REDCING NON-MEDICALLY INDICATED EARLY ELECTIVE DELIVERIES:

Improvement Phase, Hard Stop Policy, and Next Steps

Frequently Asked Questions
May 2013
Reducing Non-medically Indicated Early Elective Deliveries (“NMIED”)  
FAQs: Improvement phase, Hard Stop policy, and next steps

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Reducing Non-medically Indicated Early Elective Deliveries (“NMIED”)

FAQs: Improvement phase, Hard Stop policy, and next steps

Improvement phase

1. What challenges have other hospitals encountered when implementing their EED policy/procedures?

- Establishing a fail-proof process that is unable to be bypassed is ideal, but it is safe to say you should expect to respond to individual practice variations and misunderstandings for some time.

- Physicians trying to bypass the policy may make diagnoses changes to fit the medical indications justifying early delivery. This is where it is important to have a strong physician champion, department chair, or medical director who is willing to have the conversations necessary to fully explore diagnoses and educate the provider if it is not appropriate. Examples would be medical indications such as “impending macrosomia,” or the mother whose hypertension diagnosed in the office has somehow resolved upon presentation for delivery. These episodes will become fewer as time goes on, but could be a challenge for some time.

- Obtaining private practitioner compliance may take a while. Using the education provided in these resources will improve that variation to a certain degree, but changes in hospital processes and provider reimbursement will eventually terminate any practice deviations. Meanwhile, one-on-one counseling and conversations between your leadership or physician champion and the deviating practitioners will help to close the gaps.

- Ensuring adequate staffing levels in order to mobilize appropriate personnel for EED processes. It is important to plan for the extra staff time necessary to schedule delivery requests, verify medical indications, and perform other communications in the process (both written and verbal), as well as to gather the necessary information. The escalation process for requests requiring leadership intervention also requires more time from both staff and executives.
• Social issues, such as delivery upon maternal request. In these cases, individual counseling of physicians using the ACOG guidelines may be helpful. Suggest the delivering practitioners educate their patients to the fact that your facility does not allow early elective deliveries without a medical indication. Your hospital’s public health campaign, in cooperation with local agencies such as the March of Dimes, will serve to educate parents and eventually also decrease maternal requests.

• Scheduling conflicts, especially with cesarean sections. Some hospitals have made it a policy to give higher priority to deliveries with a medical indication, regardless of the gestation, during day shift hours, sometimes requiring elective deliveries to be done on other shifts or quieter days. If conflicts occur, these cases may be referred to your maternal-fetal medicine specialist, medical director, or department chair for resolution.

2. What do we do if a provider refuses to comply with hospital policy eliminating NMIEDs, or tries to negotiate exceptions to the policy?

• Use logic and literature to build a consensus among hospital providers.

• Materials in this resource demonstrate that no professional organization supports NMIED, and your hospital will benefit from eliminating NMIED because it will:
  o Improve patient outcomes and avoid harm
  o Reduce costs of care
  o Adhere to best practices promoted by ACOG and other professional organizations
  o Avoid problems with reimbursement from insurers and Medicaid

• An outlier may conform to guidelines if data demonstrating their practice patterns vs. their colleagues is presented, instead of forcing a doctor to follow new rules.

3. What about issues with physician autonomy and resistance to “cookbook” medicine such as “I’m a Board Certified OB/GYN, I can do what I want”… “I have been delivering babies for 25 years and there has not been any problem”…. “No one should ever look over my shoulder.”

• It is important not to allow a few physicians to affect the majority.

• Physician level data can be very persuasive. However, using accurate data is critical; if the data is wrong, everyone loses credibility.

• Use your physician champion to point out that this type of reaction is outdated thinking. However, be aware that these attitudes are reflective of the provider’s underlying anxiety about loss of control and autonomy, as well as a lack of understanding that standardization of care improves patient outcomes. Therefore, begin the intervention by first educating the provider concerning current standardization and patient safety theory.
- Other areas which have focused on evidence-based care and patient safety have already developed protocols and strong guidelines designed to decrease wasteful variations in practice. For example, standardized approaches in Internal Medicine and Surgery include:
  - Use of ASA and beta-blockers with efforts toward standardized door-to-cath times for myocardial infarctions.
  - Pre-operative antibiotics and VTE prevention.
  - Very strict protocols for standardized treatment for strokes.
  - Other publicly reported payment-based standards.

- Obstetrical services have been “below the radar” because, up until recently, the patient safety movement has been driven by Medicare (which has focused improvement and reimbursement attention on other areas, such as healthcare-acquired infections and readmissions). Now it has been taken up by Medicare, commercial insurers, and Medicaid in many states, with more states to come.

4. Why not just do an amniocentesis for lung maturity study instead of monitoring gestational age?

- ACOG Committee Practice Bulletins numbers 97 and 107 state “A fetal maturity test result before 39 weeks of gestation, in the absence of appropriate clinical circumstances, is not an indication for delivery.”

5. What difference does a couple of days make? What about 38 weeks + 5-6 days?

- Bryan Oshiro, MD, Associate Professor of OB/Gyn at Loma Linda University compiled a detailed slide deck with several examples of studies of neonatal harm relative to gestational age at time of delivery. There are elegant graphic depictions of numerous studies showing the frequency of specific harms relative to gestational age at birth.

- A study by Wilmink, et al published in AJOG looked at the timing of elective cesarean sections at term to assess perinatal outcome associated with this timing. All elective cesarean sections of singleton pregnancies at term (n = 20,973) were reviewed. More than half of the neonates were born at <39 weeks of gestation, and they were at significantly higher risk for the composite primary outcome than neonates born thereafter. The absolute risks were 20.6 percent and 12.5 percent for birth at <38 and 39 weeks, respectively, as compared to 9.5 percent for neonates born > or = 39 weeks.

6. Does an EED policy increase the risk of stillbirth?

- Anyone who remains pregnant is at risk for having a stillbirth. But that risk is extremely low. U.S. natality data indicates the stillbirth risk is 3.6 per 10,000 births, or one stillbirth for every 3,000 deliveries at 38 weeks. This rate includes patients with high-risk conditions such as hypertension, diabetes, and other medical conditions, and babies with birth defects. This rate should be even lower if only restricted to low risk patients.
Another source of data showing no increase in stillbirth by proceeding to term includes observational studies looking at term stillbirth rates before and after implementation of programs to reduce EED before 39 weeks. Three studies, totaling nearly 1.2 million mothers, saw no difference in stillbirths after reducing the rates of elective deliveries before 39 weeks gestation. One single hospital study with 24,000 mothers did show an increase in stillbirths. However, unlike the other studies, the study population was smaller, the follow-up time was shorter, and there were significant changes in the population demographics. Many of the stillbirths occurred in a high-risk population and occurred during week 37.

<table>
<thead>
<tr>
<th>Intervention Study</th>
<th>Total Population Studied</th>
<th>Stillbirth Rate Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>**Oshiro (2009)**¹ (large health system)</td>
<td>160,394</td>
<td>Decline during intervention period</td>
</tr>
<tr>
<td>**Clark (2010)**² (large health system)</td>
<td>433,551</td>
<td>No change during the intervention period</td>
</tr>
<tr>
<td>**Ehrenthal (2011)**³ (single hospital)</td>
<td>24,028 (&gt;37 wk only)</td>
<td>Increase noted at 37 and 38 wks</td>
</tr>
<tr>
<td>**Benedetti (2012)**⁴ (state of Washington)</td>
<td>505,445 (&gt;37wk only)</td>
<td>No change during the intervention period</td>
</tr>
</tbody>
</table>

7. **How do we determine gestational age for “late to care” patients (dated only by U.S. after 20 weeks)?**
   - Recommend fetal lung maturity testing before scheduled elective procedure.
   - In patients with one prior low transverse cesarean section, there is low risk in awaiting labor before the cesarean section.

Implementation of a HARD STOP policy to ELIMINATE non-medically indicated early elective deliveries
8. What is a “Hard Stop” NMIED?

- All deliveries not meeting medical risk criteria for scheduling an EED must be reviewed by the appropriate medical leader, such as the OB Director or Department Chair, before scheduling can occur. All intervention and discussion occurs in “real time,” and not as part of a retrospective quality improvement effort. If there is no medical justification for the early delivery, the Hard Stop process will not allow it to proceed.

- Here is an example of such a policy: Cobre Valley Regional Medical Center (Globe, AZ) - Hard Stop Policy for Early Elective Deliveries.

9. What is critical to consider prior to instituting a “Hard Stop” EED policy?

- Be sure to educate leadership and obtain administration buy-in. Medical leadership support will make or break the implementation of the program.

- Avoid processes for which the nursing staff must become the “police.”

- Most reports of success with hard stops in the literature have involved a hospital-based physician who can “take the heat” from other physicians and uphold the EED process. The considerations you should give when selecting your physician champion become even more important when rolling out a hard stop policy.

- Consider having your QI Committee review all scheduled deliveries at less than 39 weeks gestation for a period of time in order to determine the unit’s current state of readiness to move to a “Hard Stop.” You may find more educational or process improvement requirements should be addressed before making that step.

10. Are there examples of successfully implemented “Hard Stop” policies?

- One year after “Hard Stop,” Oregon hospitals lowered early elective births by as much as 86 percent.

- Case studies of the EED reduction programs at Seton, Sinai, Woman’s Baton Rouge are included in this API Snapshot article.

- Dignity Health successfully reduced NMIEDs by more than 85 percent in less than a year, saving an estimated $1 million in neonatal intensive care unit costs. Engaging physicians and putting strong rules in place for when a delivery could be scheduled allowed Dignity Health to succeed; however, the most effective measures were policies requiring physicians scheduling a delivery before 39 weeks to demonstrate and document a valid medical necessity. Without medical necessity, staff would not allow the delivery to be scheduled and moms-to-be were sent home until the baby was full term.

11. Is there support in the literature for implementation of a “Hard Stop” policy?
• The study most often cited is by Steven Clark, MD et al: “Reduction in elective delivery at <39 weeks of gestation: comparative effectiveness of 3 approaches to change and the impact on neonatal intensive care admission and stillbirth,” published in AJOG in 2010. This showed physician education and the adoption of policies backed only by peer review are less effective than “Hard Stop” hospital policies to prevent EEDs. It further estimated that a 5 percent rate of elective early term delivery would be reasonable as a national quality benchmark.

• The study is also described in this article on Reuters Health.

12. Who is in the best position to be the “gatekeeper” regarding a requested EED?

• ACOG District II suggests:
  o Establish a “gatekeeper” to review all medical indications prior to scheduling a delivery to be sure deliveries are occurring only when a medical exception is present. A nurse manager with a clinical background may be an appropriate person for this, but it is important not to place nursing staff in the middle of a dispute.
  o If a delivery is attempted to be scheduled without an appropriate medical indication, the reviewer may then present the case to the attending, the chief resident, or other appropriate staff who will review and confirm documentation if the gestational age is less than 39 weeks.
  o If there is further cause for concern, the attending physician may approach the OB department chair to evaluate its accuracy and decide on the necessary intervention.
  o If an intervention is then needed, the case may be escalated to the hospital’s quality improvement committee.

13. What other helpful tips are there for implementing a “Hard Stop” policy?

• Start by using a “soft stop” policy using only peer review or retrospective case review for at least a few months to show the entire department how a few refusers can negatively affect outcomes. At that point, a “Hard Stop” is usually an easier sell.

• The most effective method to eliminate elective deliveries is to review the case at the time it is scheduled.

• Verify that an appropriate medical indication is documented no later than 24 hours prior to the procedure so if the patient has been inadvertently scheduled before 39 weeks, the procedure can be cancelled prior to the patient presenting to L&D.

• For hospitals using the operating room, the OR team may not proceed with a delivery if there is no medical indication. Be sure to determine if that is the case at your hospital.

• Require every physician to write a full note in the chart upon admission describing why they plan to perform a non-medically indicated cesarean or induction before 39 weeks.
• Require all cases be reviewed in the Perinatal Committee and require that formal letters be returned and placed in their medical staff file. The Department Chair can use physician-level data on this measure for Ongoing Professional Practice Evaluation (Joint Commission requirement).

• Consider reviewing medical staff bylaws to address recalcitrant physicians.

• Address all non-appropriate indications on a case-by-case basis in real time, not by retrospective review. In these instances, your escalation process and leadership willingness to support the policy changes on a case-by-case basis become critical.

Next steps

14. What else are some hospitals doing in response to the evidence of harm related to elective inductions, regardless of gestational age?

• As part of the Choosing Wisely Campaign, ACOG and AAFP are telling women and their maternity care providers not to schedule elective, non-medically indicated inductions of labor between 39 weeks 0 days and 41 weeks 0 days unless the cervix is deemed favorable. “Favorable” means the cervix is already thinned out and beginning to dilate and the baby is settling into the pelvis. Doctors and midwives use a tool called the Bishop Score to give an objective measurement of cervical ripeness. Although ACOG and AAFP do not define “favorable,” studies show cesarean risk is elevated with a Bishop Score of 8 or lower in a woman having her first birth and 6 or lower in women who have already given birth vaginally.

• Some hospitals are instituting a “Hard Stop” for any inductions involving an unfavorable cervix. For example:
  o Magee Women’s Hospital has had a Hard Stop policy forbidding cervical ripening all together and inductions only for Bishop’s scores >8 for nulliparous women, >=6 for multiparous women, since 2004 (Obstet & Gynecol, 113(4), April 2009).
  o Providence Health in Oregon has had the same policy since 2007 (MCN, 33(3), May/June 2008).
  o Baystate Medical Center has had a policy forbidding all nulliparous elective inductions regardless of Bishop Score since 2011.
  o Summa Akron City Hospital has a policy forbidding nulliparous elective inductions with Bishop Scores of <8, and has taken Cervidil off the formulary.

15. What resources will help us in spreading these process improvements to other hospitals in our organization?

• Learn about the other units and how they work first before initiating spread of quality improvement efforts.

• Identify a team from the unit where you are trying to spread your knowledge. They need to own the effort, and then work to make the changes, or the change will not stick.
• Share your tools and resources with other units, but let the other team make the tools fit their unit and its own culture.

• When trying to replicate your success, work on culture and communication changes, as well as process changes.

• Banner Health uses Clinical Performance Groups (CPGs), which provide focused, accountable leadership for improving patient outcomes across their system by insuring that best clinical practices are in use. Each CPG focuses on a specialty and includes a medical director, clinical nursing director, and a process director. The medical and clinical directors have expertise in the specialty area as well as leadership experience within the organization. The process director is an industrial engineer who may or may not have healthcare experience but who has experience with development of metrics, designing a robust process and implementation. This article describes how this model has been used successfully in obstetrics to reduce Banner Health’s rate of elective deliveries at less than 39 weeks gestation.

• AHRQ provides this Quality Improvement Intervention Spread Planner.

• IHI provides this white paper, “A framework for spread: From local improvements to system-wide change.”