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OHSU HEALTH SYSTEM OFFICE OF CLINICAL INTEGRATION AND EVIDENCE-BASED PRACTICE

GUIDELINE FOR INDUCTION OF LABOR

Background: The purpose of induction of labor is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor^[1]. Generally, induction of labor has merit as a therapeutic option when benefits of expeditious delivery outweigh the risk of continuing the pregnancy. ^[2] The goal of this guideline is to develop clinical practice recommendations for the appropriate setting, monitoring, and methods of induction in order to improve maternal and neonatal health outcomes.

Prevalence: The rate of induction of labor more than doubled from 1990 through 2012, from 9.6% to 23.3%. Induction rates were at least twice as high in 2010 as in 1990 for all gestational age groups except post-term births, which rose 90%.^[3] In 2017 the rate of induction of labor increased to 25.7%.^[4] The OHSU Labor and Delivery Unit is a high-risk pregnancy tertiary referral center and the rate of induction of labor is 43%^[5].

Risks: Risks of IOL are similar to spontaneous labor and may include excessive bleeding, infection and need for cesarean delivery (CD). Rarely, risks may also include uterine rupture and fetal morbidity. These risks are increased in the context of a medically complex maternal or fetal patient.

Definitions:

Induction of labor: The ripening of the cervix and stimulation of uterine contractions before the spontaneous onset of labor with goal to achieve vaginal delivery.

Latent phase of labor: Initial phase of labor when the rate of cervical dilation is typically slow. The diagnosis is based

on contraction frequency, findings on digital cervical examination, and clinician judgment. Generally agreed that women are in latent phase when are contracting with cervical dilation \leq 6cm.

Active phase of labor: The point when latent phase ends and the rate of change of cervical dilation significantly increases.

Cervical Ripening: a prelude to the onset of active labor whereby the cervix becomes soft and compliant. This allows its shape to change from being long and closed, to being thinned out and starting to open. It either occurs naturally or as a result of physical or pharmacological interventions^[6].

Foley Catheter: a long, rubber tube with an inflatable balloon on one end that a clinician can fill with air or sterile water and used to ripen the cervix.

Cook[®] Catheter: a silicone double balloon catheter that is inflated and used to ripen the cervix.

PGE1: or misoprostol is a prostaglandin analogue which is used as a medication. It causes uterine contractions and the ripening of the cervix. ^[7]

PGE2: or dinoprostone is also a prostaglandin analogue used to ripen the cervix and stimulate uterine muscle for labor induction.

Guideline Eligibility Criteria: All patients undergoing induction of labor.

Guideline Exclusion Criteria:

- Non-cephalic presentation of a live fetus
- >2 cesarean deliveries
- Any other contraindication to a vaginal delivery



Clinical Practice Recommendations:

Assessment

The Bishop score should be used to rate the readiness of the cervix of labor. With this scoring system, a number ranging from 0-13 is given to rate the condition of the cervix. Cervical Ripening should be considered with a Bishop score of less than 6. – **Strong Recommendation, Moderate Quality of Evidence** ^[8]

Induction of Labor Phase 1: Cervical Ripening

Outpatient

- In low risk patients, outpatient cervical ripening with Foley Catheter may be considered. – **Conditional Recommendation, Low Quality Evidence** ^[9, 10]

Methods for Cervical Ripening:

- It is reasonable to offer membrane sweeping for cervical ripening, with the timing and frequency at the discretion of the provider and patient. – **Strong Recommendation, High Quality Evidence** ^[11, 12]
- Evidence was inconclusive for cervical ripening with castor oil or acupuncture. If patient is interested in these methods, risk/benefit discussion with provider should include dialogue of inconclusive evidence. – **Conditional Recommendation, Moderate Quality Evidence** ^[13, 14]
- Sexual intercourse should not be routinely recommended solely for the purpose of cervical ripening. Inform patient that in the evidence, sexual intercourse was not effective for this purpose. – **Conditional Recommendation, Moderate Quality Evidence** ^[15-17]

Inpatient

Monitoring:

- For inpatient cervical ripening, fetal wellbeing should be assessed according to the pharmacologic agent used (see Table 1). – **Consensus Statement**

Methods for Cervical Ripening:

- Shared decision making should be used when choosing the method for cervical ripening. – **Strong Recommendation, Very low Quality Evidence** ^[18, 19]
- For inpatient cervical ripening, breast stimulation with a breast pump may be considered. – **Conditional Recommendation, Low Quality Evidence** ^[20, 21]

To assist patients and providers in choosing methods of cervical ripening, OHSU Health System has developed a tiered approach in which the methods are separated by preferred and alternative methods. The preferred options are chosen because the evidence has shown them to be as efficacious and without an increased risk of adverse events, and more cost effective than the alternative methods ^[22-26]. The tiered approach allows the opportunity to offer other methods if a patient and provider prefer an alternative method. Varying levels of evidence support each method's effectiveness and each method has its own strengths and limitations.

- Preferred Options (see Table 1 for more details) includes:
 - Misoprostol
 - Vaginal administration, 25µ misoprostol every four hours – **Strong Recommendation, Moderate Quality Evidence**^[27] or



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- Oral administration, 50µ misoprostol every four hours – **Strong Recommendation, Low Quality Evidence**^[23, 28] or
- Oral misoprostol stepwise regimen of 50µ then 100µ after four hours followed by another 100µ after four hours – **Strong Recommendation, Very Low Quality Evidence** ^[29, 30]
- For Induction termination or fetal demise < 28 week size uterus refer to “Medical Induction for TOP Protocol” OHSU Clinical Guideline for alternative misoprostol dosing regimen.

OR

- Foley catheter alone filled with 60mL of saline – **Strong Recommendation, Low Quality Evidence** ^[31-34]

OR

- Foley catheter combined with any of the above misoprostol options – **Strong Recommendation, Moderate Quality Evidence** ^[33-38]
- Foley catheter filled with 60mL saline (or Cook® Catheter) with concurrent oxytocin, start at 2 mu/min and increase by 2 mu/min every 30 min until regular contraction pattern – **Conditional Recommendation, Very Low Quality Evidence** ^[39-41]

- Preferred option for patients undergoing trial of labor after cesarean (TOLAC)

- Alternative Options (see Table 1 for more details) includes:

- Dinoprostone 10mg vaginal insert – **Conditional Recommendation, Moderate Quality Evidence** ^[23, 42, 43]

OR

- Cook® Catheter used per the manufacturer’s instructions – **Conditional Recommendation, Moderate Quality Evidence** ^[25, 44]

- Amniotomy, Oxytocin alone, Laminaria tent, and extra-amniotic saline infusion were not included in this evidence appraisal and can be used at the discretion of the clinician. – **Consensus Statement**

Induction of Labor Phase 2: Active Labor

Oxytocin:

- Once the cervix is ripened, it is reasonable to use either a lower dose oxytocin protocol (start at 2mU/min and increase by 2 mu/min q 30 min) or higher dose oxytocin protocol (start at 4 mu/min and increase by 4 mu/min every 30 minutes) for induction of labor. – **Strong Recommendation, Moderate Quality Evidence** ^[45, 46]

Induction of Labor: Additional Considerations

Nutrition and Hydration:

- Low risk patients for aspiration should have unrestricted oral intake of fluid during induction of labor. – **Strong Recommendation, Moderate Quality Evidence**^[47]
- It is reasonable to offer intravenous D5NS/D5LR at the rate of 250mL/h during active labor in women undergoing induction of labor, may improve outcomes such as shortened duration of labor and reduction in the incidence of cesarean delivery.-**Conditional Recommendation, Moderate Quality Evidence** ^[47]
- Solid food intake was not included in this evidence appraisal and should be a discussion between patient, provider and anesthesia team. – Consensus Statement

Epidural analgesia:



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- Provide patients in early labor (i.e., <5 cm dilation) the option of neuraxial analgesia on an individualized basis – **Conditional Recommendation, Moderate Quality Evidence**
- Do not withhold neuraxial analgesia on the basis of achieving an arbitrary cervical dilation – **Strong Recommendation, Moderate Quality Evidence**

Continuous labor support:

Continuous support during labor may improve outcomes for women and infants, defined as support from nurse, midwife, doula, childbirth educator, family member, friend or spouse/partner. Outcome include increased spontaneous vaginal birth, shorter duration of labor, and decreased caesarean birth, instrumental vaginal birth, use of any analgesia, use of regional analgesia, low five-minute Apgar score and negative feelings about childbirth experiences. – **Conditional Recommendation, Low Quality Evidence** ^[12, 48]

Failed Induction Definition

If the maternal and fetal status allow, cesarean deliveries for failed induction of labor in the latent phase can be avoided by allowing longer durations of the latent phase (up to 24 hours or longer) and requiring that oxytocin be administered for at least 15 hours *after membrane rupture* before deeming the induction a failure. – **Strong Recommendation, Moderate Quality Evidence** ^[2, 49, 50]



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Table 1. Cervical Ripening Options

Intervention	Dose, timing, and route	Monitoring	Special Considerations	Contraindications
Preferred Methods				
Misoprostol	<u>Option 1: Vaginal:</u> 25 µ every 4 hours. Max 6 doses <u>Option 2: Oral:</u> 50 µ every 4 hours. Max 6 doses <u>Option 3: Oral Stepwise:</u> begin with 50 µ, then continue with 100 µ every 4 hours. Max 6 total doses	Continuous electronic fetal heart rate monitoring (CEFM) and tocometry (TOCO) for at least 3 hours after administration depending on contraction patterns.	- Consider stepwise dosing for patients with a BMI ≥ 30 ^[51] or if patient is not responding to 50 µ every 4 hours. -For Induction termination/fetal demise < 28 wk size uterus refer to “Medical Induction for TOP Protocol” OHSU Clinical Guideline.	Patients with a uterine scar More than 5 painful contractions in 10 min
Foley Catheter plus misoprostol	FC: <u>Saline information below</u> , leave in up to 24h Miso: <u>Option 1, 2 or 3 above for dosing</u>	CEFM and TOCO for at least 3 hours after administration	-Consider step dosing for patients with a BMI ≥ 30 [51] or if patient is not responding to 50 µ every 4 hours -Caution when used with low lying placenta	Uterine scar
Foley Catheter	Fill to 60 mL with saline and leave in for up to 24h	CEFM and TOCO for at least 30 min post placement	Caution when used with low lying placenta	
Foley Catheter plus oxytocin	FC: Fill to 60 mL with saline Oxytocin: Start at 2mU/min and increase by 2 mu/min q 30 min)	CEFM and TOCO	-Preferred option for patients TOLAC -Use caution when patient has prolonged QT syndrome -Caution when used with low lying placenta	
Alternative Methods				
Dinoprostone	<u>Insert:</u> 10 mg	CEFM and TOCO continuously while in place and at least for 15 min after removal	May be less effective in patients with a BMI ≥ 30 ^[52]	Patients with a parity ≥ 5 Uterine scar More than 5 painful contractions in 10 min
Cook® Catheter	Use per manufacturer’s instructions (Appendix A)	CEFM and TOCO for at least 30 min post placement	Caution when used with low lying placenta	Use per manufacturer’s instructions (Appendix A)



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Quality Measures:

- Length of time from induction start to delivery
- Overall vaginal delivery (VD) rate
- VD rate in first 24 hrs. after admission
- Chorioamnionitis rates
- Length of 2nd stage
- Cesarean delivery (CD) rates
- Unexpected newborn complications: Severe

Implementation Plan:

- Outpatient ripening protocol to be developed during implementation.
- Breast stimulation protocol to be developed during implementation.
- Information on induction of labor and the various methods of cervical ripening and induction to be added to OHSU sponsored birth classes
- When choosing pharmacologic agents for cervical ripening, providers should consider their institution's formulary.
- Clinical decision aids and patient education materials to be developed during implementation



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Guideline Preparation

This guideline was prepared by the Office of Clinical Integration (CI) and Evidence-Based Practice (EBP) in collaboration with content experts at OHSU Health System.

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Development Process

This guideline was developed using the process outlined in the CI and EBP Manual (2016). The review summary documents the following steps:

1. Review Preparation
 - PICO questions established
 - Evidence search confirmed with content experts
2. Review of Existing Internal and External Guidelines
 - Literature Review of Relevant Evidence
3. Critically Analyze the Evidence
4. Summarize the Evidence by preparing the guideline, and order sets

Evaluating the Quality of the Evidence

Published clinical guidelines were evaluated for this review using the **University of Pennsylvania’s Trustworthy Guideline Rating Scale**. The summary of these guidelines are included in the evidence summary. The rating scale is based on the Institute of Medicine’s “Standards for Developing Trustworthy Clinical Practice Guidelines” (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains. This scale evaluates a guideline’s transparency, conflict of interest, development group, systematic review, supporting evidence, recommendations, external review and currency and updates. The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guideline does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated).

The **GRADE (Grading of Recommendations, Assessment, Development and Evaluation)** criteria were utilized to evaluate the body of evidence used to make clinical recommendations. The table below defines how the quality of the evidence is rated and how a strong versus conditional recommendation is established. The evidence summary reflects the critical points of evidence.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
WEAK	Desirable effects closely balanced with undesirable effects
Quality	Type of Evidence
High	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies



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Moderate	Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies
Low	Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

Expert Teams will be involved with every review and update.

Disclaimer

Guideline recommendations are made from the best evidence, clinical expertise and consensus, in addition to thoughtful consideration for the patients and families cared for within the Integrated Delivery System. When evidence was lacking or inconclusive, content experts made recommendations based on consensus. Expert consensus is implied when a reference is not otherwise indicated.

The guideline is not intended to impose standards of care preventing selective variation in practice that is necessary to meet the unique needs of individual patients. The physician must consider each patient and family's circumstance to make the ultimate judgment regarding best care.

Criteria for increasing or decreasing level

<p>Reductions Study quality has serious (-1) or very serious (-2) problems Important inconsistency in evidence (-1) Directness is somewhat (-1) or seriously (-2) uncertain Sparse or imprecise data (-1) Reporting bias highly probable (-1)</p> <p>Increases Evidence of association † strong (+1) or very strong (+2) † Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders Very strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity.</p>

Recommendations

Recommendations for the guidelines were directed by the existing evidence, content experts, and consensus. Patient and family preference were included when possible. When evidence is lacking, options in care are provided in the guideline and the order sets that accompany the guideline.

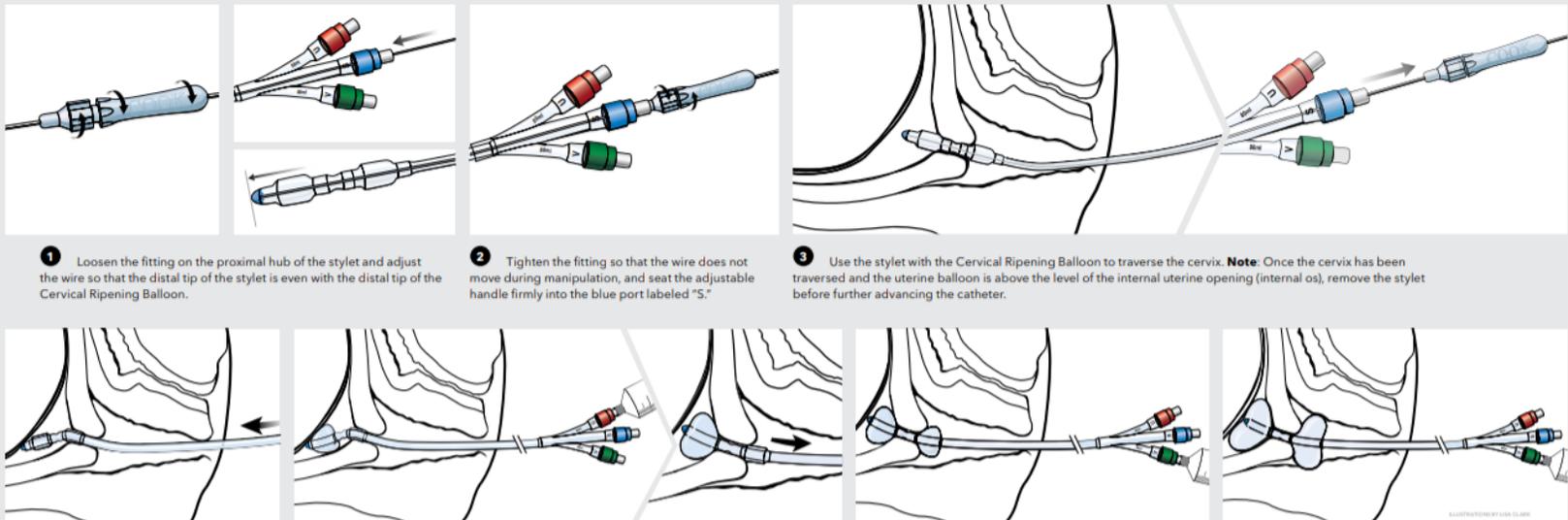
Approval Process

Guidelines are reviewed and approved by the Content Expert Team, Office of CI and EBP, Knowledge Management and Therapeutics Committee, Professional Board, and other appropriate hospital committees as deemed appropriate for the guideline's intended use. Guidelines are reviewed and updated as necessary every 2 to 3 years within the Office of CI and EBP at OHSU. Content

Appendix A. Cook® Catheter Instruction Guide

Cervical Ripening Balloon WITH STYLET

Technique for cervical dilation



- 1** Loosen the fitting on the proximal hub of the stylet and adjust the wire so that the distal tip of the stylet is even with the distal tip of the Cervical Ripening Balloon.
- 2** Tighten the fitting so that the wire does not move during manipulation, and seat the adjustable handle firmly into the blue port labeled "S."
- 3** Use the stylet with the Cervical Ripening Balloon to traverse the cervix. **Note:** Once the cervix has been traversed and the uterine balloon is above the level of the internal uterine opening (internal os), remove the stylet before further advancing the catheter.
- 4** Advance the Cervical Ripening Balloon through the cervix until both balloons have entered the cervical canal.
- 5** Inflate the uterine balloon with 40 mL of saline. Once the uterine balloon is inflated, pull the device back until the balloon abuts the internal cervical os.
- 6** The vaginal balloon is now visible outside the external cervical os and should be inflated with 20 mL of saline.
- 7** Once the balloons are situated on each side of the cervix and the device has been fixed in place, add more fluid to each balloon in turn, until each balloon contains a maximum of 80 mL of fluid. Time the balloon placement so that the balloon is in place no longer than 12 hours before active labor is induced.

Refer to the Instructions for Use for complete information on product usage and a complete list of precautions, warnings, and contraindications.

ILLUSTRATIONS BY USA-GLASS

