Kathleen Rice Simpson, PhD, RNC, CNS-BC, FAAN

CERVICAL RIPENING AND LABOR INDUCTION AND AUGMENTATION, 5TH EDITION

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AWHONN
PROMOTING THE HEALTH OF WOMEN AND NEWBORNS

About AWHONN

Headquartered in Washington, DC, the Association of Women's Health, Obstetric and Neonatal Nurses is a leader among the nation's nursing associations, serving more than 22,000 health care professionals in the United States, Canada, and abroad and representing more than 350,000 nurses in our specialty.

AWHONN advances the nursing profession by providing nurses with critical information and support to help them deliver the highest quality care for women and newborns. Though its many evidence-based education and practice resources, legislative programs, research, and coalition work with other organizations and associations, AWHONN has firmly established itself as the leading association of women's health, obstetric, and neonatal nurses.

AWHONN members strive to deliver superior health care to women and newborns in hospital, home care, and ambulatory care settings. The rich diversity of member's skills and experience make AWHONN *the* voice for women's health and neonatal nursing. It is through their dedication, knowledge, skill, and expertise that we create resources aimed at achieving our mission to promote the health of women and newborns.

Cervical Ripening and Labor Induction and Augmentation, 5th ed.

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About the Author

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MESH Terms
Cervical Ripening
Labor, Induced
Laminaria
Amniotomy
Prostaglandins
Oxytocin
Watchful Waiting
Informed Consent
Decision Making, Shared

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ABSTRACT

Cervical ripening and induction and augmentation of labor are common procedures in labor and birth units. The potential risks and benefits for the procedure should be explained to women so that they can make informed decisions. Clinicians should be knowledgeable about the methods and medications used and be skilled in maternal–fetal assessment. Adequate nurse staffing is required to monitor the mother and fetus to promote the best possible outcomes. This practice monograph includes information on mechanical and pharmacologic methods for cervical ripening; labor induction and augmentation with oxytocin, a high alert drug; and nurse staffing levels and skills needed to provide safe and effective care during cervical ripening and labor induction and augmentation.

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INTRODUCTION

Labor at term for healthy women may begin spontaneously or may be artificially induced. Factors that influence how and when labor starts for healthy women at term are complex, not universally agreed upon, and not equitably applied to all women in all clinical settings. Whether a healthy woman at term waits for labor to begin on its own or undergoes induction of labor is based on evolving evidence; her preferences; and the opinions and philosophies of the primary care providers who attend her during pregnancy, labor, and birth, such as midwives and physicians. Some but not all women who undergo induction of labor are fully informed about their options, the process, and potential risks and benefits. Interventions to artificially initiate labor may be necessary when there is a medical indication for birth before labor begins naturally. This medical indication may be related to the condition of the woman, fetus, or both. Labor may be electively initiated in the absence of a medical indication for the convenience of the provider or the woman. Convenience and artificial interference with the labor and birth process are consistently evidenced in the natality data collected from certificates of live birth in the United States. Data are captured related to the time of day and day of the week of birth which show distinct birth time and date differences based on spontaneous initiation of labor, induction of labor, and cesarean birth (Matthews & Curtain, 2015; Martin, Hamilton, Osterman, & Driscoll, 2019). Critical to the success of induction of labor and to the most optimal maternal-newborn outcomes are candidates with favorable cervical status, appropriate timing based on gestational age of the fetus, and vigilant nursing care.

Knowledge of the indications, contraindications, potential complications and expected processes and outcomes for each of the techniques and pharmacologic agents used to ripen the cervix and stimulate labor is required for perinatal nurses, since they provide most of the hands-on, direct care for women who undergo cervical ripening and labor induction and augmentation. Knowledge and skills in maternal-fetal assessment before initiation of the procedure and throughout labor and birth are essential to keep the woman and fetus or newborn safe and to promote the best possible outcomes. Adequate nurse staffing is required to allow frequent bedside attendance for ongoing assessment and support. Timely and accurate communication between the nurse and other members of the health care team, including the woman and her family, is vital. It is important that the woman is provided with enough information at the appropriate literacy level and language so that she can participate in decisions before and during labor as a full partner in her own care. This monograph from the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) is designed to cover the information that perinatal nurses need to know to provide safe and effective care for women who undergo cervical ripening and labor induction and augmentation.

DEFINITION OF TERMS

Cervical ripening is a process that causes the physical softening, thinning, and dilating of the cervix in

preparation for labor and birth (American College of Obstetricians and Gynecologists [ACOG], 2009b).

Induction of labor is the use of pharmacologic and/or mechanical methods to initiate labor. Examples of methods include but are not limited to artificial rupture of membranes, balloons, oxytocin, prostaglandin, laminaria, or other cervical ripening agents (ACOG, 2014).

Augmentation of labor is the use of pharmacologic methods or artificial rupture of membranes to increase the frequency and/or strength of contractions following the onset of spontaneous labor or spontaneous rupture of membranes (ACOG, 2014).

Tachysystole is excessive uterine activity that can be spontaneous or induced. Tachysystole is defined as more than five contractions in 10 minutes averaged over 30 minutes (Macones, Hankins, Spong, Hauth, & Moore, 2008). The Society of Obstetricians and Gynaecologists of Canada (SOGC) defined excessive uterine activity as more than five contractions in 10 minutes averaged for 30 minutes, subdivided into two categories: with and without fetal heart rate (FHR) changes (Leduc, Biringer, Lee, & Dy, 2013).

Gestational age at birth is classified as the following:

- *Preterm*: less than 37 weeks and 0 days,
- *Late preterm*: 34 weeks and 0 days through 36 weeks and 6 days, and
- *Term*: greater than or equal to 37 weeks and 0 days using best estimated due date and is divided into the following categories:
  - *Early term*: 37 weeks and 0 days through 38 weeks and 6 days,
  - *Full term*: 39 weeks and 0 days through 40 weeks and 6 days,
  - *Late term*: 41 weeks and 0 days through 41 weeks and 6 days, and
  - *Post term*: Greater than or equal to 42 weeks and 0 days (ACOG, 2014).

INCIDENCE

According to the National Center for Health Statistics (Martin et al., 2019), in 2018 (the most recent year for which this type of detailed natality data are available), rates of induction and augmentation of labor in the United States were 27.1% and 21.5% respectively for all births. The 2018 induction rate (27.1%) was 184% higher than the 1990 rate (9.5%) and the highest since these data have been recorded from birth certificates (Martin et al., 2019). The induction rate increased by 5% from 2017 (25.7%) to 2018 (27.1%) (Martin et al., 2019). Induction rates in 2018 differed by race: White women 30.3%, Black women 25.2%, and Hispanic women 22.8% (Martin et al., 2019). The augmentation rate increased slightly (1.26%) from 2017 (21.28%) to 2018 (21.55%). Augmentation rates are similar among the three categories of race reported, and all are between 21% and 22% (Martin et al., 2019). The latest natality data are available from the National Center for Health Statistics (2019).

Most clinicians would note that these numbers seem low compared to what they experience in clinical practice. The induction rate is calculated based on all women who give birth (Martin et al., 2019). If women who had planned or repeat cesarean births were excluded from the denominator, and the figures were calculated based on all others who could have had labor inductions, the reported rate of induction would be higher. It is likely that data about induction and augmentation are significantly underreported on birth certificates (Menacker & Martin, 2008). Further, limited data exist with which to differentiate medically indicated and non-medically indicated (elective) labor inductions because the distinction is not noted on the United States Standard Certificate of Live Birth. Therefore, exact rates are unknown.

MEDICAL INDICATIONS

Induction of labor has merit as a therapeutic option when the benefits of expeditious birth outweigh the risks of continuing a pregnancy (ACOG, 2009b; American College of Nurse-Midwives [ACNM], 2016; Leduc et al., 2013). Box 1 lists criteria, indications, and contraindications for cervical ripening and labor induction and augmentation (American Academy of Pediatrics [AAP] & ACOG, 2017; ACOG, 2009b, 2011; ACOG & Society for Maternal-Fetal Medicine [SMFM], 2014, 2019a, 2019b; AWHONN, 2010). In 2011, the Eunice Kennedy Shriver National Institute of Child Health and Human Development offered further recommendations for timing of medically indicated births before 39 completed weeks gestation based on a review of the evidence by an expert panel of perinatal clinicians and scientists (Spong et al., 2011). A helpful patient safety checklist for collecting important patient information as part of scheduling an induction of labor was published by ACOG in 2011. In 2019, ACOG and SMFM (2019a, 2019b) provided updated, joint recommendations about timing of medically indicated, late preterm and early term births and avoiding nonmedically indicated, early term births. ACOG (2019a) reaffirmed the practice bulletin "Induction of Labor" in its entirety. Hospitals accredited by The Joint Commission (2020a) that have at least 300 live births per year are required to report on the perinatal care core measures that follow:

- PC-01: Women with elective vaginal births or elective cesarean births at greater than 37 and less than 39 completed weeks gestation (process measure).
- PC-02: Nulliparous women with term, singleton fetuses in vertex presentation born by cesarean (outcome measure).
- PC-06: The percentage of newborns with unexpected complications among full-term newborns with no preexisting conditions (outcome measure).

Additional details related to potential medical indications for induction of labor can be found by reviewing the *Specifications Manual for Joint Commission National Quality Core Measures* (The Joint Commission, 2020a).

NONMEDICAL INDICATIONS (ELECTIVE)

According to ACOG (2009b), labor may be induced for logistical reasons, such as a history of rapid labor and distance from the hospital, or for psychosocial indications. Interpretation of psychosocial indications varies among maternity care providers and is most commonly noted as elective (i.e., nonmedical indication)

BOX 1 CRITERIA, INDICATIONS, AND CONTRAINDICATIONS FOR CERVICAL RIPENING AND LABOR INDUCTION AND AUGMENTATION

CRITERIA FOR CERVICAL RIPENING AND INDUCTION OF LABOR

Generally, induction of labor has merit as a therapeutic option when the benefits of expeditious birth outweigh the risks of continuing the pregnancy. The benefits of labor induction need to be weighed against the potential maternal and fetal risks associated with this procedure. Before 41 0/7 weeks gestation, induction of labor generally should be performed based on maternal and fetal medical indications. Inductions at 41 0/7 weeks gestation and beyond should be performed to reduce the risk of cesarean birth and the risk of perinatal morbidity and mortality.

- Gestational age, status of the cervix, pelvic adequacy, and size and presentation of the fetus should be assessed.
- Any potential risks to the woman and fetus should be considered, including risks of continuing the pregnancy and risks of induction of labor.
- The medical record should document that a discussion was held between the woman and her health care provider about the indications for induction; the agents and methods of induction, including the risks, benefits, and alternative approaches; and the possible need for repeat induction or cesarean birth.
- Cervical ripening and induction agents should be administered by trained personnel, e.g., registered nurses, who are familiar with the effects on the woman and fetus.
- Prostaglandin preparations should be administered where uterine activity and FHR can be monitored continuously via electronic fetal monitoring (EFM) for an initial observation period. Fetal heart rate monitoring via EFM should be continued if regular uterine contractions persist.
- Fetal heart rate and uterine contractions should be monitored closely via EFM during induction and augmentation with oxytocin as for any woman at high risk in active labor.
- A physician capable of performing a cesarean birth should be readily available.
- For women undergoing trial of labor after a cesarean (TOLAC), induction of labor for maternal or fetal indications remains an option.
- Misoprostol should not be used for third trimester cervical ripening or labor induction in women who have had cesarean birth or major uterine surgery.

INDICATIONS FOR CERVICAL RIPENING AND INDUCTION OF LABOR

Indications for the induction of labor are not absolute; the maternity care provider should consider maternal and fetal conditions, gestational age, status of cervix, and other factors. Following are examples of maternal or fetal conditions that may be indications for the induction of labor:

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

Examples of medical indications in late preterm or early term births include the following:

- Preeclampsia, eclampsia, gestational hypertension, or complicated chronic hypertension
- Oligohydramnios
- Previous classical cesarean birth or prior myomectomy
- Placenta previa or placenta accreta
- Multiple gestation
- Fetal growth restriction
- Pregestational diabetes with vascular disease
- Poorly controlled pregestational or gestational diabetes
- Premature rupture of membranes
- Cholestasis of pregnancy
- Alloimmunization of pregnancy with known or suspected fetal growth effects

Labor may also be induced for logistic reasons such as risk of rapid labor, distance from the hospital, or psychosocial indications. In such circumstances, at least one of the following criteria should be met or fetal lung maturity should be established:

- Ultrasound measurement at less than 20 weeks gestation supports gestational age of 39 weeks or greater.
- Fetal heart tones have been documented as present for 30 weeks by Doppler ultrasound.
- It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test result.
- Testing for fetal lung maturity should not be performed and is contraindicated when birth is mandated for fetal or maternal indications. Conversely, a fetal lung test that indicated maturity before 39 weeks gestation in the absence of appropriate clinical circumstances is not an indication for elective labor induction.

CONTRAINDICATION TO INDUCTION OF LABOR

Generally, the contraindications for labor induction are the same as those for spontaneous labor and vaginal birth. They include but are not limited to the following:

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

NURSE STAFFING FOR CERVICAL RIPENING AND INDUCTION AND AUGMENTATION OF LABOR

- One registered nurse to two women undergoing cervical ripening with a pharmacologic agent
- One registered nurse to one woman undergoing induction or augmentation of labor with oxytocin

Sources: AAP & ACOG, 2017; ACOG, 2009b, 2011; ACOG & SMFM, 2014, 2019a, 2019b; AWHONN, 2010.

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induction of labor. In a 2009 evidence report from the Agency for Healthcare Research and Quality, Caughey et al. summarized the literature on maternal and neonatal outcomes related to elective induction of labor and concluded that elective induction of labor at greater than or equal to 41 weeks gestation decreased risk of cesarean birth and meconium-stained amniotic fluid and was likely a cost-effective intervention. In 2014, ACOG and SMFM jointly published an obstetric care consensus on safe prevention of the primary cesarean birth that included guidelines for the timing of birth: induction of labor generally should be performed based on maternal and fetal medical indications for women at less than 41 0/7 weeks gestation. For women at greater than or equal to 41 0/7 weeks gestation, induction should be performed to reduce the risks of cesarean birth and perinatal morbidity and mortality. Guidelines to enhance the likelihood of successful induction of labor included cervical ripening for women with unfavorable cervixes. If maternal and fetal status do not indicate otherwise, the latent phase of labor should be allowed to continue for as long as 24 hours or more, and oxytocin should be administered for at least 12 to 18 hours after the rupture of membranes before failure of induction is diagnosed (ACOG & SMFM, 2014).

Timing of Elective Induction of Labor Based on Weeks of Pregnancy

Results of a recent, rigorously designed, multicenter, randomized, clinical trial (Randomized Trial of Induction Versus Expectant Management [ARRIVE]) confirmed that it is safe for the healthy woman and fetus to await spontaneous labor (Grobman, Rice, et al., 2018). In a study of 6,106 low-risk nulliparous women randomized to elective induction ($n = 3,062$) or expectant management ($n = 3,044$), researchers found no differences between groups related to the primary outcome: a neonatal composite measure that included perinatal death or severe neonatal complications and consisted of one or more of the following during the antepartum or intrapartum period or during the birth hospitalization: need for respiratory support within 72 hours after birth, Apgar score of 3 or less at 5 minutes, hypoxic–ischemic encephalopathy, seizure, infection (confirmed sepsis or pneumonia), meconium aspiration syndrome, birth trauma (bone fracture, neurologic injury, or retinal hemorrhage), intracranial or subgaleal hemorrhage, or hypotension requiring vasopressor support (Grobman, Rice, et al., 2018). Women randomized to the elective induction group agreed to induction between 39 0/7 weeks to 39 4/7 weeks gestation. Women in the expectant management group agreed not to have elective birth before 40 5/7 weeks gestation but to have birth initiated no later than 42 2/7 weeks gestation (Grobman, Rice, et al., 2018). Women in the elective induction group gave birth at a significantly earlier median gestational age than women in the expectant management group (39.3 weeks [interquartile range, 39.1 to 39.6 weeks] vs. 40.0 weeks [interquartile range, 39.3 to 40.7 weeks], $p < 0.001$; Grobman, Rice, et al., 2018).

The World Health Organization (2018) recommended that elective induction of labor for healthy, low-risk women be deferred until 41 0/7 weeks gestation. SOGC (Leduc et al., 2013) suggested that labor induction should not be performed solely based on the preferences of the maternity care provider or the woman but should be offered once the healthy, low-risk woman reaches 41 0/7 weeks gestation. In the United Kingdom, the National Institute for Health and Care Excellence (2008, 2014) recommended that women with uncomplicated pregnancies should be offered induction of labor between 41 0/7 and 42 0/7 weeks gestation to avoid the risks associated with prolonged pregnancy. Exact timing should take into account the woman's preferences and local circumstances. The International Federation of Gynecology and Obstetrics (FIGO) and other organizations recommended induction of labor for prolonged pregnancy defined as greater than or equal to 41 weeks gestation (Jacob et al., 2014).

When labor is induced electively, the pregnant woman should be at least 39 completed weeks gestation to avoid the risk of iatrogenic prematurity (AAP & ACOG, 2017; ACOG, 2009b, 2011; ACOG & SMFM, 2018, 2019a, 2019b; Chiossi et al., 2013; Raju, Higgins, Stark, & Leveno, 2006; The Joint Commission, 2020a; Tita et al., 2018). Because early term births without medical indications can result in preventable neonatal morbidity, professional organizations have promulgated recommendations to avoid them. As per ACOG (2009b, 2011), gestational age of 39 completed weeks should be confirmed by at least one method before elective birth: ultrasound measurement at less than 20 weeks, documented fetal heart tones present at 30 weeks by Doppler ultrasonography, or it has been 36 weeks since the documentation of a positive serum or urine human chorionic gonadotropin pregnancy test result (ACOG, 2009b, 2011). Post-term pregnancy is generally defined as 42 weeks gestation or greater (ACOG, 2014). Post-term pregnancy is included as a medical indication by ACOG (2009b); however, when a woman reaches 41 weeks gestation, most experts agree that birth is indicated (ACOG & SMFM, 2014). In a multicenter, randomized, controlled trial of 2,760 low-risk, nulliparous and multiparous women randomized to elective induction at 41 weeks or expectant management until 42 weeks and then induction of labor, Wennerholm et al. (2019) found perinatal mortality to be increased in the expectant management group; the trial was stopped early because of these results.

PREPARATION FOR CERVICAL RIPENING, INDUCTION, OR AUGMENTATION

Risk-Benefit Analysis and Informed Consent

Detailed Discussion and Shared Decision-Making

Women who are undergoing medical procedures should have adequate, objective information with which to make informed decisions about the potential risks and benefits of having procedures, having alternative procedures, or doing nothing. This information should include indications for induction, agents and methods of cervical ripening and labor stimulation, and their risks (AAP & ACOG, 2017; ACNM, 2016; AWHONN, 2019a). As an ethical doctrine, the informed consent process enables a pregnant woman to make a knowledgeable and voluntary decision about accepting or declining medical care (ACOG, 2009a; AWHONN, 2019a). The

informed consent process should occur at the appropriate literacy level and in a language the woman can understand (National Quality Forum, 2018; Simpson, 2019a; The Joint Commission, 2020a).

Multiple pharmacologic agents and techniques can be used to artificially initiate labor or labor can begin on its own. During the prenatal period when the woman and fetus are healthy, all available options, including awaiting the spontaneous onset of labor and elective induction of labor, should be objectively discussed in detail. If medical, obstetric, or neonatal complications arise during pregnancy or labor, the woman should be thoroughly advised of all options, including potential risks and benefits for herself and the fetus. The woman is an essential member of the health care team and should be centrally involved in all labor and birth decisions as a full partner in her own care (AWHONN, 2019a). Some clinicians may be reluctant to offer detailed information about potential risk; however, women are interested in and have the right to be told about common potential complications (Declercq, Sakala, Corry, Applebaum, & Herrlich, 2013). In a study of 3,337 nulliparous pregnant women, two-thirds of those who received detailed information about potential risks of labor induction during prepared childbirth classes found the information helpful in deciding whether to undergo elective induction (Simpson, Newman, & Chirino, 2010).

When they described the experience of elective induction of labor, women often noted that they were not fully informed about the process and potential risks (Moore, Low, Titler, Dalton, & Sampselle, 2014; Simpson et al., 2010). Women who perceive pressure from their maternity care providers may be more likely to undergo induction of labor without medical indication, so options for healthy low-risk women at term should be offered in a neutral nonjudgmental manner (Declercq et al., 2013; Jou, Kozhimannil, Johnson, & Sakala, 2015; Sakala, Declercq, Turon, & Corry, 2018; Simpson et al., 2010; Stevens & Miller, 2012). It is important to consider that many women may be receptive to recommendations regarding induction of labor from their maternity care providers; therefore, providers should carefully offer choices for interventions rather than appearing to recommend the procedures. The traditional, hierarchical relationship and historical balance of power between providers and patients can confound the most well-intentioned, insightful attempts to participate in a discussion that results in truly informed consent (ACOG, 2009a). Being aware of how pregnant women may respond to the suggestion of elective labor induction could be useful in planning these types of interactions (Simpson, 2014).

Ideally a discussion about the labor and birth process begins during the prenatal period and offers an opportunity for questions and answers. When the pregnant woman presents to the hospital for labor induction, perinatal nurses should be able to assume that she has been fully informed of risks, benefits, and alternatives, including waiting for labor to begin on its own; has participated in a thorough discussion with her maternity care provider; and has had all of her questions and concerns addressed. If it is apparent during admission that the woman is not fully informed about the intended method of labor induction, the maternity care provider who ordered the induction or a designee should be notified and is expected to speak to the woman on the telephone or in person about the potential risks and benefits of the process. All of the woman's questions and concerns should be addressed before proceeding. For example, the woman may not be aware that a balloon catheter will be inserted for cervical ripening or that an intravenous (IV) line and continuous fetal monitoring are part of the process for induction of labor with oxytocin. The role of the nurse is to confirm that the informed consent process between the provider and the woman has occurred.

Length of Stay in the Intrapartum Setting

For nulliparous women specifically, ACOG and SMFM (2014) recommended that before induction of labor, an unfavorable cervix should be ripened to enhance the likelihood of vaginal birth. Cervical ripening with mechanical methods or pharmacologic agents may take many hours and will likely occur in the hospital setting. Women should be aware that induced labor is significantly longer than spontaneous labor; a latent phase as long as 18 hours during labor induction for nulliparous women is not unusual (ACOG, 2009b) and has been well documented in the literature (ACOG & SMFM, 2014; Harper et al., 2012; Grobman, Bailit, et al., 2018; Grobman, Rice, et al, 2018; Hoffman et al., 2006; Incerti et al., 2011; Rouse, Owen, Savage, & Hauth, 2001; Zhang et al., 2010). In the ARRIVE trial of low-risk nulliparous women at term, length of stay in the intrapartum setting averaged 20 hours for the elective induction group and 14 hours for the expectant management group (Grobman, Rice, et al., 2018). Similar results for intrapartum length of stay were found in a randomized, controlled trial of 2,760 low-risk nulliparous and multiparous women in Sweden: 20.1 hours for the elective induction group and 13.6 hours for expectant management group (Wennerholm et al., 2019). As per ACOG & SMFM (2014), length of the latent phase labor is longer than previously believed; therefore, a prolonged latent phase (>20 hours in nulliparous women and >14 hours in multiparous women) should not be the sole indication for cesarean birth.

Likelihood of Vaginal Birth

Results of the ARRIVE trial (Grobman, Rice, et al., 2018) have minimized concerns that elective induction of labor for low-risk, nulliparous women increases risk of cesarean birth in the context of a labor management protocol that includes the following: a) cervical ripening for a modified Bishop score less than 5, b) at least 12 hours in the latent phase after completion of cervical ripening, c) rupture of membranes, and d) use of oxytocin before considering the induction failed. The cesarean birth rate of the elective induction group was 18.6% compared 22.2% in the expectant management group. Low risk was defined as no pregnancy complications such as breech presentation; placental abnormalities; fetal demise; bleeding; rupture of membranes; and major, maternal, medical illness associated with increased risk for adverse pregnancy outcome such as diabetes, systemic lupus erythematous, any hypertensive disorder, cardiac disease, and renal insufficiency; oligohydramnios; and fetal growth restriction (Grobman, Rice, et al., 2018).

Similar results of a retrospective study of 55,694 births from 2012 to 2017 in 21 hospitals in the Northeast United States appear to

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confirm no increased risk of cesarean birth for low-risk, nulliparous women at term who have elective induction of labor (Souter, Painter, Sitcov, & Caughey, 2019). In a meta-analysis of six cohort studies published between 2012 and 2018, Grobman and Caughey (2019) found that elective induction of labor at 39 weeks was associated with a lower risk of cesarean, maternal infection, and adverse neonatal outcomes compared to expectant management. In a meta-analysis of 157 randomized trials of induction of labor versus expectant management, Mishanina et al. (2014) found no increase in the rate of cesarean birth for women having induction of labor. The studies included in this meta-analysis were not limited to low-risk, nulliparous women at term.

Publication of the results of the ARRIVE trial (Grobman, Rice et al., 2018) prompted responses from professional organizations and experts concerned about widespread adoption of elective induction of labor at 39 weeks as a method to decrease risk of cesarean birth. For example, AWHONN (2018a) supported shared decision-making between the woman and her maternity team and highlighted the need to ensure safe nurse staffing and unit capacity when elective induction of labor is performed. ACNM (2018) acknowledged the quality of the research but urged caution in applying the results in clinical practice without further consideration of other evidence-based practices that decrease risk of cesarean birth. ACNM promoted informed decision-making and highlighted the additional costs and resources involved in elective procedures with longer intrapartum length of stay and exposure to unnecessary interventions. Similar, more detailed concerns were offered by nurse-midwives Breedlove (2019) and Phillippi and King (2018). The California Maternal Quality Care Collaborative was explicit in cautioning hospitals considering adoption of policies to allow providers to admit women for elective induction of labor at 39 weeks that doing so without simultaneous adoption of strict guidelines for definitions of failed labor induction and management of active phase labor abnormalities could result in a significant increase in the risk of cesarean birth (Main, 2018).

ACOG and SMFM (2018) issued a statement to clarify clinical implications and recommended that before elective induction of labor, nulliparous women should be healthy with no medical or obstetric complications, that ultrasounds performed early in the pregnancy should confirm dating of at least 39 weeks gestation, and that clinicians should adhere to clinical protocols that optimize chances of vaginal birth as described in the study:

> Elective induction of labor should not be offered to women under circumstances that are inconsistent with the study protocol unless performed as part of research or quality improvement. As induction of labor involves coordination between the health care provider and the infrastructure in which induction and [birth] will occur, it is critical that personnel and facilities coordinate polices related to the offering of elective induction of labor (ACOG & SMFM, 2018, para. 5).

A formal, confirmatory statement from SMFM (2018) as part of their consult series and endorsed by ACOG (2018) soon followed. These recommendations seem reasonable and can be used to select appropriate candidates for elective induction and inform nulliparous women at term of their options. Especially pertinent are the recommendations for coordination between the provider and the nurses at the hospital (ACOG & SMFM, 2018).

Unit capacity and nurse staffing are important aspects of safe care during elective induction. These aspects should be determined based on the needs of the other patients on the unit, including women in spontaneous, preterm or term labor; women with medical or obstetric indications for induction; nonlaboring women with complications; women undergoing cesarean; women in recovery after birth; and mother-newborn couplets. Coordinating with the charge nurse to assure availability of adequate resources is essential (AWHONN, 2018b). Elective induction of labor should not be performed unless there are enough nurses to provide the appropriate care, assessment, and support as per the AWHONN (2010) nurse staffing standards. These standards indicate one registered nurse to two women undergoing cervical ripening with a pharmacologic agent and one registered nurse to one woman undergoing induction of labor with oxytocin. Induction of labor requires high intensity nursing care and assessment, including evaluation of maternal and fetal status every 15 minutes (see Box 2). As the induction is elective, there is no need to jeopardize maternal or fetal safety by conducting the procedure in the context of inadequate nurse staffing. This includes risks to the woman being considered for induction and to the other women on the unit who need nursing care. Elective induction of labor should be deferred until there are registered nurses available as per the AWHONN (2010) nurse staffing standards.

Interventions Involved in Cervical Ripening and Labor Induction

As part of the informed consent process, women considering labor induction should be aware that it often is not an isolated intervention. Labor induction often results in a cascade of other interventions and activities that have the potential to negatively affect the childbirth process. Labor induction in the United States requires the establishment of IV access, bed rest, and continuous EFM. Amniotomy, significant discomfort, the use of epidural analgesia/anesthesia, and a prolonged stay on the labor unit are also frequently involved. Use of oxytocin and prostaglandin agents increases the risk of fetal compromise during labor and neonatal depression at birth, primarily as a result of uterine tachysystole (Ayres-de-Campos & Arulkumaran, 2015; Ayres-de-Campos, Spong, & Chandraharan, 2015; Bakker, Kurver, Kuik, & Van Geijn, 2007; Hamilton, Warrick, Knox, O'Keefe, & Garite, 2012; Heuser et al., 2013; Selin et al., 2019). Each woman has individual myometrial sensitivity to oxytocin and prostaglandin (Page, McCool, & Guidera, 2017; Reinl et al., 2017; Uvnas-Moberg et al., 2019). Because of the lack of knowledge about the exact physiology of labor, it is difficult to determine the optimal dosage necessary to approximate normal labor with artificial, pharmacologic compounds.

The discomfort and frequency of oxytocin-induced contractions sets the stage for use of epidural analgesia/anesthesia, which in turn increases the risk of complications, such as hypotension (in

approximately 10% of women with low dose neuraxial labor analgesia), fever (in approximately 30% of women with neuraxial labor analgesia, generally unrelated to infection, causing diagnostic confusion), and FHR decelerations and bradycardia (in 17%-42% of women; ACOG, 2019b). Epidural analgesia/anesthesia prolongs labor by approximately 90 minutes but does not increase risk of cesarean birth or have a significant, negative effect on breastfeeding based on most recent data (ACOG, 2019b).

Summary of What Women Need to Know

In summary, women considering options for timing of birth should be aware of the following:

- Awaiting the spontaneous onset of labor is safe for healthy mothers and fetuses.
- Women have the right to be fully informed of the various options for initiation of labor, including awaiting spontaneous labor, procedures to initiate labor artificially, and their potential risks and benefits. This information should be offered in language they can understand and adequate time should be provided for questions.
- Induction of labor is recommended at 41 or more weeks gestation to minimize risk of adverse maternal and neonatal outcomes.
- Elective induction of labor does not increase risk of cesarean birth for nulliparous women if cervical ripening is used as needed and labor management allows for adequate time to progress through the latent, active, first, and second stages of labor as per labor management guidelines published by ACOG and SMFM (2014) or used in the ARRIVE trial (Grobman, Rice, et al., 2018).
- Elective induction of labor will likely take significantly longer than spontaneous labor.
- Induction of labor will likely involve an IV, bed rest, and continuous EFM; amniotomy, significant discomfort, and the use of epidural analgesia/anesthesia also frequently occur.

Assessment

The nurse who provides care for the woman during cervical ripening and induction and augmentation of labor must be aware of appropriate indications for the use of each mechanical method and pharmacologic agent, their actions, expected results, and potential risks. Before any cervical ripening or labor induction agent is used, maternal status and fetal well-being should be established, and the cervix, pelvis, fetal size, and presentation should be assessed (AAP & ACOG, 2017). The indications for preinduction cervical ripening and induction of labor should be documented (ACOG, 2011). Ongoing maternal and fetal assessments during labor induction/augmentation are presented in Box 2. Avoidance of potential complications such as uterine tachysystole and fetal compromise is an important aspect of the nurse's role during cervical ripening and labor induction and augmentation, and recognition of and response to the discomfort caused by cervical ripening or induction agents should be timely. If the woman chooses neuraxial analgesia and it is offered in the birth setting, it should be provided as soon as possible after her request. Absence of fetal well-being necessitates direct bedside evaluation by a physician or nurse-midwife, interdisciplinary discussion, and written documentation of further clinical-management plans before proceeding.

Assessment of the cervix includes documentation of the Bishop score (Bishop, 1964; Table 1) and the presence or absence of uterine activity. Status of the cervix is the most important factor in predicting the success of induction of labor. Perinatal nurses are qualified to assess and document status of the cervix based on the Bishop scoring system. The perinatal nurse may perform the initial assessment via vaginal examination before initiation of pharmacologic therapy for cervical ripening and labor induction or augmentation and ongoing vaginal examinations to assess labor progress. If the total Bishop score is more than 8, the probability of vaginal birth following induction of labor is similar to that of spontaneous labor (ACOG, 2009b). An unfavorable cervix is generally defined by a Bishop score of 6 or less (ACOG, 2009b). Risk of cesarean birth after labor induction is inversely related to the Bishop score; thus, cervical ripening is recommended for any woman with an unfavorable cervix (ACOG & SMFM, 2014). A modified Bishop score is sometimes used to evaluate cervical status and includes three factors: fetal station, dilation of cervix, and length of cervix or cervical effacement (Grobman, Rice, et al., 2018). Scores can range from 1 to 12; less than 5 is considered an unripe cervix.

Documentation

A written or electronic labor flow sheet with cues for appropriate documentation facilitates timely and accurate entry of data to the medical record. The flow sheet works well as the main source of comprehensive data about maternal and fetal status, nursing interventions, and events during labor. Narrative notes can be used for specific clinical events, interventions, and the maternal or fetal response as indicated. Description of communication between the nurse and the provider should be included. See Box 2 for suggested frequencies of assessment during cervical ripening and labor induction and augmentation. Key data that may be included are characteristics of the FHR pattern (baseline rate, variability, and presence or absence of accelerations and decelerations), characteristics of uterine activity (frequency, duration, and intensity of contractions and uterine resting tone), oxytocin rate, maternal response (including pain perception), and maternal position. Any intrauterine resuscitation measures or interventions to resolve tachysystole should also be documented in the medical record.

Clinical Protocol and Unit Policy Development

The ACOG (2009b) and SOGC (Leduc et al., 2013; Lee, Dy, & Azzam, 2016) recommended that health care providers at each institution develop a policy or protocol for cervical ripening and induction and augmentation of labor. Suggestions for key characteristics are presented in Box 3. A sample protocol for labor induction and augmentation with oxytocin is presented in Appendix A. Preferably, nurses, midwives, and physicians develop these policies or protocols jointly based on current evidence and published guidelines from professional organizations such as AWHONN, ACNM, ACOG, SMFM, SOGC, and The Joint Commission. The oxytocin infusion is

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BOX 2 MATERNAL–FETAL ASSESSMENTS DURING LABOR AND BIRTH

RISK STATUS AS A DETERMINANT OF TIMING AND TYPE OF ASSESSMENT

Low-risk in this context generally includes women who have no meconium staining, intrapartum bleeding, or abnormal or undetermined fetal test results before birth or at initial admission; no increased risk of developing fetal acidemia during labor (e.g., congenital anomalies, intrauterine growth restriction); no maternal condition that may affect fetal well-being (e.g., prior cesarean scar, diabetes, hypertensive disease); and no requirement for induction or augmentation of labor with oxytocin (AAP & ACOG, 2017). There is insufficient evidence to make a recommendation for frequency of maternal and fetal assessment for low risk women during the latent phase of labor from 0 to <4 cm dilation of the cervix. Therefore, frequency of assessment is at the discretion of the provider (AWHONN, 2018b).

MATERNAL VITAL SIGNS

Maternal vital signs should be assessed and recorded at regular intervals, at least every 4 hours. This frequency may be increased, particularly as active labor progresses according to clinical signs and symptoms (AAP & ACOG, 2017).

INTERMITTENT AUSCULTATION OF FETAL HEART RATE/PALPATION OF UTERINE ACTIVITY

In the absence of risk factors and no oxytocin in use, one recommended approach to fetal surveillance is to determine, evaluate, and record the FHR every 30 minutes in the active phase of the first stage of labor and at least every 15 minutes during the second stage of labor (AAP & ACOG, 2017) unless fetal risk status or response to labor indicates the need for more frequent assessment. Uterine activity is generally assessed at the same frequency as FHR.

AWHONN (2018b) recommends auscultation of the FHR within the range of every 15 to 30 minutes during the latent phase (4–5 cm dilation of the cervix) and the active phase (>6 cm dilation of the cervix) of the first stage of labor, every 15 minutes during the passive fetal descent phase of the second stage of labor, and every 5 to 15 minutes during the active pushing phase of the second stage of labor (AWHONN, 2018b). Uterine activity is generally assessed at the same frequency as FHR.

Either protocol is acceptable and should be based on the individual clinical situation.

When risk factors or complications are present on admission or develop during labor, use the following protocol based on the individual, clinical situation:

- AAP & ACOG (2017) recommend determining, evaluating and recording the FHR at least every 15 minutes during the active phase of the first stage of labor and at least every 5 minutes during the active pushing phase of the second stage of labor, preferably before, during, and after a uterine contractions. Uterine activity is generally assessed at the same frequency as FHR (AAP & ACOG, 2017).

MONITORING OF FETAL HEART RATE AND UTERINE ACTIVITY

Periodic review and documentation of the EFM tracing should be completed during active labor based on clinical status and underlying risk factors (ACOG, 2010).

If no risk factors are present at the time of the woman's admission, a standard approach is to evaluate/review the FHR every 30 minutes during the latent phase (4–5 cm dilation of the cervix) and the active phase (> 6 cm dilation of the cervix) of the first stage of labor, every 30 minutes during the passive fetal descent phase of the second stage of labor, and every 15 minutes during the active pushing phase of the second stage of labor unless fetal risk status or response to labor indicates the need for more frequent assessment (AAP & ACOG, 2017; ACOG, 2009b; AWHONN 2018b, 2019b). Uterine activity is generally assessed at the same frequency as FHR.

If risk factors are present at admission or develop during labor, generally, it is recommended to evaluate/review the FHR every 15 minutes during the latent phase (4–5 cm dilation of the cervix) and the active phase (> 6 cm dilation of the cervix) of the first stage of labor, every 15 minutes during the passive fetal descent phase of the second stage of labor, and every 5 minutes during the active pushing phase of the second stage of labor (AAP & ACOG, 2017; ACOG, 2009b; AWHONN 2018b, 2019b). The exact nature of the risk factor and/or complication will guide the frequency of assessment. Uterine activity is generally assessed at the same frequency as FHR.

CERVICAL RIPENING, LABOR INDUCTION, AND LABOR AUGMENTATION

Prostaglandin preparations for cervical ripening (e.g., misoprostol or vaginal insert) should be administered where FHR and uterine activity can be monitored continuously for an initial observation period (4 hours after intravaginal misoprostol and 2 hours after oral misoprostol). With the dinoprostone (Cervidil, prostaglandin E2) vaginal insert, FHR and uterine activity should be monitored continuously while in place and for at least 15 minutes after removal. Further monitoring of fetal status and uterine activity during cervical ripening can be governed by individual indications for induction and fetal status (ACOG, 2009b).

- When pharmacologic agents are used for cervical ripening, assessment of FHR and uterine activity every 30 minutes seems reasonable (AWHONN, 2010).
- During induction or augmentation with oxytocin, FHR monitoring should be performed as it is with high-risk women (AAP & ACOG, 2017; AWHONN, 2018a). When using EFM, the FHR should be evaluated/reviewed every 15 minutes during the first stage of labor and during the passive fetal descent phase of the second stage of labor, and every 5 minutes during the active pushing phase of the second stage of labor (AAP & ACOG, 2017; ACOG, 2009b; AWHONN 2018a; 2019b). Uterine activity is generally assessed at the same frequency as FHR.

SPECIAL CONSIDERATIONS FOR THE SECOND STAGE OF LABOR

When EFM is used to record FHR data permanently, periodic documentation can be used to summarize evaluation of fetal status as outlined by unit protocols. Thus, while evaluation of the FHR may occur every 5 minutes or every 15 minutes based on risk status, a summary of fetal status may be documented in the medical record less frequently. It is challenging to simultaneously record FHR and uterine activity data during the second stage of labor while providing support and encouragement for the woman in labor. Continuous, bedside attendance by the nurse is recommended during pushing efforts in the second stage of labor (AAP & ACOG, 2017; AWHONN, 2010; 2019b). During the

(continued)

BOX 2 *CONTINUED*

active pushing phase of the second stage of labor, summary documentation of fetal status every 15 to 30 minutes, which indicates continuous, nursing bedside attendance and evaluation, is reasonable (AWHONN, 2018a, 2019b).

LABOR PROGRESS

For women who are at no increased risk for complications, an evaluation of the quality of uterine contractions and vaginal examinations should be sufficient to detect abnormalities in the progress of labor (AAP & ACOG, 2017).

- Vaginal examinations include an assessment of dilation and effacement of the cervix and station of the presenting part of the fetus.
- Generally, uterine activity should be assessed each time the FHR is assessed because uterine activity has implications for fetal status.

ADDITIONAL PARAMETERS FOR ASSESSMENT DURING LABOR

- Assess character and amount of amniotic fluid (e.g., clear, bloody, meconium stained, odorous).
- Assess character and amount of bloody show/vaginal bleeding.
- Assess maternal and fetal response to labor.
- Assess level of maternal discomfort, coping, and effectiveness of pain management/pain relief measures.
- Assess labor support person(s) interactions with the woman and contributions to labor support as indicated.

Source: Information in this box adapted from "Labor and Birth," by K. R. Simpson and N. O'Brien-Abel, in K. R. Simpson, P. A. Creehan, N. O'Brien-Abel, C. Roth, and A. J. Rohan (Eds.), *AWHONN's Perinatal Nursing* (5th ed., pp. 326–412), 2021, Philadelphia, PA: Wolters-Kluwer. Copyright 2021 by Association of Women's Health, Obstetric and Neonatal Nurses. Adapted with permission.

titrated by the nurse based on provider orders and the maternal and fetal response to the medication. The Joint Commission (2020b) has specific criteria for orders and policies regarding when medications are titrated, including name of medication and route, starting dose, incremental increases or decreases, frequency of changes in dose, maximum dose, and the objective clinical measure to be used to guide changes (for example, uterine activity, labor progress, and/or fetal status). An ideal approach is to develop a single, standard, unit policy or protocol for each pharmacologic agent instead of individual protocols for various providers (Lee et al., 2016). For example, an interdisciplinary team should come to consensus on the IV solution and concentration of oxytocin, rate of dosage increases, and interval between increases in dosage rate based on available evidence and published guidelines. Once the interdisciplinary team agrees on a policy or protocol, all providers should be expected to follow it.

Oxytocin as a High-Alert Medication

In 2007, the Institute for Safe Medication Practices (ISMP) designated IV oxytocin as a high-alert medication, and this designation has continued to the present (ISMP, 2018). High-alert medications are drugs that carry a heightened risk of causing significant patient harm when they are used in error (ISMP, 2018). Errors with high-alert medications may or may not be more common than with other drugs; however, patient injury and consequences of associated errors may be more devastating (ISMP, 2018). When using high-alert medications, clinicians should follow principles of safe care, including the application of processes to prevent errors and harm, methods to identify errors and harm when they occur, and methods to mitigate harm that may result from errors (ISMP, 2018). Standardization of care processes for oxytocin administration as outlined in Box 3 is consistent with ISMP recommendations for high-alert medications (ISMP, 2018).

Medication errors with IV oxytocin are usually dose-related and commonly involve uterine tachysystole with subsequent indeterminate or abnormal (category II or III) FHR patterns (ACOG, 2009b). Given the recommendation from AAP and ACOG (2017) and AWHONN (2018a) to evaluate the FHR and uterine activity every 15 minutes during oxytocin administration, prolonged periods of oxytocin-induced uterine tachysystole generally should be preventable. See Appendix B for a tool that can be used to evaluate the clinical response to tachysystole. Ongoing monitoring of the response to tachysystole can be helpful to identify opportunities for quality improvement (Simpson, Knox, Martin, George, & Watson, 2011).

TABLE 1 BISHOP SCORING SYSTEM

	Factor				
Score	Dilation (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	≥ 5	≥ 80	+1, +2	—	—

Note. Adapted from: "Pelvic Scoring for Elective Induction," by E. H. Bishop, 1964, *Obstetrics & Gynecology, 24*, p. 267. Copyright 1964 by American College of Obstetricians and Gynecologists. Adapted with permission.

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BOX 3 KEY CHARACTERISTICS OF CLINICAL PROTOCOLS AND UNIT POLICIES FOR CERVICAL RIPENING AND INDUCTION AND AUGMENTATION OF LABOR

PRIORITIZATION AND DOCUMENTATION

- Criteria for designating patient priority for cervical ripening and induction based on the nature and intensity of the indication to use as a framework for decision-making during periods of limited staffing, rooms, or other resources.
- Documentation of indication by primary care provider.
- Documentation of risk-benefit analysis discussions between pregnant women and maternity care providers and informed, decision-making processes.
- Specific recommendations for care of women with histories of cesarean birth or uterine scar.

NURSE STAFFING CONSIDERATIONS

- Experience of registered nurse.
- Availability of registered nurses to meet recommended nurse-to-patient ratios: one nurse to two women undergoing cervical ripening with pharmacologic agents; one nurse to one woman undergoing labor induction or augmentation with oxytocin.
- Acuity of woman (e.g., medical or obstetric complications).
- Ongoing evaluation of labor status (frequency/characteristics of assessment).
- Availability and skill level of support personnel.
- Contingency plans such as on-call list.

PATIENT ASSESSMENT

- Establishment of maternal-fetal well-being.
- Establishment of at least 39 completed weeks gestation if procedure is being performed without a medical indication.
- Documentation of cervical status, including Bishop score.
- Documentation of pelvic examination.
- Method of fetal assessment.
- Frequency of maternal-fetal assessments.
- Assessment of specific patient needs and requests.

METHODS AND DOSAGES

- Cervical ripening agents to be used.
- Initial dosage of oxytocin or misoprostol.
- Intervals and amounts for increases in oxytocin dosage.
- Intervals and amounts for misoprostol dosages.
- Orders for oxytocin and documentation in milliunits per minute (mU/min).
- Titration of oxytocin dosage based on progress of labor and maternal-fetal response.
- Dosage of misoprostol based on progress of labor and maternal-fetal status.
- Maintenance or decrease in oxytocin dosage if labor is progressing.

COMPLICATIONS

- Definition of tachysystole.
- Interventions for tachysystole.
- Interventions for indeterminate or abnormal fetal status.
- Criteria for notification of nurse-midwife or physician.
- Criteria for bedside evaluation by the nurse-midwife or physician.

UNIT POLICY

- Algorithm/chain of consultation for addressing clinical disagreements.
- Methods for documenting all key concepts and interventions outlined in the policy/protocol.
- An expectation that the policy will be followed by all members of the team.
- Deferring elective induction of labor if there are inadequate unit resources (e.g., registered nurses, available labor rooms, mother-baby rooms).

As with other high-alert medications, the lowest possible dose to achieve the desired therapeutic effect should be used.

Nurse Staffing Considerations

The number of women who are scheduled for procedures for cervical ripening and/or induction of labor influences nursing staff requirements for labor and birth units. Because induction of labor is likely to occur during the daytime (Matthews & Curtin, 2015), more nurses may be needed during this time than during late evening or early morning. Likewise, births are clustered during the hours between 6 am and 6 pm, although births are more evenly distributed over 24 hours on Saturdays and Sundays (Martin et al., 2019). A record of women who are scheduled for labor induction should be maintained on the unit to plan for staffing and personnel needs based on expected patient volume. Many units limit the number of scheduled labor inductions that can be performed on a given day to ensure that adequate nurses and rooms are available to provide the appropriate level of care. Patient safety is at risk when scheduled procedures such as elective labor induction and cesarean birth are clustered on one or two weekdays for the convenience of providers without concurrent changes in nurse staffing. Small-volume units especially may not have enough nurses to safely handle these artificial peaks in census on busy days and not enough volume on other days to earn productive nursing hours required by the budget and simultaneously ensure that at least two nurses with obstetric skills are available at all times for pregnant women who present for care (AWHONN, 2010).

Criteria for designating patient priority for induction of labor based on the nature and intensity of the indication when resources are limited can provide a useful decision-making framework if disagreements arise. Ideally, these criteria are developed jointly by nurse, midwife, and physician members of an interdisciplinary unit practice committee. Elective inductions may need to be postponed or rescheduled, especially if enough resources are not available. If there is concern for fetal status, a nonstress test may be conducted to confirm fetal well-being while the woman waits for labor induction. An on-call system for perinatal nurses may help secure staffing resources as needed in a timely manner.

The appropriate number of qualified, professional, registered nurses should be in attendance during cervical ripening and induction and augmentation of labor (AWHONN, 2010). The current recommendation for the nurse-to-woman ratio for women undergoing cervical ripening with pharmacologic agents is one nurse to two women, and the current recommendation for the nurse-to-woman ratio during induction or augmentation of labor with oxytocin is one nurse to one woman (AWHONN, 2010; Leduc et al., 2013). If a nurse cannot clinically evaluate the effects of medication at least every 15 minutes, or a physician who has privileges to perform a cesarean birth is not readily available, oxytocin infusion should be discontinued or the initial or subsequent doses of misoprostol delayed until that level of maternal-fetal care can be provided.

CERVICAL RIPENING

Cervical ripening is a complex process that results in physical softening and distensibility of the cervix and eventually leads to beginning cervical effacement and dilation with the goal of vaginal birth (Penfield & Wing, 2017). A number of mechanical and pharmacologic methods have been used to induce cervical ripening (see Box 4). Table 2 provides information about pharmacologic methods of cervical ripening and induction and augmentation of labor. The ideal ripening agent or procedure should be simple to use, noninvasive, and effective within a reasonable amount of time; it should not stimulate or induce labor during the ripening process or increase maternal, fetal, or neonatal morbidity. The ideal agent or procedure for cervical ripening has not yet been identified. Based on the results of the most recent Cochrane review, mechanical methods are less likely to result in tachysystole and tachysystole-associated changes in FHR while having similar rates of success compared to pharmacologic agents (de Vaan et al., 2019).

Mechanical Methods of Cervical Ripening

Cervical ripening can be achieved by awaiting spontaneous labor, mechanical methods, or pharmacologic methods. Mechanical methods include membrane sweeping, amniotomy, transcervical balloon catheters, and hygroscopic or osmotic dilators. Mechanical methods are less likely to result in tachysystole and have similar rates of success as pharmacologic agents for cervical ripening (Cromi et al., 2012; de Vaan et al., 2019; Fox et al., 2011). When compared with oxytocin, mechanical methods for labor induction have less risk of cesarean birth (de Vaan et al., 2019).

Pharmacologic Methods of Cervical Ripening

Various hormonal preparations are available to induce cervical ripening. These agents include prostaglandin E2 (PGE2) preparations (dinoprostone, e.g., Prepidil gel or Cervidil insert) and prostaglandin E1 (PGE1) preparations (misoprostol, e.g., Cytotec). Prepidil and Cervidil are approved by the U.S. Food & Drug Administration (FDA) for cervical ripening. Use of misoprostol for cervical ripening, labor induction, or control of postpartum bleeding is not approved by the FDA (n.d.-a), although it has been used for these indications for many years. Nurses who care for women who receive any of these agents should be aware that they may lead to the onset of labor, particularly if the cervix is favorable. When the cervix is unfavorable, cervical softening and thinning are more likely to occur.

Prostaglandin E2

The mechanism of action of PGE2 (dinoprostone) is similar to the natural ripening process (Penfield & Wing, 2017). Some women go into spontaneous labor following administration. The prostaglandin preparations currently used successfully for cervical ripening produce the desired cervical changes, but all tend to increase myometrial contractility (de Vaan et al., 2019). For this reason, prostaglandins for cervical ripening must be viewed as the first step in labor induction. General side effects of prostaglandins include tachysystole, fever, chills, vomiting, and diarrhea (Penfield & Wing, 2017). Dinoprostone induces cervical ripening by directly softening the cervix, relaxing the cervical smooth muscle, and producing uterine contractions. Prepidil is less commonly used among the options for cervical ripening. Information about Prepidil can be found on the product label (Pfizer, 2019).

Cervidil. The Cervidil vaginal insert is a thin, flat, rectangular-shaped, cross-linked, polymer hydrogel that releases dinoprostone from a 10 mg reservoir at a controlled rate of approximately 0.3 mg/hr in vivo (Ferring Pharmaceuticals, 2017). The reservoir chip is encased within a pouch of knitted Dacron polyester with a removal cord. The system comes assembled and packaged in sterile foil packets.

Cervidil may be inserted by the perinatal nurse when the nurse has demonstrated competence in insertion, and the activity is within the scope of practice as defined by state or provincial regulations. Institutional guidelines should be established for the nurse's role related to the use of Cervidil. Unlike the transcervical preparations, Cervidil does not require visualization of the cervix for insertion. The insert is placed into the posterior fornix of the vagina with its long axis transverse to the long axis of the vagina. The ribbon end of the retrieval system may be allowed to extrude distally from the vagina or tucked into the vagina. Once placed, Cervidil absorbs moisture, swells, and releases dinoprostone at a controlled rate. The system makes Cervidil relatively simple to insert and requires only a single, digital examination.

Cervidil is removed after 12 hours or when active labor begins (Ferring Pharmaceuticals, 2017). Regular contractions (three in 10 min lasting 60 sec or more with moderate discomfort) will occur in

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TABLE 2 PHARMACOLOGIC AGENTS FOR CERVICAL RIPENING AND INDUCTION AND AUGMENTATION OF LABOR

Factor	Pitocin (oxytocin)	Cervidil (dinoprostone)	Cytotec (misoprostol)
Storage and Preparation	Room temperature storage. Available in 20-unit ampules. Several variations in the dilution rate exist. Some protocols suggest adding 10 units of oxytocin to 1,000 ml of an isotonic electrolyte intravenous (IV) solution resulting in an infusion dosage rate of 1 mU/min = 6 ml/hr. Other commonly reported dilutions are 20 units of oxytocin to 1,000 ml IV fluid (1 mU/min = 3 ml/hr) and 30 units of oxytocin to 500 ml of IV fluid or 60 units of oxytocin to 1,000 mL IV fluid (1 mU/min = 1 ml/hr). One advantage to using 30 units in 500 ml IV fluid or 60 units in 1,000 ml IV fluid is that they result in a 1:1 solution (1 mU/min = 1 ml/hr); therefore, no calculations are needed. The key issue is consistency in practice within each institution.	Keep frozen (−20° C) until immediately before use. No warming required.	Available in 100 and 200-microgram (mcg) tablets. 100-mcg tablet is not scored; dose should be prepared (cut in four equal pieces) by hospital pharmacy.
Initial Administration	Administered IV in an isotonic electrolyte solution then into the main IV line at port most proximal to venous site. Start at 1–2 mU/min.	10 mg in a controlled-release, vaginal insert with removable cord.	25 mcg (1/4 of 100 mcg tablet) placed in the posterior vaginal fornix should be considered for the initial dose. Adverse effects can be minimized by using the lowest dose (25 mcg) no more than every 3–6 hr. Oral administration at equivalent doses to vaginal route is not as efficacious; generally, the dose should not exceed 50 mcg; the 25 mcg dose has fewer side effects.
Patient Considerations	Bedrest is not required during infusion. Electronic fetal monitoring (EFM) telemetry can be used during ambulation or sitting on a chair or birthing ball. Careful, close monitoring for women with histories of prior cesarean birth or uterine scar; use lowest dose possible to achieve labor progress.	Contraindicated in women with histories of prior cesarean birth or uterine scar. Recumbent positioning (ideally lateral) for 2 hr following insertion. Continuous monitoring of fetal heart rate (FHR) and uterine activity is indicated while insert is in place. Ambulation is an option if continuous EFM telemetry is available.	Contraindicated in women with histories of prior cesarean birth or uterine scar. Baseline uterine activity is a relative contraindication to the use of prostaglandins because the addition of an exogenous uterotonic agent could lead to excessive uterine activity. Continuous monitoring of FHR and uterine activity is indicated for 4 hr after intravaginal dose and 2 hr after oral dose.
Effects	Wide variations in time from initial dose to uterine activity.	Uterine contractions usually occur within 5–7 hr.	Wide variations exist in time of onset of uterine contractions.

(continued)

TABLE 2 *CONTINUED*

Factor	Pitocin (oxytocin)	Cervidil (dinoprostone)	Cytotec (misoprostol)
	The biologic half-life is approximately 10–12 min. Three to four half-lives are needed to reach physiologic steady state (30–60 min) at which time full effect of dosage on the uterine response can be assessed.		Onset of action is approximately 20 min, peak action is approximately 1–2 hr, duration of action is 4 hr when administered intravaginally; can be 4–6 hr for some women. Onset of action is 8 to 11 min and peak action is approximately 30 min when administered orally, half-life is 90 min, duration of action is approximately 2 hr.
Adjusting Dosage	Advance by 1–2 mU/min at intervals no less than every 30–60 min until adequate labor progress is achieved. Titrate dose to maternal-fetal response to labor. Use lowest dose possible to achieve adequate progress of labor (progressive cervical effacement and cervical dilation of approximately 0.5–1.0 cm/hr once active labor has been achieved). Reevaluate clinical situation if dosage rate reaches 20 mU/min. Contractions should not be more frequent than every 2 min. Avoid tachysystole. When uterine tachysystole occurs with a normal (category I) FHR tracing, reposition woman and consider an IV fluid bolus. If these interventions do not resolve tachysystole, decrease dose. When tachysystole occurs with an indeterminate or abnormal (category II or III) FHR tracing, decrease or stop oxytocin and initiate intrauterine resuscitative measures. If intrauterine resuscitative measures are not successful, discontinue oxytocin.	Remove after 12 hr or at onset of active labor. Remove if uterine tachysystole and/or abnormal (category III) FHR occurs. Removal may be indicated for some types of indeterminate (category II) FHR tracing.	Redosing is permissible if cervical condition remains unfavorable, uterine activity is minimal, FHR is normal (category I), and it has been at least 3 hr since last dose. Consider observation for up to 2 hr after spontaneous rupture of membranes before redosing. Consider delaying or avoiding administration in a woman with frequent, low amplitude, painless contractions or 2 or more painful contractions per 10 min, particularly if a uterotonic has already been administered. Redosing is *withheld* if the FHR is indeterminate or abnormal (category II or III) because increased uterine activity can further compromise fetal status.
Monitoring	Administer in labor and birth suite where uterine activity and FHR can be recorded continuously via EFM and evaluated at a minimum every 15 min during the first stage of labor and during the passive fetal descent phase of the second stage of labor and every 5 min during the second stage of labor.	Administer at or near the labor and birth suite where uterine activity and FHR can be monitored continuously while in place and for at least 15 min after removal. Ambulation is an option after initial 2 hr if continuous EFM telemetry is available.	Administer at or near labor and birth suite where uterine activity and FHR can be monitored as appropriate based on route of administration and maternal and fetal status. Continuous monitoring of FHR and uterine activity is indicated for 4 hr after intravaginal dose and 2 hr after oral dose.

(continued)

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TABLE 2 *CONTINUED*

Factor	Pitocin (oxytocin)	Cervidil (dinoprostone)	Cytotec (misoprostol)
Use with Oxytocin, if Needed	N/A	Oxytocin should be delayed for at least 30–60 min after removal of insert. Previous exposure to PGE_2 potentiates contractile response to oxytocin, so careful monitoring of FHR and uterine activity is warranted.	Oxytocin should be delayed until at least 4 hr after last dose when administered vaginally and at least 2 hours after the last dose when administered orally. Previous exposure to misoprostol potentiates contractile response to oxytocin, so careful monitoring of FHR and uterine activity is warranted.
Complications	Risk of uterine tachysystole is dose related. Approximately 50% of cases of tachysystole will result in an indeterminate or abnormal (category II or III) FHR. Terbutaline, 0.25 mg subcutaneously, can be used in an attempt to correct indeterminate or abnormal FHR pattern or uterine tachysystole if intrauterine resuscitative measures and discontinuation of oxytocin are not successful in resolving the FHR pattern and/or uterine tachysystole.	Rate of uterine tachysystole is about 5%; usually occurs within 1 hr of administration but may occur up to 9.5 hr after administration. Terbutaline, 0.25 mg subcutaneously, can be used in an attempt to correct indeterminate or abnormal FHR pattern or uterine tachysystole if removal of insert has not been successful in resolving the FHR pattern and/or uterine tachysystole. Side effects of prostaglandins include tachysystole, fever, chills, vomiting, and diarrhea.	Uterine tachysystole is more common with misoprostol as compared to Cervidil and oxytocin. Rates of uterine tachysystole are lower with lower dosages (25 mcg) and when dosed less frequently (i.e., less problems when dosed every 6 hr instead of every 3 hr). Terbutaline 0.25 mg subcutaneously, can be used in an attempt to correct indeterminate or abnormal FHR pattern or uterine tachysystole. Side effects of prostaglandins include tachysystole, fever, chills, vomiting, and diarrhea.

about 25% of women after placement (Rayburn, Tassone, & Pearman, 2000). One major advantage of Cervidil is that the system can be easily and quickly removed in the event of uterine tachysystole or other complications. Another advantage is less risk of tachysystole and tachysystole-related FHR changes compared to misoprostol (Liu et al., 2014). Tachysystole usually occurs within 1 hour after insertion but can occur up to 9.5 hours after insertion (ACOG, 2009b). If uterine tachysystole occurs, complete reversal of the prostaglandin-induced uterine pattern usually occurs within 15 minutes of removal. If necessary, the woman may be given tocolytic therapy (0.25 mg of terbutaline subcutaneously).

Exposure to PGE2 potentiates the contractile response to oxytocin (Ferring Pharmaceuticals, 2017), so careful maternal and fetal monitoring are warranted when oxytocin is administered after Cervidil has been used for cervical ripening. Administration of oxytocin should be delayed until at least 30 to 60 minutes after removal of the Cervidil insert (ACOG, 2009b). Continuous monitoring of the FHR and uterine activity is indicated while Cervidil is in place (Ferring Pharmaceuticals, 2017). Ambulation while Cervidil is in place is an option if continuous EFM via telemetry is available. There have been no studies using methods other than continuous EFM for maternal-fetal assessment. There is risk of initiation of regular contractions progressing to active labor, and an approximate 5% rate of tachysystole, with Cervidil (ACOG, 2009b; Ferring Pharmaceuticals, 2017). Cervidil is not appropriate for outpatient cervical ripening because its use in the outpatient setting has not been studied (ACOG, 2009b). There is a risk of uterine rupture when prostaglandins are used for women who attempt vaginal birth after cesarean (VBAC); thus, Cervidil is not recommended for those women (Ferring Pharmaceuticals, 2017).

Prostaglandin E1/Misoprostol

Misoprostol is a synthetic PGE1 analogue that is used for cervical ripening and induction of labor. Misoprostol was originally approved by the FDA for prevention of peptic ulcers and remains unapproved for cervical ripening, induction of labor, and postpartum hemorrhage. Misoprostol labeling (Searle, 2018) notes that tachysystole, uterine tetany (with marked impairment of uteroplacental blood flow), uterine rupture, meconium stained amniotic fluid, amniotic fluid embolism, maternal shock, fetal bradycardia, and fetal and maternal death have been reported. Risk of uterine rupture as per Searle (2018) appears to increase as gestational age advances; with prior uterine surgery, including cesarean birth; and with grand multiparity. The FDA (2015) prepared a patient information sheet with warnings in lay language

BOX 4 MECHANICAL METHODS OF CERVICAL RIPENING AND LABOR INDUCTION

Qualified physicians and advanced-practice nurses such as certified nurse-midwives, perinatal nurse practitioners, women's health nurse practitioners, and perinatal clinical nurse specialists perform membrane stripping and amniotomy and insert balloon catheters and hygroscopic/osmotic dilators.

MEMBRANE STRIPPING

- Digital separation of the chorioamniotic membrane from the wall of the cervix and lower uterine segment by inserting a gloved finger beyond the internal cervical os and then rotating the finger 360 degrees along the lower uterine segment.
- Typically performed during an office visit for a pregnant woman at 39 weeks gestation or greater with a partially dilated cervix to hasten the onset of spontaneous labor.
- Routine membrane stripping is not recommended given no evidence of improved maternal or neonatal outcomes.
- The woman should call her maternity care provider or come to the hospital if the membranes rupture, bleeding occurs, fetal activity decreases, fever develops, regular contractions begin, or discomfort persists between uterine contractions.

AMNIOTOMY

- Artificial rupture of membranes, performed by a qualified, maternity care provider, involves the perforation of the chorioamniotic membranes with a plastic hook, and typically requires cervical dilation of at least 2-3 centimeters.
- For women with normally progressing labor and no evidence of fetal compromise, routine amniotomy is not necessary unless it is required to facilitate monitoring.
- Effective method of labor induction for multiparous women with favorable cervixes.
- Artificial rupture of membranes should only be performed when the vertex, not the umbilical cord or other part of the fetus, is well-applied to the cervix.
- Risks include the possibility of umbilical cord prolapse, cesarean birth, variable decelerations, intraamniotic infection, fetal injury, bleeding from an undiagnosed vasa previa, and commitment to labor with an uncertain outcome.
- Early amniotomy is contraindicated in the presence of maternal infection, such as HIV; active, perineal herpes simplex; and possibly viral hepatitis.
- Documentation in the medical record should include the indication for amniotomy; amount, color, and odor of amniotic fluid; FHR characteristics before amniotomy; fetal response following the procedure; cervical status; and station of fetus.
- After amniotomy for induction or augmentation of labor, assessment of the woman's temperature every 1 to 2 hours is reasonable, and this frequency may be increased if temperature becomes elevated.

TRANSCERVICAL BALLOON CATHETERS

- A deflated Foley catheter (#16–#18, French, with a 30-ml balloon) is inserted into the extra-amniotic space and then inflated above the internal os with 30 to 60 ml of sterile water.
- The inflated balloon is then retracted to rest against the internal os.
- Appears to be effective for preinduction, cervical ripening by causing direct pressure, overstretching of the lower uterine segment and cervix, and stimulating the release of local prostaglandin.
- The balloon catheter usually falls out when cervical dilation occurs.
- A double-balloon device specifically designed for cervical ripening can be used.
- Extra-amniotic saline infusion, i.e., continuous infusion of isotonic fluid into the extra-amniotic space at rates of 30 to 40 ml/hour, can be used although this technique has not been found to improve induction outcomes when compared to balloon catheter alone.
- Remove the catheter after 24 hours if it has not fallen out on its own.
- Use is associated with minimal risk of infection.

HYGROSCOPIC/OSMOTIC DILATORS

- Used primarily during pregnancy termination rather than for cervical ripening in term pregnancies.
- Natural: laminaria tents (made from cold water seaweed); synthetic: Dilapan-S.
- Absorb fluid from cervical tissue and allow for controlled dilation by mechanical pressure and release of prostaglandin.
- Synthetic dilators are more expensive than laminaria; however, they work more quickly.
- Insertion of many, small laminaria (2 or 3 mm) is preferable to insertion of a few larger ones (6 mm).
- Progressively placed until the cervix is full; the tails are allowed to fall into the vagina for ease of identification and removal.
- Laminaria are kept in place with 4-inch square gauze sponges tucked into the fornix.
- The number of laminaria inserted should be documented in medical record; the number removed after the procedure should be documented in the medical record.

ADDITIONAL CONSIDERATIONS

- Because the woman is positioned recumbent to facilitate the procedure, care should be taken to minimize the effects of supine hypotension. The woman should be encouraged to

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BOX 4 *CONTINUED*

assume a lateral position as soon as possible after the procedure.

- In addition to maternal-fetal status before and after the procedure and description of the procedure, nursing assessment and documentation includes notation of the onset of regular painful contractions, fever, rupture of membranes, bleeding, and continuous uterine pain, should any of these occur.
- No data or published guidelines currently exist regarding the frequency of maternal-fetal assessments during mechanical dilation for cervical ripening. Therefore, maternal-fetal status and institutional policies and procedures determine frequency of assessment.
- Advantages of mechanical methods of cervical ripening include low risk of tachysystole, few maternal systemic side effects, low cost, and convenient storage.
- Disadvantages of mechanical methods include some discomfort; small, increased risk of maternal and neonatal infection; and potential disruption of a low-lying placenta.

Source: Adapted from "Labor and Birth," by K. R. Simpson and N. O'Brien-Abel, in K. R. Simpson, P. A. Creehan, N. O'Brien-Abel, C. Roth, and A. J. Rohan (Eds.), *AWHONN's Perinatal Nursing* (5th ed., pp. 326–412), Philadelphia, PA: Wolters-Kluwer. Copyright 2020 by Association of Women's Health, Obstetric and Neonatal Nurses. Adapted with permission.

about the use of misoprostol for cervical ripening, induction of labor, and postpartum hemorrhage.

Oral and vaginal misoprostol can be administered by perinatal nurses; however, in some institutions, vaginal administration is deferred to qualified physicians or advanced-practice nurses. If vaginal misoprostol administration is delegated to perinatal nurses, they must have demonstrated competence in insertion, and the activity must be within the scope of practice as defined by state or provincial regulations. Table 2 summarizes key points about the use of prostaglandins for cervical ripening.

Vaginal Administration. When used for cervical ripening or induction of labor, 25 micrograms (mcg) placed in the posterior vaginal fornix should be considered for the initial dose (ACOG, 2009b; FIGO, 2017). Tachysystole and indeterminate or abnormal FHR changes have been associated with both the 25-mcg and the 50-mcg doses (Crane, Young, Butt, Bennett, & Hutchens, 2001; Kreft et al., 2014; McMaster et al., 2015; Penfield & Wing, 2017). Higher dosages have been associated with an increased rate of tachysystole (ACOG, 2009b; Kreft et al., 2014; McMaster, Sanchez-Ramos, & Kaunitz, 2015; Penfield & Wing, 2017; Stephenson & Wing, 2015). The incidence of tachysystole with and without indeterminate or abnormal FHR changes was significantly higher with misoprostol than with Cervidil, Prepidil, and oxytocin (Hofmeyr, Gülmezoglu, & Pileggi, 2010; Liu et al., 2014; Penfield & Wing, 2017; Stephenson & Wing, 2015). A 4- to 6-hour interval between doses was associated with less uterine tachysystole than the 3-hour interval (ACOG, 2009b; Penfield & Wing, 2017; Stephenson & Wing, 2015).

Uterine rupture is a complication of the use of misoprostol for cervical ripening and labor induction, especially for women who have uterine scars (FDA, 2015; Lydon-Rochelle, Holt, Easterling, & Martin, 2001; Penfield & Wing, 2017; Searle, 2018; Weeks et al., 2007). Uterine rupture after the use of misoprostol or oxytocin can occur in the unscarred uterus, although the risk is lower than for women with previous uterine scars (Akhan, Iyibozkurt, & Turfanda, 2001; Bennett, 1997; Catanzarite, Cousins, Dowling, & Daneshmand, 2006; Khabbaz et al., 2001). Misoprostol is contraindicated in women with histories of prior uterine surgery or cesarean birth because of the risk of uterine rupture (ACOG, 2009b, 2010c; Lydon-Rochelle et al., 2001; Weeks et al., 2007; Penfield & Wing, 2017). There are minimal recent data on uterine rupture at term with a prior uterine scar associated with misoprostol because this practice has been eliminated in the United States.

Because the 100-mcg tablet is not scored, there is no assurance that the PGE1 is uniformly dispersed throughout the tablet. It is possible that one-fourth of a tablet may contain more or less than 25 mcg of PGE1. The hospital pharmacist should prepare the tablet in four equal parts before administration to ensure the accuracy of the dose.

Advocates of misoprostol for cervical ripening and induction of labor cite low cost, ease of insertion, and quick action as main advantages (Penfield & Wing, 2017). The most commonly reported adverse effects are tachysystole and tachysystole with changes in FHR (Alfirevic, Aflaifel, & Weeks, 2014; Alfirevic et al., 2015; Chatsis & Fry, 2018; Handal-Orefice et al., 2019; Kreft et al., 2014; McMaster et al., 2015). These adverse effects can be minimized by using the lowest dose (25 mcg) no more frequently than every 3 to 6 hours (ACOG, 2009b; Alfirevic et al., 2014; McMaster, et al., 2015; Weeks, Navaratnam, & Alfirevic, 2017). If uterine tachysystole and an indeterminate or abnormal FHR pattern occur with misoprostol and there is no response to routine corrective measures (e.g., maternal repositioning, supplemental oxygen, IV fluid bolus), consider cesarean birth (ACOG, 2009b). Terbutaline, 0.25 mg subcutaneously, also can be used in an attempt to correct an indeterminate or abnormal FHR pattern or uterine tachysystole (ACOG, 2009b).

Onset of action of vaginally administered misoprostol is approximately 20 minutes (Tang, Gemzell-Danielsson, & Ho., 2007). Plasma concentration of misoprostol after vaginal administration rises gradually and reaches peak levels in 1 to 2 hours; concentration declines slowly to an average of 61% of peak level at 4 hours (Goldberg, Greenberg, & Darney, 2001; Song, 2000; Zieman, Fong, Benowitz,

Banskter, & Darney, 1997). Duration of action for vaginally administered misoprostol is usually approximately 4 hours; however, some women will have increased plasma concentrations up to 6 hours after vaginal administration (Tang et al., 2007; Zieman et al., 1997). Therefore, administration of oxytocin should be delayed for at least 4 hours after the last dose of vaginal misoprostol (ACOG, 2009b).

Oral Administration. Some providers use oral misoprostol, which at equivalent doses is not as effective as misoprostol administered vaginally; however, oral administration is associated with fewer indeterminate or abnormal FHR patterns and episodes of tachysystole (ACOG, 2009b). Oral administration may also be more comfortable and convenient and may increase a woman's satisfaction (Alfirevic et al., 2014; Penfield & Wing, 2017). Oral misoprostol at 25 mcg appears to have more favorable results than a dose of 50 mcg for induction of labor (Bendix, Friis-Petersen, Andersen, Bodker, & Lokkengaard, 2019). There is a clear, positive, dose-response relationship between the dosage of oral misoprostol and the rate of tachysystole: 25 mcg is associated with a lower rate of tachysystole, and 50 mcg is associated with a higher rate (Alfirevic et al., 2014, 2015; Penfield & Wing, 2017; Weeks et al., 2017). Based on the most recent Cochrane review by Alfirevic et al. (2014), generally 25 mcg orally is the preferred dose when administered to a woman with a viable fetus in the third trimester. This dose is recommended by FIGO (2017) as well.

Onset of action of orally administered misoprostol is approximately 8 to 11 minutes (Tang et al., 2007). Oral misoprostol reaches its peak serum level within 30 minutes and has a half-life of 90 minutes because misoprostol acid is rapidly metabolized by the liver and excreted by the kidneys (Tang et al., 2007). With oral misoprostol, sustained uterine activity is achieved in 90 minutes, and the duration of action is approximately 2 hours (Tang et al., 2007; Weeks et al., 2017). Therefore, administration of oxytocin should be delayed for at least 2 hours after the last dose of oral misoprostol (ACOG, 2009b).

INDUCTION AND AUGMENTATION OF LABOR

Pharmacologic Methods of Induction of Labor

Oxytocin for Induction of Labor

Oxytocin is the most commonly used agent for induction of labor in the United States (ACOG, 2009b). Synthetic oxytocin is indicted only for the medical rather than the elective induction of labor (FDA, n.d.-b), although it is routinely used for both. Oxytocin is an effective means of labor induction in women with favorable cervixes, but it is not effective as a cervical ripening agent (Penfield & Wing, 2017). Use of oxytocin after the pre-induction administration of cervical ripening prostaglandin agents appears to be more effective than oxytocin alone as a method of induction (ACOG & SMFM, 2014; Alfirevic, Kelly, & Dowswell, 2009; Penfield & Wing, 2017). An unfavorable cervix is generally defined by a Bishop score of 6 or less in most randomized trials. If the total score is more than 8, the probability of vaginal birth after labor induction is similar to that after spontaneous labor (ACOG, 2009b). Cervical ripening should be used when labor is induced in women with unfavorable cervixes (ACOG & SMFM, 2014).

Pharmacokinetics and Pharmacodynamics. Oxytocin is a peptide that consists of nine amino acids. Endogenous oxytocin is synthesized by the hypothalamus and then transported to the posterior lobe of the pituitary gland where it is released into the woman's circulation (Blackburn, 2018). It is released in response to breast stimulation, sensory stimulation of the lower genital tract, and cervical stretching. Oxytocin released in response to vaginal and cervical stretching results in uterine contractions. Minimal change occurs in myometrial sensitivity to oxytocin from 34 weeks gestation until term; however, when spontaneous labor is initiated, uterine sensitivity to oxytocin increases rapidly (ACOG, 2009b; Page et al., 2017). Based on this physiologic mechanism, oxytocin is more effective to augment labor than to induce labor (Penfield & Wing, 2017). Synthetic oxytocin is chemically and physiologically identical to endogenous oxytocin (FDA, n.d.-b). In the 1970s, 1980s, and 1990s, there was significant research interest in the pharmacokinetics and pharmacodynamics of oxytocin on the initiation and progress of labor in humans and related clinical implications. However, no recent studies on these topics were found in a recent, extensive literature search.

Oxytocin circulates in the blood as a free peptide and has a molecular weight of 1007.2 g/mol (National Center for Biotechnology Information, n.d.). The volume of distribution is estimated to be 305 ± 46 ml/kg; thus, oxytocin is distributed into the intravascular and extravascular compartments (Zeeman et al., 1997). Plasma clearance of oxytocin occurs through the woman's kidneys and liver by the enzyme oxytocinase; only a small amount is excreted unchanged in the urine. Maternal metabolic clearance rate of oxytocin is 19 to 21 ml/kg/min and is unaffected by pregnancy (Zeeman et al., 1997).

During the first stage of spontaneous labor, the circulating concentration of endogenous oxytocin is approximately equal to the concentration that would be achieved with a continuous infusion of exogenous oxytocin at 2 to 4 mU/min (Dawood, Ylikorkala, Trivedi, & Fuchs, 1979). The fetus is thought to secrete oxytocin during labor at a level similar to an infusion of oxytocin at approximately 3 mU/min (Dawood, Wang, Gupta, & Fuchs, 1978). Thus, the combined maternal and fetal contributions to maternal plasma oxytocin concentration is equivalent to 5 to 7 mU/min. Although there has been considerable variation in reports of the biologic half-life of oxytocin, it is generally agreed to be 10 to 12 minutes (Arias, 2000; Dawood, 1995a; Page et al., 2017). Based on early data from in vitro studies, Theobald (1961) estimated a plasma half-life of 3 to 4 minutes, but Seitchik, Amico, Robinson, and Castillo (1984) used in vivo methods to study oxytocin pharmacokinetics and found half-life was probably closer to 10 to 15 minutes.

Oxytocin concentration and saturation follow first order kinetics with a progressive, linear, stepwise increase with each increase in the infusion rate (Arias, 2000). Three to four half-lives of oxytocin are generally needed to reach a steady-state plasma concentration. Uterine response to oxytocin usually occurs within 3 to 5 minutes after IV administration begins. During an incremental phase of uterine

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activity when oxytocin is initiated, contractions progressively increase in frequency and strength and are followed by a stable phase during which any further increase in oxytocin will not lead to further, normal changes in uterine contractions (Dawood, 1995b; Phaneuf, Rodriguez, Tamby-Raja, MacKenzie, & Lopez-Bernal, 2000). Instead, abnormal uterine activity such as frequent low-intensity contractions, coupling or tripling of contractions, or uterine tachysystole may occur with further increases in oxytocin. There is a longstanding myth that these types of abnormal uterine activity patterns are best treated with oxytocin rate increases (i.e., "pit through the pattern"); however, an understanding of their genesis (excessive oxytocin and oxytocin receptor site desensitization) should guide clinicians to reduce the rate or discontinue oxytocin until uterine activity returns to normal. Often a rest period of 30 to 60 minutes with an IV fluid bolus of lactated Ringer's solution will allow oxytocin receptors to be sensitive to artificial oxytocin and produce uterine contractions that will result in normal uterine activity and labor progress (Dawood, 1995b; Phaneuf et al., 2000; Zeeman et al., 1997).

Continued increases in oxytocin rates over a prolonged period can result in oxytocin receptor desensitization or down-regulation, which makes oxytocin less effective in producing normal uterine contractions. Several groups of researchers found a direct inverse relationship between the duration and dosage of oxytocin and the number of oxytocin receptor sites available for oxytocin uptake during labor (Phaneuf et al., 1998, 2000; Robinson, Schumann, Zhang, & Young, 2003). Prolonged oxytocin infusion at higher than appropriate doses can result in side effects such as dysfunctional uterine activity patterns and uterine tachysystole (Dawood, 1995b; Phaneuf et al., 2000). Once active labor is established, oxytocin rates should be decreased or discontinued to prevent receptor down-regulation, especially in cases of long labor induction. Prolonged high-dose oxytocin infusions are counterproductive to the augmentation of established labor (Robinson et al., 2003).

Reducing or discontinuing oxytocin may result in an equal or shorter length of labor than continued or incrementally increased oxytocin after active labor is achieved (Daniel-Spiegel, Weiner, Ben-Shlomo, & Shalev, 2004). In a recent meta-analysis and systematic review, Saccone et al. (2017) found that in comparison to continuation of oxytocin, discontinuation of oxytocin once 5 cm cervical dilation was reached reduced risk of uterine tachysystole and cesarean birth. In another systematic review of oxytocin discontinuation after the active phase of induced labor, findings were similar: the incidence of uterine "hyperstimulation", cesarean birth, and "nonreassuring" FHR tracings were all significantly higher among women with continued oxytocin than among those with discontinued oxytocin at active labor (Hernández-Martínez et al., 2019). In a randomized trial of 200 women in labor, Boie et al. (2018) found that the risk of excessive uterine activity and FHR abnormalities were decreased with oxytocin regimens that included discontinuation of oxytocin at 5 cm dilation of the cervix. Finally, in a recent Cochrane review, Bor, Lederfoug, Boie, Knoblauch, and Stornes (2016) concluded that discontinuation of oxytocin once active labor is reached reduces uterine tachysystole with abnormal FHR tracings and may reduce cesarean birth.

Tachysystole. Tachysystole is the most concerning side effect of oxytocin and should be avoided (Hobson, Abdelmalek, & Farine, 2019). The definition of tachysystole is more than five contractions in 10 minutes averaged over a 30-minute window. Other characteristics of excessive uterine activity are contractions that last 2 minutes or longer, insufficient return of uterine resting tone between contractions via palpation, or intraamniotic pressure above 25 mmHg between contractions via intrauterine pressure catheter. Tachysystole and other aspects of excessive uterine activity can have a negative effect on fetal oxygenation during labor by interfering with the reperfusion of the intervillous space that should occur during adequate uterine relaxation between contractions (Hobson et al., 2019).

Normal uterine contractions produce intermittent diminution of blood flow to the intervillous space where oxygen exchange occurs. During a contraction, uteroplacental blood flow is reduced by approximately 60% (Turner, Mitchell, & Kumar, 2020). In the presence of a normal placenta, a healthy, term fetus is able to tolerate intermittent decreases in uteroplacental blood flow during contractions that occur at a frequency that allows for adequate fetal and placental reperfusion (Ayres-de-Campos & Arulkumaran, 2015; Turner et al., 2020). The decreased intervillous blood flow associated with tachysystole ultimately leads to decreased oxygen transfer to the fetus (Simpson & James, 2008). When fetal oxygenation is sufficiently impaired to produce fetal metabolic acidosis from anaerobic glycolysis, direct myocardial depression occurs, and the FHR pattern becomes indeterminate or abnormal (ACOG & AAP, 2014). When the intermittent interruption in blood flow caused by excessive uterine activity exceeds a critical level, the fetus responds with evolving hypoxia, acidosis, and ultimately asphyxia if the situation is prolonged (ACOG & AAP, 2014; Turner et al., 2020). Therefore, every effort should be made to avoid tachysystole and treat it appropriately when identified (Simpson & Knox, 2009). Waiting until the FHR is indeterminate or abnormal to treat tachysystole is not consistent with fetal safety.

When tachysystole occurs during induced or augmented labor and the FHR pattern is normal, ACOG (2010) recommended decreasing oxytocin. If there are changes in the FHR pattern, further interventions such as discontinuation of oxytocin, maternal repositioning, and an IV fluid bolus should be considered (ACOG, 2010). Simultaneous initiation of maternal repositioning, an IV fluid bolus, and discontinuation of oxytocin will usually resolve oxytocin-induced tachysystole within 10 minutes (Simpson & James, 2008). If the FHR tracing evolves to minimal variability and oxygen is administered to the woman as an intrauterine resuscitation measure, oxytocin should be discontinued to minimize effects of physiologic stress on the fetus associated with the intermittent interruption in blood flow that occurs during contractions. See Box 5 for a suggested protocol for treatment of tachysystole.

The use of oxytocin for induction or augmentation of labor doubles the risk of tachysystole (Heuser et al., 2013). A dose-response relationship between oxytocin and tachysystole exists, and approximately one-fourth of FHR tracings with oxytocin-induced tachysystole reflect unfavorable FHR changes (Heuser et al., 2013). In a study of more than 50,000 births, tachysystole increased risk of

operative vaginal birth; rate of admission to the neonatal intensive care unit; and a composite, adverse, neonatal outcome that included sepsis, intraventricular hemorrhage, necrotizing enterocolitis, pneumothorax, and low Apgar scores by approximately 30% (Heuser et al., 2013). Frey et al. (2014) found that tachysystole was more common in women whose fetus had an adverse neonatal outcome (defined by a composite measure of neonatal morbidity including admission to the neonatal intensive care unit, umbilical artery pH less than or equal to 7.1, and 5-minute Apgar score less than 7) than in women whose fetuses did not have the adverse neonatal outcome. Likewise, in a study of 28,486 births, Jonsson, Norden-Lindberg, Ostlund, and Hanson (2008) found oxytocin-induced tachysystole in the last 2 hours of labor was a significant risk factor for neonatal acidemia (umbilical artery pH < 7.05). In a study of 7,319 women, tachysystole in the second stage of labor was associated with adverse neonatal outcomes per a composite, neonatal morbidity, outcome variable that included need for hypothermic treatment, need for ventilatory support, meconium aspiration, seizures, suspected sepsis, and death (Zahedi-Spung et al., 2019). These researchers concluded that neonatal resuscitation teams should be notified and neonatal resuscitation should be anticipated following tachysystole in the second stage of labor.

Oxytocin Safety. While oxytocin is the most frequently used medication for labor induction and augmentation, it is also the drug most commonly associated with preventable adverse events during childbirth (Clark, Belfort, Dildy, & Meyers, 2008). The risks of oxytocin are generally dose-related and in addition to tachysystole include fetal compromise, a progressive decrease in fetal oxygen status, neonatal acidemia, abruption placentae, and uterine rupture (ACOG, 2009b; Bakker et al., 2007; Simpson & James, 2008). Errors with administration of oxytocin involve mistaken administration of IV fluids with oxytocin for IV fluid resuscitation during indeterminate or abnormal FHR patterns and/or maternal hypotension and inappropriate, elective administration of oxytocin to women who are at less than 39 completed weeks gestation (Simpson & Knox, 2009). Oxytocin is also often implicated in professional liability claims and thus poses a dual concern for individual clinicians and the organizations in which they practice (Clark, Simpson, Knox, & Garite, 2009). Approximately half of all paid obstetric litigation claims involve allegations of oxytocin misuse (Clark et al., 2008).

During labor, administration of oxytocin can be a source of clinical conflict between nurses and physicians (Simpson, James, & Knox, 2006; Simpson & Lyndon, 2009). Standardized policies for use of oxytocin, including agreed-upon definitions and interventions for tachysystole, promote patient safety (Clark et al., 2007; Jackson, Wickstrom, & Anderson, 2019; Krening, Rehling-Anthony, & Garko, 2012; Lee et al., 2016; O'Rourke et al., 2011; Simpson & Knox, 2009; Sundin, Mazac, Eillis, & Garbo, 2018). Use of an oxytocin checklist has been associated with less tachysystole, decreased maximum oxytocin infusion rates, and fewer cesarean births (Clark et al., 2007; Jackson et al., 2019; Krening et al., 2012; Sundin et al., 2018).

Dosage and Rate Increase Intervals. Based on physiologic and pharmacokinetic principles, Seitchik et al. (1984) recommended an interval of at least a 40 minutes between increases in oxytocin dosages because the full effect of such increases on the uterine response cannot be evaluated until steady-state concentration has been achieved. Seitchik et al. (1984) used a sensitive oxytocin radioimmunoassay to show that approximately 40 minutes were required to reach steady-state plasma concentration; if the infusion rate was increased before steady-state concentration was achieved, women in labor received higher doses of oxytocin than necessary. The work of Seitchik and Castillo (1982, 1983) and Seitchik et al. (1984) provided the basis for oxytocin protocols with dosage increases at 30 to 60 minutes. In the literature, consensus does not exist on the ideal oxytocin dosage regimen, although data support a lower dosage rate (Budden, Chen, & Henry, 2014; Crane & Young, 1998; Healy et al., 2019; Reddy, 2019; Selin et al., 2019). The most commonly used regimen in the United States is to start at 1 to 2 mU/min with incremental doses of 1 to 2 mU/min every 30 to 40 minutes.

Randomized trials have been conducted to compare low-dose versus high-dose oxytocin; however, most were conducted more than two to three decades ago. In general, researchers noted that higher doses and shorter intervals between dose increases led to more uterine tachysystole and indeterminate or abnormal FHR patterns and did not result in a clinically significant decrease in length of labor. These studies were summarized in a meta-analysis by Crane and Young (1998) who concluded that low-dose protocols resulted in fewer episodes of excessive uterine activity, fewer operative vaginal births, a higher rate of spontaneous vaginal birth, and a trend toward a lower rate of cesarean birth. In the most recent Cochrane review, Budden et al. (2014) concluded that high-dose compared to low-dose oxytocin did not increase the rate of vaginal birth within 24 hours but did increase the rate of "hyperstimulation". In a 2018 multicenter, randomized trial, high-dose oxytocin increased risk of tachysystole and "fetal distress" without reducing the rate of cesarean birth (Selin et al., 2019). These findings were similar to the cumulative results of the earlier studies (Crane & Young, 1998).

In a secondary analysis of a prospective, observational cohort to identify predictors of cesarean birth for nulliparous women at term (the Genesis study, $N = 2{,}336$, Burke et al., 2017), Healy et al. (2019) compared outcomes of women who received low-dose oxytocin for induction of labor (1 mU/min increasing every 30 minutes) to outcomes of women who received high-dose oxytocin (5 mU/minute increasing every 15 minutes). There were no differences related to duration of labor or infant outcomes between groups. However, there were more instances of "nonreassuring" FHR tracings and maternal fevers in the high-dose group. In the low-dose group, there were more instances of fetal malposition and operative vaginal birth (Healy et al., 2019). In secondary analysis of data from the ARRIVE trial (Grobman, Rice et al., 2018), Reddy (2019) evaluated outcomes of women ($n = 2{,}145$) induced with a low-dose oxytocin regimen of 0.5 to 2 mU/min as the starting dose increased by 1 to 2 mU/min every 15 to 45 minutes compared to women ($n = 899$) induced with mid- to high-dose regimens (0.5 to 2 mU/min as the starting dose increased by 3 to 6 mU/min every 15 to 45 minutes up to 6 mU/min as the starting dose increased by 3 to 6 mU/min every 15 to 45 minutes). Based on a composite outcome that included 5-minute Apgar score less than 3, hypoxic ischemic encephalopathy, seizure, infection, meconium aspiration syndrome, birth trauma, need for respiratory support within 72 hours after birth, intracranial or

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BOX 5 SUGGESTED CLINICAL PROTOCOL TO MANAGE OXYTOCIN-INDUCED UTERINE TACHYSYSTOLE

Oxytocin-induced tachysystole with normal fetal heart rate (FHR):

- Assist the woman to a lateral position.
- Give IV fluid bolus of at least 500 ml lactated Ringer's solution as indicated.
- If uterine activity has not returned to normal after 10 to 15 minutes, decrease oxytocin rate by at least half. If uterine activity has not returned to normal after 10 to 15 more minutes, discontinue oxytocin until uterine activity is normal.
- Resume oxytocin after resolution of tachysystole. If oxytocin has been discontinued for less than 20 to 30 minutes; the FHR is normal; and contraction frequency, intensity, and duration are normal, resume oxytocin at no more than half the rate that caused the tachysystole and gradually increase the rate as appropriate based on unit protocol and maternal and fetal status. If the oxytocin is discontinued for more than 30 to 40 minutes, resume oxytocin at the initial dose ordered.

Oxytocin-induced tachysystole with indeterminate or abnormal FHR:

- Discontinue oxytocin.
- Assist the woman to a lateral position.
- Give IV fluid bolus of at least 500 ml of lactated Ringer's solution as indicated.
- Consider oxygen at 10 L/min via nonrebreather face mask; discontinue as soon as possible based on the FHR pattern.
- If no response, consider 0.25 mg terbutaline administered subcutaneously.
- Resume oxytocin after resolution of tachysystole. If oxytocin has been discontinued for less than 20 to 30 minutes; the FHR is normal; and contraction frequency, intensity, and duration are normal, resume oxytocin at no more than half the rate that caused the tachysystole and gradually increase the rate as appropriate based on unit protocol and maternal and fetal status. If the oxytocin is discontinued for more than 30 to 40 minutes, resume oxytocin at the initial dose ordered.

subgaleal hemorrhage, hypotension requiring vasopressor support or perinatal death, there were significantly more adverse neonatal outcomes in the group induced with the mid- to high-dose regimens than in the low-dose group (Reddy, 2019). There were no differences in cesarean birth rates between groups.

Generally, starting doses of 1 to 2 mU/min with increases in 1 to 2-mU/min increments every 30 to 40 minutes are most appropriate and commonly used. See Appendix A for a sample protocol for labor induction and augmentation with oxytocin. Data from multiple, clinical studies and physiologic and pharmacologic principles have shown that for 90% of pregnant women at term, 6 mU/min or less of oxytocin will successfully induce labor (Dawood, 1995a, b; Seitchik et al., 1984). An intravenous infusion of 6 mU/min of oxytocin is thought to approximate the plasma concentration of oxytocin during spontaneous labor (Cuppett & Caritis, 2013). Induction of labor may require more oxytocin than augmentation of labor because in spontaneous active labor, the unripe cervix is not a significant factor, and oxytocin receptor sites are thought to be increased in number and sensitivity (Carbillon, Seince, & Uzan, 2001; Dawood, 1995a). Other factors that may influence the dose response to oxytocin include a woman's body surface area, parity, week of gestation, status of cervix, and phase of labor (Carlson, Corwin, & Lowe, 2017; Dawood, 1995a; Maeder et al., 2017; Shenouda et al., 2019; Uvnäs-Moberg et al., 2019).

Administration. Oxytocin is administered intravenously and piggybacked into the mainline solution at the port most proximal to the venous site (see Table 2). The dilution rate varies, and some protocols suggest adding 10 units of oxytocin to 1,000 ml of an isotonic electrolyte IV solution to result in an infusion dosage rate of 1 mU/min or 6 ml/hr. However, other commonly reported dilutions are 20 units of oxytocin to 1,000 ml IV fluid (1 mU/min = 3 ml/hr) and 30 units of oxytocin to 500 ml IV fluid or 60 units of oxytocin to 1,000 ml IV fluid (1 mU/min = 1 ml/hr). One advantage to the dilution rates of 30 units of oxytocin to 500 ml IV fluid or 60 units of oxytocin to 1,000 ml IV fluid is that they result in a 1:1 solution (1 mU/min = 1 ml/hr). Therefore, no calculations are needed for dosage increases, an important consideration to ensure medication safety. The key issues are how many milliunits per minute are administered and consistency in clinical practice within each institution. To enhance communication among members of the maternity care team and to prevent confusion, oxytocin administration rates should always be ordered by the physician or certified nurse-midwife as mU per minute and documented in the medical record as such.

The responsibility of the nurse during oxytocin administration involves careful titration of the drug to maternal and fetal responses. The titration process includes decreasing or discontinuing when contractions are too frequent, fetal status is indeterminate, or fetal status is abnormal. The nurse is also responsible for increasing the dosage when uterine activity and labor progress are inadequate. Often during oxytocin infusion, physicians and nurses focus on the rate increase outlined in the institutional protocol and ignore the clinical criteria for dosage increases. For example, if cervical effacement occurs or if the woman progresses in labor as expected based on parity and other individual clinical factors, there is no need to increase the oxytocin rate, even if contractions appear to be mild and infrequent. Labor progress and maternal and fetal response to the medication should be the primary considerations.

When uterine tachysystole occurs or fetal status is such that oxytocin is discontinued, data are limited to guide decision-making about the timing and dosage of subsequent IV oxytocin administration. Physiologic and pharmacologic principles may be used to determine the most appropriate dosage. If oxytocin has been discontinued for less than 20 to 30 minutes; the FHR is normal; and contraction

frequency, intensity, and duration are normal, a suggested protocol may include restarting oxytocin at least at a lower rate of infusion than before the tachysystole occurred. In this clinical situation, many practitioners restart the infusion at half the rate that caused the tachysystole and gradually increase the rate as appropriate based on unit protocol and maternal-fetal status. However, if the oxytocin is discontinued for more than 30 to 40 minutes, most of the exogenous oxytocin is metabolized, and plasma levels are similar to those of a woman who has not received IV oxytocin. In this clinical situation, a suggested protocol may include restarting the oxytocin at or near the initial dose ordered. There are individual differences in myometrial sensitivity and the response to oxytocin during labor (Page et al., 2017; Reinl et al., 2017; Uvnas-Moberg et al., 2019). It may be necessary to use a lower dose and increase the interval between dosages when there is evidence of the woman's previous sensitivity to the drug (see Box 5).

Augmentation of Labor

Management of Labor Dystocia

Labor is often augmented with oxytocin or amniotomy or both when abnormal progress is diagnosed. Two practical classifications for labor abnormalities are discussed in a consensus statement on prevention of the primary cesarean birth (ACOG & SMFM, 2014): slower than normal labor (protraction disorders) and complete cessation of contractions (arrest disorders). These disorders require the woman to be in the active phase of labor; thus, a prolonged latent phase is not indicative of dystocia, and this diagnosis cannot be made in the latent phase of labor. A latent phase as long as 18 hours during labor induction for nulliparous women is not unusual, and most women will give birth vaginally if time is allowed to achieve active labor (ACOG, 2009b; ACOG & SMFM, 2014; Harper et al., 2012; Zhang et al., 2010). In a retrospective cohort study of the 38,484 primary cesarean births among the 228,562 births that occurred at sites participating in the Consortium on Safe Labor, the most common indications for primary cesarean were failure to progress (35.4%), "nonreassuring" FHR tracing (27.3%), and fetal malpresentation (18.5%), although frequencies for each indication varied by parity (Boyle et al., 2013). Gregory, Curtin, Taffel, and Notzon (1998) found similar indications in previous U.S. data from 1985 and 1994. Often, women have cesarean birth because of failure to progress in labor when active labor has not begun or labor has not been abnormally long (ACOG & SMFM, 2014). A systematic review of the evidence about labor dystocia, sponsored by the Agency for Healthcare Research and Quality, was recently published (Myers et al., 2020). The results highlighted the gaps in the current literature and the many areas that need more study including supportive labor care techniques and their potential link to a decreased risk of cesarean birth (Simpson, 2020).

The duration of normal labor varies significantly among childbearing women. For some women, labor progresses more slowly than expected but still within normal limits (Abalos et al., 2018; Neal et al., 2018; Oladapo et al., 2018; Tilden et al., 2019); therefore, augmentation may not be necessary. It is important to use recent data on normal labor progress to guide decision-making about the potential indications for labor augmentation (ACOG & SMFM, 2014). Recommendations for clinical practice from ACOG and SMFM (2014) include the following:

- A prolonged latent phase (>20 hr in nulliparous women and >14 hr in multiparous women) should not be an indication for cesarean birth.
- Slow but progressive first stage of labor should not be an indication for cesarean birth.
- If maternal and fetal status allow, cesarean birth for failed induction of labor in the latent phase can be avoided by allowing longer durations of the latent phase (≥24 hours) and requiring that oxytocin be administered for at least 12 to 18 hours after rupture of membranes before diagnosing failure of induction.
- Cervical dilation of 6 cm should be considered the threshold for the active phase of labor for most women; thus, before 6 cm of dilation is achieved, standards of progress in the active phase should not be applied.
- Cesarean birth for arrest in the active phase of the first stage of labor should be reserved for women with greater than or equal to 6 cm of cervical dilation with ruptured membranes who fail to progress despite 4 hours of adequate uterine activity or at least 6 hours of oxytocin administration with inadequate uterine activity and no cervical change.
- A specific, absolute, maximum length of time spent in the second stage of labor beyond which operative vaginal birth should be considered has not been identified.
- Before diagnosing arrest in the second stage of labor, if maternal and fetal conditions permit, allow for at least 2 hours of pushing in multiparous women and at least 3 hours of pushing in nulliparous women; longer durations may be appropriate on individualized basis (e.g., with use of epidural analgesia or with fetal malposition) as long as progress is being documented.

A universally agreed upon, ideal, cesarean birth rate does not exist (Betrán et al., 2018; Clark, Garite, Hamilton, Belfort, & Hankins, 2018). The goals for any childbirth are labor and birth aligned with respectful care for the woman and a healthy mother and newborn (Betrán et al., 2018; Clark et al., 2013; Simpson, 2019b). During labor, a cesarean birth is sometimes indicated based on medical, obstetric, or fetal factors, and this timely intervention results in optimal outcomes for the woman and newborn. The clinical quandary is how to balance longer than expected labor and hopes for a vaginal birth with maternal and fetal well-being (Caughey, 2017; Clark et al., 2013, 2018; Cohen & Friedman, 2018; Simpson, 2016). Although results of some studies on allowing more time for labor to progress to vaginal birth are encouraging (ACOG & SMFM, 2014; Bell, Joy, Gullo, Higgins, & Stevenson, 2017; Gimovsky & Berghella, 2016; Harper et al., 2012; Rouse et al., 2001; Thuillier et al., 2018; Zhang et al., 2010), evidence suggests that a cautious approach based on the individual clinical situation is warranted because small but significant risks of adverse outcomes exist for women and newborns with prolonged, first and second stage labor (Grobman et al., 2016; Laughon et al., 2014; Rosenbloom et al., 2017, 2019; Zipori, Grunwalkd, Ginsberg, Beloosesky, & Weiner, 2019).

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Oxytocin Dosage for Augmentation of Labor

From a physiologic and pharmacologic standpoint, less oxytocin is needed for labor augmentation than for labor induction. Oxytocin receptor concentration increases as pregnancy continues and peaks in spontaneous early labor (Calderyro-Barcia, & Sereno, 1959; Irani & Foster, 2015). Cervical resistance is less for women in spontaneous active labor than for women who have not yet experienced cervical effacement and dilation. The response to oxytocin seems to depend on preexisting uterine activity and sensitivity rather than the amount given (Arias, 2000). Recent data from randomized trials do not support use of high-dose oxytocin for induction or augmentation of labor because of concerns about tachysystole and adverse fetal outcomes with no benefit in reducing risk of cesarean birth.

In a systematic review of 10 studies conducted on five continents from 1987 to 2004 to compare low-dose and high-dose oxytocin for augmentation of labor, Wei, Luo, Qi, Xu, and Fraser (2010) suggested that high-dose oxytocin (starting range of 4 to 10 mU/min) may be beneficial to shorten labor and decrease risk of cesarean birth. Two of the 10 included studies were conducted in Africa, which has very different clinical conditions than those in the United States. Twice as many women with high-dose oxytocin had tachysystole than women with low-dose oxytocin, but the studies included no further information about the effects on FHR patterns. In the high-dose groups, researchers found more newborns with Apgar scores less than 7 at 5 minutes of life and umbilical artery pH less than 7.10 (Wei et al., 2010). Wei et al. (2010) concluded that 50 women would need to be exposed to high-dose oxytocin during labor augmentation to potentially avoid one cesarean birth. These findings are different from more recent studies of low-dose versus high-dose oxytocin for induction of labor in which researchers found no benefits toward reducing the rate of cesarean birth in the high-dose groups but did find more adverse outcomes (Healy et al., 2019; Reddy, 2019). In a multicenter, randomized trial of 1,351 healthy women at term who presented in spontaneous labor with singleton fetuses in vertex presentation, high-dose oxytocin for augmentation of labor increased risk of tachysystole and fetal distress with no benefit toward reducing cesarean births (Selin et al., 2019).

A high dose of oxytocin did not decrease risk of cesarean in a retrospective analysis of data from the Consortium on Safe Labor in which Zhang et al. (2011) compared starting doses of oxytocin of 1 mU/min, 2 mU/min, and 4 mU/min for augmentation of labor. Information on intervals between dosage increases was available for only two of the six hospitals included in the study. Length of augmented labor from start of oxytocin in nulliparous women was 6.9 hours for the 1 mU/min group, 5.3 hours for the 2 mU/min group, and 6.3 hours for the 4 mU/min group (Zhang et al., 2011). Starting at 2 mU/min seemed to be associated with the shortest duration of augmented labor for nulliparous women. There were similar findings for multiparous women, although these are of less clinical significance when considering that differences in length of augmented labor among groups varied from 6 to 24 to 48 minutes. Length of augmented labor from start of oxytocin in multiparous women was 3.8 hours for the 1 mU/min group, 3.1 hours for the 2 mU/min group, and 3.4 hours for the 4 mU/min group (Zhang et al., 2011). There was no difference in the cesarean birth rate among the groups after controlling for potential confounding variables (Zhang et al., 2011).

Induction for Women Who Attempt VBAC

Waiting for spontaneous labor and avoiding cervical ripening agents and oxytocin appear to significantly decrease the risk of uterine rupture for women who attempt VBAC (ACOG, 2019c). Data suggest that prostaglandins and high rates of oxytocin infusion increase the risk for rupture (ACOG, 2019c). There appears to be a dose-response effect between the rate of oxytocin and uterine rupture, but no evidence indicates the maximum rate at which risk of uterine rupture during labor of women attempting VBAC is minimized (ACOG, 2019c). It has been theorized that prostaglandins induce local biochemical modifications that weaken the previous uterine scar and predispose it to rupture (Penfield & Wing, 2017). Misoprostol should not be used for cervical ripening in the third trimester or for labor induction in women who have had cesarean birth or major uterine surgery (ACOG, 2019c). Per the manufacturer, Cervidil should not be used for cervical ripening for women with histories of cesarean birth or major uterine surgery (Ferring Pharmaceuticals, 2017). If labor induction for women with histories of cesarean or uterine scars is indicated, ACOG (2019c) recommends an appropriate dose of oxytocin and close monitoring of maternal and fetal status during labor and birth. Mechanical cervical ripening with a balloon catheter is recommended as appropriate (ACOG, 2019c).

SUMMARY

Multiple methods of cervical ripening, labor induction, and labor augmentation are in used in the United States and Canada. Each method has risks and benefits to the mother and fetus. The state of the cervix is an important clinical indicator for the likelihood of the success of induction. Cervical readiness can increase the chances of success if the indication for induction allows time for cervical ripening. Oxytocin has been used for many years and has been proven to be safe and effective for induction and augmentation. A physiologic oxytocin regimen for labor induction appears to be the best approach for most women because the risks of higher doses and increasing the doses at more frequent intervals (such as tachysystole and cesarean birth for indeterminate or abnormal fetal status) do not outweigh the benefits (if any) of a slightly shorter labor. Recent, randomized trials have confirmed these findings. Cervidil is approved by the FDA for cervical ripening. Misoprostol is sometimes used for cervical ripening. However, tachysystole and indeterminate or abnormal FHR patterns related to tachysystole are more common with misoprostol than with oxytocin. Lower doses of misoprostol and increased intervals between doses will decrease risk to the woman and fetus. Women who attempt VBAC are at increased risk for uterine rupture if pharmacologic agents, especially prostaglandins or high-dose oxytocin, are used for cervical ripening or labor induction.

Elective labor inductions expend significant financial and human resources. Intrapartum length of stay is considerably longer when labor is induced, especially in the context of an unfavorable cervix

(ACOG & SMFM, 2014; Grobman, Bailit et al., 2018; Grobman, Rice et al., 2018; Simpson, 2010; Wennerholm et al., 2019). When a woman receives oxytocin, a one nurse to one woman ratio is necessary to maintain adequate surveillance of the woman and fetus and to perform an assessment of maternal-fetal status at least every 15 minutes as recommended by AAP & ACOG (2017) and AWHONN (2010; 2018a).

The ARRIVE trial (Grobman, Rice, et al. 2018) may lead some to believe that elective induction of labor for women at 39 weeks gestation is an ideal way to decrease the risk of cesarean birth, but there are important caveats that must be considered. A labor management protocol similar to the one used in the ARRIVE trial or the criteria for failed induction of labor recommended by ACOG & SMFM (2014) must be used when elective induction of nulliparous women is conducted or there may be the unintended consequence of increasing the cesarean rate (Main, 2018). Physicians, nurse-midwives, labor nurses, and women in labor must be willing to adopt, work within, and accept a labor management protocol that allows for the adequate progress of the latent, active, and second stage of labor while maternal and fetal well-being are maintained. Women must be low-risk as defined in the study (Grobman, Rice, et al. 2018). The rates of cesarean in the control group (22.2%) and the intervention group (18.6%) in the ARRIVE trial (Grobman, Rice, et al., 2018) were lower than rates of cesarean for low-risk, nulliparous women in the United States, which were 26% in 2017 and 25.9% in 2018 (Martin et al., 2019). Therefore, these results may not be generalizable to the general population of low-risk, nulliparous women (Main, 2018). There must be adequate nurse staffing and enough labor rooms to handle elective procedures and address the needs of the other patients on the unit.

Significant costs may be associated with the increased need for labor nurses, labor beds, and surgical rooms to accommodate potential physician and consumer demand for elective induction of labor at 39 weeks gestation. Not all hospitals have these types of financial, facility, and human resources available (Breedlove, 2019). Based on their findings, Grobman, Rice, et al. (2018) estimated that 28 low-risk, nulliparous women would need to be induced to avoid one cesarean birth. This represents a significant number of women who would be exposed to oxytocin with associated risks and who would have 20-hour, intrapartum lengths of stay compared to 14-hour lengths of stay with spontaneous labor. The nurse staffing costs for an additional 6 hours of labor for 28 women (168 nursing hours with one nurse to one woman in labor if oxytocin is the method of induction) are substantial. Hersh, Skeith, Sargent, and Caughey (2019) estimated that elective induction for all low-risk, nulliparous women in the United States (approximately 1.6 million) would lead to an additional $2.26 billion in health care costs.

Some have suggested the use of cervical ripening in the outpatient setting for elective induction of labor as a method to decrease costs by decreasing the associated intrapartum length of stay. Evidence from randomized, controlled trials in the United States is needed before outpatient cervical ripening can be considered. The role of the labor nurse in educating patients and monitoring the woman and fetus and the outcomes and experiences of women who undergo outpatient cervical ripening at home should be fully evaluated using rigorous study methods. Evaluation of mechanical methods of cervical ripening, such as balloon bulb catheters, on an outpatient basis could be an initial step. Given the risk of excessive uterine activity, outpatient cervical ripening using pharmacologic methods may not be feasible or safe.

Other, less cost-intensive strategies may be used to decrease the cesarean rate. For example, ACOG (2019a) suggested low-intervention practices such as delaying admission to the hospital until labor is established for healthy women and continuous, one-to-one, emotional support provided by support personnel such as doulas. Likewise, ACOG and SMFM (2014) noted that one of the most effective ways to improve birth outcomes is the continuous presence of supportive personnel or doulas.

Following established labor management guidelines may be an effective way for clinicians and hospitals to establish additional time frames for allowing labor to progress to vaginal birth when the woman and fetus are doing well (Bell et al., 2017; Main et al., 2019; Marrs, La Rosa, Caughey, & Saade, 2019; Neal et al., 2017). There are wide variations in the cesarean birth rate among hospitals in the United States, and some hospitals have rates 10 times higher than others (Kozhimannil, Law, & Virnig, 2013). Reducing variation in practice may be an effective strategy improve quality and decrease costs (Kozhimannil et al., 2013). In 2015, the American College of Nurse-Midwives began the Reducing Primary Cesareans Project (ACNM, n.d.-b), a multihospital learning collaborative to help maternity care professionals and health systems make system changes to reduce the incidence of primary cesarean births in the United States. This project is part of ACNM's Healthy Birth Initiative, which includes tools that can be used by women, maternity care providers, hospital policymakers, payers, and other organizations to decrease the incidence of cesareans (ACNM, n.d.-a). In 2015, the Council on Patient Safety in Women's Health Care published a patient safety bundle: Safe Reduction of Primary Cesarean Birth, which included detailed suggestions for reducing the risk of cesarean. Subsequently, in 2018, the National Partnership for Maternal Safety published the related consensus bundle on safe reduction of primary cesarean births (Lagrew et al., 2018). The California Maternal Quality Care Collaborative offers the Toolkit to Support Vaginal Birth and Reduce Primary Cesareans (Smith, Peterson, Lagrew, & Main, 2017), which has proven to be successful in reducing cesarean births (Main et al., 2019).

The increase in the elective induction rate over the past two decades has profoundly changed the practice of perinatal nursing. Instead of predominantly caring for women who present in spontaneous active labor, many labor nurses now spend a significant portion of their time titrating oxytocin infusions and managing the side effects of oxytocin. Given the results of the ARRIVE trial (Gobman, Rice et al., 2018), there is potential for an increase in the rate of elective induction and a concomitant escalation of the medicalization of childbirth (Migliorelli, De Oliveira, & Martinez de Tejada, 2020).

Clinical practices based on the best available evidence promote the safest care possible for women and their fetuses when women undergo artificial initiation of labor. These practices include but are not limited to the following:

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- Educating women throughout pregnancy about the benefits of avoiding unnecessary interventions.
- Providing women with adequate information to make fully informed decisions about their labor and birth processes, including options for initiating labor.
- Informing women that it is safe to wait for spontaneous labor until 41 completed weeks gestation when the woman and fetus are healthy.
- Requiring that elective labor induction be limited to women who have reached at least 39 completed weeks gestation.
- Ensuring cervical readiness before labor induction.
- Prioritizing inductions of labor based on indication and maternal-fetal condition.
- Standardizing physiologic oxytocin protocols, including a standard concentration and standard dosing regimen.
- Carefully titrating oxytocin based on the maternal-fetal response.
- Using a standard definition of tachysystole (more than five contractions in 10 minutes averaged over 30 minutes) that does not include the woman's perception of pain or the fetal response.
- Ensuring that management of tachysystole occurs in a timely and appropriate manner and that interventions are not delayed until there is an indeterminate or abnormal FHR pattern.
- Requiring a ratio of one registered nurse to one woman during oxytocin infusion and a ratio of one registered nurse to two women during cervical ripening with pharmacologic agents.
- Coming to a common understanding among members of the maternity care team regarding how labor induction will be conducted as outlined in a standard written unit policy or protocol and an agreement that all team members will follow the policy or protocol.

Much work needs to be done to educate pregnant women so they have enough information to make informed decisions about labor induction. Induction of labor is a complex issue that involves all participating parties: the pregnant woman, her family, her physician or midwife or both, the institution, and the perinatal nurse. More data are needed to fully evaluate the risks and benefits of induction of labor. On the basis of what is known, a cautious process that allows for individualization to each clinical situation should be developed by each institution to ensure the best outcomes for mothers and newborns.

Evaluating quality of care is a critical aspect of professional practice and is essential to make improvements as necessary to promote safe, effective care and optimal outcomes. Consider using some of the structure, process, and outcome measures provided in Appendix B. Each of these measures has been found to be helpful in assessing care quality by The Joint Commission or in the context of clinical research.

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APPENDIX A. PROTOCOL FOR INDUCTION/AUGMENTATION OF LABOR WITH OXYTOCIN

Purpose

To promote safe and effective use of oxytocin for induction and augmentation of labor.

Responsibilities of Physician, Nurse-Midwife, and Nurse

The decision to use oxytocin for labor induction or augmentation is the responsibility of the attending physician and/or certified nurse-midwife.

Labor nurses may refuse to administer oxytocin if in their best judgment it is contraindicated or if the needs of the service make it difficult or impossible to adequately monitor maternal-fetal status. The attending physician and/or certified nurse-midwife will be notified.

Guidelines for Practice

Before Oxytocin Administration

Verify that the physician and/or certified nurse-midwife has discussed the indications and potential risks and benefits of induction or augmentation of labor with the pregnant woman and that her consent is documented in the medical record.

Verify that the indication for induction is documented in the medical record. If indication is elective, verify gestational age of 39 or more completed weeks gestation.

Follow routine admission procedure and perform vaginal examination to evaluate cervical status and fetal station and presentation. Document the Bishop score in the medical record (see Table A1). The labor nurse, certified nurse-midwife, attending physician or resident physician in training may determine cervical status based on the Bishop score. The labor nurse may perform the initial vaginal examination and subsequent vaginal examinations during labor.

Assist the woman to a comfortable position, preferably the left or right lateral position or an upright position.

Apply the electronic fetal monitor and record the fetal heart rate (FHR) and uterine activity (UA) for at least 30 minutes before initiation of oxytocin infusion. Before oxytocin is administered, the FHR should be normal. Notify physician and/or certified nurse-midwife if the FHR is indeterminate or abnormal.

Oxytocin Dosage and Administration

Use a premixed solution of 30 units oxytocin in 500 ml of lactated Ringers solution (1 milliunit per min [mU/min] = 1 milliliter per hour [ml/hr]).

Start oxytocin at 1 to 2 mU/min and gradually increase by 1 to 2 mU/min every 30 to 40 minutes until adequate progress of labor is established and/or contractions are every 2 to 3 minutes.

Once adequate labor is established, maintain or decrease oxytocin to baseline rate necessary for continued labor progress.

Decrease or discontinue oxytocin infusion during the second stage of labor to approximate physiologic, second-stage contraction pattern.

The oxytocin infusion may be increased to 20mU/min per this protocol at the discretion of the nurse. A bedside evaluation of the attending physician and/or certified nurse-midwife is needed to increase beyond 20mU/min. This should be considered only in unusual clinical situations.

Maternal–Fetal Assessment and Documentation

The assessment of maternal and fetal status described below should occur every 15 minutes during the first stage of labor, and during the passive fetal descent phase of the second stage of labor, and every 5 minutes during the active, pushing phase of the second stage of labor while oxytocin is administered. Summary documentation may occur at 30-minute intervals during the active, pushing phase of second stage labor with a note that the nurse is in continuous bedside attendance to assess maternal and fetal status. The following

TABLE A1 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	≥ 5	≥ 80	+1, +2		

Note. From "Pelvic scoring for elective induction." By E. H. Bishop. *Obstetrics & Gynecology, 24*, p. 267. Copyright 1964 by American College of Obstetricians and Gynecologists. Used with permission.

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documentation is required in the medical record each time the oxytocin dosage rate is increased or decreased (or at least every 15 min if the dosage is unchanged):

- Fetal heart rate: baseline rate, baseline variability, presence or absence of FHR accelerations, presence or absence of FHR decelerations, and interventions as appropriate.
- Uterine activity: contraction frequency, duration, intensity, and uterine resting tone by palpation or intrauterine pressure catheter.
- Maternal response to labor: the woman's response to the contractions, e.g., not feeling contractions, using breathing techniques with contractions, requiring intense labor coaching with contractions, comfort with contractions with epidural analgesia.
- Oxytocin dose: in milliunits per minute.

If a registered nurse is not available to clinically evaluate the effects of the oxytocin infusion at least every 15 minutes, the infusion should be discontinued until that level of nursing care is available (AAP & ACOG, 2017; AWHONN, 2018; Simpson, 2020). The attending physician or certified nurse-midwife will be notified.

Maternal Activity

Encourage the woman to try alternatives to bed rest such as ambulation in the labor room or hall, use of a rocking chair or birthing ball, or a warm shower. When the woman is out of bed during oxytocin infusion, an electronic fetal monitoring (EFM) telemetry unit should be used to monitor FHR and uterine activity.

Tachysystole

The definition of tachysystole is more than five contractions in 10 minutes averaged over 30 minutes. Other characteristics of excessive uterine activity are contractions that last 2 minutes or longer, insufficient return of uterine resting tone between contractions via palpation, or intraamniotic pressure above 25 mmHg between contractions via intrauterine pressure catheter.

Suggested Clinical Protocol for Oxytocin-Induced, Uterine Tachysystole

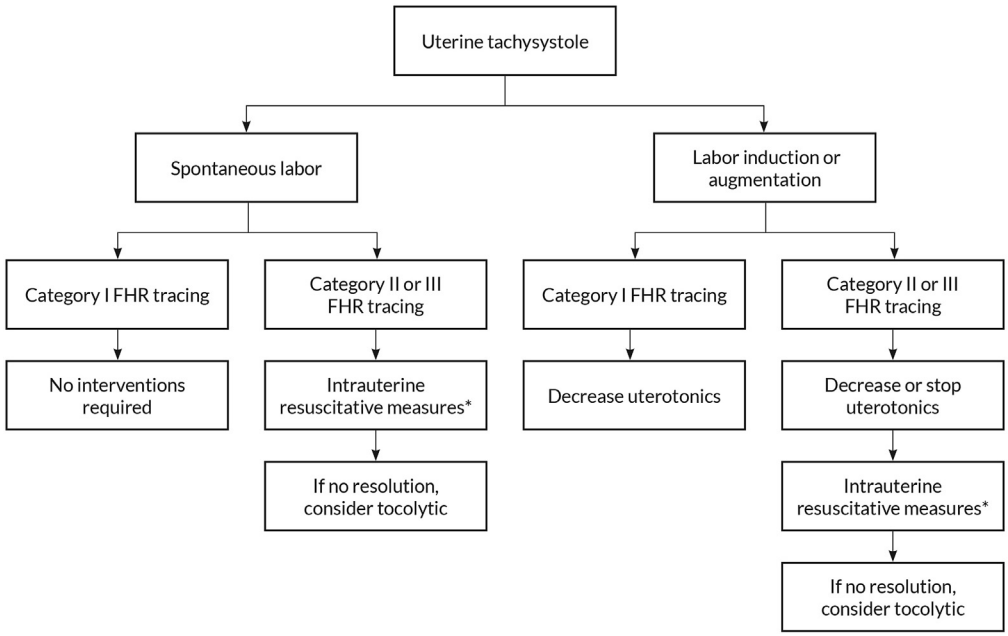
Oxytocin-Induced Tachysystole With Normal FHR.

- Reposition the woman to left or right.
- Initiate intravenous fluid bolus of lactated Ringer's solution (~500 ml).
- If uterine activity has not returned to normal after 10 to 15 minutes, decrease oxytocin rate by at least half. If uterine activity has not returned to normal after 10 to 15 more minutes, discontinue oxytocin until uterine activity is less than five contractions in 10 minutes.

Oxytocin-Induced Tachysystole With Indeterminate or Abnormal FHR.

- Discontinue oxytocin.
- Reposition the woman to left or right.
- Initiate intravenous fluid bolus of lactated Ringer's solution (~500 ml).

FIGURE A1 MANAGEMENT ALGORITHM OF INTRAPARTUM FETAL HEART RATE TRACINGS BASED ON THREE-TIERED CATEGORY SYSTEM



From "ACOG Practice Bulletin No.106: Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles," by American College of Obstetricians and Gynecologists, 2010, *Obstetrics & Gynecology, 114*, p. 1237. Copyright 2009 by American College of Obstetricians and Gynecologists. Reprinted with permission.

- Consider oxygen at 10 L/min via nonrebreather facemask if the first interventions above do not resolve the indeterminate or abnormal FHR pattern. Discontinue as soon as possible.
- If no response, consider 0.25 mg terbutaline administered subcutaneously.
- Notify maternity care provider of actions taken and maternal and fetal response.

Resumption of Oxytocin After Resolution of Tachysystole. If oxytocin has been discontinued for less than 20 to 30 minutes; the FHR is normal; and contraction frequency, intensity, and duration are normal, resume oxytocin at no more than half the rate that caused the tachysystole and gradually increase the rate as appropriate based on unit protocol and maternal and fetal status. If the oxytocin is discontinued for more than 30 to 40 minutes, resume oxytocin at the initial dose ordered.

Indeterminate/Abnormal Fetal Status. Identification of indeterminate/abnormal fetal status requires notification of the physician and/or certified nurse-midwife after interventions to resolve the clinical situation. Documentation in the medical record should include interventions to resolve the clinical situation, the maternal and fetal response, and the content of the conversation between the nurse and the provider.

Epidural Analgesia/Anesthesia. Women who receive oxytocin who have epidural analgesia/anesthesia should have pelvic examinations periodically as clinically indicated to assess labor progress.

Internal Monitoring. Internal monitoring may be appropriate based on the individual, clinical situation. If an interpretable FHR tracing and/or uterine activity tracing cannot be recorded, a fetal scalp electrode and/or intrauterine pressure catheter may be placed if indicated. Membranes must be ruptured and the cervix must be at least 2 to 3 cm dilated before the nurse can insert either device.

Insertion of a fetal scalp electrode or intrauterine pressure catheter requires the order of a physician or certified nurse-midwife. Oxytocin is not in itself an indication for internal monitoring if external monitoring produces an interpretable tracing and there is not a clinical need for more accurate data about intrauterine pressure.

If internal monitors cannot be inserted and/or the FHR and/or uterine activity cannot be recorded, the oxytocin infusion should be discontinued until interpretable FHR and uterine activity patterns can be recorded. The physician and/or certified nurse-midwife who ordered the oxytocin should be notified.

Care of Women Who Attempt Vaginal Birth After Cesarean (VBAC). Oxytocin may be used to induce or augment labor for women who attempt VBAC. Verify that the consent for VBAC has been obtained and is included in the medical record. Continuous EFM is recommended with insertion of an intrauterine pressure catheter as soon as clinically possible. The lowest dose of oxytocin required to achieve adequate labor progress should be used. Oxytocin rates beyond 20 mU/min are not recommended.

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APPENDIX B. QUALITY MEASURES RELATED TO CERVICAL RIPENING AND INDUCTION AND AUGMENTATION OF LABOR

STRUCTURE MEASURES

Perinatal Structure Measures

Requirement for 39 completed weeks gestation before elective labor induction and elective cesarean birth; hard stop included in policy	Yes/No
Criteria for prioritizing labor inductions based on medical necessity	Yes/No
Standard policy for oxytocin administration	Yes/No
Standard order set for oxytocin administration based on components of policy in Appendix A	Yes/No
Agreed-upon definition of tachysystole based on NICHD/ACOG/AWHONN; an indeterminate or abnormal fetal heart rate pattern is not required; the woman's perception of pain is not included in the definition	Yes/No
Agreed-upon treatment for tachysystole linked to provider orders or a unit protocol that does not require additional orders before implementation	Yes/No
Standard policy for misoprostol administration	Yes/No
Standard order set for misoprostol administration based on components of policy listed above (see Box 3)	Yes/No

Note. Adapted from Table 3. Perinatal Patient Safety Structures and Processes Comparison Data: Findings from Initial Risk Assessment and Status as of October 2007 for 16 Hospitals in "A Comprehensive Perinatal Patient Safety Program to Reduce Preventable Adverse Outcomes and Costs of Liability Claims," by K. R. Simpson, C. C. Kortz, and G. E. Knox, 2009, *Joint Commission Journal on Quality and Patient Safety, 35,* p. 570. Copyright 2009 by The Joint Commission. Used with permission. ACOG = American College of Obstetricians and Gynecologists; AWHONN = Association of Women's Health, Obstetric and Neonatal Nurses; NICHD = Eunice Kennedy Shiver National Institute of Child Health and Human Development.

PROCESS MEASURES

Expected Aspects of Care During Induction of Labor

Aspect of Care	Results		
≥39 completed weeks gestation if elective	Yes	No	NA (<39 weeks)
If <39 completed weeks gestation, indication is consistent with ACOG and TJC clinical indications	Yes	No	NA (≥ 39 weeks)
Cervical readiness (Bishop score >8 nulliparous women or >6 multiparous women) or ripening before labor induction (if indication is medical)	Yes	No	
Oxytocin protocol starting at 1-2 mU/min; increase by 1-2 mU/min; at least 30 min between oxytocin dosage increases	Yes	No	
Fetal status is normal	Yes	No	
Appropriate and timely interventions for tachysystole[a] if it occurs (treatment is not delayed until the fetal heart rate is indeterminate/abnormal). Use tool to evaluate response to tachysystole	Yes	No	NA (tachysystole did not occur)
Compliance with all expected aspects of care	Yes	No	

Expected Aspects of Care During Augmentation of Labor

Aspect of Care	Results		
Oxytocin protocol starting at 1-2 mU/min; increase by 1-2 mU/min; at least 30 min between oxytocin dosage increases	Yes	No	
Fetal status is normal	Yes	No	
Appropriate and timely interventions for tachysystole[a] if it occurs (treatment is not delayed until the FHR is indeterminate/abnormal) Use tool to evaluate response to tachysystole	Yes	No	NA (tachysystole did not occur)
Compliance with all expected aspects of care	Yes	No	

Note. Adapted From "MHA Keystone Obstetrics: A Statewide Collaborative for Perinatal Patient Safety in Michigan," by K. R. Simpson, G. E. Knox, M. Martin, C. George, and S. R. Watson, 2011, *Joint Commission Journal on Quality and Patient Safety, 37*(12), pp. 547– 548. Copyright 2011 by The Joint Commission. Used with permission.

[a]Standard definition of tachysystole is more than five contractions in 10 min averaged over 30 min. An indeterminate/abnormal FHR pattern or the woman's perception of pain is not included in the definition.

TACHYSYSTOLE AUDIT TOOL

Tachysystole is defined as more than five contractions in 10 minutes averaged over 30 minutes.
Expected Process of Care: Excessive uterine activity will be identified, and interventions will be initiated within 20 minutes of its development. Interventions are based on whether the fetal heart rate (FHR) pattern is normal or indeterminate or abnormal.

Care Data		Times
Beginning		
Identification		
How many minutes before identification?		
Interventions initiated	Yes/No	
Repositioning	Yes/No	
Administration of lactated Ringer's solution by IV	Yes/No	
Decrease oxytocin by half of current rate (normal FHR pattern)	Yes/No	
Discontinue oxytocin (indeterminate or abnormal FHR pattern or if half dosage decrease does not correct excessive uterine activity)	Yes/No	
Terbutaline 0.25 mg subcutaneously	Yes/No	
Resolution time		
Total length of excessive uterine activity period in minutes		
Indeterminate or Abnormal FHR Characteristics (if applicable)		
	Absent or Present	Accurately Interpreted
FHR (bradycardia or tachycardia)	Rate	Yes/No
Variability (absent or minimal)	Yes/No	Yes/No
Decelerations (late, variable, prolonged, recurrent, intermittent)	Yes/No	Yes/No
Overall Evaluation of Care		
Expected Care Process Met	Yes	No

Note. Adapted from "Oxytocin as a High Alert Medication: Implications for Perinatal Patient Safety," by K. R. Simpson and G. E. Knox, 2009, *MCN The American Journal of Maternal/Child Nursing, 34*(1), p. 14. Copyright 2009 by Wolters Kluwer. Adapted with permission.

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ADDITIONAL OUTCOME MEASURE AND PATIENT CENTERED MEASURES FOR ELECTIVE INDUCTION OF LABOR

Outcome Measure
Infants (>39 wks/0 days gestation) with Apgar scores less than 7 at 5 minutes whose mothers had elective inductions of labor
Patient Centered Measures
Do you feel you were adequately prepared for what to expect during your labor induction?
What do you know now that you wish you had known before consenting to labor induction or asking that your labor be induced?

Note. From Simpson, Knox, Martin, George, & Watson (2011); Simpson, Newman, & Chirino. (2010).