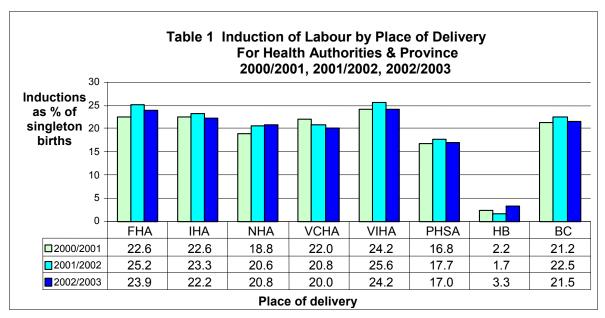
Obstetric Guideline 1

CERVICAL RIPENING & INDUCTION OF LABOUR

Induction of labour is the initiation of labour by medical or surgical means prior to the spontaneous onset of labour, for the purpose of accomplishing delivery of the fetal/placental unit. As suggested in Table 1 below, the rate of induction of labour in BC varies by location and appears to be increasing. This data, although it is only for singleton pregancies, is consistent with CIHI data that indicates the rate of induction in Canada has steadily increased from 1991 (12.9%) to 2000 (27.2%). The purpose of this guideline is to provide the most current evidenced-based information and professional recommendations on cervical ripening and induction of labour.



Source: BC Perinatal Database Registry Annual Report 2004

Health Authority Legend:

FHA Fraser VIHA Vancouver Island

IHA Interior PHSA Provincial Health Services Authority

NHA Northern HB Home Births

VCHA Vancouver Coastal BC British Columbia Total

1. INDICATIONS FOR INDUCTION OF LABOUR

Percentage of total inductions in BC April 1, 2002 – March 31, 2003

		April 1, 2002 - March
•	Post-term, > 41 completed weeks (287 days) ³	35 %
•	Maternal disease, e.g. diabetes, hypertension	25 %
•	Prelabour rupture of membranes at term ^{4,5,6,7}	19 %
•	Other/Unknown	12 %
•	Evidence of fetal compromise	7 %
•	Fetal demise	1 %
•	Logistics, e.g. geographic, past rapid labour at term	1 %

March 2005 Page 1 of 10

2. RISKS

Labour induction is an active intervention with potential risks for the mother and fetus. Therefore, elective induction in the absence of maternal or fetal indications should not be undertaken. The risks and benefits of induction in the given situation should be reviewed with the pregnant woman and her partner.³ Risks include:

- Increased risk of caesarean delivery
- Fetal compromise/non-reassuring fetal heart rate tracing
- Hyperstimulation of the uterus
- Uterine rupture
- Cord prolapse with ARM
- Inadvertent delivery of preterm infant (unlikely with confirmed ultrasound dating)
- Maternal water intoxication (rare)
- Medical-Legal: oxytocin is commonly considered by the courts as a cofactor associated with fetal and/or neonatal compromise

3. CONTRAINDICATIONS

3.1 ABSOLUTE³

- Previous classical, inverted T, or unknown uterine incision
- Previous hysterotomy or myomectomy of the uterine corpus involving entry of the uterine cavity or extensive myometrial dissection
- Previous uterine rupture
- Presence of placenta previa, transverse lie or any other contra-indications to labour
- Active genital herpes

3.2 RELATIVE

- Grand multiparity (>5)
- Malpresentations
- Over-distention of the uterus, e.g. polyhydramnios or multiple pregnancy
- Invasive carcinoma of the cervix
- Use caution with combined fetal macrosomia (EFW >4,000 g) and previous caesarean

NOTE: Vaginal Birth after previous Caesarean section⁶

- Medical induction of labour with oxytocin may be associated with an increased risk of uterine rupture and should be used carefully after appropriate counseling.
- Medical induction of labour with **prostaglandin** E₂ (dinoprostone) is associated with an increased risk of uterine rupture and **should not be used except in rare circumstances after appropriate counseling.**
- Prostaglandin E₁(misoprostol) is associated with a high risk of uterine rupture and should not be used.
- A Foley catheter may be used safely to ripen the cervix in a woman planning a VBAC.

March 2005 Page 2 of 10

4. INDUCTION PREREQUISITES

- Each facility, in conjunction with its perinatal committee, should implement appropriate induction policies, protocols, and audit processes, including protocols for oxytocin use.
- For medical induction of labour the following must be available:
 - A qualified registered nurse, familiar with the processes of induction and the agents used, able to detect both maternal and fetal complications, able to initiate and interpret electronic fetal surveillance and uterine monitoring, and able to intervene appropriately.
 - Electronic fetal monitor. (Continuous intrapartum electronic fetal monitoring is recommended by the SOGC when oxytocin is being used for induction of labour, however the recommendation is supported by consensus opinion rather than empirical evidence).
- It should be recognized that induction of labour in the nullipara is associated with twice the chance of caesarean delivery compared with spontaneous labour. Although there is no evidence-based information indicating that operating room facilities be a requisite for induction of labour, it is incumbent on rural facilities without caesarean delivery capability to determine their local practice and procedures regarding induction of labour and indications for patient transfer. Before initiating induction, patient transfer systems must be in place.³
- There should be discussion and disclosure of risk factors (including anticipated obstetrical risk, advantages and limitations of local maternity care services, and transport risk) with the patient prior to the induction, and informed consent should be obtained.
- Before induction starts, the indication for, and method of induction must be clearly documented on the patient's chart.
- The primary care provider should determine accurate gestational age, the Bishop Score (ripeness) of the cervix (See 6. below), and assess the potential for cephalo-pelvic disproportion via abdominal and pelvic examination.
- Electronic fetal surveillance and uterine monitoring should be performed for at least 20 minutes prior to the administration of any ripening/induction agents.

5. GENERAL MANAGEMENT OF INDUCTION OF LABOUR

- Prostaglandins and oxytocin must not be used concurrently.
- During the induction, the primary care provider must be immediately available by telephone/pager and available to come promptly to the labour and delivery area.
- Oral intake should be determined by the assessment of risk for uterine hyperstimulation and/or fetal compromise.

6. CERVICAL ASSESSMENT

Reports on labour induction have shown that the state of the cervix is the most important predictor of success.³ The 'ripeness' or 'favorability' of the cervix should be determined *prior to induction*. Bishop described a scoring system based on cervical examination that predicted delivery in multiparous women.⁹ A score of ≥ 6 is considered favorable and is likely to result in successful labour induction and a score of < 6 indicates that cervical ripening is warranted. A modified version of the Bishop Score is presented on the next page in Table 2.

March 2005 Page 3 of 10

Table 2 Modified Bishop Score

Criteria	Points Assigned		
	0	1	2
Dilation	0	1-2 cm	3-4 cm
Effacement	0-30 %	40-50 %	60-70 %
Cervical Length	>3 cm	1 – 3 cm	<1 cm
Consistency	Firm	Medium	Soft
Position	Posterior	Mid	Anterior
Station	-3	-2	-1 to <u>></u> 0

7.0 PREPARATION OF THE UNFAVOURABLE CERVIX FOR INDUCTION

If the cervix is unfavorable or there is a Bishop Score < 6, (i.e. closed, posterior, thick, firm), then ripening of the cervix should be considered. Oxytocin should not be used to ripen the cervix as a meta-analysis of five trials concludes that it is not effective. Note that the induction prerequisites should be met prior to administering any of the following ripening agents.

7.1 INTRACERVICAL PGE₂ GEL (PREPIDIL ®) AND INTRAVAGINAL PGE₂ GEL (PROSTIN ®) (Ripening and induction agents)

A. Cautions

- Over-distention of the uterus (polyhydramnios or multiple pregnancy)
- Fetal malpresentation
- History of asthma, glaucoma or epilepsy
- Grandmultiparity
- Clinical evidence of fetal compromise
- Unexplained vaginal bleeding
- Rupture of membranes vaginal prostaglandin can be used with ROM.⁷ Caution is recommended with intracervical prostaglandins.

B. Dosage and Insertion: Intracervical PGE2 gel (Prepidil ®)

- The recommended dosage is 0.5 mg
- Each prefilled syringe contains 0.5 mg dinoprostone¹¹
- The gel is inserted under direct vision using a vaginal speculum. Care should be taken that the gel is placed in the cervical canal and not in the lower uterine segment (see package insert)
- Caution: Do not use Intravaginal PGE2 gel (Prostin ®) intracervically

C. Dosage and Insertion: Intravaginal PGE2 gel (Prostin ®)

- The manufacturers' recommended initial dose is 1.0 mg into the posterior fornix
- A dose of 1.0 to 2.0 mg may be repeated at least 6 hours later if labour is not established
- Prefilled syringes contain 1 or 2 mg of dinoprostone¹¹
- In some obstetrical units registered nurses insert vaginal prostaglandin into the patients for induction. This may be done as a Transfer of Function and requires written hospital policies and procedures.

March 2005 Page 4 of 10

D. Following PGE2 Gel Insertion

- Patient maintains bedrest for 1 hour
- Electronic fetal heart surveillance and uterine monitoring for a minimum of 1 hour. This may need to be extended in the presence of a non-reassuring fetal heart rate tracing.
- It is recommended that **PGE2 gel insertion should be done no more frequently than every 6 hours** for a maximum of 3 insertions, then reassess if not in labour
- Oxytocin may be administered 6 hours following the last insertion of PGE2³ gel
- If **hyperstimulation** leads to a non-reassuring fetal heart rate pattern:
 - a) attempt to remove any remaining PGE2 gel, and
 - b) administer a tocolytic agent, e.g. Nitroglycerin 50-250 mcg IV or one or two metered doses 400-800 mcg sublingual spray^{3,12}

E. Outpatient Use of Prostaglandins

• There is little data on the outpatient use of prostaglandins. However, current practice in Canada is to allow selected mothers to go home after 1 hour of assessment/observation immediately following insertion of the gel.

7.2 CERVIDIL ® VAGINAL INSERT

There is published Canadian data supporting the outpatient use of Cervidil, re: safety, efficacy and hospital utilization. ¹⁸

A. Advantages

- String present for quick removal if there is uterine hyperstimulation
- Oxytocin may be used after 30 minutes of Cervidil removal³

B. Contraindications & Cautions (see p. 4)

- The manufacturer of Cervidil indicates that it should not be used with ruptured membranes^{3,11}
- Previous uterine surgery there is insufficient evidence to determine if this agent can be used safely in women with uterine scars

C. Dosage and Insertion

- Inserted digitally and placed transversely in the posterior fornix of the vagina
- Cervidil contains 10 mg prostaglandin E2 which is slowly released at approximately 0.3 mg/hour up to 24 hours without loss of potency

D. Following Cervidil Insertion

• The appropriate form of fetal surveillance to be used in the presence of a Cervidil insert is not clear at this time. Accumulated experience suggests that the incidence of hypertonus is no greater than that associated with intracervical or intravaginal prostaglandin gel. Hypertonus is most likely to occur if the device is left in place after regular contractions have become established. An ACOG committee opinion recommends continuous electronic fetal surveillance for as long as the device is in place, however current practice in many centres follows monitoring guidelines similar to those used after application of intracervical or intravaginal gel.

March 2005 Page 5 of 10

Cervical Ripening & Induction of Labour

- Cervidil should be removed:
 - a) if labour is established
 - b) 12 hours following insertion; some may leave it in for 24 hours ¹³
 - c) if uterine hyperstimulation occurs
- If hyperstimulation leads to non-reassuring fetal heart findings:
 - a) remove Cervidil from vagina
 - b) administer a tocolytic agent, e.g. Nitroglycerin 50-250mcg IV or one or two metered doses 400-800 mcg sublingual spray^{3,12}

7.3 FOLEY CATHETER³

The cervix may be ripened the evening prior to induction by inserting a #16/18 Foley catheter through the cervical canal above the internal os (some physicians have had better success with the larger gauge Foley). After insertion, the bulb is inflated with 30-60 cc of water and, as an option taped to the inside of the leg (providing a small degree of traction on the catheter) and left in place until it spontaneously falls out or up to 24 hours.

NB: the Foley catheter should be chosen with the correct caliber bulb to allow such inflation (not a 5-10 cc bulb). Compared with prostaglandin gel, the foley catheter is considerably less expensive, and results in no difference in operative delivery rates or maternal or neonatal morbidity.³

A. Potential Risks

- Infection
- Bleeding
- Rupture of membranes

B. Procedure

- Visualize cervix with a speculum
- Cleanse cervix
- Advance Foley catheter 2-3 cm beyond the internal os
- Inflate balloon with sterile water. Some practitioners tape the catheter to the inner thigh under tension as they believe that this may increase the effectiveness.

C. Contraindications

- Low lying placenta
- Rupture of membranes (relative contraindication)
- Cervicitis (relative contraindication)

7.4 LAMINARIA

The information for foley catheters applies to Laminaria except that Laminaria has a higher rate of infections.

March 2005 Page 6 of 10

8. LABOUR INDUCTION WITH FAVOURABLE CERVIX (BISHOP \geq 6)

8.1 MISOPROSTOL (Cytotec ®)

Research has shown that Misoprostol could be a safe, cheap, and effective mode of inducing labour compared to oxytocin and other prostaglandins. There has been more research published on the use of misoprostol for induction than on the use of most other inducing agents. The ACOG supports the use of misoprostol for the induction of labor in well-defined protocols. However, the optimal dose, route of administration and dose interval have yet to be fine-tuned by further research and pilot projects. The current evidence suggests an increased risk of hyperstimulation but no worse maternal, fetal, or neonatal outcomes. Misoprostol is currently not approved by the Health Protection Branch of Canada for the indication of cervical ripening or induction of labour at term with a viable fetus. The SOGC recommends its use only within a structured research project³ and the BCRCP supports this SOGC recommendation.

8.2 SWEEPING OF THE MEMBRANES

The research evidence for sweeping the membranes suggest that it can result in the onset of labour and may decrease the frequency of post-term pregnancy. Sweeping the membranes is thought to increase local prostaglandin F_2a production and release and is currently performed by many physicians.

8.3 AMNIOTOMY / ARTIFICIAL RUPTURE OF MEMBRANES (ARM)

A. Risks

- Cord prolapse if the presenting part is not well applied to the cervix
- Infection
- With polyhydramnios, increased risk of both cord prolapse and possible abruption

B. Criteria

- Cervix is favorable Bishop Score \geq 6 (dilated \geq 2.0 cm and \leq 1.0 cm long)
- Presenting part is well applied to the cervix

C. Combined ARM and Oxytocin infusion

A meta-analysis of ARM and oxytocin demonstrated that the combination is more effective than amniotomy alone as measured by time to delivery, and likelihood of operative delivery.³

8.4 INTRAVENOUS OXYTOCIN

The goal of oxytocin administration is to effect uterine activity that is sufficient to produce cervical change and fetal descent while avoiding uterine hyperstimulation. **Oxytocin is always most efficient once cervical ripening has occurred**, thus allowing a combined oxytocin/ARM approach to induction.

A. Prior to Initiating Oxytocin Infusion

- Ensure availability of 1:1 nursing care
- Ensure a minimum six hour interval since the administration of PGE2 gel

March 2005 Page 7 of 10

- Initiate an IV of balanced solution (mainline) using an 18-gauge intracatheter at a site that allows mobility of the patient's arm
- Connect the oxytocin solution to a constant infusion pump and using a secondary site, connect to the main infusion
- Ensure availability of a conversion table giving the equivalent of oxytocin in mU/minute and mls/hour. The conversion table should preferably be attached to the infusion pump.
- Obtain a 20 minute electronic fetal heart strip to obtain baseline data prior to initiating the oxytocin infusion

B. Dosage and Concentration: Low Dose Oxytocin

- Institutional protocols vary and at the moment there is little existing evidence to support one protocol over another. It should be remembered that oxytocin is a hormone (not a drug) and does not react with the typical dose-response curve. Its action depends upon the presence of oxytocin receptors and stimulation of cyclic aMP.
- Although ACOG suggested that low dose and high dose protocols can be used ¹⁶, both the SOGC and BCRCP support the use of low dose oxytocin³. The BCRCP supports the use of low-dose oxytocin protocols for the initial management of oxytocin induction. The minimum dose required to achieve labour, with dose increment time intervals of no less than 30 minutes apart should be used. However, if high-dose oxytocin is being considered in specific clinical situations, e.g. where low-dose oxytocin is ineffective, an obstetrical consultation should occur. Intravenous oxytocin has a half-life of five to 12 minutes, a time to steady plasma concentration of 40 minutes, and a steady state uterine response of 30 minutes or longer. Dawood ¹⁷ reported that approximately 90% of women achieve adequate uterine activity with incremental doses of oxytocin, and rarely more than 6 mU/minute is required. A common preparation is to mix 10 IU of oxytocin with 1000 ml balanced solution to give an infusion rate of 6 mls/hour = 1 mU/minute (IVAC).

Note: 1 International Unit equals 1,000 milliunits (mU)

- Start oxytocin infusion at 0.5 or 1.0 mU/minute and increase by 1.0 or 2.0 mU/minute every 30-60 minutes^{3,11} until ideal contraction pattern is achieved (i.e. 3-4 contractions in 10 minutes, duration <90 seconds, 30 seconds relaxation between contractions) **OR** until a maximum dose of 20 mU/minute is attained. If higher doses are required, then the use of oxytocin should be reassessed, and a physician's order is needed. When intrauterine death is the indication for induction, higher doses may be needed.
- Note that these dosage recommendations are applicable for augmentation of labour as well as induction of labour.

C. Management During Oxytocin Infusion

- Assessment and documentation of uterine contractions and fetal heart data should occur with every oxytocin increase. There is no evidence to suggest oxytocin affects maternal BP or P.
- Once an ideal contraction pattern is achieved:
 - a) titrate the oxytocin dose to maintain the contraction pattern
 - b) assess maternal vital signs as frequently as maternal condition dictates
- Continuous electronic fetal surveillance and uterine monitoring throughout the induction is recommended by the SOGC. *However*, when the oxytocin dose and maternal/fetal

March 2005 Page 8 of 10

conditions are stable, and there is NO evidence of fetal compromise, intermittent electronic monitoring may be commenced to allow for periods of ambulation, bath, or position change.

- If uterine hyperstimulation (6 or more contractions in 2 consecutive 10 minute windows, or contractions lasting greater then 120 seconds) occurs with fetal heart decelerations/abnormalities:
 - a) DISCONTINUE OXYTOCIN INFUSION
 - b) reposition to left or right side
 - c) give O2 per mask @ 10 L
 - d) increase mainline IV (balanced solution) if not contraindicated by maternal condition
 - e) notify responsible physician
 - f) prepare for possible caesarean delivery if fetal heart does not return to normal
- If intrauterine resuscitation is successful, oxytocin may be restarted at ½ the last dose.
- Should excessive uterine contractions occur without fetal compromise then decrease the oxytocin infusion rate.
- The continuation of the oxytocin infusion with the birth of the infant remains optional. Following delivery, oxytocin 10 IU intramuscularly and/or infusion of 20 IU in 1,000 mls R/L or N/S @ 100-125 mls/hour should be continued for at least one hour to prevent uterine atony.

9. OUTCOME INDICATORS FOR INDUCTION OF LABOUR

A non-inclusive list of maternal and newborn outcome indicators for induction of labour is listed below. Data on these indicators may be accessed via the BC Perinatal Database Registry.

- Induction rates
- Indications for induction
- Non reassuring fetal surveillance
- Tetanic contractions
- Cord prolapse
- Uterine rupture
- Length of first stage and second stage of labour
- Operative delivery rate by caesarean delivery, forceps, and vacuum
- Gestational age at delivery
- 1 and 5 minute Appars
- Meconium aspiration
- Birth injury
- Perinatal death

REFERENCES

1. BCRCP, (2004). British Columbia Perinatal Database Registry Annual Report 2004. BCRCP, Vancouver.

http://www.rcp.gov.bc.ca/

2. Health Canada. (2003). Canadian Perinatal Health Report, 2003. Minister of Public Works and Government Services Canada. Ottawa. http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/cphr-rspc03/

March 2005 Page 9 of 10

- 3. Society of Obstetricians and Gynaecologists of Canada (2001). Induction of Labour: Clinical Practice Guideline for Obstetrics. No.107, August, 1-12. http://www.sogc.org/SOGCnet/sogc_docs/common/guide/pdfs/ps107.pdf
- 4. Tan BP, & Hannah ME. (2001). Prostaglandins versus oxytocin for prelabour rupture of membranes at term. Cochrane Database of Systematic Reviews. Issue 2.
- 5. Tan BP, & Hannah ME. (2001). Oxytocin for prelabour rupture of membranes at or near term. Cochrane Database of Systematic Reviews. Issue 2.
- 6. SOGC. (2004). Guidelines for Vaginal Birth after Previous Caesarean Birth. Clinical Practice Guideline No: 147. July. SOGC. http://www.sogc.org/SOGCnet/sogc_docs/common/guide/pdfs/ps147_e.pdf
- 7. Hannah M., Ohlsson A., Farine D., Hewson S., Hodnett E., Myhr T., Wang E., Weston J., & Willan A., (1996). Induction of Labor Compared with Expectant Management for Prelabour Rupture of Membranes at Term. The New England Journal of Medicine, 334(16), 1005-1010.
- 8. SOGC. (2002). Fetal Health Surveillance in Labour: Clinical Practice Guideline No: 112, March. SOGC. http://www.sogc.org/sogcnet/sogc_docs/common/guide/pdfs/ps112.pdf
- 9. Bishop E. (1962). Pelvic scoring for elective induction. <u>Obstetrics and Gynecology, (24)</u>: 266-268.
- 10. ACOG Committee Opinion. (1998). Monitoring During Induction of Labor with Dinoprostone. Washington DC: ACOG. No. 209, October, p.1.
- 11. <u>Canadian Pharmaceutical Association</u>. (2004). CPS Compendium of Pharmaceuticals and Specialties.
- 12. Straszak-Suri, M., & Nimrod, C. (1992). Medical Management of Uterine Hyperstimulation. Journal SOGC(14). P. 59-65.
- 13. Wing D., Ortiz-Omphroy G., & Paul, R. (1997). A comparison of intermittent vaginal administration of misoprostol with continuous dinoprostone for cervical ripening and labor induction. <u>American Journal of Obstetrics and Gynecology (177)</u> NO.3 September, 612-618.
- 14. ACOG. (1999). Induction of labour with misoprostol. ACOG Committee Opinion 228.
- 15. Boulvain M., Irior O. (1997). Stripping/sweeping of the membranes to induce labour or to prevent post-term pregnancy. In: Neilson JP, Crowther CA, Hodnett ED, Hofmeyr GJ (eds.) Pregnancy and Childbirth Module of The Cochrane Database of Systematic Reviews, [updated 02 December 1997]. Available in The Cochrane Library [database on disk and CDROM]. The Cochrane Collaboration; Issue 1. Oxford: Update Software; 1998. Updated quarterly.
- 16. ACOG. (1999). Induction of Labor. Technical Bulletin 10.
- 17. Dawood M. (1995). Pharmacologic stimulation of uterine contractions. <u>Seminars in Perinatology</u>, 19(1), 73-83.
- 18. Biem SR, Turnell RW, Olatunbosun O, Tauh M, & Biem HJ. (2003). A randomized controlled trial of outpatient versus inpatient labour induction with vaginal controlled-release prostaglandin-E2: effectiveness and satisfaction.

March 2005 Page 10 of 10