Implementation Strategy

The implementation strategy in this section provides an overview diagram, an outline of the rapid cycle method, Mobilize, Assess, Plan, Implement, Track (MAP-IT), and an implementation checklist to guide eliminating non-medically indicated (elective) deliveries <39 weeks through change in practice and hospital guidelines. See Appendix C for the Plan, Do, Study, Act (PDSA) model.[38]

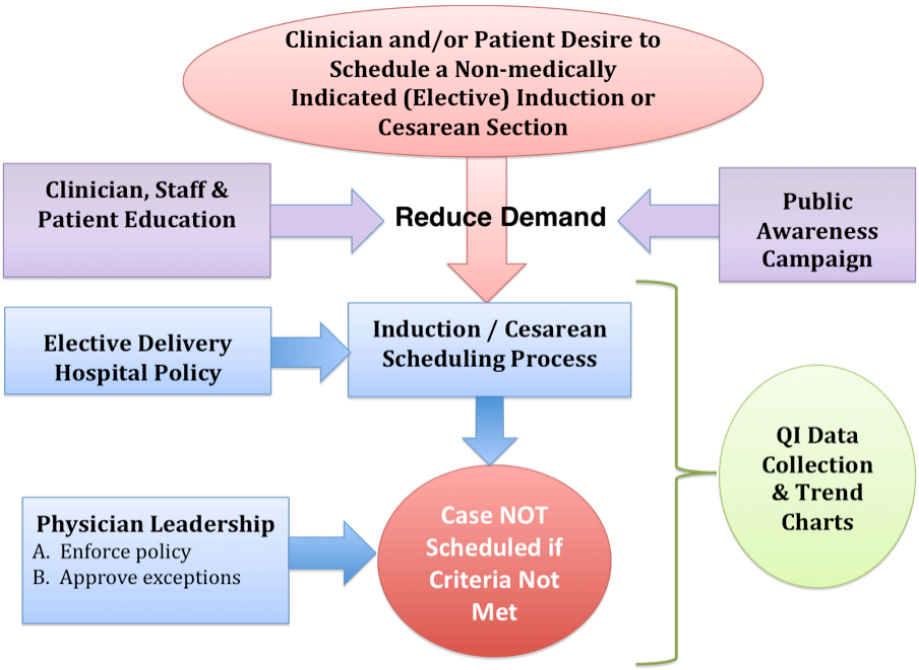
Effective implementation requires strategies and tactics that will drive improvement, mitigate barriers and measure process and outcome results.[39] Included in this section are sample documents that can be modified to address local hospital needs.

Although the principles and specific tools provided in this toolkit serve as a useful implementation guide, the toolkit should be tailored to the unique environment of each particular facility. In general, successful implementation includes strong leadership and collaboration among all stakeholders. Patients and practitioners must understand the risks involved with delivering <39 weeks when there is no medical indication. Policies must be established for consistent scheduling processes for inductions and cesarean deliveries. Strong medical leadership must support hospital staff in enforcing best practice. Finally, ambiguity should be expected. For example, gestational age dating may be ambiguous for patients with late prenatal care or those without an early ultrasound. Therefore, when issues or questions arise, they should be addressed and procedures adjusted accordingly.

THE BIG PICTURE

The flowchart below shows primary components to implement a project aimed at eliminating elective deliveries prior to 39 weeks.

Figure 13: Graphic Overview of Key Components



Reduce Demand

- **Clinician/Staff Education:** Provide clinicians with data about their patients' complications (maternal and neonatal). Emphasize avoiding elective deliveries <39 weeks.
- **Patient Education:** Provide women with educational materials that define "full term" and emphasize the importance of full 39 weeks of gestation; have structured informed consent discussion that outlines risk of non-medically indicated elective deliveries prior to 39 weeks gestation.
- **Public Awareness Campaign:** Support clinician efforts to educate women and their families through public awareness campaigns, e.g., health fairs and multimedia social marketing.

Key Change Tactics

- **Elective Delivery Hospital Policy:** Policy and procedure guides scheduling and oversight to eliminate elective deliveries <39 weeks.
  - Establish standards that follow ACOG and national quality criteria.
  - Establish policies for approving appropriate exceptions to standards that are guided by strong physician leadership.
  - Establish policies that provide clear direction to nursing staff and clerks for scheduling process.
- **Induction/Cesarean Scheduling Process:** Create and use standard forms for scheduling that collect gestational age and indication for delivery; both pieces of information determine whether the requested interventions are defined as medically indicated. Refer all exceptions to physician leadership per hospital policy.
- **Physician Leadership:** Policy establishes "medical ownership;" department quality committee chairs or other identified leaders approve all exceptions to the elective delivery policy.

QI Data Collection & Trend Charts

- **Targeted QI Data Collection:** Select QI data measures that track the amount of improvements made to both processes and outcomes; these measures guide the QI implementation process. Collect data using the Scheduling Form, the Data Collection Form, log books, fetal monitor system reports or electronic medical records.
- **Trend Charts**: Create charts to display desired QI data measures; display and discuss charts with clinicians and staff.

RAPID CYCLE QI METHODOLOGY
Mobilize, Assess, Plan, Implement, Track (MAP-IT)[40]

☐ **Step 1**
Mobilize QI Team
Recruit champions: clinical staff who visualize the ideal, set goals and follow through to realize defined aims.

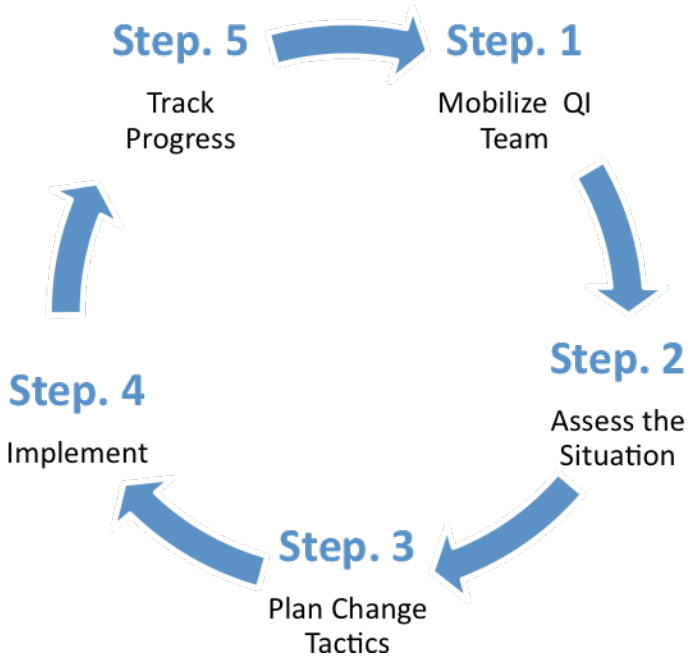
☐ **Step 2**
Assess the Situation
Determine current practices for delivery scheduling; identify ***QI Data****:* criteria for approved induction and cesarean deliveries performed <39 weeks.

☐ **Step 3**
Plan Change Tactics
Policy, Scheduling Process***, Empowered Physician Leadership***: Change policies, oversight, scheduling processes, and other relevant policies and procedures (e.g., clinician and patient education) that support a protocol to reduce elective deliveries <39 weeks.

☐ **Step 4**
Implement
Convene department meetings to conduct ***Clinician Education***, influence department culture, gather buy-in and support rollout of change tactics to accomplish the goal.

☐ **Step 5**
Track Progress
Analyze data and present results to clinical staff via ***Trend Charts*** on elective delivieres. Review and repeat steps; when necessary, revise newly implemented tactics to ensure sustainable results.

Figure 14: MAP-IT QI Methodology



Primary components are in bold italics and are outlined in the Big Picture Model on page 27.

Adapted with permission from: *Healthy people in healthy communities: A community planning guide using healthy people 2010.* Washington, D.C.: U.S. Department of Health and Human Services. The Office of Disease Prevention and Health Promotion.

IMPLEMENTATION CHECK LIST

Step 1: Mobilize a QI Team

- ☐ Recruit QI champions.
  - Ideal: Labor & delivery (L&D) manager and/or perinatal QI nurse AND OB/GYN chair
- ☐ Schedule QI champions' meeting: Date: _____ Time: _____
  - Review toolkit to eliminate elective deliveries <39 weeks gestation
  - Discuss preliminary hospital data as outlined in Step 2
  - Identify QI team members to recruit
- ☐ Recruit QI team to support the QI champions; team members commit to regular meetings until goals are accomplished
  - Team members to consider
    - Obstetrician (department chair)
    - Nurse midwives
    - L&D charge nurses
    - Director of women's services
    - Lead scheduler
    - Pediatrician or neonatologist
    - Quality or nurse educator
    - L&D manager
    - Risk manager
    - Data analyst/decision support
- ☐ State goals clearly; start a MAP-IT Worksheet (see Appendix C)
  - Suggested language: "By ____ (choose a realistic date) all inductions of labor and scheduled cesarean deliveries before 39 weeks performed at _____ (name of hospital) will have a medical or obstetric indication ____"
- ☐ Schedule first QI team meeting to review <39 week toolkit, assess the situation (Step 2), perform baseline assessment, develop implementation plan of action with timeline and benchmark(s)

Step 2: Assess the Situation

- ☐ Review ACOG's indications for induction of labor and dating criteria
- ☐ Collect data: Data collection over time will provide the QI team with specific data to track implementation progress. (See data form contained in "Data Collection and QI Measurement" section)
  - Identify number of elective deliveries <39 weeks: induction of labor and cesarean section
  - Identify: 1) gestational age; 2) method of gestational age determination (and whether ACOG criteria were used); 3) indication for delivery.
- ☐ Perform a baseline assessment 2-3 months before implementation using the Data Collection Form. (See "Data Collection and QI Measurement" section) Modify data collected as indicated based on the baseline assessment
- ☐ Identify barriers to change. (See barriers discussion in this section)
  - Policy and/or leadership barriers, e.g., lack of scheduling criteria or enforcement oversight
  - Clinician and patient barriers, e.g., clinicians' and women's lack knowledge of risks; attitudes about convenience for determining timing of birth
  - Others:_____
- ☐ Assess strategies for mitigating barriers, (See strategies discussion in this section)
  - Assess the type of feedback clinicians receive:
    - Are the clinicians informed how many infants they cared for who were born <39 weeks are admitted to the Neonatal Intensive Care Unit?
  - Critique the scheduling process for labor induction and cesarean sections, including:
    - Is gestational age recorded when procedure is scheduled?
    - Is the method of gestational age assessment recorded?
    - Is the reason for induction or cesarean known and recorded?
    - Are the scheduling personnel aware of the ACOG indications for induction of labor and cesarean delivery?
    - How are scheduling problems currently handled?
- ☐ Engage additional stakeholders and leaders who have influence and can drive change

Step 3: Plan Change Tactics

- ☐ Develop revised scheduling processes and delivery guidelines based on ACOG criteria.
  - Adopt or modify scheduling algorithm and forms. (See this section.)
  - Basic information documented in forms:
    - Gestational age and how it was determined
    - Reason for scheduling
- ☐ Establish appeal process for deliveries <39 weeks when criteria are not in guidelines or are questionable.
- ☐ Institute interventions for physicians who fail to follow guidelines.
- ☐ Appoint physician leader(s) to enforce scheduling process and approve exceptions.
- ☐ Implement process to obtain informed patient consent for the procedure. (See this section and Appendix A.)
- ☐ Integrate patient education about the importance of the last weeks of pregnancy. (See "Patient Education" section.)
- ☐ Obtain agreement from obstetricians and key personnel on scheduling process and criteria.
  - Document the medical indication for the delivery.
  - Standardize dating criteria, e.g., consider obtaining ultrasounds before 20 weeks on all patients.
- ☐ Amend hospital policy and procedures to support elimination of elective deliveries <39 weeks (See this section and Appendix A.)

Step 4: Implement

- ☐ Convene department meetings to secure buy-in and to educate staff about new policies and procedures
- ☐ Conduct Obstetrical (OB), clinical provider and staff education
  - See slides in the "Clinician Education" section
  - Outline key points to be used by hospital and office staff when discussing criteria for <39 week delivery (See "Patient Education" section)
- ☐ Integrate patient education
  - Distribute patient education materials prior to admission, e.g., at physician offices, prenatal classes, and tours (See "Patient Education" section)
  - Encourage clinicians to discuss with their patients the risks of delivery prior to 39 weeks during prenatal visits
- ☐ Arrange "kick off" meeting to launch the new philosophy, policies and procedures

Step 5: Track Progress

- ☐ Use data and audit tools to track the number of elective deliveries <39 weeks and other key measures. (See "Data Collection and QI Measurement" section)
- ☐ Report to staff and providers regularly; obtain input and suggestions about:
  - Outcome and process data
  - Issues, concerns, and recommendations from all clinicians and staff
- ☐ Make adjustments to the data plan, protocol, and forms as needed
- ☐ Perform on-going data collection to ensure the changes are routinely followed
- ☐ Repeat MAP-IT steps and re-adjust the plan after implementing small tests of change

BARRIERS AND STRATEGIES TO MITIGATE BARRIERS

The use of multiple, tailored strategies and tactics to mitigate barriers is the most effective approach to implementation.[39, 41, 42] Three successful strategies include: 1) discourse (communication); 2) education (formal and informal); and 3) data (audit and trend charts).[43] Tactics are the tools to implement strategies and include, for example: new or updated scheduling forms (or some other type of "reminder" document) are communication tactics; grand rounds and toolkits are education tactics; data collection forms are data collection tactics.

Tactics for resolving three common barriers to eliminating non-medically indicated (elective) deliveries prior to 39 weeks are described below.

CLINICIAN BARRIERS: PHYSICIANS WHO ARE RESISTANT

Some physicians are early adopters (change behaviors readily when new data emerges) while other are late adopters (resistant to behavior change).[44] Late adopters change when they are persuaded to see that risks outweigh perceived benefits of practice. [45, 46]

Strategies:
Arrange for a respected **physician leader** to talk with reluctant physicians to better understand their position on the issue. Generally, resistance to change around <39 week deliveries is due to:

1. Perception of little or no harm to the baby or increased risk to the mother. Provide a summary of evidence from literature in this toolkit; provide data and feedback on your hospital outcomes in general and specifically on the physicians' practices.
2. Increased inconvenience. The new/updated scheduling process may be different, with more requirements than before its implementation. It is important to publicize the scheduling process well in advance; train schedulers and nursing staff to facilitate its implementation; streamline the process making it easy for physicians and their office staff to schedule patients.

Some physicians remain resistant to change despite education. Policies and procedures enable (and empower) nurses and clerical staff to consult the department chair, perinatologist, or medical director when physicians are not following scheduling criteria. However, nurses and clerical staff should not be solely responsible for approving or denying physician scheduling requests.

RESOURCE BARRIERS: TIME AND STAFF LIMITATIONS

Strategies that **optimize resource allocation** and a realistic data collection plan address common hospital limitations: competing work priorities for nurse leaders; limited time to develop the forms, organize meetings, revise policies and procedures, and to collect and analyze data.

Strategies:
Garner support from **senior administrative leaders** within your organization.

- Meet with risk management officers, quality or safety officers—administrators responsible for reducing institutional risk and liability.
    - Describe project goals; outline the compelling research that elective deliveries prior to 39 weeks should be eliminated
    - Provide statements from Joint Commission, ACOG and March of Dimes to highlight the national prominence of the issue
    - Outline the implementation plan and contents of the toolkit; ask for advice about helping the hospital meet compliance in this area

    - Highlight the importance of an early survey (baseline data collection and analysis) to see current hospital trends and the need for resource allocation to accomplish this first step toward compliance
- Meet with department leaders including Nursing and Medical Directors in the Neonatal Intensive Care Unit (NICU) to identify whether data on the number of infants admitted between 37 0/7 and 38 6/7 weeks gestation is being collected
    - Use available data about NICU admissions, keeping in mind that static numbers of NICU admissions for infants of this gestational age does not preclude opportunities for improvement
- Network and connect with other local leaders who are working on similar projects; learn their methods for identifying and allocating resources to meet project goals

CONTEXT BARRIERS: PATIENTS REQUEST ELECTIVE PROCEDURES

Patients are often unaware of the risks of early delivery and may pressure clinicians for early <39 week deliveries.[16]

- Enlist childbirth educators to inform women and their families that the last weeks of pregnancy are important; this information can be disseminated during hospital tours
- Enlist office staff of outpatient providers to give a copy of “Why the Last Weeks of Pregnancy Count” to all women
- Provide a copy of this toolkit to outpatient providers’ offices to reinforce information among clinicians and office staff
- Develop community education campaigns; speak at women’s church group meetings; provide handouts during local community fairs; contact the local newspaper to announce the hospital’s project; host a booth in the hospital lobby where information is distributed to health professionals and hospital visitors
- Document informed consent discussions with patients in the medical record to ensure that women are aware of the risks of early delivery to their infants

Form 1: Scheduling

BEST MEDICAL CENTER

SAMPLE SCHEDULING FORM FOR INDUCTIONS AND CESAREAN SECTIONS

Call (XXX) XXX-XXXX or Fax (XXX) XXX-XXXX

Name _____ Phone _____
OB Provider _____ G/P _____
Type of Delivery Planned: ☐ Induction; ☐ C/S Desired Date/Time: _____

DATING.....
EDC: _____ Gestational Age at Date of Induction or C/S: _____ (week+day)

EDC Based on: ☐ US 10-20 weeks; ☐ Doppler FHT+ for 30 weeks; ☐ +hCG for 36 weeks
☐ Other dating criteria: _____ *(details)*

By ACOG Guidelines, women should be 39 wks or greater before initiating an elective (no indication) delivery. ACOG also states that a mature fetal lung test in the absence of clinical indication is not considered an indication for delivery.

☐ Fetal Lung Maturity test result: _____ Date: _____

INDICATION.....

Obstetric and Medical Conditions (OK if <39 weeks)
(need to deliver <39 weeks dependent on severity of condition)

- ☐ Abruption
- ☐ Previa
- ☐ Preeclampsia
- ☐ Gestational HTN
- ☐ GDM with Insulin
- ☐ ≥41+0 weeks
- ☐ PROM
- ☐ Fetal Demise (current)
- ☐ Fetal Demise (prior)
- ☐ Oligohydramnios
- ☐ Polyhydramnios
- ☐ IUGR
- ☐ Non-reassuring fetal status
- ☐ Isoimmunization
- ☐ Fetal malformation
- ☐ Twin with complication
- ☐ Heart disease
- ☐ Liver disease (e.g. cholestasis of preg.)
- ☐ Chronic HTN
- ☐ Diabetes (Type I or II)
- ☐ Renal disease
- ☐ Coag/Thrombophilia
- ☐ Pulmonary disease
- ☐ HIV infection
- ☐ Other: _____

Perinatology consult obtained and agrees with plan:
_____
(consultant name)

Scheduled C/S (≥39 wks)

- ☐ Prior C/S
- ☐ Prior classical C/S
- ☐ Prior myomectomy *(may be earlier with fetal lung maturity test)*
- ☐ Breech presentation
- ☐ Other malpresentation
- ☐ Patient choice
- ☐ Other: _____
- ☐ Twin w/o complication *(ok ≥38 wks)*

Elective Induction (≥39wks)

- ☐ Patient choice/social
- ☐ Macrosomia
- ☐ Distance
- ☐ Other: _____

Description/Details: _____

CERVICAL EXAM *(for inductions)* .....
Date of Exam: _____ *(within 7 days of date of induction)*

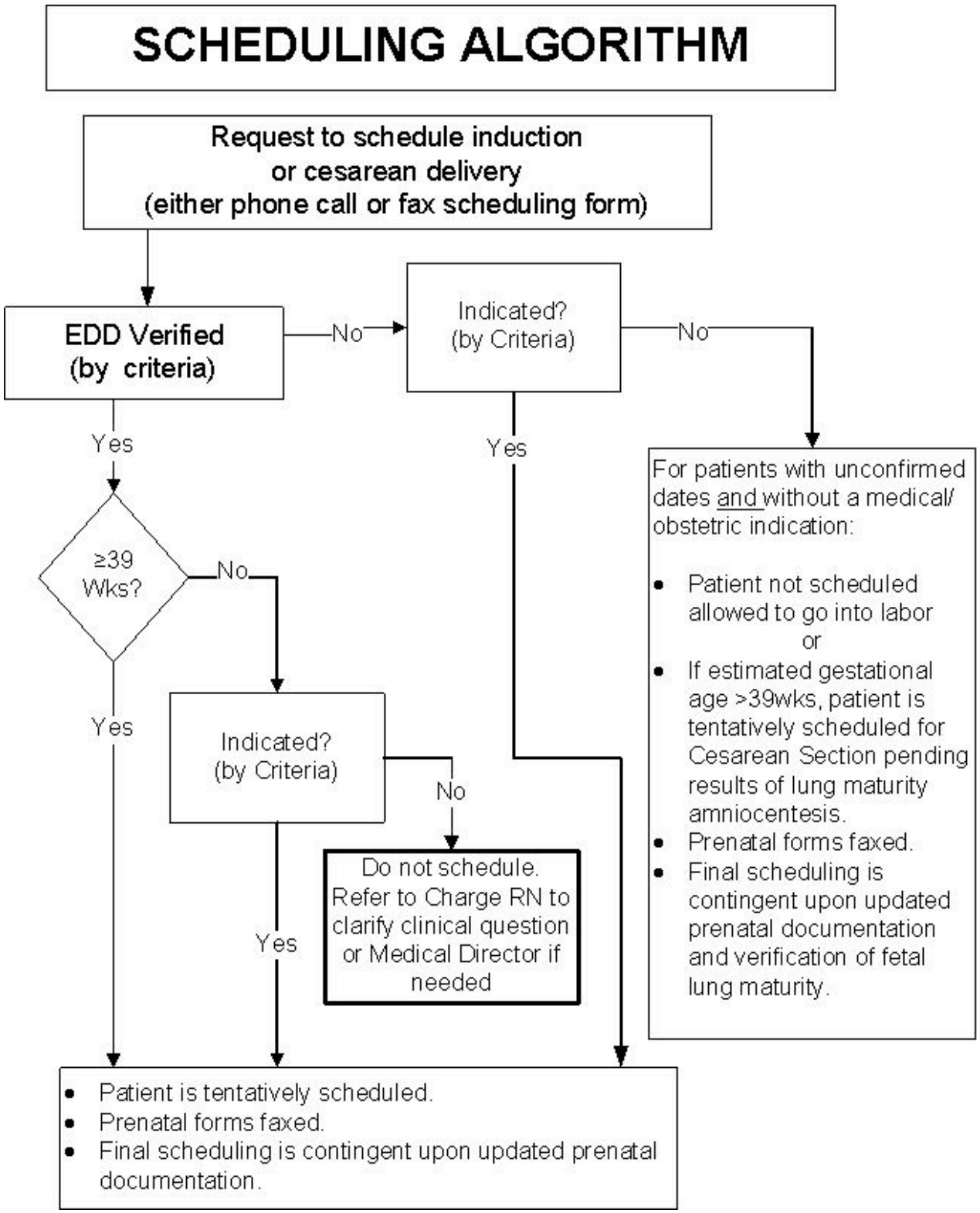
Bishop Score: *circle each element of the exam below and add:* **Total Score:** _____

Score	Dilation	Effacement	Station	Consistency	Position
0	Closed	0-30%	-3	Firm	Posterior
1	1-2	40-50%	-2	Medium	Midposition
2	3-4	60-70%	-1, 0	Soft	Anterior
3	5-6	80%	+1, +2	-------	----------

This section is used only by those hospitals using cervical exam criteria for scheduling inductions.

SCHEDULING OFFICE USE .....Procedure NOT Scheduled: ☐
Scheduled? ☐ by:_____ Confirmed Date/Time:_____
Referred to Dept Chair? ☐ PrenatalRecordpresentinLD: ☐ Yes

Figure 15: Scheduling Algorithm



SAMPLE POLICY AND PROCEDURE

POLICY INDEX:	**Page 1 of 3**
POLICY TITLE: Cesarean Section/Induction of Labor Scheduling Policy	
DEPARTMENT AND USERS DISTRIBUTION: Maternal Child Health, Labor and Delivery	

Original Date of Issue: _____

Reviewed Date							
Revised Date							

PURPOSE

The purpose of this policy is to eliminate non-medically indicated (elective) deliveries prior to 39 weeks.

POLICY STATEMENT

Non-medically indicated cesarean section or induction of labor prior to 39 completed weeks gestation requires approval of the Obstetrics and Gynecology department chair or designee. Note: Amniocentesis and documentation of fetal lung maturity is not an indication for delivery <39 weeks.

DEFINITIONS

Medical and obstetric indications for cesarean section or induction of labor that DO NOT require approval from the OB/GYN department chair or designee include:

INDICATION

Obstetric and Medical Conditions (OK if <39 weeks)

(need to deliver <39 weeks dependent on severity of condition)

- ☐ Abruption
- ☐ Previa
- ☐ Preeclampsia
- ☐ Gestational HTN
- ☐ GDM with Insulin
- ☐ ≥41+0 weeks
- ☐ PROM
- ☐ Fetal Demise (current)
- ☐ Fetal Demise (prior)
- ☐ Oligohydramnios
- ☐ Polyhydramnios
- ☐ IUGR
- ☐ Non-reassuring fetal status
- ☐ Isoimmunization
- ☐ Fetal malformation
- ☐ Twin with complication
- ☐ Heart disease
- ☐ Liver disease (e.g. cholestasis of preg.)
- ☐ Chronic HTN
- ☐ Diabetes (Type I or II)
- ☐ Renal disease
- ☐ Coag/Thrombophilia
- ☐ Pulmonary disease
- ☐ HIV infection
- ☐ Other: _____

Perinatology consult obtained and agrees with plan: _____ (consultant name)

Scheduled C/S (≥39 wks)

- ☐ Prior C/S
- ☐ Prior classical C/S
- ☐ Prior myomectomy *(may be earlier with fetal lung maturity test)*
- ☐ Breech presentation
- ☐ Other malpresentation
- ☐ Patient choice
- ☐ Other: _____
- ☐ Twin w/o complication *(ok ≥38 wks)*

Elective Induction (≥39wks)

- ☐ Patient choice/social
- ☐ Macrosomia
- ☐ Distance
- ☐ Other: _____

MONITORING

Data will be collected using the hospital Data Collection Form. These data will be aggregated and shared with the clinicians on a regular basis.

POLICY INDEX:	Page 2 of 3
POLICY TITLE: Cesarean Section/Induction of Labor Scheduling Policy	
DEPARTMENT AND USERS DISTRIBUTION: Maternal Child Health, Labor and Delivery	

PROCEDURES

1. Confirmation of Gestational Age

Gestational age needs to be confirmed using one of the ACOG criteria:

- "Ultrasound measurement at less than 20 weeks of gestation supports a gestational age of 39 weeks or greater."[11]
- "Fetal heart tones have been documented as present for 30 weeks by Doppler ultrasonography."[11]
- "It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test."[11]

If the patient does not meet ACOG's criteria for confirmation of gestational age, an amniocentesis to confirm fetal lung maturity after 39 weeks or allowing the patient to go into labor should be considered.

2. Scheduling

a) Provider or designee contacts the L&D scheduler with the request to schedule the induction or cesarean section. (This may be a phone call or the faxing of the scheduling form.)
b) The provider or designee provides the L&D scheduler with the woman's name and other patient identifiers as necessary, indication for the procedure, and the gestational age at the time of the scheduled cesarean section or induction. Note: All components of the hospital scheduling form must be communicated prior to the procedure being scheduled.
c) If the gestational age is < 39 weeks, the L&D scheduler compares the information provided to them to the predetermined list of medical and obstetric indications for cesarean sections and induction of labor prior to 39 weeks. If the indication is on the list then the procedure is defined as medically indicated and gets scheduled.
d) If the indication provided does not appear on the approved list AND gestational age is <39 weeks on the requested scheduled procedure date, the L&D scheduler will inform the provider. Note: If the provider requests that the non-medically indicated cesarean section or induction of labor be performed prior to 39 weeks, then the L&D scheduler will inform the provider that he is not authorized to schedule the procedure without documented permission from the OB/GYN department chair or designee.
e) Women who have medical indications for delivery have priority over women having elective cesarean sections and inductions of labor. These decisions are the discretion of the L&D unit charge nurse in consultation with the designated physician leader.

POLICY INDEX:	**Page 3 of 3**
POLICY TITLE: Cesarean Section/Induction of Labor Scheduling Policy	
DEPARTMENT AND USERS DISTRIBUTION: Maternal Child Health, Labor and Delivery	

3. Informed Consent

All patients with a scheduled non-medically indicated (elective) delivery (either cesarean section or induction of labor) prior to 39 weeks will have an informed consent discussion.[47] The informed consent discussion must be documented in the medical record. The informed consent discussion will include the usual discussion of risks and benefits of induction of labor or cesarean section and also include a discussion of the risks to the baby of being born electively prior to 39 weeks gestation. Note: Hospital leaders may choose to develop an informed consent form to be signed by the patient after her provider has discussed the treatment with her and before the procedure is performed. See Appendix A for sample consent forms developed for use at other hospitals around the country.

REFERENCES

ACOG. (2009). Induction of labor. American Congress of Obstetricians and Gynecologist Practice Bulletin No. 107. *Obstet Gynecol.* 114(2), pp. 386-97.

ACOG. (2004). Informed Consent. American Congress of Obstetricians and Gynecologist Committee Opinion Number 439. August 2004:1-8.

GUIDELINES FOR INFORMED CONSENT DISCUSSIONS

Informed consent is a process for promoting patient autonomy in medical care decision making that includes ongoing, shared information and developing choices for each individual patient. The informed consent process should first establish that the patient is capable of medical decision making and include a discussion between the patient and her care provider about the risks, benefits and complications of the recommended course of treatment and the risks, benefits and complications of any alternative approaches.[47] Informed consent discussions should be documented in the medical record and hospital leaders may choose to develop an informed consent form to facilitate the documentation process. Informed consent discussions take place before the procedure is performed. Agreement by the patient to a therapeutic plan should be voluntary.

The preferences of patients have significant ethical authority but are not without limits. Physicians have an obligation to not perform actions that are known to cause harm and may refuse to perform procedures that have no documented medical benefits even when requested by their patients.[48] Therefore, a patient's negative right to refuse unwanted interventions is a powerful patient right. However, the positive right to receive any desired intervention is limited because it is the physician who is granted the authority and license to order diagnostic tests, prescribe medications or perform surgery.[49]

Providers who choose to perform elective deliveries prior to 39 weeks need to supplement the information they currently discuss with patients regarding the risks of induction or augmentation of labor or cesarean delivery. The supplemental information should include patient education materials that describe the risks to the infant who is delivered prior to 39 weeks. The information outlined earlier in the toolkit and in the patient education section can be utilized by clinicians to guide the content of the important discussions, which support a women's ability to make an informed decision.

See Appendix A for sample consent forms developed for use at other hospitals around the country. When selecting procedures, consideration of risks to benefits shifts based on the medical condition of each woman and infant. Thus, informed consent discussions need to be tailored to the specific medical condition of each woman and infant.