fetal monitoring – uterine and fetal. This allows for proper interpretation of the fetal tolerance to the induction/augmentation process and the absence of uterine tachysystole. For cases in which continuous electronic fetal monitoring is not possible due to inability to trace the fetus due to motion or maternal habitus, intermittent post contraction auscultation every 15 minutes during the first stage of labor and every 5 minutes during the second stage of labor is acceptable. Uterine contractions are to be assessed palpation to identify uterine activity and if uterine tachysystole is present.
 - b. Initiation of intravenous access with a large bore intravenous catheter (preferably an 18 gauge catheter). Lactated Ringers solution should be infusing through a programmable infusion pump.
 - c. Laboratory specimens for a type and screen, CBC with platelets and any other ordered laboratory specimens are to be obtained and sent to the appropriate laboratory setting.
3. Assess and review:
 - a. Baseline maternal vital signs
 - b. Pain rating – provide pharmaceutical and nonpharmaceutical comfort promoting interventions for relief as identified by the patient. Reassess pain rating one hour from the intervention.
 - c. Review the fetal heart rate tracing for the presence of accelerations, moderate variability, and no recurrent decelerations.
 - d. Report any abnormalities of maternal or fetal findings to the care provider.
 - e. Review the orders with care provider in light of abnormal findings.
4. Assess the patient/significant other's level of understanding about the procedure and determine if informed consent was obtained. Verbal acknowledgement by the patient is acceptable. Information is provided to the patient/significant other addressing learning barriers that were identified.

Oxytocin for Induction

Interventions

(Continued)

5. Prepare the appropriate equipment as appropriate for the method of labor induction/augmentation.
 - a. Misoprostol 25 microgram tablet (prepared by Pharmacy only)
 - i. Sterile examination gloves
 - ii. Water soluble lubricating jelly
 - b. Oxytocin 30 units into 500 mL normal saline. Solution labeled, as per SMH policy, set up with IV pump tubing and attached at the stopcock of the mainline IV.
 - i. Programmable infusion pump
6. Misoprostol Induction
 - a. Assist the care provider as needed with the insertion of the misoprostol.
 - b. The patient is to be positioned after placement in the either the right or left lateral recumbent position to avoid supine hypotension.
 - c. Misoprostol 25 micrograms may be repeated every 4 – 6 hours, until regular contractions or adequate intensity ensure. No doses higher than 25 micrograms may be used to stimulate labor in viable pregnancies.
 - d. Maternal vital signs and fetal heart rate interpretation is assessed as per stage of labor.
 - e. Repeat doses of misoprostol should be placed if adequate labor has been established.
 - f. If adequate labor is not established after 12 to 24 hours of misoprostol administration, misoprostol may be discontinued and oxytocin administered beginning 4 hours after the last misoprostol dose.
7. Oxytocin Induction/Augmentation
 - a. Start the oxytocin infusion using a programmable infusion pump as per care provider's orders, ensuring the dosing regimen falls within the acceptable standard of care. Always clarify orders with the care provider if orders fall outside the usual dosing regimen. Usual orders include:
 - i. 1 or 2 mUnits/min. and increase by 1– 2 mUnits/min (specifically ordered by care-provider) every 30 minutes until every 2 – 3 minute contractions: absence of uterine tachysystole, and fetal heart rate indicated fetal tolerance of labor (maximum dose: 42 milliunits/min.). The care provider may order the incremental dosage at a frequency greater than every 30 minutes but no less than every 30 minutes.
 - ii. With the present dosing regimen of 1mUnit/min equaling 1 mL/hr, it will never be necessary to alter the concentration of the oxytocin solutions.
 - iii. Increase the infusion as ordered to maintain a rate that stimulates contractions every 2 – 3 minutes, lasting 45 – 90 seconds with an intensity of moderate quality or at least 50 mmHg above the resting tone with an IUPC. Blood pressure is assessed as outlined in the Standard of Care for the Intrapartum Patient. Prior to each increase the maternal pulse is assessed and the fetal heart rate monitor strip is reviewed. A pain rating is performed at least every 1 hour.
 - iv. During the induction/augmentation procedure, the patient is maintained in the left or right lateral recumbent or semirecumbent position to avoid vena cava compression.
8. Intake and output is maintained throughout the entire induction/augmentation process and recorded every hour. Ensure urinary output is maintained at >30 mL/hr.
9. Continuously evaluate the patient for complications associated with the intrapartum use of oxytocin and misoprostol (e.g.: fetal compromise, water intoxication, cardiovascular events, pulmonary edema, tachysystole).
10. **If uterine tachysystole is present AND the fetal heart rate does not indicate compromise, decrease the oxytocin to the previous dose and notify the care provider.**
 - a. Uterine tachysystole is defined as: more than 5 contractions in a 10 minute period and each contraction lasting at least 45 seconds, averaged over 30 minutes.
11. **Discontinue the oxytocin and notify the attending and the resident for:**
 - a. Uterine tachysystole that does not respond to a decrease in oxytocin dose.
 - b. Fetal heart rate pattern demonstrating the following:
 - i. Fetal bradycardia
 - ii. Recurrent late decelerations
 - iii. Recurrent variable decelerations with absent or minimal baseline variability.

Oxytocin for Induction

Interventions

(Continued)

- c. Provide appropriate nursing interventions as related to the following complications:
 - i. Administer oxygen via nonrebreather mask, administer an intravenous fluid bolus of lactated Ringers solution, position the patient on her side, notify the care provider, and have terbutaline 0.25 mg available for administration (especially if the patient is receiving misoprostol for induction of labor) if ordered by the care provider; especially if there are indications of fetal compromise (recurrent late decelerations, minimal / absent fetal heart rate variability, prolonged decelerations, bradycardia).
 - d. Notify the care provider if urinary output is <30 mL/hr, cardiovascular effects or pulmonary edema is noted.
12. If oxytocin is discontinued and the uterine and fetal heart rate patterns subsequently normalize, the oxytocin may be restarted at approximately onehalf the dose for every 10 minutes since discontinuation (e.g. half the discontinued dose if 10 minutes passed, onefourth the dose if 20 minutes have passed, one eighth the dose at 30 minutes).
13. Document relevant information on the appropriate records as per SMH standards.
-

Documentation

1. On OB electronic system:
 - a. Nursing Admission History
 - b. Laborrecord
 - c. Intake and output
 - d. IV record
 - e. Patient teaching
 - f. Oxytocin Checklist
 - g. History and Physical
 - h. Progress notes
 2. Faxed Induction Sheet
-

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Revised: 2/00, 6/01, 10.01, 2/04, 3/05, 7/05,10/06,2/07, 6/07,12/07, 10/08, 12/09, 8/10



Patient Safety Checklist ✓

Number 5 • December 2011
(Replaces Patient Safety Checklist No. 1, November 2011)

SCHEDULING INDUCTION OF LABOR

Date _____ Patient _____ Date of birth _____ MR # _____

Physician or certified nurse–midwife _____ Last menstrual period _____

Gravidity/Parity _____

Estimated date of delivery _____ Best estimated gestational age at delivery _____

Proposed induction date _____ Proposed admission time _____

Gestational age of 39 0/7 weeks or older confirmed by either of the following criteria (1):

Ultrasound measurement at less than 20 weeks of gestation supports gestational age of 39 weeks or greater

Fetal heart tones have been documented as present for 30 weeks of gestation by Doppler ultrasonography

Indication for induction: (choose one)

Medical complication or condition (1): Diagnosis: _____

Nonmedically indicated (1–3): Circumstances: _____

Patient counseled about risks, benefits, and alternatives to induction of labor (1)

Consent form signed as required by institution

Bishop Score (see below) (1): _____

Bishop Scoring System

Score	Factor				
	Dilation (cm)	Position of Cervix	Effacement (%)	Station*	Cervical Consistency
0	Closed	Posterior	0–30	-3	Firm
1	1–2	Midposition	40–50	-2	Medium
2	3–4	Anterior	60–70	-1, 0	Soft
3	5–6	—	80	+1, +2	—

*Station reflects a –3 to +3 scale.

Modified from Bishop EH. Pelvic scoring for elective induction. *Obstet Gynecol* 1964;24:266–8.

Pertinent prenatal laboratory test results (eg, group B streptococci or hematocrit) available (4, 5)

Special concerns (eg, allergies, medical problems, and special needs): _____

To be completed by reviewer:

Approved induction after 39 0/7 weeks of gestation by aforementioned dating criteria

Approved induction before 39 0/7 weeks of gestation (medical indication)

HARD STOP – gestational age, indication, consent, or other issues prevent initiating induction without further information or consultation with department chair

References

1. Induction of Labor. ACOG Practice Bulletin No. 107. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2009;114:386–97.
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4. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Antepartum care. In: Guidelines for perinatal care. 6th ed. Elk Grove Village (IL): AAP; Washington, DC: ACOG; 2007. p. 83–137.
5. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Perinatal infections. In: Guidelines for perinatal care. 6th ed. Elk Grove Village (IL): AAP; Washington, DC: ACOG; 2007. p. 303–48.

Standardization of health care processes and reduced variation has been shown to improve outcomes and quality of care. The American College of Obstetricians and Gynecologists has developed a series of patient safety checklists to help facilitate the standardization process. This checklist reflects emerging clinical, scientific, and patient safety advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Although the components of a particular checklist may be adapted to local resources, standardization of checklists within an institution is strongly encouraged.

How to Use This Checklist

The Patient Safety Checklist on Scheduling Induction of Labor should be completed by the health care provider and submitted to the respective hospital to schedule an induction of labor. The hospital should establish procedures to review the appropriateness of the scheduling based on the information contained in the checklist. A hard stop should be called if there are questions that arise that require further information or consultation with the department chair.

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Scheduling induction of labor. Patient Safety Checklist No. 5. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:1473–4.



Patient Safety Checklist ✓

Number 2 • November 2011

INPATIENT INDUCTION OF LABOR

Date _____ Patient _____ Date of birth _____ MR # _____
 Physician or certified nurse–midwife _____ Last menstrual period _____
 Gravidity/Parity _____
 Estimated date of delivery _____ Best estimated gestational age at delivery _____
 Indication for induction _____

Fetal Presentation (1)

- Vertex
- Other _____
 - If other, physician or certified nurse–midwife notified

Estimated fetal weight _____

- Patient has a completed medical history and physical examination
 - Known allergies identified _____
 - Medical factors that could effect anesthetic choices identified _____
 - Pertinent prenatal laboratory test results (eg, group B streptococci or hematocrit) available (2, 3)
 - Other special concerns identified (eg, medical problems and special needs): _____
- Patient counseled about risks and benefits of induction of labor (1)
 - Consent form signed as required by institution

Bishop Score (see below) (1): _____

Bishop Scoring System

Score	Factor				
	Dilation (cm)	Position of Cervix	Effacement (%)	Station*	Cervical Consistency
0	Closed	Posterior	0–30	-3	Firm
1	1–2	Midposition	40–50	-2	Medium
2	3–4	Anterior	60–70	-1, 0	Soft
3	5–6	—	80	+1, +2	—

*Station reflects a –3 to +3 scale.

Modified from Bishop EH. Pelvic scoring for elective induction. *Obstet Gynecol* 1964;24:266–8.

- Orders received (1)
 - Oxytocin
 - Cervical ripening

References

1. Induction of labor. ACOG Practice Bulletin No. 107. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2009;114:386–97.
2. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Antepartum care. In: *Guidelines for perinatal care*. 6th ed. Elk Grove Village (IL): AAP; Washington, DC: ACOG; 2007. p. 83–137.
3. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Perinatal infections. In: *Guidelines for perinatal care*. 6th ed. Elk Grove Village (IL): AAP; Washington, DC: ACOG; 2007. p. 303–48.

Standardization of health care processes and reduced variation has been shown to improve outcomes and quality of care. The American College of Obstetricians and Gynecologists has developed a series of patient safety checklists to help facilitate the standardization process. This checklist reflects emerging clinical, scientific, and patient safety advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Although the components of a particular checklist may be adapted to local resources, standardization of checklists within an institution is strongly encouraged.

How to Use This Checklist

The Patient Safety Checklist on Inpatient Induction of Labor should be completed by the health care provider at the time of the patient's admission.

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Inpatient induction of labor. Patient Safety Checklist No. 2. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:1205–6.

ACOG PRACTICE BULLETIN



CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS

NUMBER 107, AUGUST 2009

Replaces Practice Bulletin Number 10, November 1999; Committee Opinion Number 228, November 1999; Committee Opinion Number 248, December 2000; Committee Opinion Number 283, May 2003

Induction of Labor

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins—Obstetrics with the assistance of Mildred Ramirez, MD, and Susan Ramin, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

More than 22% of all gravid women undergo induction of labor in the United States, and the overall rate of induction of labor in the United States has more than doubled since 1990 to 225 per 1,000 live births in 2006 (1). The goal of induction of labor is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor. Generally, induction of labor has merit as a therapeutic option when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy. The benefits of labor induction must be weighed against the potential maternal and fetal risks associated with this procedure (2). The purpose of this document is to review current methods for cervical ripening and induction of labor and to summarize the effectiveness of these approaches based on appropriately conducted outcomes-based research. These practice guidelines classify the indications for and contraindications to induction of labor, describe the various agents used for cervical ripening, cite methods used to induce labor, and outline the requirements for the safe clinical use of the various methods of inducing labor.

Background

In 1948, Theobald and associates described their use of the posterior pituitary extract, oxytocin, by intravenous drip for labor induction (3). Five years later, oxytocin was the first polypeptide hormone synthesized by du Vigneaud and associates (4). This synthetic polypeptide hormone has since been used to stimulate uterine contractions. Other methods used for induction of labor include membrane stripping, amniotomy, nipple stimulation, and administration of prostaglandin E analogues.

Cervical Ripening

The goal of cervical ripening is to facilitate the process of cervical softening, thinning, and dilating with resultant reduction in the rate of failed induction and

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induction to delivery time. Cervical remodeling is a critical component of normal parturition. Observed changes not only include collagen breakdown and rearrangement but also changes in the glycosaminoglycans, increased production of cytokines, and white blood cell infiltration (5). If induction is indicated and the status of the cervix is unfavorable, agents for cervical ripening may be used. The status of the cervix can be determined by the Bishop pelvic scoring system (Table 1) (6). An unfavorable cervix generally has been defined as a Bishop score of 6 or less in most randomized trials. If the total score is more than 8, the probability of vaginal delivery after labor induction is similar to that after spontaneous labor.

Effective methods for cervical ripening include the use of mechanical cervical dilators and administration of synthetic prostaglandin E₁ (PGE₁) and prostaglandin E₂ (PGE₂) (7–10). Mechanical dilation methods are effective in ripening the cervix and include hygroscopic dilators, osmotic dilators (*Laminaria japonicum*), Foley catheters (14–26 F) with inflation volume of 30–80 mL, double balloon devices (Atad Ripener Device), and extraamniotic saline infusion using infusion rates of 30–40 mL/h (11–19). *Laminaria japonicum* ripens the cervix but may be associated with increased peripartum infections (7, 20). In women undergoing induction with an unfavorable cervix, mechanical methods, except extraamniotic saline infusion, are associated with a decreased cesarean delivery rate when compared with oxytocin alone (18). Multiple studies have demonstrated the efficacy of mechanical cervical dilators. There is insufficient evidence to assess how effective (vaginal delivery within 24 hours) mechanical methods are compared with prostaglandins (18). Advantages of the Foley catheter include low cost when compared with prostaglandins, stability at room temperature, and reduced risk of uterine tachysystole with or without fetal heart rate (FHR) changes (18, 21).

Misoprostol, a synthetic PGE₁ analogue, can be administered intravaginally, orally, or sublingually and is used for both cervical ripening and induction of labor. It

currently is available in a 100-mcg (unscored) or a 200-mcg tablet, and can be broken to provide 25-mcg or 50-mcg doses. There is extensive clinical experience with this agent and a large body of published reports supporting its safety and efficacy when used appropriately. No studies indicate that intrapartum exposure to misoprostol (or other prostaglandin cervical ripening agents) has any long-term adverse health consequences to the fetus in the absence of fetal distress, nor is there a plausible biologic basis for such a concern. Although misoprostol currently is approved by the U.S. Food and Drug Administration (FDA) for the prevention of peptic ulcers, the FDA in 2002 approved a new label on the use of misoprostol during pregnancy for cervical ripening and for the induction of labor. This labeling does not contain claims regarding the efficacy or safety of misoprostol, nor does it stipulate doses or dose intervals. The majority of adverse maternal and fetal outcomes associated with misoprostol therapy resulted from the use of doses greater than 25 mcg.

Two PGE₂ preparations are commercially available: a gel available in a 2.5-mL syringe containing 0.5 mg of dinoprostone and a vaginal insert containing 10 mg of dinoprostone. Both are approved by the FDA for cervical ripening in women at or near term. The vaginal insert releases prostaglandins at a slower rate (0.3 mg/h) than the gel. Compared with placebo or oxytocin alone, vaginal prostaglandins used for cervical ripening increase the likelihood of delivery within 24 hours, do not reduce the rate of cesarean delivery, and increase the risk of uterine tachysystole with associated FHR changes (22).

Methods of Labor Induction

Oxytocin

Oxytocin is one of the most commonly used drugs in the United States. The physiology of oxytocin-stimulated labor is similar to that of spontaneous labor, although individual patients vary in sensitivity and response to oxytocin. Based on pharmacokinetic studies of synthetic

Table 1. Bishop Scoring System

Score	Factor				
	Dilation (cm)	Position of Cervix	Effacement (%)	Station*	Cervical Consistency
0	Closed	Posterior	0–30	–3	Firm
1	1–2	Midposition	40–50	–2	Medium
2	3–4	Anterior	60–70	–1, 0	Soft
3	5–6	—	80	+1, +2	—

*Station reflects a –3 to +3 scale.

Modified from Bishop EH. Pelvic scoring for elective induction. *Obstet Gynecol* 1964;24:267.

oxytocin, uterine response ensues after 3–5 minutes of infusion, and a steady level of oxytocin in plasma is achieved by 40 minutes (23). The uterine response to oxytocin depends on the duration of the pregnancy; there is a gradual increase in response from 20 to 30 weeks of gestation, followed by a plateau from 34 weeks of gestation until term, when sensitivity increases (24). Lower body mass index and greater cervical dilation, parity, or gestational age are predictors of successful response to oxytocin for induction (25).

Membrane Stripping

Stripping or sweeping the amniotic membranes is commonly practiced to induce labor. Significant increases in phospholipase A₂ activity and prostaglandin F_{2α} (PGF_{2α}) levels occur from membrane stripping (26). Stripping membranes increases the likelihood of spontaneous labor within 48 hours and reduces the incidence of induction with other methods (27). Although membrane sweeping has been associated with increased risk of prelabor rupture of membranes (28), other published systematic reviews, including one with 1,525 women, have not corroborated this finding (27). Women who undergo membrane stripping may experience discomfort from the procedure as well as vaginal bleeding and irregular uterine contractions within the ensuing 24 hours (27). There are insufficient data to guide clinical practice for membrane stripping in women whose group B streptococcus culture is positive.

Amniotomy

Artificial rupture of the membranes may be used as a method of labor induction, especially if the condition of the cervix is favorable. Used alone for inducing labor, amniotomy can be associated with unpredictable and sometimes long intervals before the onset of contractions. There is insufficient evidence on the efficacy and safety of amniotomy alone for labor induction (29). In a trial of amniotomy combined with early oxytocin infusion compared with amniotomy alone, the induction-to-delivery interval was shorter with the amniotomy-plus-oxytocin method (30). There are insufficient data to guide the timing of amniotomy in patients who are receiving intrapartum prophylaxis for group B streptococcal infection.

Nipple Stimulation

Nipple stimulation or unilateral breast stimulation has been used as a natural and inexpensive nonmedical method for inducing labor. In a systematic review of 6 trials including 719 women that compared breast stimulation with no intervention, a significant decrease in the number of women not in labor at 72 hours was noted, but

only in women with favorable cervixes (31). None of the women had uterine tachysystole with or without FHR changes, and there were no differences in meconium-stained amniotic fluid or cesarean delivery rates (31). Breast stimulation was associated with a decrease in postpartum hemorrhage (31). This method has only been studied in low-risk pregnancies.

Labor Induction Terminology

At a 2008 workshop sponsored by the American College of Obstetricians and Gynecologists, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and the Society for Maternal–Fetal Medicine on intrapartum electronic FHR monitoring, the definitions for FHR pattern categorization were reviewed and updated. The existing classification systems for FHR patterns were assessed and new recommendations for use in the United States were made (32). In particular, it was determined that the terms hyperstimulation and hypercontractility should be abandoned. It was recommended that the term tachysystole, with or without corresponding FHR decelerations, be used instead.

Uterine Contractions

Uterine contractions are quantified as the number of contractions present in a 10-minute window, averaged over 30 minutes. Contraction frequency alone is a partial assessment of uterine activity. Other factors such as duration, intensity, and relaxation time between contractions are equally important in clinical practice. The following represents terminology to describe uterine activity:

- *Normal*: Five contractions or less in 10 minutes, averaged over a 30-minute window
- *Tachysystole*: More than five contractions in 10 minutes, averaged over a 30-minute window

Listed are characteristics of uterine contractions:

- Tachysystole should always be qualified as to the presence or absence of associated FHR decelerations.
- The term tachysystole applies to both spontaneous and stimulated labor. The clinical response to tachysystole may differ depending on whether contractions are spontaneous or stimulated.

The majority of literature cited in this Practice Bulletin was published prior to the 2008 NICHD definitions and interpretations of FHR tracings. Consequently, it is difficult to generalize the results of the cited literature, which used nonstandardized and ambiguous definitions for FHR patterns.

Clinical Considerations and Recommendations

► *What are the indications and contraindications to induction of labor?*

Indications for induction of labor are not absolute but should take into account maternal and fetal conditions, gestational age, cervical status, and other factors. Following are examples of maternal or fetal conditions that may be indications for induction of labor:

- Abruptio placentae
- Chorioamnionitis
- Fetal demise
- Gestational hypertension
- Preeclampsia, eclampsia
- Premature rupture of membranes
- Postterm pregnancy
- Maternal medical conditions (eg, diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension, antiphospholipid syndrome)
- Fetal compromise (eg, severe fetal growth restriction, isoimmunization, oligohydramnios)

Labor also may be induced for logistic reasons, for example, risk of rapid labor, distance from hospital, or psychosocial indications. In such circumstances, at least one of the gestational age criteria in the box should be met, or fetal lung maturity should be established. A mature fetal lung test result before 39 weeks of gestation, in the absence of appropriate clinical circumstances, is not an indication for delivery.

The individual patient and clinical situation should be considered in determining when induction of labor is contraindicated. Generally, the contraindications to labor induction are the same as those for spontaneous labor and vaginal delivery. They include, but are not limited to, the following situations:

- Vasa previa or complete placenta previa
- Transverse fetal lie
- Umbilical cord prolapse
- Previous classical cesarean delivery
- Active genital herpes infection
- Previous myomectomy entering the endometrial cavity

► *What criteria should be met before the cervix is ripened or labor is induced?*

Assessment of gestational age and consideration of any potential risks to the mother or fetus are of paramount

Confirmation of Term Gestation

- Ultrasound measurement at less than 20 weeks of gestation supports gestational age of 39 weeks or greater.
- Fetal heart tones have been documented as present for 30 weeks by Doppler ultrasonography.
- It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test result.

importance for appropriate evaluation and counseling before initiating cervical ripening or labor induction. The patient should be counseled regarding the indications for induction, the agents and methods of labor stimulation, and the possible need for repeat induction or cesarean delivery. Although prospective studies are limited in evaluating the benefits of elective induction of labor, nulliparous women undergoing induction of labor with unfavorable cervixes should be counseled about a two-fold increased risk of cesarean delivery (33, 34, 35). In addition, labor progression differs significantly for women with an elective induction of labor compared with women who have spontaneous onset of labor (36). Allowing at least 12–18 hours of latent labor before diagnosing a failed induction may reduce the risk of cesarean delivery (37, 38).

Additional requirements for cervical ripening and induction of labor include assessment of the cervix, pelvis, fetal size, and presentation. Monitoring FHR and uterine contractions is recommended as for any high-risk patient in active labor. Although trained nursing personnel can monitor labor induction, a physician capable of performing a cesarean delivery should be readily available.

► *What is the relative effectiveness of available methods for cervical ripening in reducing the duration of labor?*

A systematic review found that in patients with an unfavorable cervix, Foley catheter placement before oxytocin induction significantly reduced the duration of labor (21). This review also concluded that catheter placement resulted in a reduced risk of cesarean delivery. When the Foley catheter was compared with PGE₂ gel, the majority of the studies have found no difference in duration of induction to delivery or cesarean delivery rate. The use of prostaglandins is associated with an increased risk of tachysystole with or without FHR changes when compared with the Foley catheter (21). The use of different size Foley catheters, insufflation volumes, as well as dif-

ferent misoprostol protocols, yields inconsistent results to determine induction to delivery times, cesarean delivery rate, and risk of meconium passage (18, 21). The addition of oxytocin along with the use of the Foley catheter does not appear to shorten the time of delivery in a randomized controlled trial (39).

Studies examining extraamniotic saline infused through the Foley catheter compared with use of the Foley catheter with concurrent oxytocin administration report conflicting results on the time from induction to delivery (19, 40, 41). Differences in methodology could explain the opposing findings. The Foley catheter is a reasonable and effective alternative for cervical ripening and inducing labor.

Intracervical or intravaginal PGE₂ (dinoprostone) commonly is used and is superior to placebo or no therapy in promoting cervical ripening (42). Several prospective randomized clinical trials and two meta-analyses have demonstrated that PGE₁ (misoprostol) is an effective method for cervical ripening (43–48). Misoprostol administered intravaginally has been reported to be either superior to or as efficacious as dinoprostone gel (48–51). Vaginal misoprostol has been associated with less use of epidural analgesia, more vaginal deliveries within 24 hours, and more uterine tachysystole with or without FHR changes compared with dinoprostone and oxytocin (48). In contrast, misoprostol compared with oxytocin for cervical ripening resulted in longer intervals to active labor and delivery in a randomized controlled trial (52). It is difficult, however, to compare the results of studies on misoprostol because of differences in endpoints, including Bishop score, duration of labor, total oxytocin use, successful induction, and cesarean delivery rate. Pharmacologic methods for cervical ripening do not decrease the likelihood of cesarean delivery.

► *How should prostaglandins be administered?*

One quarter of an unscored 100-mcg tablet (ie, approximately 25 mcg) of misoprostol should be considered as the initial dose for cervical ripening and labor induction. The frequency of administration should not be more than every 3–6 hours. In addition, oxytocin should not be administered less than 4 hours after the last misoprostol dose. Misoprostol in higher doses (50 mcg every 6 hours) may be appropriate in some situations, although higher doses are associated with an increased risk of complications, including uterine tachysystole with FHR decelerations.

If there is inadequate cervical change with minimal uterine activity after one dose of intracervical dinoprostone, a second dose may be given 6–12 hours later. The manufacturers recommend a maximum cumulative dose

of 1.5 mg of dinoprostone (three doses or 7.5 mL of gel) within a 24-hour period. A minimum safe time interval between prostaglandin administration and initiation of oxytocin has not been determined. According to the manufacturers' guidelines, after use of 1.5 mg of dinoprostone in the cervix or 2.5 mg in the vagina, oxytocin induction should be delayed for 6–12 hours because the effect of prostaglandins may be heightened with oxytocin. After use of dinoprostone in sustained-release form, delaying oxytocin induction for 30–60 minutes after removal is sufficient. Limited data are available on the use of buccal or sublingual misoprostol for cervical ripening or induction of labor, and these methods are not recommended for clinical use until further studies support their safety (53).

► *What are the potential complications with each method of cervical ripening, and how are they managed?*

Tachysystole with or without FHR changes is more common with vaginal misoprostol compared with vaginal prostaglandin E₂, intracervical prostaglandin E₂, and oxytocin (48). Tachysystole (defined in some studies as greater than 5 uterine contractions in 10 minutes in consecutive 10-minute intervals) and tachysystole with associated FHR decelerations are increased with a 50-mcg or greater dose of misoprostol (43, 47, 48, 54). There seems to be a trend toward lower rates of uterine tachysystole with FHR changes with lower dosages of misoprostol (25 mcg every 6 hours versus every 3 hours) (48).

The use of misoprostol in women with prior cesarean delivery or major uterine surgery has been associated with an increase in uterine rupture and, therefore, should be avoided in the third trimester (55, 56). An increase in meconium-stained amniotic fluid also has been reported with misoprostol use (47, 48). Although misoprostol appears to be safe and effective in inducing labor in women with unfavorable cervixes, further studies are needed to determine the optimal route, dosage, timing interval, and pharmacokinetics of misoprostol. Moreover, data are needed on the management of complications related to misoprostol use and when it should be discontinued. If uterine tachysystole and a Category III FHR tracing (defined as either a sinusoidal pattern or an absent baseline FHR variability and any of the following: recurrent late decelerations, recurrent variable decelerations, or bradycardia) occurs with misoprostol use and there is no response to routine corrective measures (maternal repositioning and supplemental oxygen administration), cesarean delivery should be considered (32). Subcutaneous terbutaline also can be used in an attempt to correct the Category III FHR tracing or uterine tachysystole.

The intracervical PGE₂ gel (0.5 mg) has a 1% rate of uterine tachysystole with associated FHR changes while the intravaginal PGE₂ gel (2–5 mg) or vaginal insert is associated with a 5% rate (42, 57, 58). Uterine tachysystole typically begins within 1 hour after the gel or insert is placed but may occur up to 9 1/2 hours after the vaginal insert has been placed (57–59).

Removing the PGE₂ vaginal insert usually will help reverse the effect of uterine tachysystole. Irrigation of the cervix and vagina is not beneficial. Maternal side effects from the use of low-dose PGE₂ (fever, vomiting, and diarrhea) are quite uncommon (60). Prophylactic antiemetics, antipyretics, and antidiarrheal agents usually are not needed. The manufacturers recommend that caution be exercised when using PGE₂ in patients with glaucoma, severe hepatic or renal dysfunction, or asthma. However, PGE₂ is a bronchodilator, and there are no reports of bronchoconstriction or significant blood pressure changes after the administration of the low-dose gel.

Increased maternal and neonatal infections have been reported in connection with the use of *Laminaria japonicum* and hygroscopic dilators when compared with the PGE₂ analogues (7, 13, 20). The Foley catheter can cause significant vaginal bleeding in women with a low-lying placenta (21). Other reported complications include rupture of membranes, febrile morbidity, and displacement of the presenting part (61).

► ***What are the recommended guidelines for fetal surveillance after prostaglandin use?***

The prostaglandin preparations should be administered where uterine activity and the FHR can be monitored continuously for an initial observation period. Further monitoring can be governed by individual indications for induction and fetal status.

The patient should remain recumbent for at least 30 minutes. The FHR and uterine activity should be monitored continuously for a period of 30 minutes to 2 hours after administration of the PGE₂ gel (62). Uterine contractions usually are evident in the first hour and exhibit peak activity in the first 4 hours (62, 63). The FHR monitoring should be continued if regular uterine contractions persist; maternal vital signs also should be recorded.

► ***Are cervical ripening methods appropriate in an outpatient setting?***

Limited information is available on the safety of outpatient management of induction of labor. In a randomized, double-blind, controlled trial comparing 2 mg of intravaginal PGE₂ gel with placebo for 5 consecutive days as

an outpatient procedure, it was noted that PGE₂ gel was effective and safe for initiation of labor in women at term with a Bishop score of 6 or less (64). No significant differences in adverse outcomes were noted in another randomized trial of 300 women at term comparing the use of controlled-release PGE₂ in an outpatient versus inpatient setting (65). Larger controlled studies are needed to establish an effective and safe dose and vehicle for PGE₂ before use on an outpatient basis can be recommended. However, outpatient use may be appropriate in carefully selected patients. Mechanical methods may be particularly appropriate in the outpatient setting. A randomized trial comparing the Foley catheter in an outpatient versus inpatient setting for preinduction cervical ripening demonstrated similar efficacy and safety with a reduction of hospital stay of 9.6 hours (66).

► ***What are the potential complications of various methods of induction?***

The side effects of oxytocin use are principally dose related; uterine tachysystole and Category II or III FHR tracings are the most common side effects. Uterine tachysystole may result in abruptio placentae or uterine rupture. Uterine rupture secondary to oxytocin use is rare even in parous women (67). Water intoxication can occur with high concentrations of oxytocin infused with large quantities of hypotonic solutions, but is rare in doses used for labor induction.

Misoprostol appears to be safe and beneficial for inducing labor in a woman with an unfavorable cervix. Although the exact incidence of uterine tachysystole with or without FHR changes is unknown and the criteria used to define this complication are not always clear in the various reports, there are reports of uterine tachysystole with or without FHR changes occurring more frequently in women given misoprostol compared with women given PGE₂ (43, 45, 48, 68). There does not appear to be a significant increase in adverse fetal outcomes from tachysystole without associated FHR decelerations (68, 69). The occurrence of complications does appear to be dose-dependent (10, 48). Clinical trials have shown that at an equivalent dosage, the vaginal route produces greater clinical efficacy than the oral route (53). Oral misoprostol administration is associated with fewer abnormal FHR patterns and episodes of uterine tachysystole with associated FHR changes when compared with vaginal administration (70, 71).

The potential risks associated with amniotomy include prolapse of the umbilical cord, chorioamnionitis, significant umbilical cord compression, and rupture of vasa previa. The physician should palpate for an umbilical cord and avoid dislodging the fetal head. The FHR

should be assessed before and immediately after amniotomy. Amniotomy for induction of labor may be contraindicated in women known to have HIV infection because duration of ruptured membranes has been identified as an independent risk factor for vertical transmission of HIV infection (29).

Stripping the amniotic membranes is associated with bleeding from undiagnosed placenta previa or low-lying placenta, and accidental amniotomy. Bilateral breast stimulation has been associated with uterine tachysystole with associated FHR decelerations. In a systematic review, breast stimulation was associated with an increased trend in perinatal death (31). Until safety issues are studied further, this practice is not recommended in an unmonitored setting.

► ***When oxytocin is used for induction of labor, what dosage should be used and what precautions should be taken?***

Any of the low- or high-dose oxytocin regimens outlined in Table 2 are appropriate for labor induction (72–78). Low-dose regimens and less frequent increases in dose are associated with decreased uterine tachysystole with associated FHR changes (70). High-dose regimens and more frequent dose increases are associated with shorter labor and less frequent cases of chorioamnionitis and cesarean delivery for dystocia, but increased rates of uterine tachysystole with associated FHR changes (74, 79).

Each hospital's obstetrics and gynecology department should develop guidelines for the preparation and administration of oxytocin. Synthetic oxytocin generally

Table 2. Labor Stimulation with Oxytocin: Examples of Low- and High-Dose Oxytocin

Regimen	Starting Dose	Incremental Increase (mU/min)	Dosage Interval (min)
Low-Dose	0.5–2	1–2	15–40
High-Dose	6	3–6*	15–40

*The incremental increase is reduced to 3 mU/min in presence of hyperstimulation and reduced to 1 mU/min with recurrent hyperstimulation.

Data from Hauth JC, Hankins GD, Gilstrap LC 3rd, Strickland DM, Vance P. Uterine contraction pressures with oxytocin induction/augmentation. *Obstet Gynecol* 1986;68:305–9; Satin AJ, Leveno KJ, Sherman ML, Brewster DS, Cunningham FG. High- versus low-dose oxytocin for labor stimulation. *Obstet Gynecol* 1992;80:111–6; Crane JM, Young DC. Meta-analysis of low-dose versus high-dose oxytocin for labour induction. *J SOGC* 1998;20:1215–23; Cummiskey KC, Dawood MY. Induction of labor with pulsatile oxytocin. *Am J Obstet Gynecol* 1990;163:1868–74; Blakemore KJ, Qin NG, Petrie RH, Paine LL. A prospective comparison of hourly and quarter-hourly oxytocin dose increase intervals for the induction of labor at term. *Obstet Gynecol* 1990;75:757–61; Mercer B, Pilgrim P, Sibai B. Labor induction with continuous low-dose oxytocin infusion: a randomized trial. *Obstet Gynecol* 1991;77:659–63; and Muller PR, Stubbs TM, Laurent SL. A prospective randomized clinical trial comparing two oxytocin induction protocols. *Am J Obstet Gynecol* 1992;167:373–80; discussion 380–1.

is diluted 10 units in 1,000 mL of an isotonic solution for an oxytocin concentration of 10 mU/mL. Oxytocin should be administered by infusion using a pump that allows precise control of the flow rate and permits accurate minute-to-minute control. Bolus administration of oxytocin can be avoided by piggybacking the infusion into the main intravenous line near the venipuncture site.

A numeric value for the maximum dose of oxytocin has not been established. The FHR and uterine contractions should be monitored closely. Oxytocin should be administered by trained personnel who are familiar with its effects.

► ***How should complications associated with oxytocin use be managed?***

If uterine tachysystole with Category III FHR tracings occur, prompt evaluation is required and intravenous infusion of oxytocin should be decreased or discontinued to correct the pattern (32). Additional measures may include turning the woman on her side and administering oxygen or more intravenous fluid. If uterine tachysystole persists, use of terbutaline or other tocolytics may be considered. Hypotension may occur following a rapid intravenous injection of oxytocin; therefore, it is imperative that a dilute oxytocin infusion be used even in the immediate puerperium.

► ***Are there special considerations that apply for induction in a woman with ruptured membranes?***

The largest randomized study to date found that oxytocin induction reduced the time interval between premature rupture of membranes and delivery as well as the frequencies of chorioamnionitis, postpartum febrile morbidity, and neonatal antibiotic treatments, without increasing cesarean deliveries or neonatal infections (80). These data suggest that for women with premature rupture of membranes at term, labor should be induced at the time of presentation, generally with oxytocin infusion, to reduce the risk of chorioamnionitis. An adequate time for the latent phase of labor to progress should be allowed.

The same precautions should be exercised when prostaglandins are used for induction of labor with ruptured membranes as for intact membranes. Intravaginal PGE₂ for induction of labor in women with premature rupture of membranes appears to be safe and effective (81). In a randomized study of labor induction in women with premature rupture of membranes at term, only one dose of intravaginal misoprostol was necessary for successful labor induction in 86% of the patients (67). There is no evidence that use of either of these prostag-

landins increases the risk of infection in women with ruptured membranes (67, 81). There is insufficient evidence to guide the physician on use of mechanical dilators in women with ruptured membranes.

A meta-analysis that included 6,814 women with premature rupture of membranes at term compared induction of labor with prostaglandins or oxytocin to expectant management (82). A significant reduction in the risk of women developing chorioamnionitis or endometritis and a reduced number of neonates requiring admission to the neonatal intensive care unit was noted in the women who underwent induction of labor compared with expectant management (82).

► ***What methods can be used for induction of labor with intrauterine fetal demise in the late second or third trimester?***

The method and timing of delivery after a fetal death depends on the gestational age at which the death occurred, on the maternal history of a previous uterine scar, and maternal preference. Although most patients will desire prompt delivery, the timing of delivery is not critical; coagulopathies are associated with prolonged fetal retention and are uncommon. In the second trimester, dilation and evacuation can be offered if an experienced health care provider is available, although patients should be counseled that dilation and evacuation may limit efficacy of autopsy for the detection of macroscopic fetal abnormalities.

Labor induction is appropriate at later gestational ages, if second-trimester dilation and evacuation is unavailable, or based on patient preference. Much of the data for management of fetal demise has been extrapolated from randomized trials of management of second trimester pregnancy termination. Available evidence from randomized trials supports the use of vaginal misoprostol as a medical treatment to terminate nonviable pregnancies before 24 weeks of gestation (83). Based on limited data, the use of misoprostol between 24 to 28 weeks of gestation also appears to be safe and effective (84, 85). Before 28 weeks of gestation, vaginal misoprostol appears to be the most efficient method of labor induction, regardless of cervical Bishop score (84, 86), although high-dose oxytocin infusion also is an acceptable choice (87, 88). Typical dosages for misoprostol use are 200–400 mcg vaginally every 4–12 hours. After 28 weeks of gestation, induction of labor should be managed according to usual obstetric protocols. Cesarean delivery for fetal demise should be reserved for unusual circumstances because it is associated with potential maternal morbidity without any fetal benefit.

Several studies have evaluated the use of misoprostol at a dosage of 400 mcg every 6 hours in women with a stillbirth up to 28 weeks of gestation and a prior uterine scar (85, 89). There does not appear to be an increase in complications in those women. Further research is required to assess effectiveness and safety, optimal route of administration, and dose.

In patients after 28 weeks of gestation, cervical ripening with a transcervical Foley catheter has been associated with uterine rupture rates comparable to spontaneous labor (90) and this may be a helpful adjunct in patients with an unfavorable cervical assessment. Therefore, in patients with a prior low transverse cesarean delivery, trial of labor remains a favorable option. There are limited data to guide clinical practice in a patient with a prior classical cesarean delivery, and the delivery plan should be individualized.

Summary of Recommendations and Conclusions

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- Prostaglandin E analogues are effective for cervical ripening and inducing labor.
- Low- or high-dose oxytocin regimens are appropriate for women in whom induction of labor is indicated (Table 2).
- Before 28 weeks of gestation, vaginal misoprostol appears to be the most efficient method of labor induction regardless of Bishop score, although high-dose oxytocin infusion also is an acceptable choice.
- Approximately 25 mcg of misoprostol should be considered as the initial dose for cervical ripening and labor induction. The frequency of administration should not be more than every 3–6 hours.
- Intravaginal PGE₂ for induction of labor in women with premature rupture of membranes appears to be safe and effective.
- The use of misoprostol in women with prior cesarean delivery or major uterine surgery has been associated with an increase in uterine rupture and, therefore, should be avoided in the third trimester.
- The Foley catheter is a reasonable and effective alternative for cervical ripening and inducing labor.

The following recommendation is based on evidence that may be limited or inconsistent (Level B)

- ▶ Misoprostol (50 mcg every 6 hours) to induce labor may be appropriate in some situations, although higher doses are associated with an increased risk of complications, including uterine tachysystole with FHR decelerations.

Proposed Performance Measure

Percentage of patients in whom gestational age is established by clinical criteria when labor is being induced for logistic or psychosocial indications

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 2009. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS

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Management of Intrapartum Fetal Heart Rate Tracings

Intrapartum electronic fetal monitoring (EFM) is used for most women who give birth in the United States. As such, clinicians are faced daily with the management of fetal heart rate (FHR) tracings. The purpose of this document is to provide obstetric care providers with a framework for evaluation and management of intrapartum EFM patterns based on the new three-tiered categorization.

Background

In 2008, a workshop sponsored by the American College of Obstetricians and Gynecologists, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and the Society for Maternal–Fetal Medicine focused on updating EFM nomenclature, recommending an interpretative system, and setting research priorities (1). Nomenclature for baseline FHR and FHR variability, accelerations, and decelerations were reaffirmed (Table 1). New terminology was recommended for the description and quantification of uterine contractions. *Normal uterine activity* was defined as five or fewer contractions in 10 minutes, averaged over a 30-minute window. *Tachysystole* was defined as more than five contractions in 10 minutes, averaged over 30 minutes and should be categorized by the presence or absence of FHR decelerations. Tachysystole can be applied to spontaneous or induced labor. The terms hyperstimulation and hypercontractility were abandoned.

A three-tiered system for intrapartum EFM interpretation also was recommended (Box 1), with the nomenclature and interpretation described elsewhere (1). This second Practice Bulletin on intrapartum FHR tracings reviews the management of heart rate patterns based on the three-tiered classification system (Figure 1).

Clinical Considerations and Recommendations

► *How is a Category I EFM tracing managed?*

Category I FHR tracings are normal (Box 1). These tracings are not associated with fetal acidemia (2–6). Category I FHR patterns may be managed in a routine manner with either continuous or intermittent monitoring. Tracings should be periodically evaluated and documented during active labor by a health care provider (eg, this may include physician, nurse, or midwife) based on clinical

Committee on Practice Bulletins—Obstetrics. This Practice Bulletin was developed by the Committee on Practice Bulletins—Obstetrics with the assistance of George Macones, MD, and Sean Blackwell, MD, in collaboration with Thomas Moore, MD, Catherine Spong, MD, John Hauth, MD, Gary Hankins, MD, and representatives from the Association of Women's Health, Obstetric and Neonatal Nurses—Audrey Lyndon RN, PhD, Kathleen R. Simpson, PhD RN, and Anne Santa-Donato, RNC, MSN, and the American College of Nurse–Midwives—Tekoa King, CNM, MPH. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Table 1. Electronic Fetal Monitoring Definitions

Pattern	Definition
Baseline	<ul style="list-style-type: none"> • The mean FHR rounded to increments of 5 beats per minute during a 10-minute segment, excluding: <ul style="list-style-type: none"> —Periodic or episodic changes —Periods of marked FHR variability —Segments of baseline that differ by more than 25 beats per minute • The baseline must be for a minimum of 2 minutes in any 10-minute segment, or the baseline for that time period is indeterminate. In this case, one may refer to the prior 10-minute window for determination of baseline. • Normal FHR baseline: 110–160 beats per minute • Tachycardia: FHR baseline is greater than 160 beats per minute • Bradycardia: FHR baseline is less than 110 beats per minute
Baseline variability	<ul style="list-style-type: none"> • Fluctuations in the baseline FHR that are irregular in amplitude and frequency • Variability is visually quantitated as the amplitude of peak-to-trough in beats per minute. <ul style="list-style-type: none"> —Absent—amplitude range undetectable —Minimal—amplitude range detectable but 5 beats per minute or fewer —Moderate (normal)—amplitude range 6–25 beats per minute —Marked—amplitude range greater than 25 beats per minute
Acceleration	<ul style="list-style-type: none"> • A visually apparent abrupt increase (onset to peak in less than 30 seconds) in the FHR • At 32 weeks of gestation and beyond, an acceleration has a peak of 15 beats per minute or more above baseline, with a duration of 15 seconds or more but less than 2 minutes from onset to return. • Before 32 weeks of gestation, an acceleration has a peak of 10 beats per minute or more above baseline, with a duration of 10 seconds or more but less than 2 minutes from onset to return. • Prolonged acceleration lasts 2 minutes or more but less than 10 minutes in duration. • If an acceleration lasts 10 minutes or longer, it is a baseline change.
Early deceleration	<ul style="list-style-type: none"> • Visually apparent usually symmetrical gradual decrease and return of the FHR associated with a uterine contraction • A gradual FHR decrease is defined as from the onset to the FHR nadir of 30 seconds or more. • The decrease in FHR is calculated from the onset to the nadir of the deceleration. • The nadir of the deceleration occurs at the same time as the peak of the contraction. • In most cases, the onset, nadir, and recovery of the deceleration are coincident with the beginning, peak, and ending of the contraction, respectively.
Late deceleration	<ul style="list-style-type: none"> • Visually apparent usually symmetrical gradual decrease and return of the FHR associated with a uterine contraction • A gradual FHR decrease is defined as from the onset to the FHR nadir of 30 seconds or more. • The decrease in FHR is calculated from the onset to the nadir of the deceleration. • The deceleration is delayed in timing, with the nadir of the deceleration occurring after the peak of the contraction. • In most cases, the onset, nadir, and recovery of the deceleration occur after the beginning, peak, and ending of the contraction, respectively.
Variable deceleration	<ul style="list-style-type: none"> • Visually apparent abrupt decrease in FHR • An abrupt FHR decrease is defined as from the onset of the deceleration to the beginning of the FHR nadir of less than 30 seconds. • The decrease in FHR is calculated from the onset to the nadir of the deceleration. • The decrease in FHR is 15 beats per minute or greater, lasting 15 seconds or greater, and less than 2 minutes in duration. • When variable decelerations are associated with uterine contractions, their onset, depth, and duration commonly vary with successive uterine contractions.
Prolonged deceleration	<ul style="list-style-type: none"> • Visually apparent decrease in the FHR below the baseline • Decrease in FHR from the baseline that is 15 beats per minute or more, lasting 2 minutes or more but less than 10 minutes in duration. • If a deceleration lasts 10 minutes or longer, it is a baseline change.
Sinusoidal pattern	<ul style="list-style-type: none"> • Visually apparent, smooth, sine wave-like undulating pattern in FHR baseline with a cycle frequency of 3–5 per minute which persists for 20 minutes or more.

Abbreviation: FHR, fetal heart rate.

Macones GA, Hankins GD, Spong CY, Hauth J, Moore T. The 2008 National Institute of Child Health and Human Development workshop report on electronic fetal monitoring: update on definitions, interpretation, and research guidelines. *Obstet Gynecol* 2008;112:661–6.

Box 1. Three-Tiered Fetal Heart Rate Interpretation System

Category I

- Category I FHR tracings include all of the following:
- Baseline rate: 110–160 beats per minute
- Baseline FHR variability: moderate
- Late or variable decelerations: absent
- Early decelerations: present or absent
- Accelerations: present or absent

Category II

Category II FHR tracings includes all FHR tracings not categorized as Category I or Category III. Category II tracings may represent an appreciable fraction of those encountered in clinical care. Examples of Category II FHR tracings include any of the following:

Baseline rate

- Bradycardia not accompanied by absent baseline variability
- Tachycardia

Baseline FHR variability

- Minimal baseline variability
- Absent baseline variability with no recurrent decelerations
- Marked baseline variability

Accelerations

- Absence of induced accelerations after fetal stimulation

Periodic or episodic decelerations

- Recurrent variable decelerations accompanied by minimal or moderate baseline variability
- Prolonged deceleration more than 2 minutes but less than 10 minutes
- Recurrent late decelerations with moderate baseline variability
- Variable decelerations with other characteristics such as slow return to baseline, overshoots, or “shoulders”

Category III

Category III FHR tracings include either

- Absent baseline FHR variability and any of the following:
 - Recurrent late decelerations
 - Recurrent variable decelerations
 - Bradycardia
- Sinusoidal pattern

Abbreviation: FHR, fetal heart rate.

Macones GA, Hankins GD, Spong CY, Hauth J, Moore T. The 2008 National Institute of Child Health and Human Development workshop report on electronic fetal monitoring: update on definitions, interpretation, and research guidelines. *Obstet Gynecol* 2008;112:661–6.

status and underlying risk factors. Thus, during the first stage of labor the FHR tracing should be reviewed every 30 minutes and every 15 minutes during the second stage (7). Documentation of this review should include description of FHR category and overall pattern. Change in management may need to occur only if Category II or Category III features develop (Figure 1).

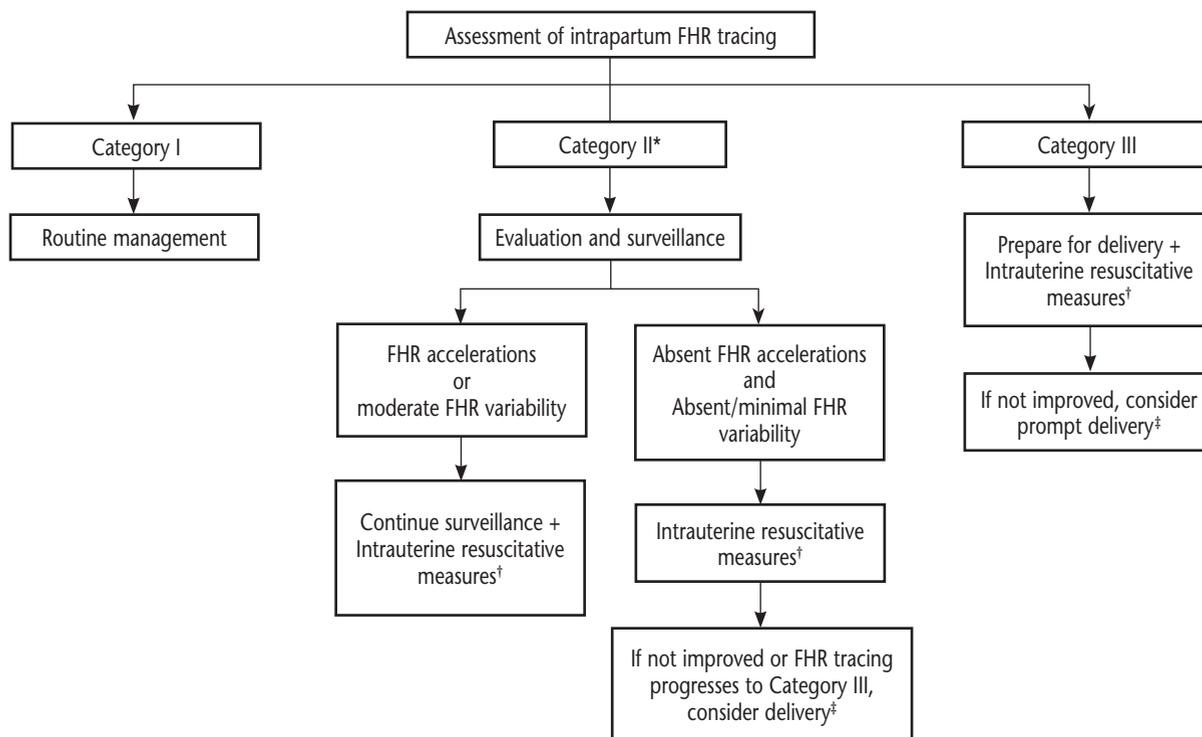
► *How is a Category II EFM tracing evaluated and managed?*

Category II FHR tracings include all FHR patterns that are not classified as Category I or Category III (Box 1). Category II tracings require evaluation, continued surveillance, initiation of appropriate corrective measures when indicated, and reevaluation. Once identified, these tracings may require more frequent evaluation, documentation, and continued surveillance, unless they revert to Category I. Given the diverse spectrum of abnormal FHR patterns in Category II, the presence of FHR accelerations (whether spontaneous or elicited by digital scalp or vibroacoustic stimulation) or moderate FHR variability or both are highly predictive of normal fetal acid–base status and, thus, may help guide clinical management (Figure 1) (8–12). The management of specific FHR abnormalities within Category II is discussed as follows.

► *How are intermittent and recurrent variable decelerations evaluated and managed?*

Intermittent variable decelerations, defined as occurring with less than 50% of contractions, are the most common FHR abnormality occurring during labor (13), most often do not require any treatment, and are associated with normal perinatal outcomes (3). Evaluation of recurrent variable decelerations includes their frequency, depth and duration, uterine contraction pattern, and other FHR characteristics such as FHR variability (14, 15). *Recurrent variable decelerations*, defined as occurring with greater than or equal to 50% of contractions, that progress to greater depth and longer duration are more indicative of impending fetal acidemia (2, 8, 14, 15). In FHR tracings with recurrent variable decelerations, the presence of moderate FHR variability or a spontaneous or induced acceleration suggests that the fetus is not currently acidemic.

Management of recurrent variable decelerations should be directed at relieving umbilical cord compression (Table 2). Maternal positioning as an initial therapeutic maneuver is a reasonable first step (16). Although there is limited evidence for improvements in short-term or long-term neonatal outcomes, amnioinfusion has been shown to decrease the recurrence of variable decelerations as well as the rate of cesarean delivery for “suspected fetal distress” (17). Adjunctive measures to promote fetal



*Given the wide variation of FHR tracings in Category II, this algorithm is not meant to represent assessment and management of all potential FHR tracings, but provide an action template for common clinical situations.

†See Table 2 for list of various intrauterine resuscitative measures

‡Timing and mode of delivery based on feasibility and maternal-fetal status

Figure 1. Management algorithm of intrapartum fetal heart rate tracings based on three-tiered category system. Abbreviation: FHR, fetal heart rate.

oxygenation also may be useful depending on the severity and duration of the recurrent variable decelerations (Table 2).

► **How are recurrent late decelerations evaluated and managed?**

Recurrent late decelerations are thought to reflect transient or chronic uteroplacental insufficiency (18). Common causes include maternal hypotension (eg, postepidural), uterine tachysystole, and maternal hypoxia. Management involves maneuvers to promote uteroplacental perfusion, which may include maternal lateral positioning, intravenous fluid bolus, maternal oxygen administration, and evaluation for tachysystole (Table 2) (16).

In Category II tracings with recurrent late decelerations, management includes intrauterine resuscitation and reevaluation to determine whether an adequate improvement in fetal status has occurred. Given the low predictive value of late decelerations for acidemia and their known false-positive rate for fetal neurologic injury (19–23),

evaluation for the presence of accelerations or moderate FHR variability or both may be useful to assess the risk of fetal acidemia (24). If despite intrauterine resuscitation measures late decelerations continue in the setting of minimal FHR variability and absent accelerations, the presence of fetal acidemia should be considered and the potential need for expedited delivery should be evaluated. If FHR variability becomes absent, then the FHR is now Category III and should be managed accordingly.

► **How is intrapartum fetal tachycardia evaluated and managed?**

Fetal tachycardia is defined as a baseline heart rate greater than 160 beats per minute (bpm) for at least 10 minutes (Table 1). Fetal tachycardia should be evaluated for identifiable underlying causes such as infection (eg, chorioamnionitis, pyelonephritis, or other maternal infections), medications (eg, terbutaline, cocaine, and other stimulants), maternal medical disorders (eg, hyperthyroidism), obstetric conditions (eg, placental abruption or fetal bleed-

Table 2. Various Intrauterine Resuscitative Measures for Category II or Category III Tracings or Both

Goal	Associated Fetal Heart Rate Abnormality*	Potential Intervention (s)†
Promote fetal oxygenation and improve uteroplacental blood flow	Recurrent late decelerations	Initiate lateral positioning (either left or right)
	Prolonged decelerations or bradycardia	Administer maternal oxygen administration
	Minimal or absent fetal heart rate variability	Administer intravenous fluid bolus Reduce uterine contraction frequency
Reduce uterine activity	Tachysystole with Category II or III tracing	Discontinue oxytocin or cervical ripening agents Administer tocolytic medication (eg, terbutaline)
Alleviate umbilical cord compression	Recurrent variable decelerations	Initiate maternal repositioning
	Prolonged decelerations or bradycardia	Initiate amnioinfusion If prolapsed umbilical cord is noted, elevate the presenting fetal part while preparations are underway for operative delivery

*Evaluation for the underlying suspected cause(s) is also an important step in management of abnormal FHR tracings.

†Depending on the suspected underlying cause(s) of FHR abnormality, combining multiple interventions simultaneously may be appropriate and potentially more effective than doing individually or serially (Simpson KR, James DC. Efficacy of intrauterine resuscitation techniques in improving fetal oxygen status during labor. *Obstet Gynecol* 2005;105:1362–8).

Data from Young BK, Katz M, Klein SA, Silverman F. Fetal blood and tissue pH with moderate bradycardia. *Am J Obstet Gynecol* 1979;135:45–7; Chauhan SP, Roach H, Naef RW 2nd, Magann EF, Morrison JC, Martin JN Jr. Cesarean section for suspected fetal distress. Does the decision-incision time make a difference? *J Reprod Med* 1997;42:347–52; Schaubberger CW, Chauhan SP. Emergency cesarean section and the 30-minute rule: definitions. *Am J Perinatol* 2009;26:221–6; and Schifrin BS, Hamilton-Rubinstein T, Shields JR. Fetal heart rate patterns and the timing of fetal injury. *J Perinatol* 1994;14:174–81.

ing), and fetal tachyarrhythmias (often associated with FHR greater than 200 bpm). In isolation, tachycardia is poorly predictive for fetal hypoxemia or acidemia, unless accompanied by minimal or absent FHR variability or recurrent decelerations or both.

Treatment for a Category II tracing with tachycardia should be directed at the underlying cause. In addition, other characteristics of the FHR tracing need to be evaluated in concert with the tachycardia, especially baseline variability. For example, a FHR tracing with tachycardia, minimal variability, and no accelerations cannot reliably exclude fetal acidemia.

► ***How are intrapartum bradycardia and prolonged decelerations evaluated and managed?***

Fetal bradycardia is defined as a baseline heart rate less than 110 bpm for at least 10 minutes (Table 1). *Prolonged decelerations* are defined as FHR decreases of at least 15 bpm below baseline that last at least 2 minutes but less than 10 minutes. Clinical intervention often is indicated before the distinction can be made between a prolonged deceleration and fetal bradycardia; thus, the immediate management of the two is similar.

Prolonged decelerations or fetal bradycardia should be evaluated for identifiable causes such as maternal hypotension (eg, postepidural), umbilical cord prolapse or occlusion, rapid fetal descent, tachysystole, placental abruption, or uterine rupture. Bradycardia due to these conditions often occurs in labor and usually is preceded by an initially normal FHR baseline. Rarely, bradycardia

also may occur in fetuses with congenital heart abnormalities or myocardial conduction defects, such as those associated with maternal collagen vascular disease. Most often the onset of bradycardia associated with congenital heart block occurs in the second trimester; it is extremely unlikely that new onset intrapartum bradycardia would be due to this condition.

Treatment for Category II tracing with bradycardia or prolonged decelerations is directed at the underlying cause (Table 2). Fetal heart rate variability during baseline periods should be evaluated in order to better assess the risk of fetal acidemia (25). If bradycardia with minimal or absent variability or prolonged decelerations or both do not resolve, then prompt delivery is recommended.

► ***How is minimal FHR variability evaluated and managed?***

As with other characteristics of the FHR tracing, baseline variability often changes with fetal sleep or wake state and over the course of labor, and it may transition from moderate to minimal and back again. Evaluation of minimal FHR variability should include evaluation of potential causes such as maternal medications (eg, opioid, magnesium sulfate), fetal sleep cycle, or fetal acidemia (26–28). For minimal variability thought to be due to recent maternal opioid administration, FHR variability often improves and returns to moderate variability within 1–2 hours. A fetal sleep cycle generally lasts 20 minutes but can persist up to 60 minutes, and moderate variability should return when the fetal sleep cycle is

complete. Thus, in these situations, continued observation and expectant management is appropriate. If minimal FHR variability is suspected to be due to decreased fetal oxygenation, then maternal repositioning, administration of oxygen, or intravenous fluid bolus may be considered (Table 2). If improvement in FHR variability does not occur with these measures and there are no FHR accelerations, additional assessment such as digital scalp or vibroacoustic stimulation should be done (12). Continued minimal variability (in the absence of accelerations or normal scalp pH) that cannot be explained or resolved with resuscitation should be considered as potentially indicative of fetal acidemia and should be managed accordingly.

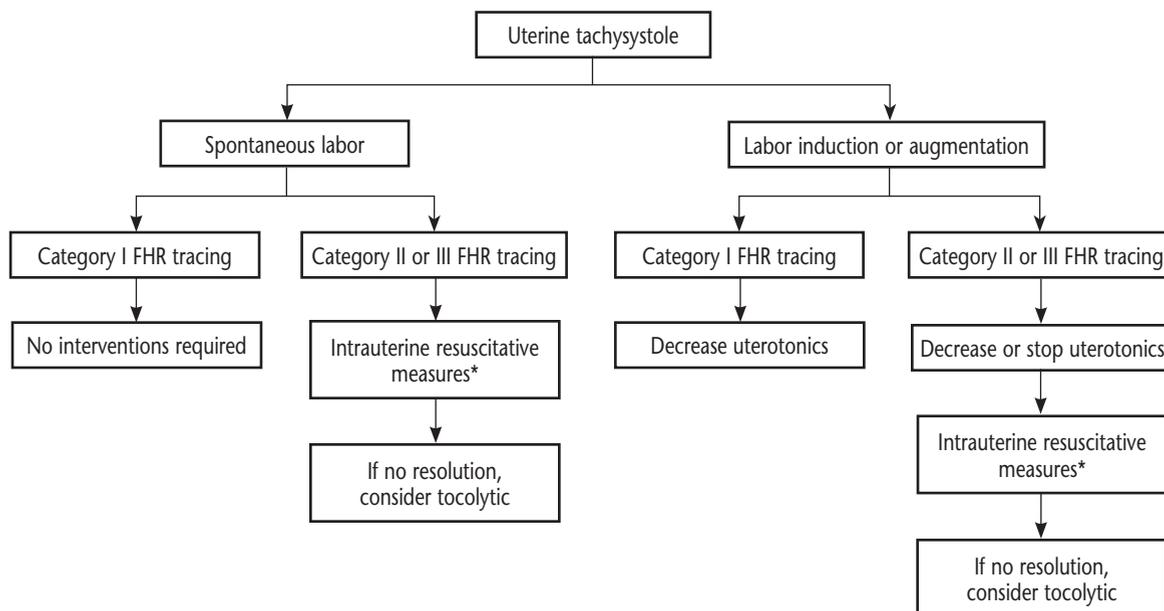
► **How is tachysystole with and without FHR changes evaluated and managed?**

Tachysystole is defined as more than five contractions in 10 minutes, averaged over 30 minutes. The presence or absence of associated FHR abnormalities is the key issue in management (Figure 2). For women with spontaneous labor, tachysystole coupled with recurrent FHR decelerations requires evaluation and treatment. Tachysystole occurring with less frequent FHR abnormalities may or may not require treatment, depending on the specific clinical situation and associated FHR characteristics such as variability and accelerations. In laboring women receiving oxytocin, management of tachysystole generally involves efforts to reduce uterine activity to minimize risk of evolving fetal hypoxemia or acidemia (29).

In labor induction or augmentation or both, a decrease in the oxytocin dose should be considered if tachysystole occurs in the presence of a Category I tracing. If there is a Category II or III tracing, oxytocin should be reduced or stopped in addition to intrauterine resuscitation (7). In addition, simultaneous initiation of multiple resuscitative measures may improve fetal condition more rapidly than the use of individual therapies (Table 2). If tachysystole induced FHR abnormalities do not resolve with these initial maneuvers, then tocolytic medications (eg, terbutaline) may be warranted (30, 31).

► **How is a Category III EFM tracing evaluated and managed?**

A Category III FHR tracing is abnormal and conveys an increased risk for fetal acidemia at the time of observation. Category III tracings have been associated with an increased risk for neonatal encephalopathy, cerebral palsy, and neonatal acidosis. Nevertheless, the predictive value of Category III tracings for abnormal neurologic outcome is poor (32). If unresolved, Category III FHR tracings most often require prompt delivery. While intrauterine resuscitation measures are used, preparations for delivery should be considered and a time frame for proceeding to delivery should be determined if the FHR does not improve (Figure 1). As discussed previously potential interventions for intrauterine resuscitation are described in Table 2; these should be modified to the appropriate clinical circumstance(s) and specific FHR pattern.



*See Table 2 for list of various intrauterine resuscitative measures

Figure 2. Management algorithm for uterine tachysystole. Abbreviation: FHR, fetal heart rate.

► *If a Category III tracing continues and intra-uterine resuscitative measures are unsuccessful, over what time interval should delivery be accomplished?*

The acceptable time frame to accomplish delivery in the setting of a Category III FHR tracing has not been established. Historically, a 30-minute rule from decision-to-incision time for emergent cesarean delivery in the setting of abnormal FHR pattern has existed (7); however, the scientific evidence to support this threshold is lacking. In a study of 2,808 women who had cesarean deliveries for emergent indications, investigators found that more than 30% of the cesarean deliveries began more than 30 minutes after the decision to operate, yet adverse neonatal outcomes were not increased among those infants delivered after more than 30 minutes (33). Multiple other studies affirm the lack of association of increased adverse outcomes with this 30-minute decision-to-incision time frame (34–38). It also should be recognized that in some cases immediate delivery in a woman with an unknown duration of a Category III tracing may not improve outcome if the fetus has already experienced hypoxic ischemic injury (39, 40).

Nevertheless, when a decision for operative delivery in the setting of a Category III EFM tracing is made, it should be accomplished as expeditiously as feasible. The decision-to-incision interval and mode of delivery should be based on the timing that best incorporates maternal and fetal risks and benefits. For instance many of these clinical scenarios will include high-risk conditions or pregnancy complications (eg, morbid obesity, eclampsia, cardiopulmonary compromise, hemorrhage), which may require maternal stabilization or additional surgical preparation before performance of emergent cesarean delivery. These factors also may vary based on the institution and local circumstances. Preparation for impending delivery of a woman with a Category III tracing often requires assessment of several logistical issues depending on the setting and clinical circumstances (see Box 2).

Summary of Conclusions and Recommendations

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- Category I FHR tracings may be managed in a routine manner because they are not associated with fetal acidemia.

Box 2. Potential Logistical Considerations in Preparation for Operative Delivery in Setting of Category III Tracing

- Obtain informed consent (verbal or written as feasible)
- Assemble surgical team (surgeon, scrub technician, and anesthesia personnel)
- Assess patient transit time and location for operative delivery
- Ensure intravenous access
- Review status of laboratory tests (eg, complete blood type and screen) and assess need for availability of blood products
- Assess need for preoperative placement of indwelling foley catheter
- Assemble personnel for neonatal resuscitation

- A Category III FHR tracing is abnormal and conveys an increased risk of fetal acidemia at the time of observation.
- Amnioinfusion has been shown to decrease the recurrence of variable decelerations as well as the rate of cesarean delivery for abnormal FHR patterns.

The following recommendations and conclusions are based on evidence that may be limited or inconsistent (Level B):

- Intravenous fluid bolus, lateral positioning and oxygen administration, when used together, may improve fetal oxygenation during labor.
- Regardless of whether labor is spontaneous or stimulated, tachysystole accompanied by Category II or Category III FHR tracing requires evaluation and initiation of appropriate treatment.
- Category II tracings require evaluation, continued surveillance, initiation of appropriate corrective measures when indicated, and reevaluation. The presence of FHR accelerations (whether spontaneous or elicited) or moderate FHR variability or both are highly predictive of normal fetal acid–base status and, thus, may help guide clinical management.

The following conclusion is based primarily on consensus and expert opinion (Level C):

- The optimal time frame to effect delivery in the setting of a Category III FHR tracing has not been established.

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Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

- Level A—Recommendations are based on good and consistent scientific evidence.
- Level B—Recommendations are based on limited or inconsistent scientific evidence.
- Level C—Recommendations are based primarily on consensus and expert opinion.

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OBSTETRICS

Implementation of a conservative checklist-based protocol for oxytocin administration: maternal and newborn outcomes

Steven Clark, MD; Michael Belfort, MD, PhD; George Saade, MD; Gary Hankins, MD; Darla Miller, RN; Donna Frye, RN; Janet Meyers, RN

OBJECTIVE: The purpose of this study was to examine the effects of a conservative and specific checklist-based protocol for oxytocin administration on maternal and newborn outcome. The protocol was based on maternal and fetal response to oxytocin rather than infusion rate.

STUDY DESIGN: This was a retrospective chart review and data extraction of the last 100 patients receiving oxytocin before implementation of the protocol and the first 100 patients receiving oxytocin after protocol implementation.

RESULTS: The 2 groups were demographically similar. For the pre- and postprotocol groups, the mean time of infusion to delivery was 8.5 ± 5.3 hours versus 8.2 ± 4.5 hours (NS), the maximum oxytocin infusion rate was 13.8 ± 6.3 mU/min versus 11.4 ± 6.1 mU/min ($P = .003$) and the cesarean delivery rate was 15% versus 13% (NS). Every index of newborn outcome was improved in the post-protocol

group, but these differences did not individually reach statistical significance. However, newborns with any index of adverse outcome were significantly fewer in the post protocol group (31 vs 18, $P = .049$). System wide implementation of this program was associated with a decline in the rate of primary cesarean delivery from 23.6% in 2005 to 21.0% in 2006.

CONCLUSION: Implementation of a specific and conservative checklist-based protocol for oxytocin infusion based on maternal and fetal response results in a significant reduction in maximum infusion rates of oxytocin without lengthening labor or increasing operative intervention. Cesarean delivery rate declined system-wide following implementation of this protocol. Newborn outcome also appears to be improved.

Key words: cesarean delivery, medication safety, oxytocin

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Oxytocin is one of the most commonly administered drugs in obstetrics. Although this agent, when carefully administered, is generally safe, adverse perinatal outcomes related to fetal hypoxia may occur in the presence of

★ EDITORS' CHOICE ★

uterine hyperstimulation.¹ Due to a lack of outcomes based data demonstrating the clear superiority of any specific regimen of oxytocin administration, current guidelines in this regard are non-specific.²⁻⁴ While no single regimen of oxytocin administration has been demonstrated superior in terms of clinical outcomes, one of the most fundamental principles of quality improvement is that, in general, greater practice variation is associated with poorer outcomes than more uniform practice patterns.^{5,6} In recent decades, the airline industry has established an enviable record of safety, due, in large part, to the extensive use of a uniform, checklist-based approach to the management of certain high risk situations.^{7,8} We examined the effects of implementation of a conservative uniform checklist-based system of oxytocin administration in a large, tertiary level facility.

MATERIALS AND METHODS

The Hospital Corporation of America is the nation's largest single health care delivery organization, with 125 obstetric facilities in 20 states. In 2004, the Perinatal Safety Division assisted with the establishment of a system wide uniform, checklist-based protocol for oxytocin administration by work groups composed of representative practicing physicians, nurses, and pharmacists from the entire organization, as well as consultants from other institutions in areas served by our hospitals. With respect to mandated response to both fetal heart rate abnormalities and uterine contraction patterns, the protocols were purposefully far more conservative than would be required by current standard of care (Tables 2 and 3).⁴ These protocols were then piloted in select facilities to further refine the safety and practicality of the checklists. The resultant checklist based protocols were then presented for adoption by individual departments of obstetrics and gynecology in each of our

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TABLE 1
Oxytocin in-use checklist

Demographic/clinical factor	Prechecklist	Postchecklist
Maternal age	27.2±5.2	27.5±5.2
Parity	1.1±1.2	1.3±1.2
Gestational age (wk)	38.8±1.7	39.0±1.4
Oxytocin onset to delivery (h)	8.7±4.3	8.6±4.5
Total time oxytocin infused (h)	8.5±5.3	8.2±4.5
Maximum oxytocin dose (mU/min)	13.8±6.3	11.4±6.1 (0.003)*
Latent phase length (h)	5.8±3.3	5.5±3.2
Active phase length (h)	2.1±1.3	2.3±1.8
Second stage length (h)	0.69±0.69	0.74±0.92
Birthweight	6.998±1.259	7.421±1.231 (0.017)*
Apgar 1 minute	7.6±1.1	7.9±0.88 (0.048)*
Apgar 5 minutes	8.7±1.0	8.8±0.98
Cervical ripening agents	16	10
Cesarean delivery	15	13
Cesarean for fetal heart rate abnormalities	6	3
Operative vaginal delivery	11	10
Cesarean for labor arrest	9	9
Newborn intensive care admission	16	11
Respiratory distress	13	6
Sepsis suspected	2	1
Sepsis confirmed	6	2
Mean days in newborn intensive care	2.29	0.81
Mean newborn intensive care days for those admitted to NICU	14.3±10.4	7.4±5.7
Infants with 1 or more newborn complication	30	18 (<i>P</i> = .049)*

facilities. These protocols are designed as default models of oxytocin administration, to be automatically implemented and uniformly followed in the absence of a specific physician order to the contrary. Individual variations from protocol are allowed as long as the physician prospectively documents her/his rationale for such an alternative approach in the medical record. The protocols are designed for use in singleton, vertex, term labor in women with an unscarred uterus. Medical indications for induction did not exempt the patient from protocol use. Uniform protocols for oxytocin mixing and infusion were utilized.

St Mark's Hospital is a tertiary level, nonteaching referral facility in Salt Lake City, UT, with an annual delivery volume of approximately 3700. The checklist-based protocols were adopted by the department of Obstetrics and Gynecology at St Marks hospital and implemented March 1, 2005. As part of our ongoing internal patient safety and quality assurance program, we collected data regarding clinical course of labor and maternal/newborn outcomes in the last 100 patients receiving oxytocin prior to the adoption of the protocol and the first 100 patients receiving oxytocin after the introduction of the protocol. Institu-

tional review board approval for publication of this analysis was obtained. Our working hypothesis was that such uniform, highly conservative practice would not significantly prolong labor or increase the intervention rate and would improve perinatal outcomes. Based upon the composite morbidity found in the pre-protocol group, we calculated that 100 patients in each group would give our analysis an 80% power to demonstrate a 50% reduction in composite adverse outcome at an alpha error of 0.05. Data extraction was undertaken by a single, experienced labor and delivery nurse from an institution in a different state. Univariate (Chi-square, Fisher exact, Student *t*, or Mann-Whitney rank sum test as appropriate) and multivariate analyses were performed.

RESULTS

All patients were delivered within a single month both before and after the protocol institution. During this period of time, there were no variations from protocol ordered by the attending physician. Demographic and clinical data are presented in Table 1. The only significant difference was a small but significant increased birthweight in the checklist managed group. The maximum dose of oxytocin used to achieve delivery was significantly lower in the checklist managed group. There was no difference in the length of any stage or phase of labor, total time of oxytocin administration, or rate of operative vaginal or abdominal delivery.

Following analysis of these data, these same protocols were implemented throughout the Hospital Corporation of America system. During the first year of system wide implementation of this protocol (2006), the primary cesarean delivery rate in approximately 220,000 deliveries fell from 23.6% (1995) to 21.0% (1996) in contrast to an annual increase in rate of primary cesarean of 1-4% in previous years (Figure).

A comparison of newborn outcomes demonstrated a statistically significant difference in 1 minute Apgar scores, with improved 1 minute Apgar scores in the checklist managed group. In addition,

fewer newborn complications were seen for every category analyzed, although individually, these did not reach statistical significance. However, when patients suffering any newborn complication requiring NICU admission or Apgar score < 8 were compared to those suffering no complication, significantly improved newborn outcome was seen in the checklist managed group (Table 1).

COMMENT

Current guidelines for oxytocin use are nonspecific, and current standard of care allows for a wide range of oxytocin doses and infusion rates.⁴ This reflects a lack of evidence-based data to support safety or efficacy benefits of any specific regimen of oxytocin administration. On the other hand, one of the basic principles of quality process improvement is that process uniformity will generally result in product or outcome improvement, compared to processes that are highly variable.^{5,6} This principle has been utilized with great success by the airline industry, which has developed highly standardized, checklist-based protocols for the management of a number of critical in-flight situations.⁸ Indeed, the aircraft checklist has long been regarded as a foundation of pilot standardization and cockpit safety.⁸ Such checklists were not developed as a result of randomized trials of various approaches but rather by pilots and other airline professionals on the basis of consensus “best practice.” This approach has resulted in a dramatic decrease in aircraft errors and accidents since its institution several decades ago.⁷ In contrast, according to the Institute of Medicine, medical errors have increased by 257% over a similar time period.⁹ Further, even less specific, non-checklist-based best practice rules are only followed in the treatment of only about half of patients in the United States.¹⁰ Accordingly, we sought to standardize our system wide approach to the administration of oxytocin, the drug most commonly implicated in avoidable medication related adverse outcomes, with the use of a highly specific checklist-based protocol (Tables 2 and 3).

TABLE 2
Pre-oxytocin checklist



HCA Perinatal Safety Initiative Pre-Oxytocin Checklist For Women with Term-Singleton Babies

“This Pre-Oxytocin checklist represents a guideline for care: however, individualized medical care is directed by the physician”

If the following checklist cannot be completed, Oxytocin should not be initiated

Date and time completed _____

1. Physician or Midwife Order on chart
2. Current history and physical on the chart*
3. Prenatal Record on chart*
4. Indication for induction is documented
5. Pelvis is documented by physician to be clinically adequate (should be on prenatal record)*
6. Estimated fetal weight within past week (clinical or ultrasound) less than 4500grams in a non-diabetic woman or less than 4250 grams in a diabetic woman*
7. Gestational age documented
8. Consent signed (General L&D consent)
9. Physician with C-section privileges is aware of the induction and readily available and this is documented in the medical record
10. Status of the cervix is assessed and documented
11. Presentation is assessed and documented (physician required to come in if nurse unable to determine)
12. Fetal Assessment completed and indicates: (complete all below)
 - A minimum of 30 minutes of fetal monitoring is required prior to starting Oxytocin
 - At least 2 accelerations (15 bpm x 15 sec) in 30 minutes are present, or a biophysical profile of 8 of 10 is present within the past 4 hours or adequate variability.**
 - No late decelerations in the last 30 minutes
 - No more than 2 Variable deceleration exceeding 60 seconds and decreasing greater than 60 bpm from baseline within the previous 30 minutes prior to starting Oxytocin infusion.

*May be delayed for non-elective admissions.

** This document does not apply to a formal Oxytocin challenge test without the intent to induce or augment labor.

**There will be some situations in which alterations in management from that described in the protocol are clinically appropriate. If, after reviewing the fetal heart rate strip and course of labor the responsible physician feels that in his or her judgment, continued use of Oxytocin is in the best interest of the mother and baby, the physician should write or dictate a note to that effect and order the Oxytocin to continue. The RN will continue to provide safe, high quality nursing care.

FINAL: September 8, 2005

The primary concern expressed by some physicians was that the conservatism built into these checklist-based protocols would unduly delay delivery or increase the need for operative intervention. Interference with physician autonomy was also a frequently cited concern. The latter concern is remarkably similar to observations of the initial response of pilots to flight protocols, where “pilot desire to be unique” and “pilot desire to demonstrate unusual competence”

were frequent initial objections. Such objections have largely disappeared in the airline industry as the safety record of this industry has improved dramatically, in large part as a result of such checklists.^{7,8}

In practice, the institution of this protocol neither prolonged labor nor increased the need for operative intervention despite a significant reduction in the maximum infusion rate of oxytocin. Our goal in developing this protocol was to

TABLE 3
"In use" oxytocin checklist



HCA

HCA Perinatal Safety Initiative

Recommended Oxytocin "In Use" Checklist for Women with Term Singleton- Babies

"This Oxytocin "In Use" Checklist represents a guideline for care: however, individualized medical care is directed by the physician."

Checklist will be completed every 30 minutes. Oxytocin should be stopped or decreased if the following checklist cannot be completed.

Date and time completed _____

Fetal Assessment indicates:

- At least 1 acceleration of 15 bpm x 15 seconds in 30 minutes or adequate variability for 10 of the previous 30 minutes.
- No more than 1 late deceleration occurred.
- No more than 2 Variable decelerations exceeding 60 seconds in duration and decreasing greater than 60 bpm from the baseline within the previous 30 minutes.

Uterine Contractions

- No more than 5 uterine contractions in 10 minutes for any 20minute interval
- No two contractions greater than 120 seconds duration
- Uterus palpates soft between contractions
- If IUPC is in place, MVU** must calculate less than 300 mm Hg and the baseline resting tone must be less than 25 mm Hg.

***If Oxytocin is stopped the Pre-Oxytocin Checklist will be reviewed before Oxytocin is reinitiated.**

**** MVU = Montevideo Units**

improve practice and outcomes without regard to the cesarean delivery rate. All educational and policy initiatives were based upon the premise that the only metric of importance is the number of healthy mothers who take home healthy babies and that cesarean delivery is best viewed as a process, not an outcome. This premise, coupled with recommendations for a more conservative approach to issues such as abnormal fetal heart rate patterns and operative vaginal delivery, would have been expected to increase the rate of primary cesarean delivery. In practice, however, we saw a *decline* in the rate of primary cesarean delivery throughout our system associated

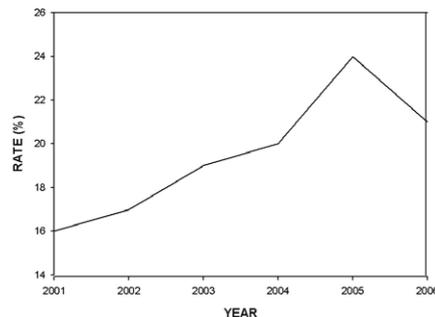
with the uniform implementation of this protocol (Figure). In light of both national trends and our own system-wide data and patient safety initiatives, we believe this to be most likely a result of less hyperstimulation associated with the use of this oxytocin protocol. While our data do not allow a definitive conclusion regarding the cause of the decreased primary cesarean rate, it is clear that system-wide implementation of this protocol did not increase the primary cesarean delivery rate.

In addition, we found improvement in every index of newborn outcome examined in the protocol managed group, although, due to small sample size, only 1

FIGURE

Primary cesarean delivery rate, Hospital Corporation of America

PRIMARY CESAREAN DELIVERY RATE



Clark. Checklist-based protocol for oxytocin. AJOG 2007.

minute Apgar score reached individual statistical significance. Overall adverse outcomes were, however, significantly lower in the protocol managed group. While statistically significant, these differences were not clinically dramatic; 1 minute Apgar score, for example, correlates poorly with long-term newborn outcome.¹¹ Further, while the combined outcome groups did demonstrate statistically significant improvement using the protocol, the *P* value was just under .05. Thus, while our data unequivocally demonstrate that this protocol does not prolong labor or increase the rate of cesarean delivery, we feel justified only in saying that this protocol appears to improve newborn outcomes. However, the 17% reduction in maximum oxytocin dose seen with protocol use was highly significant (*P* = .003). The only known adverse effect of exogenous oxytocin on the fetus is dose-related hyperstimulation. Thus, achievement of equivalent intervention rates and labor duration with a 17% reduction in the maximum dose of oxytocin certainly suggests that such improved outcomes would be born out more dramatically in a larger series. Similar labor outcomes with a lower dose of oxytocin seem in themselves a desirable goal.

In designing this checklist-based system, we chose to focus on uterine and fetal response to oxytocin, rather than on any specific dosing regimen, given the known variation in dose response of the

drug. In the absence of hyperstimulation or signs of fetal intolerance of labor, we felt the dose to be virtually irrelevant; thus, the protocol allows for any of the wide range of low or high dose oxytocin regimens approved by the American College of Obstetricians and Gynecologists.⁴ Our outcomes support such recommendations and validate our assumption in this regard. Current nursing recommendations for formal charting during labor every 30 minutes. Thus, these protocols did not increase the time required for nurse charting, rather, they simply offered a standard approach to evaluation and charting. After stopping oxytocin, resumption was allowed as soon as criteria for oxytocin initiation were once again met (Tables 2 and 3).

Several definitions of hyperstimulation have been offered in the literature, some based on specific patterns of uterine activity, and others implying that oxytocin may be continued, regardless of the nature of resultant contractions, until fetal heart rate patterns suggesting frank asphyxia are obtained.⁴ We purposefully did not utilize this confusing term; rather, we defined in a very simple manner fetal heart rate and uterine contraction patterns, which our work group felt to be indications for slowing, or stopping, the oxytocin infusion.

It should be noted that our protocols were considerably more conservative in terms of mandating a decrease in oxytocin dose based on abnormal patterns of fetal heart rate or uterine activity that would generally be required by the stan-

dard of care.⁴ However, in most of our facilities patients are cared for by nurses with different levels of experience; periodic shift changes and lack of 24-hour in-house obstetricians or residents are also realities in most hospitals in the United States. Given these variables, many physicians were favorably inclined toward the use of such protocols as default procedures, allowing them to be assured that with even a basic level of nursing fetal monitoring skills and the ability to count, it is virtually impossible for a patient to be injured by oxytocin if these conservative protocols are followed. In a larger patient population, we foresee numerous situations in which a physician's order to deviate from the protocol may be entirely appropriate. Our design group of practicing physicians and nurses felt, however, that such circumstances would clearly require physician awareness and examination of the specific monitor pattern and overall clinical situation; under such circumstances, we did not feel it unreasonable to ask a physician to articulate her/his rationale for the clinical judgment to deviate from the protocol.

We wish to emphasize that the uniform practice pattern achieved with our protocols is probably as important as the actual details of the protocols themselves. Thus, other criteria for discontinuing oxytocin within a framework of an alternative checklist-based protocol may well have given equivalent results. However, our data support the use of specific checklist-based protocols as one

appropriate way to manage oxytocin administration. Labor is not prolonged, cesarean deliveries are not increased, and newborn outcomes appear to be improved. ■

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Perinatal Labor Augmentation Safety

Process to deliver reliable care with special attention at the onset of labor reduces the likelihood of harm to both mother and baby.

Domain



Patient Care Processes:

Clinical processes that ensure delivery of high-quality care to individual patients

Aims



Safe:

Delivery of care in a manner that minimizes any risk of harm to a patient

Process Attributes



Cost to Implement

The monetary resources required to implement this process

Minimal: Just the cost of the improvement effort itself



Time to Implement

The amount of time, from months to years, it will take on average to establish this process

Fewer than 12 months



Difficulty to Implement

The challenges of implementing this process

Most Challenging: Involves multiple units or disciplines AND requires a substantial shift in culture and/or operations



Level of Evidence

The degree to which the actions in this process are supported by research and experience; based on the Cochrane scale

Some Evidence: Level III — Studies published with some control included

Details

Elements

- **Bundle components:**
 - Documentation of estimated fetal weight
 - Recognition and management of tachysystole
 - Pelvic assessment
 - Reassuring fetal status /Normal fetal status (using NICHD 3-Tier System)

Outcomes

- **Harm:** Decreased harm to patient (e.g., Harms per 100 patient days, as measured by the IHI Global Trigger Tool)
- **Cost of Care:** Decreased cost per inpatient case

<http://www.ih.org/imap/tool/#process=adf36aaa-63c5-4e2c-8c8d-e4ae8e9b29c4>

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Service Lines and Critical Functions

- Obstetrics

Key Measures

- All components of the Perinatal Augmentation Bundle completed
 - Numerator: Percent of patients where all components of the Perinatal Augmentation Bundle were completed
 - Denominator: Number of records reviewed
- Percent change in rate of mothers transferred to higher level of care
- Percent change in rate of newborns admitted to neonatal intensive care

Reasons and Implications

Importance for Patients and Families

When mothers in labor require medicines to strengthen labor, it is important that those medicines are used safely. This reduces the chance of harm for both mother and baby and means that separating mother from infant after delivery is less likely.

Requirement, Standards, Policies, and Guidelines

- [National Priorities Partnership \(NPP\)](#)
Safety
- [The Joint Commission \(TJC\)](#)
National Patient Safety Goal 3: High Alert Medications

Financial Implications

- Expense reduction can occur due to decreased length of stay of mother in labor and delivery, and infant in neonatal intensive care.
- Expense increases can occur due to greater throughput in labor and delivery (e.g., nursing time, length of stay).
- Revenue reduction can occur due to the decreased length of stay for mothers and babies.
- Overall, a positive return on investment is reported in the literature because hospitals that have increased the reliability of these components have also reported a decrease in medical malpractice set-asides and overall expenses.

Prerequisites

- Collaboration between nurses and obstetrical care providers in the labor and delivery unit
- Acceptance of standard algorithms for treatment

Resources

Additional Resources

- [American College of Obstetricians and Gynecologists \(ACOG\)](#)
Labor augmentation
- [Map of Medicine](#)
 - Caesarean Section
 - Term Labour

IHI.org Resources

- [Improvement Map Discussion Boards](#)
Join the Improvement Map Discussion Groups to help IHI build dynamic communities of learning and support. Pose questions, offer new ideas, describe your improvement success stories and experiences, and share tips with your peers for taking full advantage of all the Improvement Map has to offer.
- [Reducing Birth-Related Trauma and Liability Exposure](#)
Lehigh Valley Hospital and Health Network (Allentown, Pennsylvania, USA) reduces birth-related trauma through their work as part of a Perinatal Innovation Community.
- [Improving Safety Within the Birth Center](#)
Increased reliability in the Birth Center makes perinatal care safer at HealthPartners Regions Hospital (St. Paul, Minnesota,

<http://www.ihl.org/imap/tool/#process=adf36aaa-63c5-4e2c-8c8d-e4ae8e9b29c4>

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