

## Step 6: Does Not Routinely Employ Practices, Procedures Unsupported by Scientific Evidence

The Coalition for Improving Maternity Services:

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### ABSTRACT

Step 6 of the *Ten Steps of Mother-Friendly Care* addresses two issues: 1) the routine use of interventions (shaving, enemas, intravenous drips, withholding food and fluids, early rupture of membranes, and continuous electronic fetal monitoring; and 2) the optimal rates of induction, episiotomy, cesareans, and vaginal births after cesarean. Rationales for compliance and systematic reviews are presented.

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**Keywords:** labor preparation; perineal shaving, labor; enema, labor; intravenous drip, adverse effects; intravenous drip, labor; intravenous nutrition, labor; obstetric procedures, adverse effects; NPO, labor; nutrition, labor; oral intake, labor; amniotomy artificial rupture of membranes; electronic fetal monitoring; intrapartum cardiotocography; elective induction; labor induction; labor induced; spontaneous labor rates; rates of induction; induction and adverse effects; maternal satisfaction and induction; episiotomy, adverse effects; episiotomy, median; episiotomy, mediolateral; episiotomy rate; cesarean; cesarean rate; cesarean, adverse effects; vaginal birth, adverse effects; obstetric birth, adverse effects; pelvic-floor dysfunction; urinary incontinence; anal incontinence; vaginal birth after cesarean (VBAC); VBAC rates; elective repeat cesarean; VBAC and induction of labor

**Step 6: Does not routinely employ practices and procedures that are unsupported by scientific evidence, including, but not limited to, the following:**

- shaving [for vaginal birth];
- enemas;
- intravenous drips (IVs);
- withholding nourishment or water;
- early rupture of membranes; and
- [continuous] electronic fetal monitoring [intrapartum cardiotocography].

**Limits interventions, as follows:**

- induction rate of 10% or less;
- episiotomy rate of 20% or less, with a goal of 5% or less;



For a description and discussion of the methods used to determine the evidence basis of the Ten Steps of Mother-Friendly Care, see this issue's "Methods" article by Henci Goer on pages 5S–9S.

- total cesarean rate of 10% or less in community hospitals, and 15% or less in tertiary hospitals; and
- vaginal birth after cesarean (VBAC) rate of 60% or more, with a goal of 75% or more.

Step 6: Does not routinely employ practices and procedures that are unsupported by scientific evidence, including, but not limited to, the following:

- shaving [for vaginal birth]

### Shaving for Vaginal Birth

Rationale for Compliance	Evidence Grade
The rationale for pubic and perineal shaving for vaginal birth is to prevent infection. However:	NEB
<ul style="list-style-type: none"> <li>• maternal infection rates do not differ between shaved and unshaved women (Basevi, 2001).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>• shaved women experience irritation, redness, superficial scratches, burning, and itching (Basevi, 2001).</li> </ul>	<b>Quality:</b> C (Only 1 study, and it does not report adverse effects in the unshaved group.) <b>Quantity:</b> B <b>Consistency:</b> NA*

A = good, B = fair, C = weak, NA = not applicable, NEB = no evidence of benefit

Quality = aggregate of quality ratings for individual studies

Quantity = magnitude of effect, numbers of studies, and sample size or power

Consistency = the extent to which similar findings are reported using similar and different study designs

\*only 1 study

\*\*multiple studies in systematic review (SR)

### INCLUDED STUDIES

Basevi, V., & Lavender, T. (2001). Routine perineal shaving on admission in labour. *Cochrane Database of Systematic Reviews*, (1), CD001236.

### EXCLUDED STUDIES

Johnston, R. A., & Sidall, R. S. (1922). Is the usual method of preparing patients for delivery beneficial or necessary? *American Journal of Obstetrics and Gynecology*, 4, 645–650. **Reason:** Data included in Basevi (2001).

Kantor, H. I., Rember, R., Tabio, P., & Buchanon, R. (1965). Value of shaving the pudendal-perineal

area in delivery preparation. *Obstetrics & Gynecology*, 25, 509–512. **Reason:** Data included in Basevi (2001).

Kovavisarach, E., & Jirasettasiri, P. (2005). Randomised controlled trial of perineal shaving versus hair cutting in parturients on admission in labor. *Journal of the Medical Association of Thailand*, 88(9), 1167–1171. **Reason:** No untreated group. Women were either shaved or had pubic hair trimmed to 0.5 cm. All received enema and episiotomy, both of which could affect infection rates. Therefore, this trial is not generalizable to populations not undergoing these interventions.



For more information on the Coalition for Improving Maternity Services (CIMS) and copies of the Mother-Friendly Childbirth Initiative and accompanying Ten Steps of Mother-Friendly Care, log on to the organization's Web site ([www.motherfriendly.org](http://www.motherfriendly.org)) or call CIMS toll-free at 888-282-2467.



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Step 6: Does not routinely employ practices and procedures that are unsupported by scientific evidence, including, but not limited to, the following:

- enemas

## Enemas

Rationale for Compliance	Evidence Grade
Although these rationales are given for the routine use of enemas:	NEB
<ul style="list-style-type: none"> <li>Routine enema does not enhance dilation rate (Rutgers, 1993; Tzeng, 2005).</li> </ul>	<b>Quality:</b> C <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>Enemas do not affect mode of vaginal delivery (Tzeng, 2005).</li> </ul>	<b>Quality:</b> C <b>Quantity:</b> B <b>Consistency:</b> NA*
<ul style="list-style-type: none"> <li>Enemas do not reduce neonatal infection rates (Tzeng, 2005).</li> </ul>	<b>Quality:</b> C <b>Quantity:</b> B <b>Consistency:</b> NA*
<ul style="list-style-type: none"> <li>Enemas do not reduce maternal infection rates (Tzeng, 2005).</li> </ul>	<b>Quality:</b> C <b>Quantity:</b> B <b>Consistency:</b> NA*
Some women dislike having enemas (Rutgers, 1993).	<b>Quality:</b> C <b>Quantity:</b> C <b>Consistency:</b> NA*

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Quantity = magnitude of effect, numbers of studies, and sample size or power

Consistency = the extent to which similar findings are reported using similar and different study designs

\*only 1 study

### INCLUDED STUDIES

Rutgers, S. (1993). Hot, high and horrible. Should routine enemas still be given to women in labour? *The Central African Journal of Medicine*, 39(6), 117–120.

Tzeng, Y. L., Shih, Y. J., Teng, Y. K., Chiu, C. Y., & Huang, M. Y. (2005). Enema prior to labor: A controversial routine in Taiwan. *The Journal of Nursing Research*, 13(4), 263–270.

### EXCLUDED STUDIES

Cuervo, L. G., Bernal Mdel, P., & Mendoza, N. (2006). Effects of high volume saline enemas vs no enema during labour—The N-Ma randomised controlled trial [ISRCTN43153145]. *BMC Pregnancy and Childbirth*, 6, 8. **Reason:**

- Does not exclude women having cesarean sections.
- Underpowered to detect differences in maternal and neonatal infections.
- Extremely high combined infection rate of 46% not generalizable to other populations.
- Fails to consider possible adverse effects of high-volume enemas.

Cuervo, L. G., Rodriguez, M. N., & Delgado, M. B. (2000). Enemas during labor. *Cochrane Database of Systematic Reviews*, (2), CD000330. **Reason:** Poorly designed:

- The SR includes only 2 trials, one of them the lead author's unpublished thesis data. Of the 30 outcomes reported, 28 of them are based on his data alone.
- The SR reports 10 separate outcomes related to neonatal infection, all but one from the lead author's trial alone, so it is hardly surprising that a couple of them turn out to be significant just by chance.
- No evidence presented that lead author's trial evaluated whether infective organisms were colonic in origin.
- Investigators reject trials for arbitrary reasons such as too few perinatal infections without providing sources to support what the expected rate should be.

Kovavisarach, E., & Sringsamvong, W. (2005). Enema versus no-enema in pregnant women on admission in labor: A randomized controlled trial. *Journal of the Medical Association of Thailand*, 88(12), 1763–1767. **Reason:** Does not distinguish between formed stool and diarrhea when measuring contamination. Formed stool is less likely to contaminate the perineum. Does not define infection. No power calculation. Ninety percent episiotomy rate. Presence or absence of episiotomy wound could affect perineal infection rates; therefore, study not generalizable to populations not experiencing high episiotomy rates.

*Step 6: Does not routinely employ practices and procedures that are unsupported by scientific evidence, including, but not limited to, the following:*

- intravenous drips (IVs)*

## Intravenous Drips

Rationale for Compliance	Evidence Grade
Common rationales for routine intravenous drips (IVs) include supplying fluids, providing an "open vein" in case of emergency, and, in some cases, supplying calories. However:	
<ul style="list-style-type: none"> <li>If women drink and eat as desired in labor, the need for routine replacement fluids and calories disappears.</li> </ul>	NEB
<ul style="list-style-type: none"> <li>No study found showing that having an IV in place improves outcomes.</li> </ul>	NEB
IVs can cause discomfort and distress (Simkin, 1986; Tourangeau, 1999).	<b>Quality:</b> C <b>Quantity:</b> B <b>Consistency:</b> A
IVs interfere with mobility. There is no formal evidence of this, other than a survey reporting that of women who said they were confined to bed, two thirds gave being "connected to things" as the reason (Declercq, 2002). However, the need to deal with the IV line and pole necessarily interferes with mobility.	<b>Quality:</b> B ("Connected to things" could mean monitoring equipment as well as IVs.) <b>Quantity:</b> A <b>Consistency:</b> NA*
Infusing excessive volumes of IV fluid can cause:	
<ul style="list-style-type: none"> <li>anemia<sup>a,b</sup> (Carvalho, 1991; Kempen, 1990).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> C <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>reductions in colloid osmotic pressure<sup>a,c</sup> (Park, 1996).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> C <b>Consistency:</b> NA*
Infusing electrolyte-free solutions can cause hyponatremia <sup>a,d</sup> (Higgins, 1996; Stratton, 1995).	<b>Quality:</b> C <b>Quantity:</b> B <b>Consistency:</b> A
Infusing glucose-containing solutions can cause neonatal hyperglycemia <sup>a,e</sup> (Nordstrom, 1995).	<b>Quality:</b> C <b>Quantity:</b> C <b>Consistency:</b> NA*

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<sup>a</sup>These studies reported few or no clinical symptoms; however, trials were small and participants had uncomplicated pregnancies. This means both that trials would be unlikely to detect uncommon events and that participants would be unlikely to experience them.

<sup>b</sup>One concern with anemia is that it increases maternal risks (e.g., the likelihood of needing transfusion) should there be a hemorrhage.

<sup>c</sup>Reductions in colloid osmotic pressure can lead to edema, including fluid in maternal and fetal lungs (Park, 1996).

<sup>d</sup>Hyponatremia can lead to transient neonatal tachypnea and, in severe cases, to seizure in the newborn and seizures or coma in the mother (Grylack, 1984; Stratton, 1995).

<sup>e</sup>Studies published before 1990 confirm that infusing glucose solutions can cause fetal hyperglycemia and that this can result in hypoglycemia after birth when the maternal source of glucose is withdrawn (Grylack, 1984; Philipson, 1987).

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- Simkin, P. (1986). Stress, pain, and catecholamines in labor: Part 2. Stress associated with childbirth events: A pilot survey of new mothers. *Birth*, 13(4), 234-240. **Reason:** Published before 1990, but study is a unique source of data on the issue of maternal satisfaction.
- Stratton, J. F., Stronge, J., & Boylan, P. C. (1995). Hyponatraemia and non-electrolyte solutions in labouring primigravida. *European Journal of Obstetrics, Gynecology, and Reproductive Biology*, 59(2), 149-151.
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- Garite, T. J., Weeks, J., Peters-Phair, K., Pattillo, C., & Brewster, W. R. (2000). A randomized controlled trial of the effect of increased intravenous hydration on the course of labor in nulliparous women. *American Journal of Obstetrics and Gynecology*, 183(6), 1544-1548. **Reason:** Not relevant. Study concludes that increasing the rate of intravenous hydration decreases the incidence of prolonged labor, but the step mandates abandoning routine IV hydration and permitting laboring women to self-regulate oral intake of fluids.
- Hauch, M. A., Gaiser, R. R., Hartwell, B. L., & Datta, S. (1995). Maternal and fetal colloid osmotic pressure following fluid expansion during cesarean section. *Critical Care Medicine*, 23(3), 510-514. **Reason:** Have better quality and more recent research. The following year, the same group published another study measuring colloid osmotic pressure (Park, 1996), which is included.

*Step 6: Does not routinely employ practices and procedures that are unsupported by scientific evidence, including, but not limited to, the following:*

- withholding nourishment or water

### Oral Intake

Rationale for Compliance	Evidence Grade
<p>The rationale for denying oral intake is to reduce the risk of pulmonary aspiration and the morbidity and mortality that can result from aspiration should cesarean section under general anesthesia be required. However:</p> <ul style="list-style-type: none"> <li>• The likelihood of aspiration is vanishingly small. In the Netherlands, where women are freely allowed oral intake (Scheepers, 1998), the mortality rate from aspiration during cesarean surgery is 1.8 per 100,000 (Schuitemaker, 1997). Using the cesarean rate in first-time mothers (31%) as a proxy for unplanned cesareans (Declercq, 2002), multiplying it by the percentage of cesareans performed under general anesthesia in the United States (15%) (Hawkins, 1997), and multiplying that result by 1.8 per 100,000, the likelihood of a fed woman undergoing an unplanned cesarean under general anesthesia dying of pulmonary aspiration calculates to 8 per 10 million or 1 in 1,250,000. Moreover, this is a worst-case scenario. The Dutch study does not report the condition of the women at the time they underwent surgery. A study of 13,400 emergency surgeries under general anesthesia reported no deaths from aspiration in patients in reasonably good health (ASA physical status rankings of I or II) (Warner, 1993).</li> <li>• No length of time since previous oral intake guarantees having a stomach volume below the danger threshold of 25 ml (Carp, 1992).</li> </ul>	NEB

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**Oral Intake**

Rationale for Compliance	Evidence Grade
Depriving women of oral fluids causes moderate to high stress in many laboring women; depriving them of food causes moderate to high stress in some women (Simkin, 1986).	<b>Quality:</b> C (It is possible that most of the women reporting that oral fluid deprivation caused stress were not receiving IV fluids.) <b>Quantity:</b> C <b>Consistency:</b> NA*
Calories ingested in labor are digested (Kubli, 2002; Scrutton, 1999).	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A

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 Quality = aggregate of quality ratings for individual studies  
 Quantity = magnitude of effect, numbers of studies, and sample size or power  
 Consistency = the extent to which similar findings are reported using similar and different study designs  
 \*only 1 study

**INCLUDED STUDIES**

Carp, H., Jayaram, A., & Stoll, M. (1992). Ultrasound examination of the stomach contents of parturients. *Anesthesia and Analgesia*, 74(5), 683–687.

Declercq, E., Sakala, C., Corry, M. P., Applebaum, S., & Risher, P. (2002). *Listening to mothers: Report of the first national U.S. survey of women's childbearing experiences*. New York: Maternity Center Association.

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Scrutton, M. J., Metcalfe, G. A., Lowy, C., Seed, P. T., & O'Sullivan, G. (1999). Eating in labour. A randomised controlled trial assessing the risks and benefits. *Anaesthesia*, 54(4), 329–334.

Simkin, P. (1986). Stress, pain, and catecholamines in labor: Part 2. Stress associated with childbirth events: A pilot survey of new mothers. *Birth*, 13(4), 234–240. **Reason:** Published before 1990, but study is a unique source of data on the issue of maternal satisfaction.

Warner, M. A., Warner, M. E., & Weber, J. G. (1993). Clinical significance of pulmonary aspiration

during the perioperative period. *Anesthesiology*, 78(1), 56–62.

**EXCLUDED STUDIES**

Agarwal, A., Chari, P., & Singh, H. (1989). Fluid deprivation before operation. The effect of a small drink. *Anaesthesia*, 44(8), 632–634. **Reason:** Have better quality research on same topic. Participants were not pregnant women.

CNM Data Group. (1999). Oral intake in labor. Trends in midwifery practice. The CNM Data Group, 1996. *Journal of Nurse-Midwifery*, 44(2), 135–138. **Reason:** Study not relevant.

Hawkins, J. L., Koonin, L. M., Palmer, S. K., & Gibbs, C. P. (1997). Anesthesia-related deaths during obstetric delivery in the United States, 1979–1990. *Anesthesiology*, 86(2), 277–284. **Reason:** Study not relevant.

Michael, S., Reilly, C. S., & Caunt, J. A. (1991). Policies for oral intake during labour. A survey of maternity units in England and Wales. *Anaesthesia*, 46(12), 1071–1073. **Reason:** Study not relevant.

Parsons, M., Bidewell, J., & Nagy, S. (2006). Natural eating behavior in latent labor and its effect on outcomes in active labor. *Journal of Midwifery & Women's Health*, 51(1), e1–6. **Reason:** Study not relevant.

Scheepers, H. C., Thans, M. C., de Jong, P. A., Essed, G., Le Cessie, S., & Kanhai, H. (2001). Eating and drinking in labor: The influence of caregiver advice on women's behavior. *Birth*, 28(2), 119–123. **Reason:** Study not relevant.

Tranmer, J. E., Hodnett, E. D., Hannah, M. E., & Stevens, B. J. (2005). The effect of unrestricted oral carbohydrate intake on labor progress. *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, 34(3), 319–328. **Reason:** Study underpowered to detect differences in rare adverse outcomes. Study underpowered to

detect differences in dystocia of less than 38%. Study confounded by:

- restricting oral intake with epidural use and 79% of oral intake group had epidurals;
- IV solutions usually contained lactate or glucose;
- nearly half of oral intake group did not have oral intake; and

- other factors that could adversely affect labor progress, including epidural anesthesia, induction, confinement to bed.

Two thirds of the oral intake group reported moderate or severe thirst, indicating that they did not, in fact, have free access to oral intake.

*Step 6: Does not routinely employ practices and procedures that are unsupported by scientific evidence, including, but not limited to, the following:*

- *early rupture of membranes*

### Amniotomy

Rationale for Compliance	Evidence Grade
Amniotomy is believed to shorten labor and, by so doing, reduce the number of cesarean sections for slow progress and improve neonatal outcomes by reducing exposure to the stress of overly long labors. However:	NEB
<ul style="list-style-type: none"> <li>• Routine amniotomy shortens mean duration of labor by only a modest amount (1–2 hrs) (Fraser, 1999).</li> </ul>	<b>Quality:</b> B <sup>a</sup> <b>Quantity:</b> A <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>• Early amniotomy has less effect than amniotomy later in labor (Fraser, 1993).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> N*
<ul style="list-style-type: none"> <li>• Routine amniotomy fails to reduce the cesarean section rate (Fraser, 1999; Rouse, 1994).</li> </ul>	<b>Quality:</b> B <sup>a</sup> <b>Quantity:</b> A <b>Consistency:</b> B (Of 10 trials included in Fraser [1999], 7 reported higher cesarean rates in the amniotomy group, 2 reported lower rates, and 1 small trial had no cesareans.)
<ul style="list-style-type: none"> <li>• Routine amniotomy has no clinically significant neonatal benefits (Fraser, 1999).</li> </ul>	<b>Quality:</b> B <sup>a</sup> <b>Quantity:</b> A <b>Consistency:</b> A**
Routine amniotomy may increase the risk of nonreassuring fetal heart rate (FHR) (Fraser, 1993; Fraser, 1999, Garite, 1993; Mercer, 1995).	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> B (Fraser [1999] did not find an increased incidence, but reviewers note that a reanalysis, taking into account that amniotomy shortened labor, did increase incidence. An increase in episodes of nonreassuring FHR is biologically plausible in that releasing the amniotic fluid increases pressure on the fetal head and umbilical cord during contractions.)
Early amniotomy may increase the maternal and neonatal infection rate (Fraser, 1999; Mercer, 1995; Rouse, 1994; Soper, 1996).	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> B <sup>a</sup> (Fraser [1999], a SR, did <i>not</i> find an increased incidence, but other studies find a strong association between duration of ruptured membranes, time, and invasive procedures.)

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Amniotomy

Rationale for Compliance	Evidence Grade
Amniotomy can lead to umbilical cord prolapse (Roberts, 1997; Usta, 1999).	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A

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\*only 1 study

\*\*multiple studies in SR

<sup>a</sup>Randomized controlled trials (RCTs) of amniotomy and, hence, systematic reviews of those trials suffer from confounding factors that could affect labor progress, occurrence of adverse events (abnormal fetal heart rate, infection, cesarean section), or both, specifically:

- Substantial proportions of women in the control group, more than half in some cases, also had amniotomies.
- Women in the control group were more likely to have oxytocin (Fraser, 1999).
- Women had vaginal examinations after membrane rupture and, in some trials, internal monitoring in both arms of the trial.

In addition, trials included only women with full-term, uncomplicated pregnancies. This means that differences between groups might be wider than they appear. First, in studies where amniotomy appears to be harmless, this might not have been the case had not so many women in the control group had amniotomies or had the baby's ability to withstand stress been less than optimal. Second, where studies report harmful effects, the difference between amniotomy and control group might have been more pronounced.

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Roberts, W. E., Martin, R. W., Roach, H. H., Perry, K. G., Jr., Martin, J. N., Jr., & Morrison, J. C. (1997). Are obstetric interventions such as cervical ripening, induction of labor, amnioinfusion, or amniotomy associated with umbilical cord prolapse? *American Journal of Obstetrics and Gynecology*, 176(6), 1181–1183; discussion 1183–1185.

Rouse, D. J., McCullough, C., Wren, A. L., Owen, J., & Hauth, J. C. (1994). Active-phase labor arrest: a randomized trial of chorioamnion management. *Obstetrics & Gynecology*, 83(6), 937–940.

Soper, D. E., Mayhall, C. G., & Froggatt, J. W. (1996). Characterization and control of intraamniotic infection in an urban teaching hospital. *American Journal of Obstetrics and Gynecology*, 175(2), 304–309; discussion 309–310.

Usta, I. M., Mercer, B. M., & Sibai, B. M. (1999). Current obstetrical practice and umbilical cord prolapse. *American Journal of Perinatology*, 16(9), 479–484.

EXCLUDED STUDIES

Barrett, J. F., Savage, J., Phillips, K., & Lilford, R. J. (1992). Randomized trial of amniotomy in labour versus the intention to leave membranes intact until the second stage. *British Journal of Obstetrics and Gynaecology*, 99(1), 5–9. **Reason:** Quality poor enough to invalidate results. The Cochrane SR (Fraser, 1999) excluded the study because of “inequality between groups suggesting error in randomization technique.”

Brisson-Carroll, G., Fraser, W., Breart, G., Krauss, I., & Thornton, J. (1996). The effect of routine early amniotomy on spontaneous labor: A meta-analysis. *Obstetrics & Gynecology*, 87(5, Pt. 2), 891–896. **Reason:** This SR of amniotomy was superseded by the Cochrane SR (Fraser, 1999).

Cammu, H., & Van Eeckhout, E. (1996). A randomised controlled trial of early versus delayed use of amniotomy and oxytocin infusion in nulliparous labour. *British Journal of Obstetrics and Gynaecology*, 103(4), 313–318. **Reason:** This is an RCT of Active Management of Labor.

Step 6: Does not routinely employ practices and procedures that are unsupported by scientific evidence, including, but not limited to, the following:

- [continuous] electronic fetal monitoring [intrapartum cardiotocography]



## Continuous Electronic Fetal Monitoring

Rationale for Compliance	Evidence Grade
Compared with intermittent auscultation, routine continuous electronic fetal monitoring (EFM) in low-risk women fails to reduce perinatal death rates, low APGAR scores, admissions to special care nursery, or the incidence of cerebral palsy (CP) (Thacker, 2001).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A**
Compared with intermittent auscultation, routine continuous EFM significantly reduces the incidence of neonatal seizure (Thacker, 2001). However, that benefit was found in a trial in an institution that mandates a high-dose oxytocin protocol for any woman not progressing at the average rate (MacDonald, 1985). The likelihood of uterine hyperstimulation and, therefore, the likelihood of distressing the fetus rise as oxytocin dosage rises. A more physiologic regimen might reduce or eliminate the benefit of closer monitoring. In any case, no long-term benefits were found (Grant, 1989). Of the other nine trials in the Cochrane review, seven failed to find a difference and two found a nonsignificant difference, but all nine were underpowered to detect a difference in this rare outcome.	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> B
Compared with intermittent auscultation, routine continuous EFM in women in preterm labor fails to improve neonatal outcomes (Luthy, 1987).	<b>Quality:</b> B <b>Quantity:</b> C <b>Consistency:</b> NA*
No trials could be found evaluating routine continuous EFM with epidural analgesia, physiologic oxytocin augmentation or induction protocols, or VBAC labors. Other than one RCT of continuous EFM in women in preterm labor, published in 1987 (see above), no RCTs have evaluated the benefits versus harms of routine continuous EFM in women with fetuses at high risk of being unable to tolerate labor.	Benefit unknown; harm established (see below)
The association between FHR patterns in labor and condition at birth is weak (Milsom, 2002; Sameshima, 2004). The association between condition at birth and long-term adverse outcome is weak (Low, 1990; Milsom, 2002; Yudkin, 1994). Therefore, the association between FHR patterns and neurologic injury is necessarily weak. This means that refinements of EFM technology such as computer analysis of fetal heart rate tracings or fetal electrocardiogram analysis are extremely unlikely to improve its ability to predict encephalopathy or CP.	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
Compared with intermittent auscultation, routine continuous EFM increases the likelihood of vaginal instrumental birth and cesarean section (Thacker, 2001). The excess risk of cesarean section is greater in low-risk pregnancies and in trials with no follow-up test to verify distress (Thacker, 2001).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
The use of internal fetal monitoring increases the likelihood of infection (Soper, 1996). In addition, the fact that EFM increases the likelihood of cesarean surgery means it necessarily increases the likelihood of infection because cesarean surgery increases the incidence of infection over vaginal birth (Maternity Center Association (MCA), 2004).	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A
In cases where membranes are intact, internal EFM involves amniotomy. Amniotomy may increase the likelihood of episodes of nonreassuring FHR (see Step 6, p. 38S).	<b>Quality:</b> See Step 6, p. 38S for grades. <b>Quantity:</b> <b>Consistency:</b>
Continuous EFM necessarily interferes with mobility. There is no formal evidence of this, other than a survey reporting that of women who said they were confined to bed, two thirds gave being "connected to things" as the reason (Declercq, 2002).	<b>Quality:</b> B ("Connected to things" could mean IVs as well as monitoring equipment.) <b>Quantity:</b> A <b>Consistency:</b> NA*
Monitoring from a central unit necessarily decreases interaction between nurses and laboring women. Supportive care is highly valued by laboring women (Hodnett, 2002).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A

(Continued)

(Continued)

### Continuous Electronic Fetal Monitoring

Rationale for Compliance	Evidence Grade
The admission test strip—that is, the routine use of continuous EFM for a limited period at hospital admission—fails to provide neonatal benefits. However, it increases the use of continuous EFM (Impey, 2003; Mires, 2001).	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
The admission test strip may increase the likelihood of operative birth (cesarean plus vaginal instrumental birth) (Impey, 2003; Mires, 2001).	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> C (Mires [2001] reported that an admission test strip increased the likelihood of operative delivery; Impey [2003] did not find an increase. Differences between trial results may reflect differing philosophies and policies among study institutions.)

A = good, B = fair, C = weak, NA = not applicable

Quality = aggregate of quality ratings for individual studies

Quantity = magnitude of effect, numbers of studies, and sample size or power

Consistency = the extent to which similar findings are reported using similar and different study designs

\*only 1 study

\*\*multiple studies in SR

### INCLUDED STUDIES

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Grant, A., O'Brien, N., Joy, M. T., Hennessy, E., & MacDonald, D. (1989). Cerebral palsy among children born during the Dublin randomised trial of intrapartum monitoring. *Lancet*, 2(8674), 1233–1236. **Reason:** Published before 1990 but this study follows up a key trial of EFM included in Thacker (2001) systematic review.

Hodnett, E. (2002). Pain and women's satisfaction with the experience of childbirth: A systematic review. *American Journal of Obstetrics and Gynecology*, 186, S160–S172.

Impey, L., Reynolds, M., MacQuillan, K., Gates, S., Murphy, J., & Sheil, O. (2003). Admission cardiotocography: A randomised controlled trial. *Lancet*, 361(9356), 465–470.

Low, J. A., Muir, D. W., Pater, E. A., & Karchmar, E. J. (1990). The association of intrapartum asphyxia in the mature fetus with newborn behavior. *American Journal of Obstetrics and Gynecology*, 163(4, Pt. 1), 1131–1135.

Luthy, D. A., Shy, K. K., van Belle, G., Larson, E. B., Hughes, J. P., Benedetti, T. J., et al. (1987). A randomized trial of electronic fetal monitoring in preterm labor. *Obstetrics & Gynecology*, 69(5), 687–695. **Reason:** Published before 1990 but trial included in Thacker (2001) systematic review and is a unique source of data on this topic.

MacDonald, D., Grant, A., Sheridan-Pereira, M., Boylan, P., & Chalmers, I. (1985). The Dublin randomized controlled trial of intrapartum fetal heart rate monitoring. *American Journal of Obstetrics and Gynecology*, 152(5), 524–539. **Reason:** Study published before 1990 but trial included in Thacker (2001) systematic review and raises key point not addressed in that review.

Maternity Center Association. (2004). Harms of cesarean versus vaginal birth: A systematic review. In *Childbirth Connection, What every pregnant woman needs to know about cesarean section* (booklet; 2nd edition 2006, revised; pp. 20–27). New York: Author. Also, retrieved December 17, 2006, from <http://childbirthconnection.org/article.asp?ck=10271>

Milsom, I., Ladfors, L., Thiringer, K., Niklasson, A., Odeback, A., & Thornberg, E. (2002). Influence of maternal, obstetric and fetal risk factors on the prevalence of birth asphyxia at term in a Swedish urban population. *Acta Obstetrica et Gynecologica Scandinavica*, 81(10), 909–917.

Mires, G., Williams, F., & Howie, P. (2001). Randomised controlled trial of cardiotocography versus Doppler auscultation of fetal heart at admission in labour in low risk obstetric population. *BMJ*, 322(7300), 1457–1460; discussion 1460–1462.

Sameshima, H., Ikenoue, T., Ikeda, T., Kamitomo, M., & Ibara, S. (2004). Unselected low-risk pregnancies and the effect of continuous intrapartum fetal heart rate monitoring on umbilical blood gases and cerebral palsy. *American Journal of Obstetrics and Gynecology*, 190(1), 118–123.

Soper, D. E., Mayhall, C. G., & Froggatt, J. W. (1996). Characterization and control of intraamniotic infection in an urban teaching hospital. *American Journal of Obstetrics and Gynecology*, 175(2), 304–309; discussion 309–310.

Thacker, S. B., & Stroup, D. F. (2001). Continuous electronic heart rate monitoring for fetal assessment during labor. *Cochrane Database of Systematic Reviews* (2), CD000063.

Yudkin, P. L., Johnson, A., Clover, L. M., & Murphy, K. W. (1994). Clustering of perinatal markers of birth

asphyxia and outcome at age five years. *British Journal of Obstetrics and Gynaecology*, 101(9), 774–781.

Cheyne, H., Dunlop, A., Shields, N., & Mathers, A. M. (2003). A randomised controlled trial of admission electronic fetal monitoring in normal labour. *Midwifery*, 19(3), 221–229. **Reason:** Poorly designed. Study was underpowered.

Nelson, K. B., Dambrosia, J. M., Ting, T. Y., & Grether, J. K. (1996). Uncertain value of electronic fetal monitoring in predicting cerebral palsy. *The New England Journal of Medicine*, 334(10), 613–618. **Reason:** Not relevant.

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Badawi, N., Kurinczuk, J. J., Keogh, J. M., Alessandri, L. M., O’Sullivan, F., Burton, P. R., et al. (1998). Intrapartum risk factors for newborn encephalopathy: The Western Australian case-control study. *BMJ*, 317(7172), 1554–1558. **Reason:** Not relevant.

#### Step 6: Limits interventions, as follows:

- induction rate of 10% or less

For the purposes of this document, induced labors are defined as labors started by artificial means of whatever kind. They are associated with an increased incidence of adverse outcomes compared with labors of spontaneous onset; however, it is possible that, in some instances, this increase may result from medical complications that may have led to the use of induction. In order to determine adverse effects related to the procedure itself, this section is confined to studies of elective induction—that is, induction for non-medical reasons such as convenience.

### Induction of Labor

Rationale for Compliance	Evidence Grade
When compared with similar populations beginning labor spontaneously, elective inductions result in the following maternal outcomes:	
<ul style="list-style-type: none"> <li>• increased use of analgesia (Boulvain, 2001).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> NA*
<ul style="list-style-type: none"> <li>• increased use of epidural anesthesia (Boulvain, 2001; Cammu, 2002; Glantz, 2005; Heinberg, 2002; Maslow, 2000; Prysak, 1998; Vahratian, 2005; van Gemund, 2003).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• increased incidence of nonreassuring fetal heart rate patterns (Glantz, 2005).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> NA*
<ul style="list-style-type: none"> <li>• increased or equivalent incidence of intrapartum fever (Glantz, 2005; Luthy, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• increased incidence of shoulder dystocia (Dublin, 2000).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> NA*
<ul style="list-style-type: none"> <li>• increased or equivalent incidence of vaginal instrumental birth (vacuum extractor or forceps birth) (Cammu, 2002; Dublin, 2000; Glantz, 2005; Vahratian, 2005; van Gemund, 2003).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• increased risk of cesarean section for all mothers (Boulvain, 2001; Cammu, 2002; Glantz, 2005; Hoffman, 2006; Maslow, 2000; Prysak, 1998; Vahratian, 2005; van Gemund, 2003).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• increased risk of cesarean section for nulliparous women (Cammu, 2002; Dublin, 2000; Glantz, 2005; Hoffman, 2006; Luthy, 2004; Maslow, 2000; Prysak, 1998; Seyb, 1999; van Gemund, 2003; Vrouwenraets, 2005; Yeast, 1999).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• increased risk of cesarean section for multiparous women (Hoffman, 2006; van Gemund, 2003).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
In addition, the following factors increase the risk of cesarean with elective induction:	
<ul style="list-style-type: none"> <li>• cervical ripening is required and/or the Bishop’s score is less than 5 (Heinberg, 2002; Prysak, 1998; Vahratian, 2005; Vrouwenraets, 2005).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A

(Continued)

**(Continued)**  
**Induction of Labor**

Rationale for Compliance	Evidence Grade
<ul style="list-style-type: none"> <li>prior cesarean section (see Step 6, p. 56S)</li> <li>age 25 years or older. The risk increases further at age 35 years or older. (Ecker, 2001; Luthy, 2004; Maslow, 2000; Vrouenraets, 2005).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>use of epidural analgesia (Prysak, 1998; Seyb, 1999; Vrouenraets, 2005).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> B
<ul style="list-style-type: none"> <li>body mass index (BMI) greater than 31 (Seyb, 1999; Vrouenraets, 2005).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> A
<p>When compared with similar populations beginning labor spontaneously, elective inductions result in the following neonatal outcomes:</p> <ul style="list-style-type: none"> <li>more or comparable numbers of low-birth-weight infants (&lt;2,500 g) (Vrouenraets, 2005; Heinberg, 2002).</li> <li>increased need for neonatal resuscitation (Boulvain, 2001)</li> <li>increased or equivalent incidence of admission to neonatal intensive care units (Boulvain, 2001; Cammu, 2002; Prysak, 1998).</li> <li>increased need for neonatal phototherapy to treat jaundice (Boulvain, 2001).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> A  <b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> NA*  <b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> B  <b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> NA*
<p>When compared with similar populations beginning labor spontaneously, elective inductions result in increased costs (Maslow, 2000).</p>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> NA*
<p>When compared with similar populations beginning labor spontaneously, elective inductions result in an increased length of hospital stay (Heinberg, 2002; Glantz, 2005; van Gemund, 2003; Vrouenraets, 2005).</p>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<p>The World Health Organization convened an international consensus conference on appropriate use of technology for birth. Participants evaluated national induction rates with respect to neonatal outcomes and determined that rates higher than 10% could not be justified (World Health Organization, 1985; M. Wagner, personal communication, August 8, 2005).</p> <ul style="list-style-type: none"> <li>A large study of a model of care attempting to achieve maximum health outcomes with the minimal use of medical intervention reported a 10% induction rate (Johnson, 2005). The study comprised 5,418 women intending home birth who reached term with a live fetus and who had not been referred for pregnancy complications. Of those, 90% achieved spontaneous labor without induction. Because the vast majority of inductions are done electively or for postdates, suspected macrosomia, or prelabor rupture of membranes at term—all categories that could potentially apply to this population—the percentage of inductions that might have been done during the preterm period would have been small. Therefore, this population serves as a reasonable proxy for an achievable induction rate overall.</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> NA*

A = good, B = fair, NA = not applicable

Quality = aggregate of quality ratings for individual studies

Quantity = magnitude of effect, numbers of studies, and sample size or power

Consistency = the extent to which similar findings are reported using similar and different study designs

\*only 1 study

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- Peck, P. (2003, April). Preinduction cervical ripening significantly increases risk of cesarean. *Medscape Medical News*. Retrieved December 17, 2006, from [http://www.medscape.com/viewarticle/453298\\_print](http://www.medscape.com/viewarticle/453298_print)

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- Cammu, H., Martens, G., Ruysinck, G., & Amy, J. J. (2002). Outcome after elective labor induction in nulliparous women: a matched cohort study. *American Journal of Obstetrics and Gynecology*, 186(2), 240–244.
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- Ecker, J. L., Chen, K. T., Cohen, A. P., & Riley, L. E., & Lieberman, E. S. (2001). Increased risk of cesarean delivery with advancing maternal age: Indications and associated factors in nulliparous women. *American Journal of Obstetrics and Gynecology*, 185(4), 883–887.
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- Johnson, K. C., & Daviss, B. A. (2005). Outcomes of planned home births with certified professional midwives: Large prospective study in North America. *BMJ*, 330(7505), 1416.
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- Yeast, J. D., Jones, A., & Poskin, M. (1999). Induction of labor and the relationship to cesarean delivery: A review of 7001 consecutive inductions. *American Journal of Obstetrics and Gynecology*, 180(3, Pt. 1), 628–633.

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Wigton, T. R., & Wolk, B. M. (1994). Elective and routine induction of labor. A retrospective analysis of 274 cases. *The Journal of Reproductive Medicine*, 39(1), 21–26. **Reason:** Study compares one type of nonindi-

cated induction to another (elective versus postdates) as described by the authors. This review is limited to studies that compare elective induction with spontaneous vaginal birth.

*Step 6: Limits interventions, as follows:*

- *episiotomy rate of 20% or less, with a goal of 5% or less*

The RCTs of liberal versus restricted use of episiotomy testify to the difficulties of changing entrenched practice. In most trials, sizeable percentages of women in the “restrict episiotomy” arm were given episiotomies. Of the seven RCTs conducted to date, the episiotomy rate in the restrictive arm was 10% or less in only two and exceeded 30% in four (Hartmann, 2005). Proper data analysis of an RCT demands that investigators keep participants with their assigned group (“intent to treat”) regardless of actual treatment. To do otherwise would defeat random allotment, the principal advantage of this study design. In trials where treatment depends little on clinician judgment, few protocol violations are likely to occur, and crossover between groups is rarely an issue. However, where this is not the case and where clinician opinion favors the intervention—as is the case with many clinicians and episiotomy—high crossover rates can occur, causing a serious problem with data interpretation. By commingling the treatments, a high degree of protocol violation decreases the power of the study to detect differences between groups. This can make it falsely appear that no difference exists between groups when, in fact, it does. For example, because many women in the “restrictive use of episiotomy” arm of the sole RCT of median episiotomy had episiotomies, an “intent to treat” analysis showed no difference between groups in the incidence of anal sphincter tears (Klein, 1992). In fact, an episiotomy preceded all but one of the 53 anal injuries.

Clinician preference for performing episiotomy causes a secondary problem in establishing a goal episiotomy rate based on data from the RCTs. The 20% rate established in the Coalition for Improving Maternity Services’s *Mother-Friendly Childbirth Initiative* came from the best available evidence at the time: the Cochrane systematic review. However, as can be seen below, much lower rates than this can be supported as upper limitations for performing this procedure.

**Episiotomy**

Rationale for Compliance	Evidence Grade
Although these rationales are given for routine or frequent use of episiotomy, in fact, compared with no episiotomy:	NEB
<ul style="list-style-type: none"> <li>• Neither median nor mediolateral episiotomy reduces the incidence of anal sphincter lacerations (Eason, 2000; Hartmann, 2005; Hudelist, 2005; Larsson, 1991; MCA, 2004; Renfrew, 1998).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• Neither median nor mediolateral episiotomy improves neonatal outcomes (Argentine Episiotomy Trial Collaborative Group, 1993; Dannecker, 2004; Klein, 1992).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• Neither median nor mediolateral episiotomy causes less pain than spontaneous tears (Eason, 2000; Hartmann, 2005; Renfrew, 1998).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• Neither median nor mediolateral episiotomies heal better or faster than spontaneous tears (Hartmann, 2005; Klein, 1994).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• Neither median nor mediolateral episiotomy prevents urinary stress incontinence in either the short- or the long-term (Eason, 2000; Ewings, 2005; Hartmann, 2005; MCA, 2004; Renfrew, 1998).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A

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Episiotomy

Rationale for Compliance	Evidence Grade
<ul style="list-style-type: none"><li>Neither median nor mediolateral episiotomy prevents anal incontinence (Hartmann, 2005; MCA, 2004).</li></ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"><li>Neither median nor mediolateral episiotomy preserves pelvic floor strength (Eason, 2000; Hartmann, 2005; MCA, 2004; Renfrew, 1998).</li></ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"><li>Neither median nor mediolateral episiotomy improves sexual functioning (Eason, 2000; Hartmann, 2005; MCA, 2004; Renfrew, 1998).</li></ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
Episiotomy causes more pain than spontaneous tears (Hartmann, 2005; Klein, 1994; Larsson, 1991).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
Women with episiotomies experience more problems with healing compared with women experiencing spontaneous lacerations (Larsson, 1991; McGuinness, 1991).	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A
Women with intact perineums experience the least pain, have the strongest pelvic floors, and experience the best sexual functioning after childbirth (Klein, 1994).	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> NA*
Both median and mediolateral episiotomy adversely affect sexual functioning (Hartmann, 2005; Klein, 1994).	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
Median episiotomy predisposes to anal sphincter lacerations (Eason, 2000; Klein, 1992, 1994; Renfrew, 1998).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
Anal sphincter injury is associated with anal sphincter weakness and defects seen on ultrasound. Anal sphincter weakness or defect increases the risk of anal incontinence (MCA, 2004).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A**
Both median and mediolateral episiotomy increase the risk of anal incontinence (Hartmann, 2005; MCA, 2004).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
Median episiotomy weakens the pelvic floor (Klein, 1994).	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> NA*
Performing mediolateral episiotomy for "imminent tear" does not decrease anal injury rates (Dannecker, 2004; Larsson, 1991). (Performing median episiotomy for this reason would increase anal sphincter laceration rates because of its predisposition to extend.)	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A
Avoiding median episiotomy during vaginal instrumental birth (forceps or vacuum extraction) reduces the likelihood of anal laceration (Combs, 1990; Helwig, 1993).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
Episiotomy rates in mixed-risk, mixed-parity women can be less than 1% among all provider types (obstetricians, family practitioners, midwives) (Albers, 2005).	<b>Quality:</b> A <b>Quantity:</b> NA to reporting a rate <b>Consistency:</b> NA to reporting a rate
Episiotomy rates in low-risk, mixed-parity women can be 5% or less (Johnson, 2005; MCA, 2004).	<b>Quality:</b> A <b>Quantity:</b> NA to reporting a rate <b>Consistency:</b> NA to reporting a rate
Episiotomy rates in low-risk nulliparous women can average 9% and can be as low as 2% (MCA, 2004).	<b>Quality:</b> A <b>Quantity:</b> NA to reporting a rate <b>Consistency:</b> NA to reporting a rate

A = good, B = fair, NA = not applicable, NEB = no evidence of benefit

Quality = aggregate of quality ratings for individual studies

Quantity = magnitude of effect, numbers of studies, and sample size or power

Consistency = the extent to which similar findings are reported using similar and different study designs

\*only 1 study

\*\*multiple studies in SR

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Kettle, C. (2005). Perineal care. *Clinical Evidence*, (13), 1780–1795. **Reason:** Secondary source. Summarizes Carroli (1999), a SR that has been superseded by Hartmann (2005), plus Dannecker (2004) for the only outcome relevant here.

 Childbirth Connection's "Alert" document, NIH Cesarean Conference: Interpreting Meeting and Media Reports (updated October 2006), contains a cogent analysis of the flaws and weaknesses of the March 2006 NIH State-of-the-Science Conference. View Childbirth Connection's document online at <http://www.childbirthconnection.org/article.asp?ck=10375>

#### Step 6: Limits interventions, as follows:

- total cesarean rate of 10% or less in community hospitals, and 15% or less in tertiary hospitals

Current arguments articulated in the March 2006 National Institutes of Health (NIH) State-of-the-Science Conference Statement against setting a goal cesarean rate rest on four premises (NIH, 2006):

- Planned cesarean surgery is as safe or nearly as safe as vaginal birth provided women limit family size to one or two children (p. 12).
- Planned cesarean surgery is less risky than unplanned cesarean surgery (p. 6).
- Cesarean section may prevent urinary incontinence (p. 6).
- Currently recommended rate limits are opinion based and artificial (p. 4).

As this portion of Step 6 makes clear, cesarean section significantly increases the risk of a long list of adverse outcomes in mothers and babies, some of them catastrophic. It is true that planned cesarean surgery reduces the risk of certain harms compared with unplanned surgery. Nonetheless, the woman still emerges with a uterine scar and substantial possibility of dense surgical adhesions, both of which can have long-term consequences for her future health and reproduction.

As can be seen below, cesarean section offers little protection from urinary or anal incontinence in the childbearing years and none at all in older women. Even the minimal short-term benefits are reported in studies that did not take into account the effects of modifiable elements of conventional obstetric management in injuring and weakening the pelvic floor. Chief among these are both median and mediolateral episiotomy and vaginal instrumental delivery (MCA, 2004). Other flaws that make it difficult to determine the true excess risk, if any, of vaginal birth are (MCA, 2004):

- Definition of incontinence: Studies often combine women with mild symptoms with more severe problems or fail to distinguish frequent from infrequent symptoms.
- Time elapsed since birth: Symptoms of incontinence become milder and less frequent over time.

Moreover, urinary incontinence can often be abated or cured by conservative measures, such as losing weight or engaging in a program of pelvic floor exercises (Groutz, 2004; MCA, 2004).

Finally, the oft-cited 10–15% maximum cesarean rate first recommended in 1985 by the World Health Organization (WHO) after an international consensus conference was neither opinion-based nor artificially derived (WHO, 1985). In fact, it was founded upon the statistic that “[c]ountries with some of the lowest perinatal mortality rates in the world have caesarean section rates of less than 10%” (WHO, 1985, p. 437).

As can be seen below as well, that maximum has since been confirmed by numerous studies demonstrating that cesarean rates can be 15% or less in unselected populations without any deleterious effect on maternal or perinatal outcomes. Indeed, women and babies are likely to be healthier because they have not been unnecessarily exposed to the harms of cesarean delivery.

## Cesarean

Rationale for Compliance	Evidence Grade
When compared with vaginal birth, cesarean section increases the likelihood of these adverse maternal outcomes:	
<ul style="list-style-type: none"> <li>death (MCA, 2004).</li> </ul>	<p><b>Quality:</b> B  <b>Quantity:</b> A  <b>Consistency:</b> A**</p>
<ul style="list-style-type: none"> <li>hysterectomy (Burrows, 2004; Forna, 2004; Kwee, 2006; MCA, 2004; Selo-Ojeme, 2005): Hysterectomy increases the risk of other intraoperative complications (bladder injury) and postoperative complications (hematologic, infectious, pulmonary, genitourinary, gastrointestinal, cardiovascular, psychiatric, neurologic) (Forna, 2004; Selo-Ojeme, 2005).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> A</p>
<ul style="list-style-type: none"> <li>thromboembolic events (deep venous clots, pulmonary embolism, stroke) (Burrows, 2004; Koroukian, 2004; MCA, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> A</p>
<ul style="list-style-type: none"> <li>surgical injuries (MCA, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> NA*** However, surgical injuries to bladder, bowel, or blood vessels do not occur in vaginal birth.</p>
<ul style="list-style-type: none"> <li>anesthetic complications (Koroukian, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> B  <b>Consistency:</b> NA*</p>
<ul style="list-style-type: none"> <li>longer postpartum stays (Liu, 2005; MCA, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> A</p>
<ul style="list-style-type: none"> <li>hospital readmissions (Liu, 2005; MCA, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> A</p>
<ul style="list-style-type: none"> <li>hospital readmission sooner after discharge and for longer duration (Liu, 2005).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> NA*</p>
<ul style="list-style-type: none"> <li>infections (Burrows, 2004; Koroukian, 2004; MCA, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> A</p>
<ul style="list-style-type: none"> <li>hemorrhage requiring transfusion (cesarean during labor) (Burrows, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> B  <b>Consistency:</b> NA*</p>
<ul style="list-style-type: none"> <li>more severe and longer lasting postpartum pain (MCA, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> A**</p>
<ul style="list-style-type: none"> <li>unsatisfactory birth experience (MCA, 2004).</li> </ul>	<p><b>Quality:</b> A  <b>Quantity:</b> A  <b>Consistency:</b> A</p>

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**(Continued)**  
**Cesarean**

Rationale for Compliance	Evidence Grade
<ul style="list-style-type: none"> <li>reduced early contact with newborn (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>negative early reaction to infant (MCA, 2004).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>may cause depression (Carter, 2006; MCA, 2004). Inconsistent findings may be explained by variations in the context in which the cesarean occurs, differences in the woman's expectations, and the quality of her birth experience.</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> C
<ul style="list-style-type: none"> <li>psychological trauma (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>poor overall mental health and self-esteem (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>poor overall physical functioning (MCA, 2004).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>chronic pain (Declercq, 2002; Latthe, 2006; MCA, 2004; Nikolajsen 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>adhesions (Lyell, 2005; Myers, 2005; Phipps, 2005): Adhesions can cause chronic pain and increase the likelihood of surgical injury during future operations.</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>bowel obstruction (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A**
When compared with vaginal birth, cesarean section increases the likelihood of these adverse neonatal outcomes:	
<ul style="list-style-type: none"> <li>surgical laceration (Dessole, 2004; MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>respiratory complications serious enough to require admission to a special care nursery (Gerten, 2005; MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>may increase frequency of special care nursery admission (Fogelson, 2005).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> NA*
<ul style="list-style-type: none"> <li>not breastfeeding/failure of breastfeeding (MCA, 2004).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>may increase likelihood of asthma (Juhn, 2005; Maitra, 2004; MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> B
<ul style="list-style-type: none"> <li>sensitivity to allergens (Laubereau, 2004; Negele, 2004).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> A

(Continued)

**(Continued)**  
**Cesarean**

Rationale for Compliance	Evidence Grade
When compared with vaginal birth, a history of cesarean section increases the likelihood of these adverse reproductive outcomes:	
<ul style="list-style-type: none"> <li>infertility (MCA, 2004; Mollison, 2005; Smith, 2006). Although studies consistently find fewer subsequent births to women after cesarean at first birth compared with first vaginal birth, it is not possible to determine from population-based studies whether decreased fertility is associated with cesarean surgery or to confounding factors that both reduce fertility and increase the likelihood of cesarean section.</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>involuntary infertility (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>voluntary infertility (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> NA***
<ul style="list-style-type: none"> <li>ectopic pregnancy (MCA, 2004; Mollison, 2005). A variation specific to cesarean section is implantation within the cesarean scar (Jurkovic, 2003; Maymon, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>placenta previa (Getahun, 2006; MCA, 2004; Olive, 2005).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>major maternal morbidity in cases of placenta previa compared with women with placenta previa who have no history of cesarean section (Olive, 2005). Major maternal morbidity defined as severe postpartum hemorrhage, acute renal failure, admission to intensive care, ventilation, shock, disseminated intravascular coagulation, or hysterectomy or other procedures to control bleeding or prevent maternal death.</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> NA*
<ul style="list-style-type: none"> <li>placenta accreta (MCA, 2004). This is associated with high rates of catastrophic and life-threatening outcomes, including hysterectomy, severe hemorrhage, and the complications that accompany severe hemorrhage, such as disseminated intravascular coagulation, need for additional surgery, and maternal death (Forna, 2004; Makoha, 2004; Selo-Ojeme, 2005; Silver, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>placental abruption (Getahun, 2006; MCA, 2004; Tikkanen, 2006).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>uterine rupture in future pregnancies or labors (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A**
When compared with vaginal birth, a history of cesarean section increases the likelihood of these adverse outcomes for babies of future pregnancies:	
<ul style="list-style-type: none"> <li>perinatal death (MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>may increase unexplained stillbirth at term (Bahtiyar, 2006; MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> B
<ul style="list-style-type: none"> <li>low birth weight and preterm birth (MCA, 2004; Seidman, 1994).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A

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Cesarean

Rationale for Compliance	Evidence Grade
<ul style="list-style-type: none"><li>congenital malformation (MCA, 2004).</li></ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> C**
<ul style="list-style-type: none"><li>central nervous system injury (MCA, 2004).</li></ul>	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> NA***
Elective cesarean section offers minimal protective benefit against moderate to severe urinary incontinence in the short term and none at all in the long term (Chin, 2006; Groutz 2004; MCA, 2004). The excess percentage of women experiencing urinary incontinence at 1 year is 6% or less.	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
Elective cesarean section offers minimal protective benefit against anal incontinence in the short term and none at all in the long term (MCA, 2004). The excess percentage of women experiencing anal incontinence at 1 year is about 3%.	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
The cesarean section rate can safely be 7% or less in a mixed parity, low-risk population (Gould, 2004; Johnson, 2005; MCA, 2004).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
The cesarean section rate can safely be 12% or less in a mixed parity, mixed-risk population (MCA, 2004).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A**
The cesarean section rate can safely be 11% or less in a low-risk, nulliparous population (Johnson, 2005; MCA, 2004).	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A

A = good, B = fair, C = weak, NA = not applicable

Quality = aggregate of quality ratings for individual studies

Quantity = magnitude of effect, numbers of studies, and sample size or power

Consistency = the extent to which similar findings are reported using similar and different study designs

\*only 1 study

\*\*multiple studies in a SR

\*\*\*only 1 study in a SR

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- clinically insignificant differences between cesarean rates, especially between overall expected and higher-than-expected rates (8% vs. 13% vs. 14%);
  - failure to define asphyxia;
  - clinically insignificant absolute difference in asphyxia/trauma rates between hospitals at and below predicted cesarean-section rates (1.29% low, 1.26% expected, absolute difference 3 per 10,000); and
  - the assumption that care in expected rate hospitals was optimal.
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- Bloom, S. L., Spong, C. Y., Weiner, S. J., Landon, M. B., Rouse, D. J., Varner, M. W., et al. (2005). Complications of anesthesia for cesarean delivery. *Obstetrics & Gynecology*, 106(2), 281–287. **Reason:** Study not relevant.
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- Mahoney, S. F., & Malcoe, L. H. (2005). Cesarean delivery in Native American women: Are low rates explained by practices common to the Indian health service? *Birth*, 32(3), 170–178. **Reason:** Poorly designed. Study does not report neonatal outcomes or compare them to a similar population with higher cesarean rates. There is no means to evaluate the safety of having a low cesarean rate.

McKenna, D. S., Ester, J. B., & Fischer, J. R. (2003). Elective cesarean delivery for women with a previous anal sphincter rupture. *American Journal of Obstetrics and Gynecology*, 189(5), 1251–1256. **Reason:** Poorly designed. Study is a risk-benefit analysis of elective cesarean in women with anal sphincter laceration at first birth. Weaknesses include the following:

- Defines anal incontinence as leakage of gas as well as fecal incontinence or urgency. Most cases of incontinence are confined to gas leakage, which means weighing the adverse effects of major surgery against the benefits of preventing flatus. The investigators calculate that, for every 1,880 cases of anal incontinence prevented, one woman will die. In the Year 2000, 12 additional women would die to prevent 22,107 cases of anal incontinence.
- Assumes elective cesarean prevents all cases of anal incontinence and, at the same time, cites a study in the discussion in which 3% of women having elective cesarean had anal incontinence at 10 months postpartum.
- Calculates a 5.3% incidence of anal injury in the first pregnancy without accounting for the contribution of modifiable factors such as median episiotomy or vaginal instrumental birth.
- Fails to include consideration of many excess risks of cesarean surgery and repeat cesarean surgery from the comparison with vaginal birth, including infertility, ectopic pregnancy, uterine rupture, placental abruption, or any excess perinatal morbidity or mortality.

McKinnie, V., Swift, S. E., Wang, W., Woodman, P., O'Boyle, A., Kahn, M., et al. (2005). The effect of pregnancy and mode of delivery on the prevalence of urinary and fecal incontinence. *American Journal of Obstetrics and Gynecology*, 193(2), 512–517; discussion 517–518. **Reason:** Poorly designed. No information on episiotomy, which, because this is a U.S. study, would be median episiotomy and, therefore, an important confounding factor for anal sphincter injury and weakness. No power calculation. Not population based. No consideration of time since most recent birth. Incontinence symptoms diminish markedly in prevalence and severity in the first 6 months after childbirth.

National Collaborating Centre for Women's and Children's Health. (2004, April). *Caesarean section. Clinical guideline*. London: RCOG Press. Also, retrieved December 17, 2006, from <http://www.nice.org.uk/pdf/CG013fullguideline.pdf> **Reason:** Have better quality research. The Maternity Center Association (2004) SR reviews many of the same studies and addresses a broader range of issues of interest to women and clinicians in making informed decisions, and it excludes studies for reasons that this SR fails to consider. For example, this review accepts Cochrane Database systematic reviews with an unacceptably high degree of protocol violations (crossovers between treatment groups), while the Maternity Center Association (2004) SR does not.

Pollack, J., Nordenstam, J., Brismar, S., Lopez, A., Altman, D., & Zetterstrom, J. (2004). Anal incontinence after vaginal delivery: A five-year prospective cohort study. *Obstetrics & Gynecology*, 104(6), 1397–1402. **Reason:** Not applicable. No cesarean comparison group.

Press, J., Klein, M. C., & von Dadelszen, P. (2006). Mode of delivery and pelvic floor dysfunction: A systematic review of the literature on urinary and fecal incontinence and sexual dysfunction by mode of delivery. In *Medscape*. Retrieved December 16, 2006, from [http://www.medscape.com/viewprogram/4989\\_pnt](http://www.medscape.com/viewprogram/4989_pnt) **Reason:** Poorly written. Study fails to reveal methodology.

Puza, S., Roth, N., Macones, G. A., Mennuti, M. T., & Morgan, M. A. (1998). Does cesarean section decrease the incidence of major birth trauma? *Journal of Perinatology*, 18(1), 9–12. **Reason:** Poorly designed. This before/after study looks at whether the increase in cesarean rates resulted in decreased neonatal trauma without investigating other factors that might have changed along with change in cesarean rates.

Rouse, D. J., Landon, M., Leveno, K. J., Leindecker, S., Varner, M., Caritis, S., et al. (2004). The Maternal-Fetal Medicine Units cesarean registry: Chorioamnionitis at term and its duration-relationship to outcomes. *American Journal of Obstetrics and Gynecology*, 191(1), 211–216. **Reason:** Have better-quality research. Investigators conclude that chorioamnionitis increased maternal and neonatal morbidity after cesarean, but defined chorioamnionitis as intrapartum fever without accounting for epidural use.

Rouse, D. J., Leindecker, S., Landon, M., Bloom, S., Varner, M., Moawad, A., et al. (2005). The MFMU Cesarean Registry: Uterine atony after primary cesarean delivery. *American Journal of Obstetrics and Gynecology*, 193(3, Pt. 2), 1056–1060. **Reason:** Not applicable. No vaginal birth comparison group.

Seffah, J. D. (2005). Re-laparotomy after Cesarean section. *International Journal of Gynaecology and Obstetrics*, 88(3), 253–257. **Reason:** Study not applicable. Carried out in a resource-poor country (Ghana).

Sule, S. T., & Nwasor, E. O. (2005). Factors affecting blood loss at cesarean section. *International Journal of Gynaecology and Obstetrics*, 88(2), 150–151. **Reason:** Study not applicable. Carried out in a resource-poor country (Nigeria).

Taylor, L. K., Simpson, J. M., Roberts, C. L., Olive, E. C., & Henderson-Smart, D. J. (2005). Risk of complications in a second pregnancy following caesarean section in the first pregnancy: A population-based study. *The Medical Journal of Australia*, 183(10), 515–519. **Reason:** Study not relevant. There is no statistical analysis of outcomes at second birth of all women having cesarean at first birth versus all women having first vaginal birth. Study compares maternal and neonatal outcomes of:

- all women having initial cesarean followed by planned VBAC with all women having first vaginal birth and laboring in second pregnancy; and
- all women having initial cesarean followed by planned repeat cesarean section with all women



having first vaginal birth and planned cesarean section at second birth.

- Tran, T. S., Jamulitrat, S., Chongsuvivatwong, V., & Geater, A. (2000). Risk factors for postcesarean surgical site infection. *Obstetrics & Gynecology*, 95(3), 367–371. **Reason:** Study not applicable. Carried out in a resource-poor country (Viet Nam).
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- Viktrup, L., & Lose, G. (2001). The risk of stress incontinence 5 years after first delivery. *American Journal of Obstetrics and Gynecology*, 185(1), 82–87. **Reason:** Cannot determine relationship between obstetric management and incontinence.
- Waterstone, M., Bewley, S., & Wolfe, C. (2001). Incidence and predictors of severe obstetric morbidity: Case-control study. *BMJ*, 322(7294), 1089–1093; discussion 1093–1094. **Reason:** Have more recent research.
- Zanardo, V., Simbi, A. K., Savio, V., Micaglio, M., & Trevisanuto, D. (2004). Neonatal resuscitation by laryngeal mask airway after elective cesarean section. *Fetal Diagnosis and Therapy*, 19(3), 228–231. **Reason:** Poorly designed. Study examines need for neonatal resuscitation after elective cesarean, but defines “elective cesarean” as being carried out “before labor,” which means the cesareans may not all have been truly elective, that is, without medical indication. Fogelson (2005), an included study (see p. 53S), reported on respiratory outcomes after truly elective cesareans, that is, women undergoing “uncomplicated, term, elective repeat cesareans.”

*Step 6: Limits interventions, as follows:*

- *VBAC rate of 60% or more, with a goal of 75% or more*

Several decades of research into the question of planned VBAC versus elective repeat cesarean have produced hundreds of studies involving tens of thousands of women and a large body of knowledge on the subject. Nonetheless, many of the prominent studies are beset by serious problems that make it difficult to gauge the true comparative risks of planned vaginal birth versus elective repeat cesarean—problems that, moreover, tend to bias the picture in favor of repeat cesarean. The problems include the following:

- Planning status cannot be determined accurately in population-based studies large enough to detect differences between groups for rare, but severe, adverse outcomes. Without knowing whether repeat cesareans were truly elective and VBAC women and their babies were healthy at labor onset, we cannot have confidence that outcomes are attributable to birth route. Even the sole prospective study (Landon et al., 2004) suffers from this defect (Goer, 2005).
- Most studies comparing the two birth routes report only on outcomes occurring in the perinatal period. They do not take into account the escalating risks of accumulating cesarean surgeries when drawing conclusions about the balance between the potential harms of planned vaginal birth versus planned repeat surgery. Because of the increased risk of uterine scar rupture during VBAC labor and the increased cesarean complication rate in unplanned cesareans, there may be equipoise or near equipoise between the two alternatives provided that women limit family size to two children. However, sizeable percentages of women will go on to have more pregnancies, intended or unintended. According to the 2002 U.S. National Survey of Family Growth, 36% of women aged 40 to 44 years have more than two children (U.S. Department of Health and Human Services, 2005). That percentage will be much higher among populations where large families are the norm. The increasing risk of dense surgical adhesions and the resultant potential for experiencing chronic pain, injuries during future surgeries, and bowel obstruction is also missing from the equation.
- Scar rupture rates and vaginal birth rates in women planning VBAC depend heavily on care provider philosophy and policies regarding VBAC. Modifiable factors such as preset limits on labor duration, inducing and augmenting labor, what agents and dosages are used for those procedures, and uterine suture technique and material at the initial surgery have profound effects, as the wide ranges reported for these outcomes in the various studies attest.

When the long-term view is taken, it becomes clear that maximizing VBAC rates among women who choose VBAC and minimizing the risk of scar rupture during planned vaginal births will produce the best maternal-child health and reproductive outcomes. This is because those goals reduce exposure to the potential harms of repeated cesarean surgeries, of VBAC labors, and to the excess morbidity attendant on

unplanned cesarean sections. It also bears pointing out that the policies and procedures espoused in the *Ten Steps of Mother-Friendly Care* will best promote safer VBAC and higher VBAC rates. In furtherance of those twin goals, clinicians have the obligation to provide women with complete, unbiased, and evidence-based information on the comparative benefits and harms of planned vaginal birth versus planned repeat cesarean so that they may make an informed decision.

Nonetheless, regardless of the care provider’s opinion of the relative safety of the two options in any individual case, the choice rests solely in the hands of the pregnant woman, unless she chooses to cede her right to her care provider. VBAC denial, or instituting restrictions that amount to VBAC denial, constitutes coercion in that it forces women to consent to major surgery in order to obtain care. The American College of Obstetricians and Gynecologists (2000) guarantees women freedom from this violation of their rights, as the following passage makes clear:

*Once a patient has been informed of the material risks and benefits involved with a treatment, test, or procedure, that patient has the right to exercise full autonomy in deciding whether to undergo the treatment, test, or procedure or whether to make a choice among a variety of treatments, tests, or procedures. In the exercise of that autonomy, the informed patient also has the right to refuse to undergo any of these treatments, tests, or procedures. . . . Performing an operative procedure on a patient without the patient’s permission can constitute ‘battery’ under common law. In most circumstances this is a criminal act. . . . Such a refusal [of consent] may be based on religious beliefs, personal preference, or comfort. (pp. 46–47)*

Note that, although cesarean section is a “procedure” (something that requires a care provider to take positive action for it to occur), planned vaginal birth is not because labor is the inevitable end of pregnancy. Note too that the right to refuse is not predicated on the woman having what the clinician considers an acceptable reason.

Some have claimed that the weaknesses of the studies cannot be overcome without a randomized controlled trial, and, indeed, one is currently underway in Australia.<sup>a</sup> As will be seen below, however, those weaknesses do not prevent arriving at an adequate understanding of the comparative benefits and harms of planned vaginal birth versus planned cesarean surgery, an understanding that is, moreover, unlikely to be improved by such a trial for the reasons listed above.

## VBAC

Rationale for Compliance	Evidence Grade
Compared with one cesarean birth, accumulating cesarean surgeries imposes increasing risks of (see pp. 48S–56S for risks of an individual cesarean):	
<ul style="list-style-type: none"> <li>• adhesions (Makoha, 2004; Seidman, 1994): Known risks of adhesions include chronic pain, the possibility of causing intestinal obstruction, and increased risk of injury during subsequent surgeries.</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• cesarean scar ectopic pregnancy (Jurkovic, 2003; Maymon, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• placenta previa (Getahun, 2006; Makoha, 2004; MCA, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>• placenta accreta (Silver, 2004): Placenta accreta is associated with high rates of catastrophic and life-threatening outcomes, including hysterectomy, severe hemorrhage and the complications that accompany severe hemorrhage such as disseminated intravascular coagulation, need for additional surgery, and maternal death (Forna, 2004; Makoha, 2004; Selo-Ojeme, 2005; Silver, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A

(Continued)

**(Continued)**  
**VBAC**

Rationale for Compliance	Evidence Grade
<ul style="list-style-type: none"> <li>placenta previa/accreta <sup>b</sup> (Chattopadhyay, 1993; Makoha, 2004; Miller, 1997; Silver, 2004; To, 1995).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>hemorrhage requiring transfusion <sup>c</sup> (Makoha, 2004; Silver, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>hysterectomy (Kwee, 2006; Makoha, 2004; Selo-Ojeme, 2005; Silver, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>bladder injury <sup>d</sup> (Makoha, 2004; Phipps, 2005).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> B <b>Consistency:</b> A
<ul style="list-style-type: none"> <li>neonatal respiratory complications (Seidman, 1994).</li> </ul>	<b>Quality:</b> C <b>Quantity:</b> C <b>Consistency:</b> NA*
<p>Compared with planned vaginal birth, elective repeat cesarean section increases the risk of:</p> <ul style="list-style-type: none"> <li>maternal infection (Guise, 2003).</li> </ul>	<b>Quality:</b> C <b>Quantity:</b> B <b>Consistency:</b> A**
<ul style="list-style-type: none"> <li>hemorrhage requiring transfusion <sup>c</sup> (Guise, 2003; Macones, 2005; Mozurkewich, Hutton 2000).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> B
<ul style="list-style-type: none"> <li>hysterectomy (Guise, 2003; Mozurkewich, 2000).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> B (One SR reported fewer hysterectomies; the other reported similar rates.)
<ul style="list-style-type: none"> <li>neonatal respiratory complications (Loebel, 2004).</li> </ul>	<b>Quality:</b> B <b>Quantity:</b> C <b>Consistency:</b> NA*
<p>Vaginal birth appears to be protective against symptomatic scar rupture (Lieberman, 2001; Macones, 2005; Smith, 2004).</p>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
<p>The incidence of symptomatic uterine scar rupture can be 4 per 1,000 planned vaginal births or fewer <sup>e</sup> (Gonen 2006; Guise, 2003; Landon et al., 2004; Lieberman, 2004; Loebel, 2004; McMahan, 1996; Mozurkewich, 2000; Smith, 2004).</p>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<p>Planned repeat cesarean does not eliminate the possibility of symptomatic uterine scar rupture (Lydon-Rochelle, 2001; Mozurkewich, 2000).</p>	<b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> A
<p>Systematic reviews that calculate absolute excess risk (the arithmetic difference between the two rates) of symptomatic uterine scar rupture with planned VBAC compared with planned repeat cesarean report values of 2.3 and 2.7 per 1,000 (Guise, 2003; Mozurkewich, 2000). This means that 270–435 elective cesareans would be needed to prevent one scar rupture (number needed to treat).</p>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
<p>The perinatal mortality rate associated with symptomatic uterine scar rupture during VBAC labor is extremely low:</p>	

(Continued)

**(Continued)**  
**VBAC**

Rationale for Compliance	Evidence Grade
<ul style="list-style-type: none"> <li>The perinatal mortality rate associated with symptomatic uterine scar rupture during planned vaginal birth ranges from 1.5 to 4.0 per 10,000 VBAC labors (Guise, 2003; Landon et al., 2004; Lydon-Rochelle, 2001; Mozurkewich, 2000; Smith 2002).</li> </ul>	<p><b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> NA to reporting a range of rates</p>
<ul style="list-style-type: none"> <li>The excess risk of perinatal death associated with symptomatic uterine scar rupture compared with planned cesarean section ranges from 1.4 to 2.6 per 10,000 planned VBACs (Guise, 2004; Landon et al., 2004). To put this number into perspective, the excess risk of losing the pregnancy associated with having mid-trimester amniocentesis is 60 per 10,000 (Seeds, 2004). This means from 3,846 to 7,142 elective cesareans would be needed to prevent one perinatal death.</li> </ul>	<p><b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> NA to reporting a range of rates</p>
<p>Conclusions in the two studies examining the issue differ on whether a decision-to-incision interval of less than 20 minutes improves outcomes in cases of symptomatic uterine scar rupture (Guise, 2003). The study finding that it did included cases in which the infant required resuscitation but sustained no morbidity. If these cases are removed from consideration, only one case of asphyxia remains among the babies with later emergent delivery.</p>	<p><b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> C</p>
<p>Modifiable factors may increase the risk of symptomatic uterine scar rupture. These include:</p> <ul style="list-style-type: none"> <li>induction of labor with oxytocin (Delaney, 2003; Guise, 2003; Landon et al., 2004; Lieberman, 2001; Locatelli, 2004; Lydon-Rochelle, 2001; Macones, 2005; Smith, 2004).</li> <li>induction of labor with PGE2 (Delaney, 2003; Guise, 2003; Locatelli, 2004; Lydon-Rochelle, 2001; Macones 2005; Smith, 2004).</li> <li>induction of labor with misoprostol (Lieberman, 2001; Plaut, 1999; Wing, 1998).</li> <li>augmentation of labor (Gonen, 2006; Landon et al., 2004; Macones, 2005; Lieberman, 2001).</li> <li>possibly single-layer uterine closure<sup>h</sup> (Bujold, 2002; Durnwald, 2003).</li> </ul>	<p><b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> C<sup>f</sup></p> <p><b>Quality:</b> B <b>Quantity:</b> A <b>Consistency:</b> C<sup>f</sup></p> <p><b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> A</p> <p><b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> B<sup>g</sup></p> <p><b>Quality:</b> B <b>Quantity:</b> B <b>Consistency:</b> C<sup>i</sup></p>
<p>Adverse outcomes in planned vaginal births occur mostly in women having cesarean sections (Landon et al., 2004; Loebel, 2004; McMahon, 1996; Phipps, 2005). This argues for policies that maximize likelihood of vaginal birth.</p>	<p><b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A</p>
<p>Three out of four women or more in an unselected population who plan VBAC should have a vaginal birth. This implies that VBAC rates lower than 70% are due to modifiable factors.</p> <ul style="list-style-type: none"> <li>Many studies and systematic reviews report VBAC rates around 75% in an unselected population, and rates as high as 87% are reported (Gonen, 2006; Guise, 2003; Landon et al., 2004; Lieberman, 2004; Locatelli, 2004; Loebel, 2004; Macones, 2005; Smith, 2002).</li> <li>Rates of 95% have been reported in women with optimal profiles for VBAC (Guise, 2003).</li> </ul>	<p><b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> NA to reporting a range of rates</p> <p><b>Quality:</b> A <b>Quantity:</b> NA to reporting a rate <b>Consistency:</b> NA to reporting a rate</p>

(Continued)

**(Continued)**  
**VBAC**

Rationale for Compliance	Evidence Grade
<ul style="list-style-type: none"> <li>Rates as high as 81% have been reported among women with no prior vaginal birth (Lieberman, 2004).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> NA to reporting a rate <b>Consistency:</b> NA to reporting a rate
<ul style="list-style-type: none"> <li>Even when maternal history and obstetric factors are suboptimal for VBAC, the chance of VBAC can be at least 50/50 (Guise, 2003; Landon, 2004; Macones, 2005; Rosen, 1990).</li> </ul>	<b>Quality:</b> A <b>Quantity:</b> A <b>Consistency:</b> A
Inducing labor appears to reduce the likelihood of vaginal birth (Delaney, 2003; Guise, 2003; Landon, 2004; Locatelli, 2004). <sup>1</sup>	<b>Quality:</b> C <b>Quantity:</b> A <b>Consistency:</b> A

A = good, B = fair, C = weak, NA = not applicable

Quality = aggregate of quality ratings for individual studies

Quantity = magnitude of effect, numbers of studies, and sample size or power

Consistency = the extent to which similar findings are reported using similar and different study designs

\*only 1 study

\*\*multiple studies in a SR

\*\*\*only 1 study in a SR

<sup>a</sup>The Australian trial is being protested by Australian grassroots normal birth advocates who question the ethics of assigning healthy women to major abdominal surgery when so little new knowledge can be gained.

<sup>b</sup>The authors of a case series on cesarean scar ectopic pregnancies theorized that placenta previa/accreta results when a cesarean scar implantation develops into an intrauterine pregnancy (Jurkovic, 2003).

<sup>c</sup>Need for transfusion was used rather than hemorrhage because it is a more objective measure of blood loss. In addition, definitions of hemorrhage vary between vaginal birth and surgical delivery. The usual definition of hemorrhage at vaginal birth is 500 ml, whereas for surgery it is 1,000 ml. Moreover, while blood loss is hard to measure accurately in either case, it is especially so at vaginal birth.

<sup>d</sup>Surgical injury at repeat cesarean is more common because of the presence of adhesions.

<sup>e</sup>Studies report higher scar rupture rates, but the fact that rates this low are reported in large, unselected VBAC populations indicates that substantially higher rates are almost certainly due to modifiable factors.

<sup>f</sup>Inconsistencies can probably be explained by variations in protocol and patient selection (Locatelli, 2004; Macones, 2005). For example, one study reported an increase in scar rupture with the combination of induction with oxytocin and PGE2 but not with either agent used separately (Macones, 2005).

<sup>g</sup>Inconsistencies may be explained by variations in oxytocin augmentation protocols.

<sup>h</sup>One study found a significant increase with single-layer closure while another did not. The trial that did not raised the issue of differences in suture material and technique between the two studies possibly affecting scar strength (Durnwald, 2003). No systematic reviews could be found addressing the issue of material and technique and scar strength in subsequent VBAC labors. Until this controversy is settled, a conservative approach would dictate using double-layer closure because many studies predating the use of single-layer closure report symptomatic scar rupture rates less than 5 per 1,000.

<sup>i</sup>Inconsistencies may be explained by variations in suture material and technique.

<sup>j</sup>Only one study reporting this adjusted for the fact that indications for labor induction might also increase the likelihood of cesarean section (Delaney, 2003).

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- Neither RCT evaluates usual induction protocols. One is a trial of mifepristone and the other administers PGE2 once weekly.
  - These two trials are the only studies of oxytocin that report data on induction separate from augmentation. Starting labor versus augmenting a labor already in progress is likely to have different effects on both repeat cesarean rates and scar rupture rates.
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- Roberts, R. G., Bell, H. S., Wall, E. M., Moy, J. G., Hess, G. H., & Bower, H. P. (1997). Trial of labor or repeated cesarean section. The woman's choice. *Archives of Family Medicine*, 6(2), 120–125. **Reason:** Other included SRs excluded studies that failed to distinguish between scar dehiscence and rupture. This one failed to do so.
- Rosen, M. G., Dickinson, J. C., & Westhoff, C. L. (1991). Vaginal birth after cesarean: A meta-analysis of morbidity and mortality. *Obstetrics & Gynecology*, 77(3), 465–470. **Reason:** Other included SRs excluded studies that failed to distinguish between scar dehiscence and rupture. This one failed to do so.
- Sims, E. J., Newman, R. B., & Hulsey, T. C. (2001). Vaginal birth after cesarean: To induce or not to induce. *American Journal of Obstetrics and Gynecology*, 184(6), 1122–1124. **Reason:** Study excluded from Guise (2003) SR, an included study here.
- Stone, C., Halliday, J., Lumley, J., & Brennecke, S. (2000). Vaginal births after Caesarean (VBAC): A population study. *Paediatric and Perinatal Epidemiology*, 14(4), 340–348. **Reason:** Questionable generalizability and relevance. Study evaluates scar ruptures and perinatal deaths in Australian women giving birth in 1995 whose birth immediately prior to the index birth was a cesarean. The VBAC rate (56%) was substantially below what can be achieved in women planning vaginal birth, making its generalizability questionable. The authors attribute this to excluding women with prior cesarean but a vaginal birth in the penultimate birth. Excluding these women also makes the relevance of the study questionable. The authors depend on ICD codes to determine uterine rupture, but acknowledge that accuracy is poor. They cite a scar rupture rate in women having VBAC labor as 0.2% and no scar ruptures in women having repeat cesarean section. However, two occurred in multiparous women whose penultimate birth was vaginal, but who might have had a cesarean prior to that, and two women whose previous birth route was not identified. This means the actual scar rupture rate in the VBAC group may have been higher than reported. They exclude a case of scar rupture before labor in a multiparous woman whose penultimate birth and birth in 1995 were both cesareans. This is puzzling, as she would seem to fit their criteria for inclusion. She would then be a case of scar rupture in the planned cesarean group. All in all, this study does not seem to have any useful data for supporting or refuting any of the VBAC rationales or establishing a reasonable VBAC rate.
- Taylor, D. R., Doughty, A. S., Kaufman, H., Yang, L., & Iannucci, T. A. (2002). Uterine rupture with the use of PGE2 vaginal inserts for labor induction in women with previous cesarean sections. *The Journal of Reproductive Medicine*, 47(7), 549–554. **Reason:** Study not applicable. The high uterine rupture rate (1.8%) implies iatrogenic factors involved.
- Tucker, J. M., Hauth, J. C., Hodgkins, P., Owen, J., & Winkler, C. L. (1993). Trial of labor after a one- or two-layer closure of a low transverse uterine incision. *American Journal of Obstetrics and Gynecology*, 168(2),



545–546. **Reason:** Investigators compared scar rupture rates in VBAC labor in 149 women with single-layer uterine suturing in prior delivery versus 143 women with double-layer suturing. If the absolute increase in scar rupture rate is a few percent, which it appears to be, based on larger studies, this is still an important difference, but this study is underpowered to detect it.

Uygur, D., Gun, O., Kelekci, S., Ozturk, A., Ugur, M., & Mungan, T. (2005). Multiple repeat caesarean section: Is it safe? *European Journal of Obstetrics, Gynecology, and Reproductive Biology*, 119(2), 171–175.

**Reason:** Study lacks statistical strength. Investigators compared outcomes in 301 women with 2 or more prior cesareans with a control group of 301 women with 1 prior cesarean section. Only 44 women had 3 or 4 prior cesareans. Study is underpowered to detect uncommon but clinically important differences between groups in morbidity and certainly cannot detect differences in mortality. Moreover, investigators excluded women with placenta previa, which is strongly associated with the number of prior cesareans.

Zelop, C. M., Shipp, T. D., Repke, J. T., Cohen, A., Caughey, A. B., & Lieberman, E. (1999). Uterine rupture during induced or augmented labor in gravid women with one prior cesarean delivery. *American Journal of Obstetrics and Gynecology*, 181(4), 882–886. **Reason:** Study excluded from Guise (2003) SR, an included study here.

Zweifler, J., Garza, A., Hughes, S., Stanich, M. A., Hierholzer, A., & Lau, M. (2006). Vaginal birth after cesarean in California: before and after a change in guidelines. *Annals of Family Medicine*, 4(3), 228–234. **Reason:** Poorly designed. This before-and-after study looks at the effect on maternal and neonatal mortality in California before and after stricter guidelines for VBAC were implemented. Many factors could affect results besides the decrease in VBACs.

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