

## What is known about the maternal and newborn risks of elective induction of women at term?

### Evidence Summary No. 10

Developed as part of the OHRI-Champlain LHIN  
Knowledge to Action research program  
For BORN Ontario

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#### Disclaimer

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## What is known about the maternal and newborn risks of elective induction of women at term?

This report summarizes the evidence around the risks and benefits to mothers and newborns subsequent to induction at term when there is no medical indication to do so. Its intention is to support efforts that seek to reduce rates of unnecessary induction among women who give birth in Ontario.

### Key Messages

- There is a lack of quality evidence on the benefits and harms of elective induction among women <41 weeks gestation. Two systematic reviews assessing elective induction at (or post) term, were limited in drawing conclusions as most studies evaluated women ≥41 weeks gestation.
- Modeling of the economic and health consequences of elective induction between 39-41 weeks suggest induction to be associated with higher costs and rates of cesarean delivery. Expenditures are particularly pronounced among nulliparous women of younger gestational age with unfavorable cervixes.
- Two recently published studies have successfully implemented quality improvement initiatives that have led to reductions in rates of induction over time. Despite the inherent limitations in their observational designs, these studies present promising findings for similar hospital-based initiatives.

### Who is this summary for?

This summary was undertaken for BORN Ontario and is intended for use by local health systems stakeholders, policy-makers and decision-makers within Ontario

### Information about this evidence summary

This report covers a broad collection of literature and evidence sources **with a search emphasis on systematic reviews.**

As such, evidence summarized from systematic reviews is highlighted in blue boxes, like this one. Systematic reviews are generally favoured over other study designs, because they incorporate evidence from multiple primary studies, instead of reporting evidence from just one study.

### ✓ This summary includes:

- **Key findings** from a broad collection of recent literature and evidence sources.

### ✗ This summary does not include:

- **Recommendations;**
- **Additional information** not presented in the literature;
- **Detailed descriptions of the interventions** presented in the studies.

Many sections conclude with a **“Bottom line”** subsection that provides a statement summarizing the studies or aims to provide some context. These statements are not meant to address all of the evidence in existence on the subject, rather, only that which is featured in this document.

All papers summarized in this document are available by request to [kkonnyu@ohri.ca](mailto:kkonnyu@ohri.ca).

## I. Background

The Society of Obstetricians and Gynecologists of Canada (SOGC) defines induction of labour as “the artificial initiation of labour before its spontaneous onset for the purpose of delivery of the fetoplacental unit” (Crane et al. 2001). At term (37+0/7 to 41+0/7 weeks), induction may be chosen over expectant management due to a variety of maternal and/or fetal medical indications (e.g., maternal diabetes, fetal intrauterine growth restriction); conditions for which the benefits of the onset of labour are thought to outweigh the potential risks posed by induction (Caughey 2009). Induction in the absence of a medical indication is termed elective and the benefits, harms and costs of elective induction continue to be debated in the literature (Caughey 2009).

Despite the uncertainty surrounding elective induction, its use continues to grow and appears to be increasing at a rate faster than inductions as a whole (Caughey 2009). Thus, the objective of this review was to conduct a rapid summary of the evidence related to the benefits and harms of elective induction of labour in women at term gestational age. Its intention is to support efforts that seek to reduce levels of elective induction in Ontario.

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#### Levels of evidence:

Each piece of evidence presented in this summary is assigned a level (adapted from Cochrane MSK group, 2010):

- **Platinum:** Systematic reviews and meta-analyses
- **Gold:** Randomized controlled trials
- **Silver:** Observational studies (non-randomized trials, case-control, time-series, cohort studies, case series)
- **Bronze:** Expert committee guidelines, reports or opinions and/or clinical experience of respected authorities (e.g. commentary, editorial)
- Level of evidence cannot be determined

## II. Evidence

### a. Risks of elective induction vs. expectant management

**7/11**  A 2009 Cochrane systematic review assessed the benefits and harms of labour induction at term or post-term compared to expectant management or later induction (Gülmezoglu et al. 2006). Although the majority of findings pertained to women  $\geq 41$  weeks gestation, data from 3 early RCTs assessing women at 37-40 completed weeks gestation found elective induction to be associated with a lower risk for cesarean delivery or assisted vaginal delivery than expectant management (see references of 3 RCTs in 'References of interest' below). However, the 3 RCTs were published between 1975 and 1989 and thus may not accurately present contemporary clinical practice. Given the risks of respiratory distress syndrome and relative adverse neonatal effects related to prematurity, the reviewers conclude that "a policy of routine labour induction at 37 to 40 completed weeks for women with uncomplicated pregnancies would not be justifiable".

**6/11**  A 2009 US systematic review and meta-analysis by Caughey and colleagues assessed the impact of elective induction during the term period of pregnancy ( $\geq 37$  weeks to  $< 42$  wks) with respect to maternal and neonate outcomes (Caughey et al. 2009a). Because the review included both RCTs and observational studies, control groups of both expectant management and spontaneous labour were assessed. The review was commissioned by the Agency for Healthcare Research and Quality, and thus has an associated Evidence Report/Technology Assessment (Caughey et al. 2009b); the primary publication however (Caughey et al. 2009a) was used for the purpose of this summary.

The review included 36 studies: 11 RCTs (see Table 1) and 25 observational studies; the largest RCT was Canadian ( n=3,407). While the control group in most of the RCTs consisted of women who were expectantly managed, women who had undergone a spontaneous labour were

used as controls in all but 1 observational study. Based on reviewers quality assessments of RCTs, only 2 were rated as being good quality, with the remaining 7 being rated as fair (n=4) or poor (n=3) quality. The findings for each maternal and neonatal outcome synthesized are summarized below.

#### MATERNAL OUTCOMES

##### *Cesarean delivery*

Based on the findings of 9 RCTs comparing induction (n=3,017) vs. expectant management (n=3,112), expectant management was associated with a 22% increase in rates of cesarean section (OR 1.22, 95%CI 1.07-1.39). However, the majority of studies included women  $\geq 41$  completed weeks of gestation; the findings of the 3 trials (of poor quality) including women  $< 41$  weeks were inconclusive. In contrast to this, the findings from observational studies suggested a 35% lower risk for cesarean delivery among women having a spontaneous labour (5% vs. 7%, respectively) (OR 0.65 95% CI 0.52 to 0.81). Based on the collective evidence, the reviewers suggest that while elective induction may lead to higher rates of cesarean delivery at 41+0/7 weeks of gestation, there is insufficient evidence to know the impact of elective induction  $< 41+0/7$  weeks.

There were only 3 RCTs that examined the relationship between elective induction, parity, and cesarean delivery and thus the reviewers could not make any conclusions with respect to the risks posed to nulliparous and multiparous women specifically.

##### *Operative vaginal delivery (forceps or vacuum-assisted)*

Based on the findings of 6 RCTs comparing elective induction (n=3,017) vs. expectant management (n=3,112) there was no difference in rates of operative vaginal delivery; this finding was reiterated in the observational data comparing elective induction vs. spontaneous labour. Thus with respect operative vaginal deliveries, the reviewers rated the strength of the evidence as moderate.

### *Infections*

Although 6 studies (3 RCTs, 3 observational studies) alluded to the presence or absence of maternal infection, no study reported actual quantitative data to adequately assess this outcome. Qualitatively, four studies (2 RCTs and 2 observational studies) suggested that elective induction was not associated with an increased risk for chorioamnionitis, and 2 observational studies suggested that elective induction was not associated with an increased risk for endomyometritis. Although the findings appear consistent, the reviewers caution that given the lack of transparency in reporting infection rates, the strength of the evidence is low.

### *Blood loss and hemorrhage*

Based on the findings of 5 studies (1 RCT and 4 observational studies) there was no apparent link between elective induction and postpartum hemorrhage. However, as these studies were not powered to assess this outcome, the reviewers deemed the evidence with respect to maternal hemorrhage to be insufficient.

### *Other maternal outcomes*

Two studies (1 RCT and 1 observational study) reported data on and 3<sup>rd</sup> or 4<sup>th</sup> degree lacerations and found no associations. No studies reported outcomes of hysterectomy, length of labour, evidence of injury to internal organs, or wound complications.

## **NEONATAL OUTCOMES**

### *Meconium-stained amniotic fluid*

Based on the findings of 6 RCTs comparing elective induction (2,782) vs. expectant management (2,701), there was a significant increase in the rate of meconium-stained amniotic fluid (a sign of postmaturity and intrauterine fetal stress) among patients who expectantly managed (29% vs. 19%, OR, 2.04 [CI, 1.34 to 3.09]). However, reviewers caution that these studies were heterogeneous and ranged in quality from poor to good. Thus, the reviewers determined the strength of this evidence to be moderate.

### *Meconium aspiration syndrome*

Based on findings of 5 RCTs there was no difference on the risk of meconium aspiration syndrome among neonates delivered by elective induction vs. expectant management. However,

because 2 of the 5 studies reported non-significant increases in the rates of meconium aspiration among EM patients, the authors determined the strength of the evidence to be low and argue for further evaluation.

### *Apgar score less than 7 at 5 minutes*

Based on the findings of 13 studies (4 RCTs and 9 observational studies) there was no difference between elective induction and expectant management with respect to the rate of 5-minute Apgar score less than 7. However, there was wide variability in study results and quality, which combined with studies' lack of power to assess this relatively rare outcome, led the reviewers to determine the strength of this evidence to be low.

### *Admissions to the neonatal intensive care unit (NICU)*

Based on the findings of 3 RCTs, there was no apparent difference in the rates of admissions to the NICU. Again however, variability in the magnitude of admissions reported across studies and study, led the reviewers to rate the overall strength of this evidence to be low.

### *Other neonatal outcomes*

Other neonatal outcomes assessed, but for which there is insufficient evidence to draw conclusions, included: transient tachypnea, suspected sepsis, seizures, hypoglycemia, jaundice, polycythemia, low birth weight, neonatal death, neonatal acidemia, fetal distress, fetal respiratory distress syndrome, and initiation of successful breastfeeding.

Taken together, the reviewers conclude that "the safety of elective induction of labour requires further investigation", particularly among women <41 weeks of gestation.

### **Bottom line:**

This section summarized evidence from 2 systematic reviews of moderate quality. Although the limited evidence suggests a beneficial effect of elective induction with respect to rates of cesarean delivery, meconium stained amniotic fluid, and assisted vaginal delivery, these findings were largely based on RCTs assessing women  $\geq$ 41 weeks gestation. Both systematic reviews found the evidence pertaining to women <41 weeks

gestation to be insufficient, and thus do not support a policy recommending induction at <41 weeks gestational age. In addition, well conducted future studies are necessary to illuminate the relationship between elective induction and other maternal (e.g., infections, blood loss, perineal tears) and neonatal (e.g., meconium aspiration syndrome, admissions to NICU) outcomes which according to Caughey et al. also had low or insufficient evidence.

**b. Economic evaluation**

● A 2002 US study assessed the economic and health consequences of elective induction at term (39-41 weeks) vs. expectant management using a hypothetical cohort of 100,000 pregnant woman (Kaufman et al. 2002). Using a decision-tree model, Markov analysis, and published data on probability of medical outcomes and cost, elective inductions were found to consistently incur higher costs than expectant management and be associated with higher rates of cesarean delivery.

The authors report that although inductions were “never cost saving [they] were less expensive at later gestational ages, for multiparous patients, and for those women with a favorable cervix”. According to univariate sensitivity analyses, the model was deemed robust. The authors conclude that “elective induction of labour at term is not cost saving and results in a large excess of cesarean deliveries. Costs are significantly altered by the timing of the induction, parity, and cervical ripeness.”

**Bottom line:**

A 2002 model of the economic and health consequences of elective induction between 39-41 weeks suggested induction to be associated with higher costs and rates of cesarean delivery. Expenditures are particularly pronounced among nulliparous women of younger gestational age with unfavorable cervixes.

**Table 1. Characteristics of Randomized, Controlled Trials of Elective Induction of Labor**

Study, Year (Reference)	Study Period	Location	Setting	Control Group	Sample Size, n		Induction Method	Study Rating	Applicability to Key Question*
					Control Group	Induction of Labor Group			
Amano et al, 1999 (31)†	NS	Japan	Academic center	Spontaneous labor	72	63	Oxytocin, AROM, PGE <sub>2</sub> gel, some laminaria tents	Poor	Poor
Cole et al, 1975 (21)	NS	Scotland	Academic center	Expectant management	117	111	Oxytocin, AROM	Poor	Poor
Dyson et al, 1987 (9)	1983–1985	United States	Community hospital	Expectant management	150	152	Oxytocin, AROM, PGE <sub>2</sub> gel	Fair	Fair
Egarter et al, 1989 (22)	NS	Austria	Academic center	Expectant management	165	180	PGE <sub>2</sub> gel	Poor	Fair
Gellsen et al, 2005 (23)	NS	Turkey	Academic center	Expectant management	300	300	Oxytocin, misoprostol, Foley catheter	Fair	Fair
Hannah et al, 1992 and 1996 (8, 24)‡	November 1985–December 1995	Canada	Multicenter	Expectant management	1706	1701	Oxytocin, AROM, PGE <sub>2</sub> gel	Good	Fair
Heimstad et al, 2007 (25)	September 2002–July 2004	Norway	Academic center	Expectant management	254	254	Oxytocin, AROM, misoprostol	Fair	Fair
Martin et al, 1978 (32)	NS	Ireland	NS	Spontaneous labor	92	92	Oxytocin, AROM	Poor	Poor
Nielsen et al, 2005 (26)	1999–2002	United States	Academic center	Expectant management	110	116	Oxytocin, AROM (either or both)	Fair	Fair
NICHHD, 1994 (27)§	December 1987–July 1989	United States	Multicenter	Expectant management	174	264	Oxytocin, AROM, PGE <sub>2</sub> gel	Good	Good
Tylleskär et al, 1979 (28), and Leijon et al, 1980 and 1979 (29, 30)‡	NS	Sweden	Multicenter	Expectant management	41	43	Oxytocin, AROM	Poor	Poor

AROM = artificial rupture of membranes; NICHHD = National Institute of Child Health and Human Development; NS = not specified; PGE<sub>2</sub> = prostaglandin E<sub>2</sub>.  
 \* Key research question: What is the evidence of maternal and/or neonatal outcomes for women who have elective induction of labor compared with women who are managed expectantly?  
 † Study conducted among nulliparous women only.  
 ‡ Data were abstracted from more than 1 publication of the same study.  
 § This trial compared an expectant management group with 2 groups that underwent different methods of induction. We combined the data from the 2 methods for our analysis because we were not comparing different methods of induction.

Source: Caughey et al. 2009, references listed in ‘References of Interest’

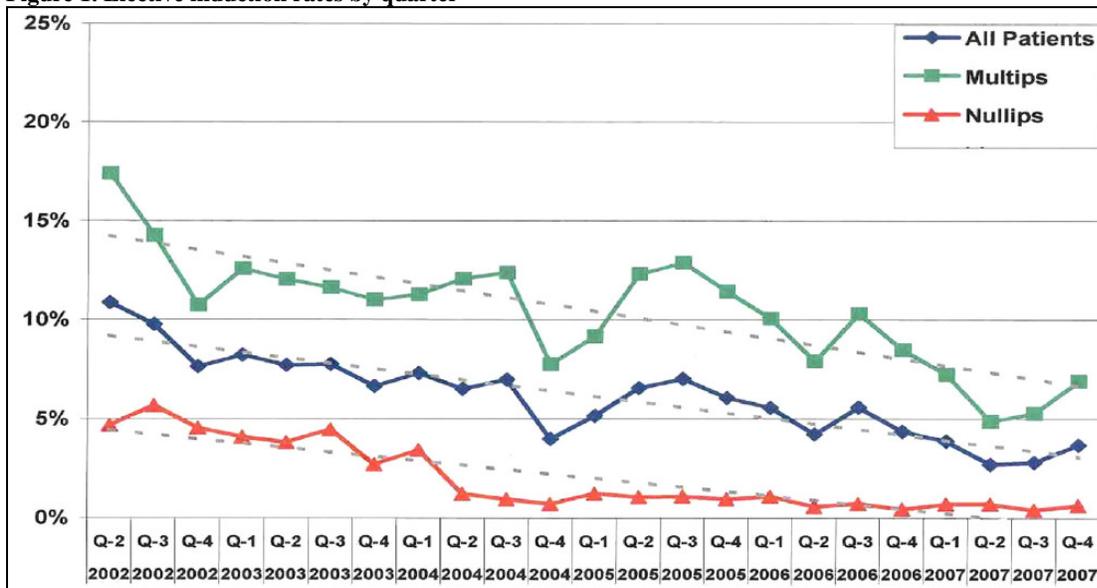
**b. Interventions to reduce the rates of elective induction**

★ A 2010 US interrupted time series, quality improvement study aimed to reduce rates of scheduled births between 36+0/7 to 38+6/7 weeks lacking medical indication across 21 Ohio maternity hospitals (The Ohio Perinatal Quality Collaborative Writing Committee 2010). Following the implementation of locally appropriate interventions based on key drivers (e.g., promotion of optimal determination of gestational age with ultrasound; use of ACOG criteria for the indication and time of scheduled births; increased awareness among pregnant women, nurses, and physicians of the risks and benefits of births between 36-38 weeks; etc) the rate of scheduled births lacking documentation of a medical or obstetric indication dropped from 25% to <5% in a 12-month period. This decline was associated with a 60% decrease in rates of induction without indication (13% to 8%). Although the study concluded that their “statewide quality collaborative was associated

with fewer scheduled births lacking a documented medical indication”, they caution that the initiative may not be as successful in the absence of sufficient investment in staff and financial resources.

★ A 2009 US case-control quality improvement study aimed to minimize the number of women ≥39 weeks undergoing elective induction in one Seattle hospital through the implementation of an induction management program (including strategies such as induction education and implementation of consent forms) (Reisner et al. 2009). Comparing program-data (3.75 years) with historic controls (previous 2 years), the program led to significant decreases in the rates of elective induction (see Figure 1; nulliparas: 4.3% to 0.8%; multiparas: 13% to 9.5%). The authors conclude that their “program aimed at reducing elective inductions was successfully implemented and sustained”.

**Figure 1. Elective induction rates by quarter**



Source: OB Database; Rosy Zingheim, RN, MN, 386-2589; 2/5/2008 in Reisner et al 2009.

**Bottom line:**  
 Two recently published American studies have successfully implemented quality improvement initiatives that have led to reductions in rates of induction over time. Despite the inherent limitations in their observational designs, these studies present promising findings for similar hospital-based initiatives.

### III. Guidelines

#### **NICE (United Kingdom)**

★ In 2008, the National Institute for Health and Clinical Excellence published the 2<sup>nd</sup> edition of their clinical guideline covering the induction of labour (National Collaborating Centre for Women's and Children's Health 2008). Specific to the appropriateness of induction at term the report offers the following guidance:

- “Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour”.
- “Women should be informed that most women will go into labour spontaneously by 42 weeks”.
- “Women with uncomplicated pregnancies should usually be offered induction of labour between 41+0 and 42+0 weeks to avoid the risks of prolonged pregnancy. The exact timing should take into account the woman's preferences and local circumstances”.

#### **Alberta Clinical Practice (Canada)**

★ In 2008, the Toward Optimal Practice program of the Alberta Medical Association published an update of the Alberta Clinical Practice guideline for the medical indication of labour (Working Group for Labour Induction 2008). According to this guideline, induction is not indicated until gestation  $\geq 41 + 1/7$  weeks (assuming no other indications for induction are present). It asserts that “induction of labour is not without risk and should only be undertaken when the continuance of pregnancy is not advisable for the well-being of the baby or the woman”. “Convenience” is listed as a contraindication for labour induction.

#### **SOGC (Canada)**

★ In 2001, the Society of Obstetricians and Gynecologists of Canada published their clinical practice guideline on induction of labour at term (Crane et al. 2001). While the scope of the guideline related more to the medical indications for induction and the safety and effectiveness of various methods, it does indicate that as far as gestational age, induction is only indicated  $\geq 41$  weeks. Additionally it recommends that since “elective induction is associated with potential complications” it should be discouraged, and only undertaken after fully informing the woman of

these risks and establishing accurate gestational age”.

#### **ACOG (US)**

★ In 2009, the American College of Obstetricians and Gynecologists published their clinical practice guideline on induction of labour (No.107) (ACOG 2009). Much like the SOGC guidelines, the scope of this guideline relates to the various approaches of induction and their effectiveness. However, in terms of the timing of induction, the guideline does recommend the confirmation of term gestational age as a criteria for induction (either based on ultrasound measurement which occurred at  $< 20$  weeks of gestation and supports gestational age of  $\geq 39$  weeks or the passing of 36 weeks since a positive serum or urine pregnancy test result). Also, in terms of potentially elective induction, the guideline advises counselling nulliparous women with unfavorable cervixes about a potentially higher risk of cesarean delivery – this recommendation however is only supported by a small group of observational and non-controlled studies rather than systematic review evidence.

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## Methods

Detailed search strategies were developed by an experienced Information Specialist (specific search terms available upon request). Searching was limited to the following databases:

- Biomed Central;
- Cochrane Database of Systematic Reviews (CDSR);
- Database of Abstracts of Reviews of Effects (DARE)
- National Health Service Economic Evaluation Databases (NHS EED)

Search concepts included Medical Subject Headings (MeSH) and non-thesaurus terms (i.e. text words). A ‘grey literature’ search was also conducted for potentially relevant studies by reviewing the web sites of relevant organizations (available upon request). We sought studies that assessed maternal and neonatal outcomes for women who had induction of labour at term (37-41 weeks) without medical indication. We were not interested in the efficacy of specific induction techniques and thus excluded placebo-controlled or head-to-head induction comparisons. Guidelines based on literature review were included. To be included, all citations had to have been published in English and be available in full text electronically.

Screening and extraction was conducted by one reviewer, and thus may have introduced a marginal amount of error. Given the publication of relevant systematic reviews, no RCTs were considered for summary in this report, but are available upon request. Two observational studies were included however as in contrast to comparing the outcomes of induction vs. no induction (captured by the synthesized literature), these prospective designs assessed interventions to reduce non-indicated/elective inductions which it was believed may benefit the stakeholders of this report. Risk of bias was only evaluated for the systematic reviews in this report, using the AMSTAR instrument.

## Risk of Bias Assessment of Systematic Reviews

AMSTAR is an 11-item measurement tool created to assess the methodological quality of systematic reviews. Each question is scored according to 1 of 4 options (yes, no, cannot answer, not applicable) and the number of ‘yes’ answers tallied. A higher score indicates increased methodological quality.

The 11 assessment criteria are as follows:

1. Was an “a priori” design provided?
2. Was there duplicate study selection and data extraction?
3. Was a comprehensive literature search performed?
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
5. Was a list of studies (included and excluded) provided?
6. Were the characteristics of the included studies provided?
7. Was the scientific quality of the included studies assessed and documented?
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
9. Were the methods used to combine the findings of studies appropriate?
10. Was the likelihood of publication bias assessed?
11. Was the conflict of interest stated?

The AMSTAR score (from 0 to 11) for each systematic review in this evidence summary is reported in the box that appears at the beginning of each finding.

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## Additional Information

**This summary was produced by:**

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**Conflict of Interest**

None declared

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