



May 2010 – Knowledge to Action Evidence Summary

## What is known about the timing of elective repeat cesarean section?

This report aims to summarize the evidence around early-term elective repeat cesarean section (ERCS) to help inform evidence-based guidelines and advance practice in the province of Ontario.

### Key Messages

- Early-term ERCS (37-38 weeks) has consistently been associated with increased risks to the neonate, including respiratory morbidity, NICU admission and lengthier hospital stays when compared with ERCS at 39-40 weeks;
- Empirical studies, guideline-producing bodies and expert consensus unanimously agree that delaying ERCS to  $\geq 39$  weeks significantly reduces these risks;
- Studies addressing the *timing* of ERCS at term are limited and generally of lower quality; most studies examining ERCS compare maternal and neonatal outcomes between VBAC and ERCS;
- Current rates of ERCS  $< 39$  weeks in Ontario exceed what is expected would be necessary and reasons for this are not well defined;
- Ensuring adherence to guidelines dictating the timing of uncomplicated, term ERCS may pose specific challenges to clinicians, health policy and decision makers.

### Who is this summary for?

This summary was undertaken as part of the OHRI-Champlain LHIN Knowledge to Action research program and is intended for use by health systems stakeholders, policy- and decision-makers.

### 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.

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

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

## Background

Despite clinical practice guidelines and an ever-growing body of evidence that support the delay of elective repeat cesarean section (ERCS) to 39 weeks gestation, recent data for the province of Ontario indicates that between 30-60% of ERCS is performed prior to this.<sup>1</sup>

Early-term birth by ERCS (<39 weeks) is associated with increased morbidity in the neonate, most notably respiratory distress syndrome (RDS) and transient tachypnea of the newborn (TTN) in addition to higher rates of admission to neonatal intensive care units (NICU). Multiple studies have produced data that, even when adjusted for possible confounding factors, have consistently shown these outcomes to be inversely related to gestational age (GA) at delivery.<sup>2</sup>

As such, many obstetric organizations around the world now advocate that uncomplicated ERCS not be performed before 39 weeks gestation.<sup>3 4 5</sup>

This evidence summary aims to advance the understanding of timing of ERCS for the early-term pregnancy by summarizing the literature in this area.

### Levels of Evidence (adapted from AHRQ 2001<sup>6</sup>)

Each piece of evidence presented in this summary is assigned a level:

- Level 1 L1** Systematic review and meta-analyses
- Level 2 L2** Randomized controlled trials
- Level 3 L3** Non-randomized controlled trial
- Level 4 L4** Observational studies with controls (e.g. case-control, time-series, cohort with controls, and health services research that includes adjustment for likely confounding variables)
- Level 5 L5** Observational studies without controls (e.g. cohort studies without controls, case series, literature reviews)
- Level 6 L6** Expert committee guidelines, reports or opinions and/or clinical experience of respected authorities (e.g. commentary and editorial)

### Contents

- i. What are trends in the timing of ERCS?
- ii. What are the rates of ERCS in Canada?
- iii. What do existing guidelines say about the timing of ERCS?
- iv. Are there Canadian guidelines for ERCS?
- v. What are the risks of early-term ERCS?
  - Composite Outcomes
  - Respiratory Morbidity
  - NICU Admission
  - Lengthier Hospital Stay
- vi. Why is ERCS often carried out before 39 weeks, despite evidence against it?
- vii. Does delay of ERCS to 39 weeks increase emergency CS and/or maternal morbidity?
- viii. What do clinicians think about timing of ERCS?
- ix. Why is a fetus deemed to be “full term” at 37 weeks?
- x. Can fetal maturity be determined in the absence of certainty around gestational age (GA)?
- xi. What can be done to improve outcomes for early-term neonates?
- xii. What is the economic impact of early-term ERCS?
- xiii. What can be done to curb unnecessary ERCS prior to 39 weeks?
- xiv. Related studies and trials underway

## Summary of Findings

### What are trends in the timing of ERCS?

- **L5** A 2003 analysis of National Center for Health Statistics (US) data for 1990-2000 showed that repeat cesarean section (RC/S) "...at 37 to 38 weeks increased from 37.6% of all RC/S between 37 and 40 weeks in 1990 to 43.2% in 2000. Reasons for this rise may include increasing use of fetal lung maturity testing, more indicated RC/S, or noncompliance with ACOG's guidelines. Further study is needed to identify factors contributing to this trend."<sup>7</sup>
- **L5** A 2008 literature review indicates that early-term birth has increased in the US by 21% over a ten year period and emphasizes that admission rates to NICU and respiratory morbidity is inversely related to advancing gestational age.<sup>8</sup>
- **L5** A 2010 Italian study found that 72% of ERCS in one region were performed before 39wks.<sup>9</sup>

### What are the rates of ERCS in Canada?

- **L5** The Public Health Agency of Canada's 2008 Canadian Perinatal Health Report finds that, between 1995-1996 and 2004-2005 ERCS increased by 18.2%; in 2004-2005, "ERCS/other" deliveries accounted for 6.7/100 of Canadian hospital births.<sup>10</sup>
- **L5** The Perinatal Partnership Program of Eastern and Southern Ontario's Annual Perinatal Statistical Report for 2007-08 indicates that 36.7% of CS in the region is ERCS.<sup>11</sup>

**Bottom Line:** ERCS accounts for a large and increasing proportion of deliveries across Canada and in the Champlain Region of Ontario.

### What do existing guidelines say about the timing of ERCS?

- **L6** **American College of Obstetricians and Gynecologists (ACOG 2007)**  
"Cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity." – this recommendation is made in the context of both elective primary cesarean section (EPCS) and ERCS.<sup>12</sup>
- **L6** **Royal College of Obstetricians and Gynecologists (RCOG 2007)**  
While not making an explicit recommendation, the RCOG reports the results of studies and a trial that show evidence favouring the delay of ERCS to 39 weeks, citing respiratory morbidity as the primary concern.<sup>13</sup>
- **L6** **National Institute for Clinical Excellence (NICE 2004)**  
"The risk of respiratory morbidity is increased in babies born by CS before labour, but this risk decreases significantly after 39 weeks. Therefore planned CS should not routinely be carried out before 39 weeks."<sup>14</sup>
- **L6** **Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG 2009)**  
"On balance, weighing up the risk of respiratory morbidity following elective caesarean section and the risk of labouring prior to caesarean section it is recommended that elective caesarean section in women without additional risks should be carried out at 'approximately' 39 weeks gestation. Such women suitable for delivery at approximately 39 weeks gestation include breech presentation and uncomplicated repeat caesarean section."<sup>15</sup>

**Bottom Line:** All clinical management guidelines located by this review recommend delaying ERCS to 39 weeks when possible.

### Are there Canadian guidelines for ERCS?

- No guidelines specific to the Canadian context and the timing of ERCS were identified.

## What are the risks of early-term ECRS?

### Composite Outcomes

- **L5** A 2010 retrospective Dutch cohort of 20,973 ECRSs at term were examined over a 6yr period for a primary composite outcome including multiple morbidities and mortality; 56.6% of ECRS took place at <39wks; incidence of the primary outcome was significant ( $p < 0.0001$ ) at 37-38wks compared with 39+ wks; almost all independent outcomes also significantly favoured the delay of ECRS to 39wks; authors conclude that: “Performing elective cesarean sections <39+0 weeks of gestation jeopardizes neonatal outcome and should be avoided whenever possible.”<sup>16</sup>
- **L5** A 2009 multi-centre, US prospective cohort study examined 13,258 ECRS over a 3yr period; 35.8% of ECRS took place before 39wks and of these, significantly more experienced respiratory morbidity, admission to a NICU and longer hospital stays leading authors to conclude that “Elective repeat cesarean delivery before 39 weeks of gestation is common and is associated with respiratory and other adverse neonatal outcomes.”<sup>17</sup>
  - Analysis of the same dataset shows that maternal outcomes are likewise significantly and negatively affected by ECRS that takes place prior to 39 weeks.<sup>18</sup>

### Respiratory Morbidity

**L1** A large, 2006 AHRQ systematic review examining cesarean delivery on maternal request concludes that, with regard to ECS: “Overall, the results showed a higher risk of respiratory morbidity from TTN or RDS among elective cesarean births than among vaginal delivery and a consistent reduction in risk with advancing gestational age approaching equality at 39 through 40 weeks.”<sup>19</sup>

**L1** A 2007 systematic review of the literature examining respiratory morbidity in term neonates delivered by ECRS identified 1 case-control and 8 observational studies (with considerable methodological heterogeneity, preventing a pooled meta-analysis); authors were, nonetheless, able to conclude that “Delivery by elective caesarean section was shown to increase the risk of respiratory morbidity in all studies eligible for inclusion. The magnitude of this relative risk seemed to depend on gestational age even in deliveries after 37 completed weeks of gestation.”<sup>20</sup>

- **L5** A 2010 retrospective Italian cohort study over a 2-yr period found the odds ratio for respiratory morbidity of ECRS at 37 vs. 39 wks was 2.70; 38 vs. 39 wks was 1.34; authors report that, given these data, 145 neonates could have been spared respiratory morbidity if elective delivery had been delayed until 39 weeks.<sup>21</sup>
- **L5** A 2010 population study of data in Burgundy, France examining outcomes for preterm and early-term neonates concludes that “...an intermediate risk of respiratory morbidity was observed in the early-term infants. Therefore, birth at 37 and 38 weeks of gestation is not low-risk for the newborn, and this information should lead to avoidance of caesarean section or labour induction without medical indication in early-term infants...”<sup>22</sup>
- **L5** A 2008 Canadian cohort study of 1,193 term neonates over a 1yr period found a significant decrease in respiratory distress at 270 days GA (38 4/7 weeks); authors conclude that “Based on our findings, we do not think it is feasible or advisable to mount a clinical trial of a policy of awaiting labor or ruptured membranes before elective cesarean delivery. Our study clearly confirms previous work that elective cesarean delivery should be delayed, if possible, beyond 37 weeks of gestation. Specifically, our results indicate that the reduction in the risk of respiratory distress is completely manifested by 38 4/7 weeks of gestation.”<sup>23</sup>

- **L5** A 2008 prospective Danish cohort study of respiratory morbidity following ECS in 2687 neonates found adjusted odds ratios of 3.7 at 37wks, 3.0 at 38wks and 1.9 at 39 wks against babies at the same GA intended for vaginal delivery; authors conclude that: “Babies delivered by elective caesarean section at 37 to 39 weeks’ gestation are at twofold to fourfold increased risk of respiratory morbidity compared with babies delivered by intended vaginal delivery. A reduction in neonatal respiratory morbidity may be obtained if elective caesarean section is postponed until 39 completed weeks of gestation.”<sup>24</sup>
  - **L5** A series of retrospective Italian cohort studies of ERCS at term showed that 55-60% were performed prior to 39wks and that respiratory morbidity was significantly increased ( $p < 0.05$ ) among these neonates as compared with those delivered at or after 39wks; in one paper, authors conclude that “A significant reduction in neonatal RDS would be obtained if elective caesarean delivery were performed after 39+0 gestational weeks of pregnancy.”<sup>25 26 27</sup>
  - **L5** A 2002 retrospective US cohort study of elective deliveries at term over a 9yr period (excluding those with other clinical indications for delivery) measured severe respiratory distress syndrome (RDS); of 18 cases requiring mechanical ventilation, 16 were electively delivered prior to 39 weeks; authors conclude that, compared with those born at or after 39 wks: “Infants born at 37 0/7-38 6/7 weeks are at significantly increased risk for severe RDS.”<sup>28</sup>
  - **L5** A 2001 retrospective Dutch cohort study of 333 ECS over a 5yr period found that of 16/17 neonates admitted to the NICU were delivered prior to 39 wks leading authors to conclude that delaying ERCS to 39 wks is beneficial to neonates.<sup>29</sup>
  - **L5** A 1999 retrospective UK study of 179,701 live births examined whether and to what extent respiratory distress syndrome (RDS) occurred in babies delivered at 34-41wks (GA validated postnatally) – of 146 babies with RDS and no obvious reason for this other than prematurity, 35 were delivered at 37-38wks GA (2 died) and 1 was delivered between 39-41wks. Authors conclude: “Elective delivery should only be undertaken before 39 wk gestation for good medical reasons.”<sup>30</sup>
  - **L5** A 1995 prospective 9yr UK cohort study of 262 term neonates admitted to the NICU for respiratory morbidity found that “The relative risk of neonatal respiratory morbidity for delivery by caesarean section before the onset of labour during the week 37+0 to 37+6 compared with the week 38+0 to 38+6 was 1.74 (95 % CI 1.1 -2.8 ;  $P < 0.02$ ) and during the week 38+0 to 38+6 compared with the week 39+0 to 39+6 was 2.4 (95% CI 1.2-4-8;  $P < 0.02$ ).... A significant reduction in neonatal respiratory morbidity would be obtained if elective caesarean section was performed in the week 39+0 to 39+6 of pregnancy.”<sup>31</sup>
- NICU Admission**
- Admission to a NICU is a negative outcome associated with increased costs to health systems; separation of baby from parents and painful procedures to the infant.<sup>32</sup>
  - **L5** A 2009 prospective observational study examined 1577 ERCSs and found a significant increase in NICU admissions among neonates delivered at 37 vs. 38 weeks; for all elective term deliveries authors conclude “Elective delivery before 39 weeks’ gestation is associated with significant neonatal morbidity... Elective delivery before 39 completed weeks’ gestation is inappropriate.”<sup>33</sup>
  - **L5** A 2009 retrospective study examined a single hospital and statewide data on ERCS over a 7yr period and found that NICU admissions were significantly higher among neonates born at 37-38wks GA; authors conclude that: “Elective singleton term CD [cesarean deliveries] are increasing and, if performed before 39 weeks gestation, there is an increased risk for NICU admission...”<sup>34</sup>
  - **L4** A 2006 US study measured adherence to ACOG guidelines for timing the delivery of ERCS and found that 50% of NICU admissions (after adjustment for fetal anomalies and exposure to pregestational diabetes) were directly associated to violations of this guideline.<sup>35</sup>
  - **L5** A 1999 Dutch cohort study of 272 ECS over a 5yr period showed that a significantly higher proportion (8 of 9) of neonates admitted to the NICU had a GA of <39wks.<sup>36</sup>

- **L5** A 1993 retrospective US cohort study of NICU admissions for RDS in term neonates delivered by ERCS found a significant association with failure to adhere to clinical management guidelines.<sup>37</sup>
- **L5** A 1977 retrospective US cohort study of 1020 consecutive NICU admissions found that 38 had been delivered electively with no maternal/fetal indication; of these, 20 had TTN; 18 developed hyaline membrane disease (HMD) related to premature delivery, and 15 of these were delivered by ERCS. Authors conclude that “In the absence of pressing medical indications and without an objective assessment of fetal maturity, elective delivery remains potentially hazardous.”<sup>38</sup>

#### ***Lengthier hospital stay***

- **L5** A 2009 retrospective study examined data on ERCS for a US hospital over a 7yr period and found that maternal stay in hospital was significantly higher among those delivered at 37wks GA.<sup>39</sup>

**Bottom Line:** While generally not high-quality, evidence addressing the timing of uncomplicated ERCS is unanimous in recommending its delay to 39 weeks.

#### **Why is ERCS often carried out before 39 weeks, despite evidence against it?**

- Little evidence exists in answer to this question. Some reasons suggested include:
  - Convenience for surgeon and patient;
  - Lack of awareness around the risks of carrying out a “slightly early” delivery;<sup>40</sup>
  - To ensure the patient’s own doctor performs the procedure;
  - Patient’s unwillingness to prolong pregnancy;<sup>41</sup>
  - **To avoid the onset of labour and maternal morbidity associated with emergency CS.**<sup>42</sup> *[emphasis added]*

**Bottom Line:** A variety of poorly defined and understood reasons exist for the frequency of ERCS <39wks in the face of mounting evidence against it; this is an area that will require additional research.

#### **Does delaying ERCS to 39 weeks increase the rate of emergency CS and/or increase maternal morbidity?**

- **L6** Many argue that because ~10% of women go into labour prior to 39 wks, delaying ERCS to this time will increase maternal morbidity associated with emergency CS; in response, some insist that the definition of emergency CS is too broad, and includes those with a planned CS that go into labour early (non-urgent), for whom neonatal outcomes are actually improved and maternal morbidity is lower; this group argues that the neonatal benefits of delaying ERCS to 39wks outweigh the maternal risks.<sup>43</sup>
- **L4** A 1999 UK time-series measured the rate of emergency CS before and after instituting a policy to delay ECS to 39wks; results showed no significant increase in emergency CS after institution of the policy, leading authors to conclude that: “There is no evidence that delaying elective caesarean delivery until 39 completed weeks of gestation results in adverse maternal outcome.”<sup>44</sup>

**Bottom Line:** There is some low-quality evidence to suggest that delay of ERCS does not decrease neonatal morbidity at the expense of maternal morbidity; more research is required to definitively answer this question.

#### **What do clinicians think about timing ERCS?**

- **L5** A 2007 survey of obstetricians in the UK shows that most (93.6%) agree that ERCS, for patients with one prior low-transverse delivery, should take place at or after 39 weeks.<sup>45</sup>

#### **Why is a fetus at 37 weeks determined to have reached “full term”?**

- **L5** A paper on RDS in term neonates discusses how it came to be that 37 weeks is deemed to be “full term” – the history raises questions about the rationale behind this (somewhat arbitrary) landmark, which does not take into account respiratory maturity. Authors conclude that “The unchallenged 1950 WHO recommendation that all babies of 37–41 wk gestation should be classified as delivering at ‘term’ has clouded clear thought. Fetal maturation is too complex to be categorized so simply.”<sup>46</sup>

**Bottom Line:** The very definition of what constitutes a “term” infant may need to be revisited, given the evolution of the concept.

### Can fetal maturity be determined in the absence of certainty around gestational age (GA)?

- Multiple studies have found that those delivered by ECS are significantly younger by postnatal examination than those delivered by TOL/VBAC, indicating that menstrual dates and other methods of determining GA are often inaccurate and/or unreliable indicators of fetal maturity.<sup>47 48 49 50 51 52</sup>
- **L6** The American College of Obstetricians and Gynecologists (ACOG) recommend that tests for pulmonary maturity be carried out on all fetuses of less than 39 GA.<sup>53</sup>
- **L6** A 2002 case study reported by Pinette et. al. describes a 35wk neonate whose lecithin-to-sphingomyelin (L/S) ratio indicated pulmonary maturity but developed RDS after delivery; the authors conclude that “... fetal pulmonary maturity should be viewed as a **probability that is a function of gestational age and amniotic fluid analysis.**”<sup>54</sup> (*emphasis added*)
- **L4** A 1982 retrospective chart review of 386 ERCSs found that those exposed to a management protocol to determine GA had no fetal respiratory distress syndrome (RDS), while 3 cases of RDS occurred in those patients not exposed to the intervention; authors conclude that such an intervention may be beneficial in determining appropriate time of delivery.<sup>55</sup>

**Bottom Line:** More research is required to determine the most accurate method to determine fetal maturity; until then, delay of uncomplicated ERCS to 39 wks remains the safest clinical option.

### What can be done to improve outcomes for early-term neonates?

- **L2** A 2005 RCT of 998 women undergoing planned ECS at term compared respiratory distress and NICU admissions of babies born to mothers receiving either betamethasone injections before delivery or usual care; there were 50% fewer NICU admissions for respiratory morbidity in the intervention group; authors conclude: “In planning elective caesareans, the risk of respiratory distress should be considered and the likely benefits of antenatal corticosteroids should be compared with those of delaying delivery until 39 weeks when possible.”<sup>56</sup>
- **L6** In response to this, an accompanying commentary argues that “A single course of steroids reduces neonatal mortality in babies born before 34 weeks and this perhaps justifies the small risk of long term side effects. However, no such substantial benefit has been shown after this gestation. Delaying delivery until 39 weeks, unless necessary, would seem a more prudent option than giving steroids whose long term safety, even as a single course, remains questionable.”<sup>57</sup>
- Several studies in the 1970’s and 1980’s examined prenatal tests for lung maturity in term fetuses with some success<sup>58 59</sup>; however, the practice has gradually fallen from favour<sup>60</sup> and most obstetricians now rely on GA estimates from menstrual dates and early ultrasounds.

**Bottom Line:** Delay of ERCS to 39 weeks remains the gold-standard for reducing harms of early delivery to the neonate.

### What is the economic impact of early-term ERCS?

- **L4** A 2009 retrospective US cohort study comparing respiratory morbidity in 672 neonates after ECS vs. VBAC concluded that “Overall, intended cesarean delivery was significantly more expensive than intended vaginal delivery for both mothers and their neonates. Both elective cesarean delivery with or without labor accrued higher costs compared with successful VBAC delivery.”<sup>61</sup>

- **L4** A 1995 UK study of term neonates admitted to the NICU for respiratory morbidity estimates that more than £2million/year could be saved by adopting a policy to delay ERCS to 39wks.<sup>62</sup>

**Bottom Line:** While data are scarce, that which exists suggests harmful outcomes resulting from early ERCS include increased costs to health systems.

#### What can be done to curb unnecessary early-term ERCS?

**L1** A 2006 systematic review of 33 studies of interventions to improve uptake of obstetrical clinical guidelines found that audit and feedback, reminders and multifaceted strategies were most effective in changing obstetrical practice; authors conclude that: “In the field of obstetric care, multifaceted strategy based on audit and feedback and facilitated by local opinion leaders is recommended to effectively change behaviors.”<sup>63</sup>

- **L4** A 2009 before-after study measured the impact of instituting a policy banning delivery before 39wks in a large, integrated US health system; despite initial resistance from clinicians, the rate of early term delivery went from 28% at baseline to <10% at 6mos; 10yrs later, the system has maintained a rate of early term delivery of <3% (these data include both induction and ECS).<sup>64</sup>
  - Authors conclude that “With institutional commitment, it is possible to substantially reduce and sustain a decline in the incidence of elective deliveries before 39 weeks of gestation.”
- Authors credit the success of their intervention to several components:
  - Having an EMR system;
  - Having a system-wide quality improvement process in place;
  - Presenting internal/local data on neonatal morbidity to clinicians;
  - Producing a patient brochure explaining the risks of early-term delivery;
  - Regular updates on performance;
  - Accountability checks and balances.

- **L4** A 2003 before-after study at a hospital in Glasgow, Scotland examined the impact of a policy to delay ERCS to 39 wks, reducing the rate of respiratory morbidity requiring NICU admission in neonates delivered by ERCS from 8.8% to 5.5%, potentially saving 29 infants unnecessary illness and the health system from as many unnecessary NICU admissions.<sup>65</sup>

**Bottom Line:** Changing practice is a complex undertaking, but can be done and is likely to have a net benefit over the long-term to both patients and health systems.

#### Related studies and trials underway

- **L2** A Danish RCT is underway comparing ECS at 38 3/7 wks against ECS at 39 3/7 wks; the study began in March 2009 and is expected to end in December 2011 with an expected enrollment of 1010 pts; the primary outcome measure is NICU admission.<sup>66</sup>

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## Additional Information

### This summary was produced by:

Sara Khangura, Jeremy Grimshaw and David Moher; Ottawa Hospital Research Institute. The format of this report is based on that developed by the SUPPORT Collaboration Network [www.support-collaboration.org](http://www.support-collaboration.org).

### Conflict of Interest

None declared

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## KTA Evidence Summary: Timing of Elective Repeat Cesarean Section

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