Key Words: misoprostol, safety checklist, induction

Abbreviations:

Bishop's Score: Scoring system based on cervical readiness for labour including: dilatation, effacement, position, consistency and station of the fetal presenting part (SOGC, 2013).

BMI: Body Mass Index

CEFM: Continuous electronic fetal monitoring

CPPS: Canadian Perinatal Programs Coalition

MD: Physician - can be family physician, Obstetrician or Maternal Fetal Medicine specialist

NST: Non-stress test as part of fetal wellbeing assessment that is a minimum of 20 minutes and assesses for normal parameters in the absence of stress, eg. labour

PGE2: Prostaglandin E2 or dinoprostone

PO: Oral dose of medication

ROM: rupture of membranes

RM: Registered Midwife

RN: Registered Nurse

SL: sublingual route of administration

SOGC: Society of Obstetrics and Gynecology of Canada

TOLAC: Trial of Labour after Caesarean section

Users/Stakeholders: Obstetricians, MFM, Family Practice, Midwives, Nursing staff in L & D

Definitions:

Tachysystole: Greater than 5 contractions in 10 minutes averaged over 30 minutes (SOGC, 2018)

Intrauterine Resuscitation: A series of interventions described by the SOGC (2018), CPPS (2009) as change in maternal position, initiation of oxygen, decreasing or discontinuing of oxytocin (does not apply in this situation), notification of the physician, fluid bolus of 250 – 500 mL of a mainline infusion, support to the woman and family and documentation/communication.

Purpose: This guideline describes the artificial initiation of labour prior to its spontaneous onset with the goal to achieving a vaginal birth of the fetus and placenta (induction of labour) using Misoprostol. Use of Misoprostol for cervical ripening is described in a different guideline (WIH Nur.0168)

Introduction/Background Context:

Misoprostol is a synthetic prostaglandin E1 analogue which has been shown to:

(1) Trigger cervical ripening through degradation of the collagen in the connective tissue stroma of the cervix

(2) Induce uterine contraction through binding to receptors in the myometrium linked to actin and myosin interaction. (Cochrane 2018)

Compared with oxytocin alone or dinoprostone (PGE2) cervical ripening followed by oxytocin augmentation, misoprostol (oral or vaginal administration) demonstrated lower rates of vaginal birth NOT achieved within 24 hours and lower rates of caesarean section. There is an increased rate of uterine tachysystole without fetal heart rate change with misoprostol compared with oxytocin and/or placebo. Tachysystole with fetal heart rate changes were more common when misoprostol was administered vaginally. There is no increased risk of maternal and/or neonatal morbidity with the use of misoprostol for labor induction (CADTH, 2018). Based on these findings, oral administration of misoprostol for the purpose of labor induction when indicated, is a safe and effective option.

Practice Guideline Statements:

- 1. Use of misoprostol for Induction of labor is suitable for all gestational ages and indications for induction of labor.
- 2. Contraindications for use of misoprostol include patients who:

- Are attempting a trial of labor after caesarean section (TOLAC)
- Have had any full thickness myometrial surgery, eg. myomectomy, open fetal surgery,
- Multiparity greater than 4
- Any contraindication to vaginal birth.
- 3. For patients under the care of midwifery misoprostol use for induction of labour requires an obstetrical consultation and a transfer of care to OB and RN.
- 4. Prior to initiating the induction process, the physician will explain and document the following: the indication for induction, the induction process and confirmation of consent.
- 5. The woman will be admitted as an inpatient for the use of misoprostol for labour induction.
- 6. Once regular uterine activity (more than 2 painful contractions in 10 min) is present, continuous monitoring will be established with a 1:1 nursing assignment.
- 7. Once uterine activity has been established causing cervical change, continue with Misoprostol dosing as ordered; this is NOT an indication to switch to labor augmentation with oxytocin.
- 8. The goal of induction by pharmacological method, ie., misoprostol, is to achieve and maintain contractions every 3-5 minutes of sufficient strength to cause cervical dilatation and/or effacement.
- Induction of labor with misoprostol is suitable regardless of Bishop Score (see Appendix A)

If cervical ripening was performed using:

- Foley catheter: the catheter may be removed before starting Misoprostol. Alternatively the catheter can remain in place if the cervix is not suitably ripe.
- Dinoprostone (PGE2), there should be an 8 hour interval between the dose of dinoprostone and starting misoprostol.
- Cervidil (PGE2), the cervidil should be removed before initiating misoprostol.
- 10. Dosing/Administration of misoprostol will be determined and ordered by a physician. Orders will be entered using CPOE (computerized physician order entry).
 - a. First dose of misoprostol 25 to 50 micrograms (mcg) by mouth

- b. Subsequent dosing of misoprostol will be at 2-6 hour intervals, 25-50 mcg by mouth with consideration for the following:
 - i. If the maternal BMI is greater than 40, dosing of 50 mcg at intervals of every 2 hours may be ordered to achieve effective contractionsThe 25 mcg dose may be increased to 50 mcg at the direction of the physician/midwife in the context of uterine activity and fetal well-being.
 - ii. The dose interval may be increased to every six hours by the direction of the physician/midwife in the context of uterine activity.
- c. The diagnosis of "failure to progress" (dilate and/or descend) will be made by the physician in the context of adequate uterine activity and an absence of change in the vaginal examination. Dosing of misoprostol will stop once this diagnosis has been made
- d. The diagnosis of "failed misoprostol induction of labour may be considered by the physician in the context of 4-5 doses of misoprostol and no/limited uterine activity. A decision to start oxytocin augmentation can be made at this time; typically 4 hours after the last dose of misoprostol.

Protocol for use of Oral Misoprostol for Labour Induction

Prior to the first dose of oral Misoprostol on admission:

- The nurse will complete vital signs and a 20 minute NST
- The nurse will complete the misoprostil safety checklist (see Appendix C) and inform the physician if the checklist indicates <u>NOT</u> to give the misoprostil, i.e. one or more "no" answers.
- The physician will review the NST, Misoprostol Safety Checklist, complete a vaginal examination and enter orders for the misoprostol induction (CPOE)

After the first and every oral administration of Misoprostol:

- 1. The nurse/RM will complete one hour of continuous fetal monitoring (CEFM)(can use wireless monitoring if available)
- 2. After one hour of continuous monitoring:
 - a. The nurse/RM will assess uterine activity by patient history and palpation and auscultate the Fetal Heart Rate hourly and document findings.
 - b. Monitor maternal vital signs (blood pressure, pulse, respiratory rate and temperature) every 4 hours until uterine activity has been established (more frequent thereafter). Once membranes have ruptured, temperature will be measured every 2 hours (Appendix D).
 - c. Encourage the patient to ambulate unless there are maternal or fetal contraindication(s).

20 minutes prior to subsequent dose(s) of Misoprostol:

- 1. The nurse will complete a 20 minute fetal monitoring tracing and complete the Misoprostol Safety Checklist.
 - a. if the tracing is atypical or abnormal, or the safety checklist indicates <u>NOT</u> to give the Misoprosol, (there is a "no" answer), the nurse will contact the physician immediately, hold the dose and await direction/orders
 - b. If the tracing is within normal limits, and the safety checklist indicates to give the Misoprostol (all answers are "yes"), the next dose of misoprostol will be given, as ordered.

Once uterine activity has been achieved at a pattern of palpable contractions every 5 minutes or 2 in 10 minutes (with pain), the nurse/RM will:

- 1. Initiate IV access as per the L & D Admission order set with Lactated Ringer's at 125 mL/hour (may be a saline lock)
- Initiate continuous fetal monitoring (Intrapartum Fetal Health Surveillance policy WIH Nur.042) and continuous tocodynometer contraction monitoring, document every 15 mins or more frequently as required.
- 3. Increase frequency of vital signs (see Appendix D):
 - a. Blood Pressure, respiratory rate, pulse and pain score will be measured every hour
 - b. Temperature will be measured every 4 hours until membranes ruptured (Standards of Nursing Care Guidelines for L & D, WIH Nur. 0158).
 - c. Once membranes are ruptured, maternal temperature is taken every 2 hours
- 4. The MD or RN will perform a vaginal exam <u>prior</u> to each dose of misoprostol to determine labour progress and document findings of the exam.
- 5. If tachysystole is present **without fetal heart rate change**, the nurse will initiate intrauterine resuscitation including notification of the physician, and administer nitroglycerin if fluid bolus not effective (as ordered) (see Appendix C).
- 6. If tachysystole **with fetal heart rate change** (as defined by 3 or more late decelerations, more than 2 complicated variable decelerations, prolonged deceleration, bradycardia, tachycardia more than 15 minutes), the nurse will inform the physician, initiate intrauterine resuscitation (Appendix B) and administer nitroglycerin as ordered (Appendix C).

- 7. If the fetal heart rate meets criteria for atypical and or abnormal regardless of uterine activity, the nurse will perform intrauterine resuscitation (Appendix B) including notification to the physician (WIH Nur. 042).
- 8. An increase in maternal temperature can be associated with the use of misoprostol. Acetaminophen 1000mg should be given, as ordered, every 6 hours if maternal temperature is greater than 38C as indicated in the CPOE. If the temperature is greater than 39C on 2 occasions (30 minutes apart) the nurse will inform the physician; blood cultures and antibiotics may be initiated at the review of the physician.
- 9. The use of artificial rupture of the membranes, fetal scalp electrode and intrauterine pressure catheter will be at the discretion of the physician.

References:

CADTH (2018) Misoprostol for Cervical Ripening and Induction of Labour: A review of clinical effectiveness, Cost-Effectiveness and Guidelines, *Rapid Response Report: Summary with Critical Approaisal, Canadian Agency for Drugs and Technologies in Health.*

Cochrane (2018) Induction of labour in women with normal pregnancies at or beyond term, retrieved from <u>https://www.cochrane.org/CD004945/PREG induction-labour-women-normal-pregnancies-or-beyond-term</u>

Canadian Perinatal Programs Coalition (2009). *Fundamentals of fetal health surveillance: A self-learning manual*. Vancouver BC: Perinatal Services BC

SOGC 0158(2013) Induction of Labour: Clinical Practice Guideline, JOGC, 35 (9).

SOGC Intrapartum Fetal Health Surveillance (2007, reaffirmed 2018). JOGC 40 (4).

Appendix A:

Bishop's Score (Misoprostol may be given regardless of Bishop score: See Protocol #1)

Criteria	Score 0	Score 1	Score 2
Cervical dilatation	Closed	1-2	3-4
Cervical effacement:	0 – 30%	40 – 50%	60 – 70%
(%) or			
Thickness/length	Greater than 3cm	1-3 cm	Less than 1 cm
Cervical Consistency	Firm	Medium	Soft
Cervical position	Posterior	Central or midposition	Anterior
		•	
Station (relation to spines)	Spines -3	Spines -2	Spines -1 or lower

Appendix B:

Intrauterine Resuscitation Measures (CPPC, 2009, SOGC 2007 & 2018):

Goal is to improve uterine blood flow, improve umbilical blood flow, improve maternal/fetal oxygenation and decrease uterine activity

- 1. Reposition to side lying and continue to reposition in different positions if fetal heart rate does not improve
- 2. Continue continuous electronic fetal monitoring
- 3. Administer a bolus of IV fluid: 250 500 mL
- 4. Consider oxygen with non-rebreather mask if maternal oxygen desaturation in conjunction with fetal heart rate decelerations
- 5. Notify physician
- 6. Reduce maternal anxiety and coach with breathing or pushing activities
- 7. Remain with patient and call for help as needed
- 8. Assess and document maternal and fetal responses to interventions
- 9. Administer tocolytic agent, if excessive uterine contractions, as ordered i.e. nitroglycerine sublingual (SL) 2 puffs (CPOE for oxytocin and misoprostol induction/augmentation)

Appendix C

Misoprostol Safety Checklist: to be answered with "yes" to all PRIOR to administering the next dose. If "no" to any, contact physician prior to giving next dose

- ✓ Is the 20 minute fetal heart rate strip normal prior to the dose? Yes or No
- ✓ Is the patient experiencing less than or equal to 5 contractions in 10 minutes averaged over 30 minutes? Yes or No
- ✓ Is there an ABSENCE of continuous pain? Yes or No
- ✓ Are the maternal vital signs within normal range? Yes or No

Parameters	Fetal heart rate normal	Fetal heart rate atypical/abnormal
Normal uterine activity	 Continue with dosing regimen Monitoring (Appendix D) 	 Initiate intrauterine resuscitation (Appendix B)
Tachysystole	 Initiate intrauterine resuscitation (Appendix B) 	 Initiate intrauterine resuscitation (Appendix B) Prepare for Code 77 or emergent C/S if not resolving

Appendix D

Monitoring Guidelines

On admission:

Maternal Vital Signs: BP, P, RR and T	Q4h vital signs, Vaginal Exam by MD/RM prior to first dose , once ROM, temperature q2h
Fetal Well Being	20 minute NST before giving initial dose of misoprostol
	Continuous fetal heart rate monitoring for one hour after initial and every subsequent dose of misoprostol Thereafter, complete hourly Intermittent Auscultation of fetal heart rate if normal
Uterine Activity/Contractions	Palpate with monitoring (WIH.Nur.042)
	Ask patient about frequency, duration and strength

If patient is not contracting or has 1 contraction in 10 minutes, she can ambulate:

Maternal Vital Signs: BP, P, RR and T	Q4h unless ROM, then T q2h
Fetal Well Being	Intermittent Auscultation q1h
Uterine Activity/Contractions	Assess hourly by patient information/history and palpation

If patient has 2 or more painful contractions in 10 minutes, initiate:

Maternal Vital Signs: BP, P and RR	Q1h, Temperature q2h(when membranes ruptured)
Fetal Well being	Continuous fetal monitoring with assessment/documentation q15 min as per policy (WIH.Nur.042)
Uterine Activity	Q15 minutes as per policy (WIH.Nur.042)