REPORT TO THE TWENTY-FIFTH LEGISLATURE
STATE OF HAWAII
2010

PURSUANT TO H.C.R. 215, S.D. 1

REQUESTING THE DEPARTMENT OF HEALTH TO REVIEW AND ASSESS THE POLICIES AND PROCEDURES IMPLEMENTED BY HOSPITALS TO REDUCE ELECTIVE CESAREAN SECTIONS AND INDUCTION OF LABOR

Prepared by
State of Hawaii
Department of Health
Health Resources Administration
Family Health Services Division
Maternal and Child Health Branch
April 2010

This Final Report is submitted by the Department of Health on behalf of the committee members consisting of the March of Dimes, Healthcare Association of Hawaii and Healthy Mothers Healthy Babies Coalition of Hawaii to address this resolution and would like to thank its contractor Dianne M. Okumura, R.N., M.P.H. for conducting the surveys and analysis of the data.

TABLE OF CONTENTS

Executive Summary 3

Recommendations 4

Introduction 5

Process 5

Hospital Surveys 7

Summary 9

Physician Surveys 10

Summary 15

Recommendations 17

Appendix I

Hospital Listing

Appendix II

Hospital Demographics

Appendix III

Hospital Survey

Appendix IV

Hospital Survey Data

Appendix V

Physician Demographics

Appendix VI

Physician Survey

Appendix VII

Physician Survey Data

Attachment A

American College of Obstetricians and Gynecologists Guidelines

Attachment B

Institute for Healthcare Improvement Design of Perinatal Care

Institute for Healthcare Improvement Perinatal Trigger Tool

Institute for Healthcare Improvement Perinatal Bundle

EXECUTIVE SUMMARY

The 2009 Hawaii State Legislature passed House Concurrent Resolution No. 215 Senate Draft 1 "REQUESTING THE DEPARTMENT OF HEALTH TO REVIEW AND ASSESS THE POLICIES AND PROCEDURES IMPLEMENTED BY HOSPITALS TO REDUCE ELECTIVE CESAREAN SECTIONS AND INDUCTION OF LABOR."

The introduction of H.C.R. 215 was in response to the increased rate of childbirth by cesarean section and induction of labor and possible relation to premature births. The Hawaii trend data from 1999 to 2006 shows a rate increase for cesarean births from 18% to 26% as reported on Hawaii resident birth certificates. This measure intends to gain more information to assist in the development of policies to reduce the number of elective cesarean sections and induction of labor prior to 39 weeks of gestation, and to help mitigate the average preterm birth rate of 10.5% in 2006-2007.

The Department of Health convened a workgroup with the March of Dimes, Healthcare Association of Hawaii and Healthy Mothers Healthy Babies Coalition of Hawaii to address this resolution. Workgroup discussions led to the development of physician and hospital surveys to assist in gathering information to develop recommendations for the improvement of practices related to elective inductions and cesarean deliveries towards the goal of reducing the preterm birth rate in Hawaii.

Of the 26 licensed hospitals in the State, 11 hospitals have obstetrics units and perform inductions and cesarean deliveries. Fifty-five percent of the hospitals surveyed have their own policies and/or guidelines in place for elective inductions and cesarean deliveries or are in the process of doing so, which they indicated was consistent with ACOG guidelines. The remainder use the American College of Obstetricians and Gynecologists (ACOG) guidelines[1] or Institute for Healthcare Improvement (IHI)[2] process. In a couple of facilities, no specific policies are in place as the matter of elective inductions and cesarean deliveries is not of concern at their facility. The majority have quality initiatives or are in the process of developing them. There appears to be a wide variation in the awareness of changes in the rates of elective inductions and cesareans amongst the hospitals. Per survey results,

[1] Refer to Attachment A for guidelines.

[2] IHI is developed to simultaneously accomplish three critical objectives, or what they call the "Triple Aim"; Improve the health of the population, enhance the patient experience of care (including quality, access, and reliability), and reduce, or at least control, the per capita cost of care. Refer to Attachment B for more information.

82% of the facilities do not have available training opportunities related to elective inductions and cesarean deliveries at this time.

A physician response rate of 55% was achieved when physician surveys were mailed or distributed. The majority of the physicians agree that malpractice does have an impact on obstetrical practice, the cause of preterm deliveries are complicated and multifactorial, scheduling delivery for low risk singleton pregnancy prior to 37 weeks may be problematic and most patients opt for cesarean deliveries if they had prior a C-section.

RECOMMENDATIONS:

- Sharing of all survey findings with respective hospitals and key physician leaders.

- A legislative resolution for the formation of a workgroup to include hospital representatives of OB/GYN departments, physicians and other community stakeholders to craft a public awareness campaign on the risks of elective inductions or cesarean deliveries before 39 weeks gestation, development of quality initiatives and training and collection of data relating to elective inductions and cesarean deliveries.

  The workgroup would concurrently request and inform a review of Title 11 Chapter 93 Broad Service Hospitals, regulations governing State Licensure of Hospitals. The review would consider the need for amendments and/or revisions to the current regulations regarding possible inclusion of requirements for policy development consistent with ACOG and/or other best practice guidelines and quality and training initiatives consistent with current best practice standards.

- Support the work of Healthcare Association of Hawaii and its coalition to evaluate methods to improve the quality, safety, efficiency, and cost of Hawaii's healthcare system, reduce medical errors and increase patient safety, seek solutions to eliminate doctor shortages, and address the role and impact of the legal system in compensating victims injured because of medical errors.

INTRODUCTION

The 2009 Hawaii State Legislature passed House Concurrent Resolution No. 215 Senate Draft 1 "REQUESTING THE DEPARTMENT OF HEALTH TO REVIEW AND ASSESS THE POLICIES AND PROCEDURES IMPLEMENTED BY HOSPITALS TO REDUCE ELECTIVE CESAREAN SECTIONS AND INDUCTION OF LABOR."

The department in consultation with the Healthcare Association of Hawaii was requested to review and assess:

(1) The criteria used by hospitals and physicians for indications to elective inductions or cesarean sections; and

(2) The policies and procedures implemented by hospitals to reduce elective cesarean sections and induction of labor.

The department was requested to submit its findings no later than twenty days prior to the convening of the Regular Session of 2010, in a report to include:

(1) Statistics on the number of hospitals having policies and procedures relating to elective cesarean sections and inductions of labor prior to thirty-nine completed weeks of gestation;

(2) Statistics on the number of hospitals with policies and procedures in line with the ACOG guidelines; and

(3) Recommendations, including suggested legislation, on improving Hawaii's rate of premature births.

PROCESS:

The Department of Health convened a workgroup consisting of representatives from the March of Dimes, Healthcare Association of Hawaii, Healthy Mothers Healthy Babies Coalition of Hawaii and several physicians with specialty in Obstetrics/Gynecology.

The workgroup collectively developed surveys of hospitals and physicians to capture sufficient information to address the request of this resolution. Although there are 29 licensed hospitals in the state, not all hospitals

provide obstetrical services or are able to perform inductions and/or cesarean sections. Although Molokai General Hospital does provide obstetric services, the patients who require induction and/or cesarean sections are transferred to Oahu. Eleven hospitals were identified as performing inductions and/or cesarean sections. Two of the hospitals are "closed" systems and only provide services to a select population.

Surveys were mailed to 11 hospitals statewide, with a follow-up telephone call to identify the specific staff member who would assist in the completion of the survey. Subsequent contact was made with all hospital staff to obtain information. All hospitals completed the hospital survey.

Physician surveys were offered at the annual meeting of the Hawaii Section of the ACOG, held in October 2009, in Kona. An incentive offering was provided for those who completed and returned surveys. Of the 65 attendees, 28 physicians returned completed surveys. Surveys were also mailed to approximately 76 physicians with instructions to return completed surveys via a self addressed envelope or facsimile. A total of 104 surveys were distributed to physicians.

HOSPITAL SURVEYS

All hospitals that were sent surveys submitted completed surveys and 1 hospital also shared their current policies and procedures. This hospital stated that it has 1) used 39 weeks as a hard stop for elective deliveries since about 2001, 2) began monitoring elective inductions in 2007, 3) in 2009 placed any elective delivery under 39 weeks as a quality measure which requires peer review, and 4) is moving to formally introduce the 39 week hard stop for elective delivery as a region wide hospital policy.

One hospital is currently awaiting administrative approval to share their procedures with the Department of Health, while 2 others are awaiting administrative approval for adoption and/or acceptance of policies relating to inductions and cesarean sections.

Inductions and Cesarean deliveries: Of significance, of the 11 hospitals, 6 which are located on the neighbor islands are aware of the rates of induction and cesarean deliveries and have not seen a change in their induction or cesarean rates since the year 2000. In comparison, the majority of the Oahu facilities track cesarean rates, but not rates of induction, and the majority have seen changes in their cesarean rates.

Facility policies: Elective inductions and cesareans policies at 5 of the facilities have been or are in the process of being developed and/or approved. Those hospitals without specific facility policies adhere to ACOG guidelines or the IHI model. IHI's model is based on evidence-based practice incorporating ACOG and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) practice guidelines to achieve a new level of safer, more effective care and to minimize some of the risks identified in medical malpractice cases.

One facility, "does not have written policies or guidelines in place expressly proscribing inductions prior to 39 weeks since they have not had issue(s) with providers attempting to do so to date." Further, for this facility, the exceptional patient who is even offered an induction prior to 39 weeks would have to undergo amniocentesis to document fetal lung maturity prior to initiating an induction.

About half of the hospitals have implemented policies or guidelines to reduce elective inductions and cesarean deliveries prior to 39 weeks. One facility is currently in the process of developing their policies which will be consistent with ACOG guidelines. The remaining hospitals do not have policies or have no intention of implementing policies at this time as they have not seen the

need to do so as elective inductions and C-sections are not done at their facilities.

Of those hospitals with policies for reduction of elective inductions and cesarean deliveries, 2 hospitals have implemented changes in their policies concerning elective inductions and 1 hospital implemented changes concerning elective cesareans during the past twelve months by:

- Stronger enforcement of the 39 week rule for elective cesareans or inductions however allow MDs to deliver elective inductions or cesareans if positive fetal lung maturity tests continue;
- Trying to follow their policy;
- Introduced the IHI bundle; and
- Have implemented changes in the scheduling process for inductions.

The majority of the hospitals have not implemented changes for elective inductions or cesareans within the last twelve months as:

- None of the procedures were conducted in their hospital;
- Facility rates are lower than the national average; or
- The issues do not apply to their facility(ies).

Quality Initiatives and Education: Sixty-four percent of the hospitals have quality initiatives currently in place regarding elective inductions and cesarean deliveries and 1 facility is in the process of working with IHI to set up markers in place and track their performance.

One hospital reviews deliveries daily and should an induction prior to 39 weeks occur, a formal interdepartmental staff peer review is conducted to ensure there are no deviations from standards of care. Another hospital conducts peer review only if an adverse outcome occurs. Of those currently without quality initiatives, 2 facilities are in the process of developing quality processes.

Five of the 11 hospitals have a committee or department that is responsible for provider education and training. Of the 5 hospitals, 2 of the hospitals have available training opportunities related to elective inductions and cesarean deliveries. In light of this, only 5 of the 11 hospitals would like to have training opportunities in these areas.

Hospital Opinions: Sixty-four percent of the hospitals feel that elective inductions and cesarean deliveries prior to the 39 weeks are major factors contributing to the increased rate of late preterm births in the past decade.

The following were identified as some of the major contributors for increased rates of late preterm births in the past decade:

- Choice – people are more informed about what is available and ask for it;
- Increase in multiple gestation in older women due to in-vitro fertilization;
- Increased patient acuity with co-morbidities such as late or no prenatal care, communication barriers, diabetes mellitus or cardiac conditions;
- Limited providers; and
- Physicians not following hospital policy.

SUMMARY:

Forty-five percent of the hospitals surveyed have their own policies and/or guidelines in place for elective inductions and cesarean deliveries or are in the process of doing so, which facilities indicated are consistent with ACOG guidelines. The remainder use ACOG or IHI guidelines. In a couple of facilities, the matter of elective inductions and cesarean deliveries is not of concern at their facilities. The majority has quality initiatives or is in the process of developing them. There appears to be a wide variation in the awareness of changes in the rates of elective inductions and cesareans amongst the hospitals. Per survey results, 82% of the facilities do not have available training opportunities related to elective inductions and cesarean deliveries at this time.

PHYSICIAN SURVEYS

A total of 104 surveys were distributed. Of those mailed, 18 were returned as "non-deliverable or return to sender"; 4 were returned with comments but survey items were blank; and 45 surveys were partially or totally completed for a 55% return rate.

Physician opinions regarding preterm delivery:
The physicians were either somewhat concerned or very concerned about preterm delivery (Chart 1) and as a whole there was no major increase seen in inductions or cesarean deliveries in their practice (Chart 2).

Chart 1. Rates of Preterm Deliveries

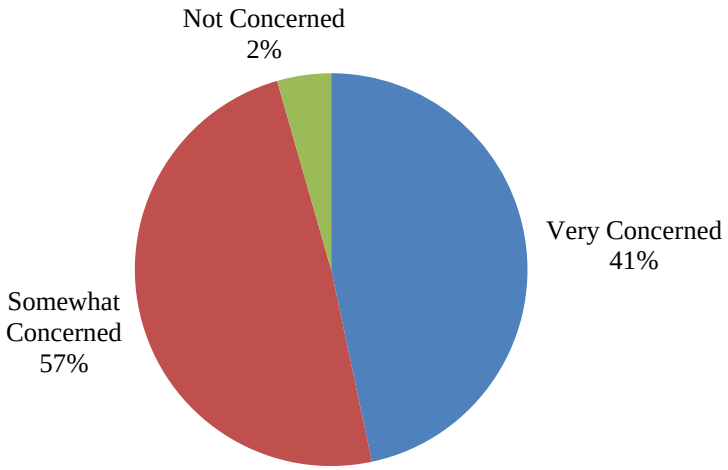
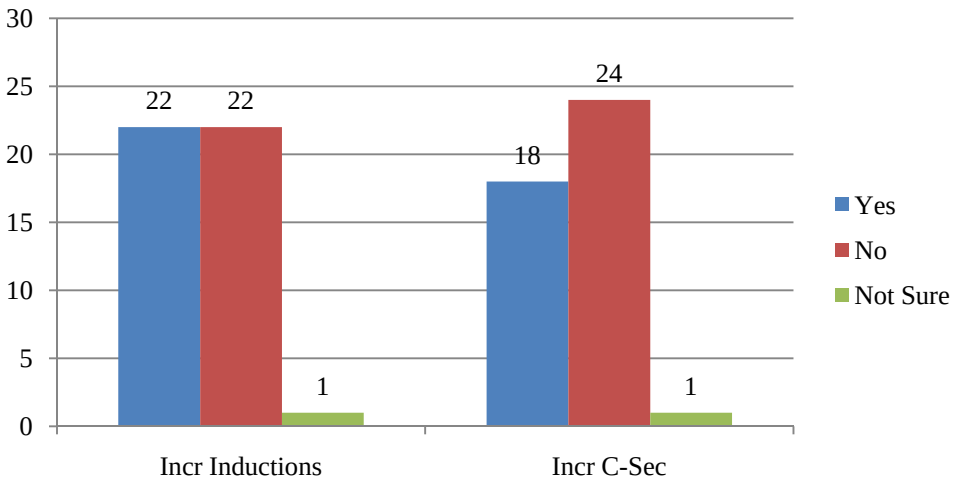


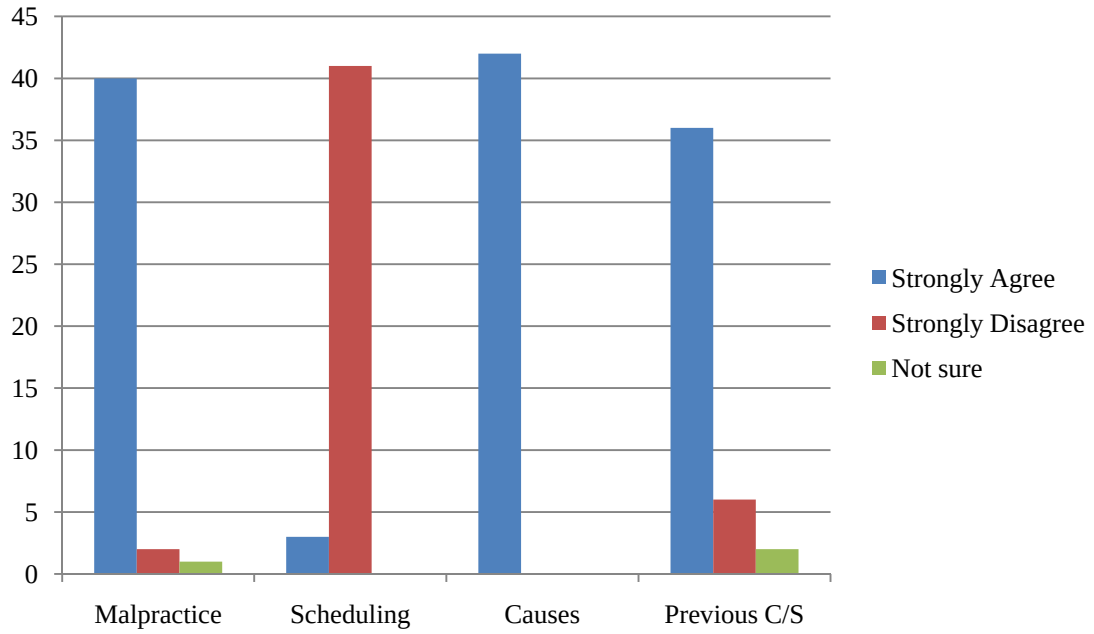
Chart 2. Increase in Inductions and Cesarean Deliveries



Physician Practice: Of significance in the data collected in relation to physician practice, the following responses were received (Chart 3):

- 89% felt that malpractice issues have a major impact on their practice.
- 91% felt that scheduling delivery for low risk singleton pregnancy prior to 37 weeks may be problematic.
- 93% felt that the causes of preterm delivery are complicated and multifactorial.
- 80% strongly agreed or agreed that most patients opt for cesarean deliveries if they had a prior C-section.

Chart 3. Statements about Obstetric Practice



There were slight differences in responses to other issues relating to practice:

- 60% were not comfortable in scheduling cesarean deliveries for low risk pregnancies.
- 58% felt that increases in infertility treatment are causing most of the increase in preterm births.
- 58% strongly agreed or agreed that there is an increase in the numbers of patients wanting to schedule their deliveries.

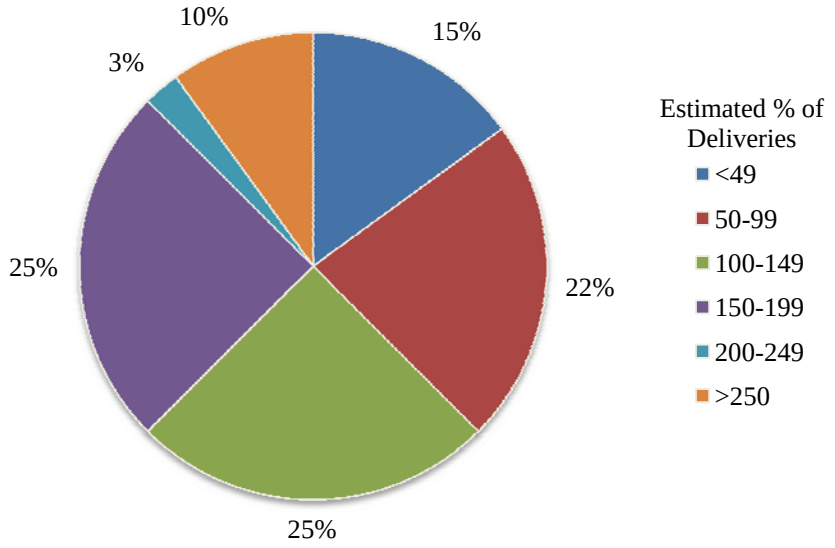
100% of respondents agreed that they would want to perform deliveries at 39 weeks. The majority of the respondents were willing to perform inductions and/or C-sections for patients with nulliparous, uncomplicated, low risk, singleton, cephalic pregnancy, with the delivery occurring at ≥ 39 weeks.

However, a few recognized that in cases where the patient is at high risk with such conditions as mild preeclampsia or increase blood pressure or other factors, delivery may occur at ≥37 weeks.

The majority of physicians also responded that they are aware of the policies and procedures of the hospital(s) where they practice, relating to elective C-sections, elective inductions and preterm birth.

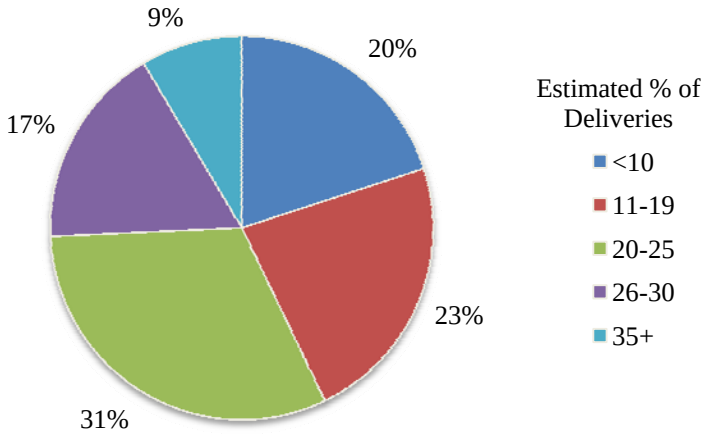
When asked to estimate the number of deliveries for 2008, physicians responded with great variation with approximately 15% <49 and 10% >250 estimated deliveries (Chart 4). Of those surveyed, 2 resident physicians indicated performing 150 deliveries each; while 5 (4 on Oahu and 1 multi-island) physicians that completed their residency on average 23 years ago, did not perform any deliveries for 2008. The physicians (3 in Oahu and 1 on NI) performing >250 deliveries, on average, completed their residency 21.5 years ago. For the neighbor isles, there was a range of 30 to >300 deliveries with an average of 146 deliveries, with 1 physician performing an estimated 300 deliveries. The 3 physicians that practice on more than 1 island estimated performing 0, 10 and150 deliveries.

Chart 4. MD Estimated Number of Deliveries Performed in 2008



Of the estimated deliveries performed there was also a wide variation of the estimated numbers of cesarean deliveries performed with a range of 43% performing between <10 to 19 cesarean deliveries and the remainder performing between 20-35+ cesarean deliveries (Chart 5). For Oahu, the average rate of cesarean deliveries was 18. For the neighbor isles, there was an estimated rate of <20-40 cesarean deliveries. The physicians that practice on more than one island estimated an average 47.5% of patients had cesarean deliveries.

Chart 5. MD Estimated Rate of Cesarean Deliveries



The majority of the physicians estimated that approximately 76-100% patients had repeat cesareans (Chart 6), with a small percentage of patients who had previous cesarean deliveries, who undergo a vaginal delivery (Chart 7). For Oahu on average 79% patients had repeat cesarean deliveries and 25.5% that had a previous cesarean delivery undergo a vaginal delivery. For the neighbor isles, it is estimated that 90-100% had repeat cesareans and 0-10% that had a previous cesarean delivery undergo a vaginal delivery. Of the 3 physicians that practice on more than one island 2 estimated an average of 75% repeat cesareans and 1 physician estimated that 50% who had a previous cesarean delivery undergo a vaginal delivery.

Chart 6. MD Estimate of Percentage of patients who h ad repeat cesarean delivery

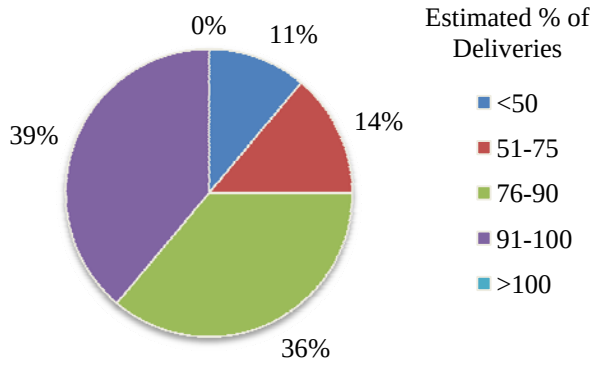
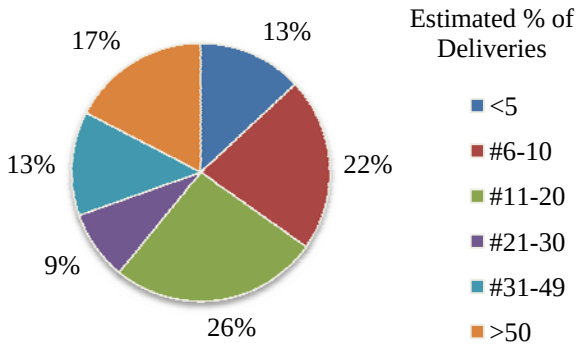
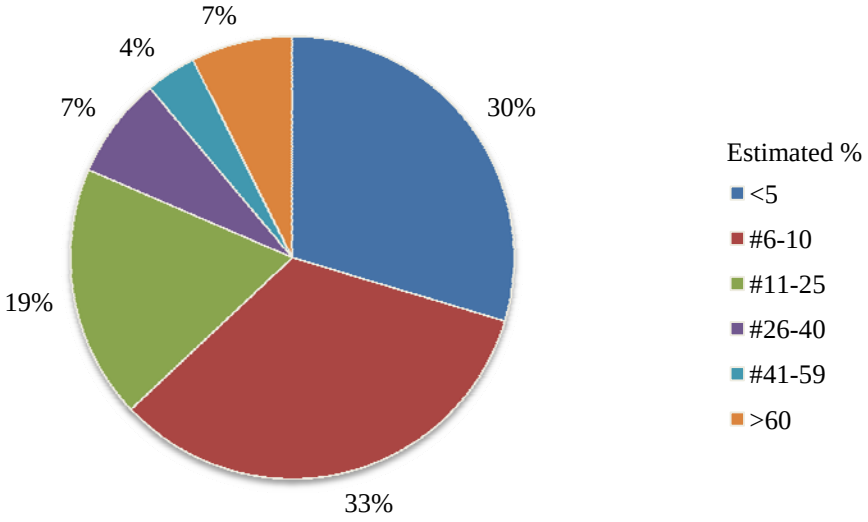


Chart 7. MD Estimate of Percentage of patients who had a previous cesarean delivery undergo a vaginal birth



Sixty-three percent of physicians estimate that ≤10% of patients undergo induction of labor (Chart 8). For Oahu, it is estimated that an average of 21.7% of patients undergo induction of labor. For the neighbor isles, it is estimated that ≤16% of patients undergo induction of labor. The physicians that practice on more than one island estimated that ≤10% undergo inductions.

Chart 8. MD Estimate of Percentage of patients that undergo induction of labor



Comments received from physicians were as follows:

- Thanks for the hard work; two Oahu hospitals are implementing procedures where elective induction must be at 39+ weeks; I have done elective inductions.

- Relating to performing a requested C-section for patients with a nulliparous, uncomplicated, low risk, singleton, cephalic pregnancy – I have done at 32 ½ weeks for a primipera unfavorable experience with floating uterus at term.
- Need to target patients not MDs – smokers, teens, drug addicts, patients with obesity issues. With economy such as it is, patients work 2 jobs, lack access to care. Need TORT reform if you want to see a difference.
- 37 or >37 – have done for previous classical cesarean section or high risk such as mild preeclampsia or elevated blood pressure or others.
- Helpful to have data per island. On big island do not do VBAC so repeat C section rates are higher. Area of interest would be primary vs. repeat C/S ratio; also hospital data would be nice. Thank you.
- Have done primary C-section, but discuss risks and benefits in depth before doing so and discuss that insurance may not cover it, usually are women with medical background (RN or MD), very very few patients request this.
- Active management at term has been shown to prevent C-sections, fetal distress, meconium, birth trauma and NICU admissions. 65% of brain damaged babies are born at term and could be prevented. Delivery by 39 weeks would prevent 6000 still births in US each year. Every pregnant woman should be offered the option of induction with prostaglandins at term. All efforts should be made to get pregnancy to term (38 weeks by US standards).
- Do not keep track of C-sections any more as only do indicated C-sections, which is no longer considered an indicator of quality care.
- Look into factors such as race, socio-economic factors, domestic violence, drug abuse, access to health care – don't get caught up with political rhetoric about elective inductions and C-sections.
- As ACOG does not support the resolution or the survey, we are not able to provide information without approval of all membership.
- Concern regarding development of regulation on practice issue, when guidelines are in place for quality and standards of care.

SUMMARY:

A physician response rate of 55% was achieved when physician surveys were mailed or distributed. There does not appear to be strong opinions on the majority of the questions asked however, the majority agree that

malpractice does have an impact on obstetrical practice, the cause of preterm deliveries are complicated and multifactorial, scheduling delivery for low risk singleton pregnancy prior to 37 weeks may be problematic and most patients opt for cesarean deliveries if they had prior a C-section.

RECOMMENDATIONS

Based on the survey results the Department of Health in collaboration with the Healthcare Association of Hawaii, March of Dimes and Healthy Babies Healthy Mothers recommend the following:

- Sharing of all survey findings with respective hospitals and key physician leaders including but not limited to, ACOG Chair, Chair of JABSOM OB/GYN, Chairs of medical staff OB/GYN departments at Castle Medical Center, Hilo Medical Center, Kaiser Foundation Hospital, Kapiolani Medical Center for Women and Children, Kauai Veterans Medical Hospital, Kona Community Hospital, Maui Memorial Medical Center, North Hawaii Community Hospital, Inc., Queen's Medical Center, Tripler Army Medical Center, and Wilcox Memorial Hospital.

- A legislative resolution for the formation of a workgroup to include hospital representatives of OB/GYN departments, physicians and other community stakeholders to craft a public awareness campaign on the risks of Elective Inductions or Cesarean Deliveries before 39 weeks gestation, development of quality initiatives and training and collection of data relating to elective inductions and cesarean deliveries.

  The workgroup would concurrently request and inform a review of Title 11 Chapter 93 Broad Service Hospitals, regulations governing State Licensure of Hospitals. The review would consider the need for amendments/revisions to the current regulations to determine the need for inclusion of requirements for policy development consistent with ACOG and/or other best practice guidelines, quality and training initiatives consistent with current best practice standards.

- Support the work of Healthcare Association of Hawaii and its coalition to evaluate methods to improve the quality, safety, efficiency, and cost of Hawaii's healthcare system, reduce medical errors and increase patient safety, seek solutions to eliminate doctor shortages, and address the role and impact of the legal system in compensating victims injured because of medical errors.

APPENDIX

HOSPITAL LISTING:

Listing of Hospitals that participated in the Survey:

Castle Medical Center
640 Ulukahiki Street
Kailua, Hawaii 96734

Hilo Medical Center
1190 Waianuenue Avenue
Hilo, Hawaii 96720

Kaiser Foundation Hospital
3288 Moanalua Road
Honolulu, Hawaii 96819

Kapiolani Medical Center for Women and Children
1319 Punahou Street
Honolulu, Hawaii 96826

Kauai Veterans Medical Hospital
P.O. Box 337
Waimea, Hawaii 96796

Kona Community Hospital
79-1019 Haukapila Street
Kealakekua, Hawaii 96750

Maui Memorial Medical Center
221 Mahalani Street
Wailuku, Hawaii 96793-2526

North Hawaii Community Hospital, Inc.
P.O. Box 2799
Kamuela, Hawaii 96743

Queen's Medical Center
1301 Punchbowl Street
Honolulu, Hawaii 96813

Tripler Army Medical Center
1 Jarrett White Road TGH
Honolulu, Hawaii 96819

Wilcox Memorial Hospital
3420 Kuhio Highway
Lihue, Hawaii 96766

HOSPITAL DEMOGRAPHICS:

Of the 11 hospitals, 6 or 54% are located on the neighbor islands, with 3 of the 6 located on the big island (Chart 9). Of the 6 hospitals, 4 are quasi-state facilities while 2 are privately operated, with 1 of the 2 under the same operation/management as a large facility on Oahu. Of the 5 hospitals on Oahu, 2 are closed systems while the other 3 are privately operated (Chart 10).

Chart 9. Hospital Demographics

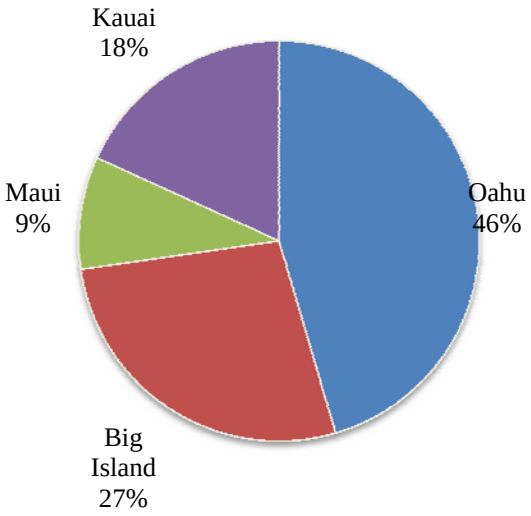
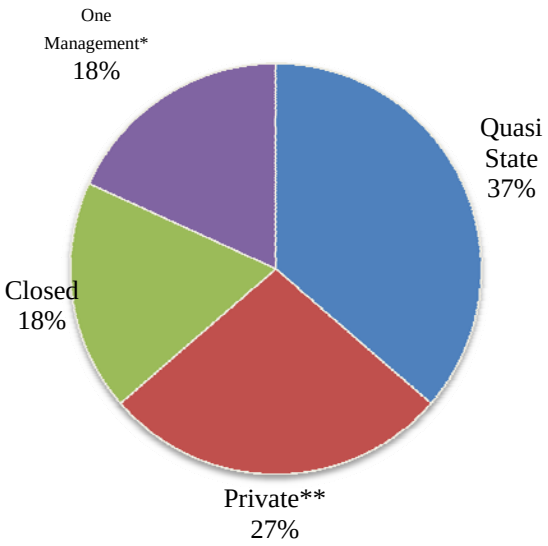


Chart 10. Hospital Status



*Note: "One management" implies that more than one hospital is under one management organization/system

**Note: "Private" implies that hospitals are under one management organization/system

HOSPITAL SURVEY:

HOSPITAL SURVEY
"Elective Inductions or Cesareans"

The 2009 Hawaii State Legislature passed a resolution requesting the Department of Health (DOH) to review and assess the policies and procedures implemented by hospitals to reduce elective cesarean sections and inductions of labor in response to rising rates of preterm births. The DOH convened a workgroup with the March of Dimes, Healthcare Association of Hawaii, and Healthy Mothers Healthy Babies Coalition of Hawaii to address this resolution. Workgroup discussions led to the development of this survey. This survey will assist to concisely gather information to develop recommendations for the improvement of practices related to elective inductions and cesarean deliveries towards the goal of reducing the preterm birth rate in Hawaii.

		Yes	No
1.	Are you aware of the rates of Inductions and Cesarean Deliveries in your institution?	☐	☐
2.	Have there been any changes in your rates of Elective Inductions and Cesarean Deliveries since 2000? If yes, please provide some details:	☐	☐
3.	Does your institution currently have a *written policy* or guidelines regarding Elective Inductions and Cesarean Deliveries?	☐	☐
	If yes, are you willing to share these with the Department of Health?	☐	☐
	If no, can you please explain why not:		
4.	Does your institution currently have any quality assurance initiatives regarding Elective Inductions and Cesarean Deliveries?	☐	☐
	If yes, are you willing to share these with the Department of Health?	☐	☐
	If no, can you please explain why not:		

5. Does your institution currently have any policies or guidelines implemented to reduce Elective Inductions and Cesarean Deliveries prior to 39 weeks? ☐ ☐

   If yes, are you willing to share these with the Department of Health? ☐ ☐

   If no, can you please explain why not:

6. What changes in hospital policy, if any, have been implemented during the past 12 months concerning:
   - Elective Induction prior to 39 weeks
   - Elective Cesarean Delivery prior to 39 weeks

	Yes	No
7. Does your institution have written policies or guidelines related to Elective Inductions and Cesarean Deliveries consistent with the American College of Obstetricians and Gynecologists Guidelines?	☐	☐
8. Are there other guidelines, policies, or procedures related to Elective Inductions and Cesarean Deliveries that your institution follows?	☐	☐
If yes, are you willing to share with the Department of Health?	☐	☐
9. Is there a committee or department in your institution that is responsible for provider education and training? If yes, please provide a contact name and phone number:	☐	☐
10. Are there training opportunities that are available related to Elective Inductions and Cesarean Deliveries available at your institution?	☐	☐
If yes, are you willing to share with the Department of Health?	☐	☐

11. Would you like assistance in identifying training opportunities for your staff regarding Elective Inductions and Cesarean Deliveries? ☐ ☐

12. Do you feel that Elective Inductions and Cesarean Deliveries prior to 39 weeks are major factors contributing to the increased rate of late preterm births in the past decade? ☐ ☐

13. What do you feel are the major factors contributing to the increased rate of late preterm births in the past decade?

Thank you for taking the time to complete this survey, your participation is greatly appreciated.

Family Health Services Division, Hawaii Department of Health
March of Dimes Hawaii Chapter

If you have any questions or concerns, please contact
Dianne M. Okumura, R.N., M.P.H.
(808) 387-5939
(808) 485-2683 - fax

HOSPITAL SURVEY DATA:

HOSPITAL SURVEY "Elective Inductions or Cesareans"	YES	NO	Some What
1. Rates of Induction and Cesarean Delivery Awareness	6	1	4
not sure about inductions as do not have data			
2. Changes of rates of Elective Inductions and Cesarean Deliveries since 2000	4	7	
by ACOG guidelines; do not track data; increase in C-sections; dept guidelines revised in 2001			
3a. Institutions with written policies or guidelines regarding Elective Inductions and Cesarean Deliveries	5	6	
don't have policy or guidelines in place proscribing inductions prior to 39 weeks as have not had issue with providers attempting to do so			
3b. Institutions willing to share written policies or guidelines regarding Elective Inductions and Cesarean Deliveries with the Department of Health	5	6	
when approved by Admin; elective inductions prior to 39 wks not an issue/not problematic at this time; follow IHI guidelines; developing; hospital choice; verbal policy only to induce when patients 41 weeks, occasionally when 40 weeks			
4a. Institutions with quality assurance initiatives regarding Elective Inductions and Cesarean Deliveries	7	4	
follow ACOG guidelines			
4b. Institutions willing to share quality assurance initiatives regarding Elective Inductions and Cesarean Deliveries with the Department of Health	5	4	1 NA
when completed as working with IHI to set up markers and trace performance; PI committee reviews IOLs & repeat C-section prior to 39 weeks only if there is an adverse outcome; when approved; developing now; IHI perinatal bundles			
5a. Institutions with policies or guidelines implemented to reduce Elective Inductions and Cesarean Deliveries prior to 39 weeks	5	5	1
have not needed to implement guidelines to reduce elective deliveries prior to 39 weeks as do not do them; not a problem			
5b. Institutions willing to share policies or guidelines implemented to reduce Elective Inductions and Cesarean Deliveries prior to 39 weeks with the Department of Health	3	3	3; 1 NA
in process and when approved will share; not a problem for past 2 years; IHI guidelines			
6a. Changes in hospital policy implemented during the past 12 months concerning Elective Induction prior to 39 weeks	2	5	2; 2 NA
rates lower than national average; NAS; none; stronger enforcement of 39 week rule for elective C/S or inductions however allow MDs to deliver elective inductions or C/S if positive fetal lung maturity test continues; trying to follow policy, IHI bundle introduced, scheduling induction process changes; under review for formal guidelines; monitoring only; implemented ACOG guidelines few years ago			
6b. Changes in hospital policy implemented during the past 12 months concerning Elective Cesarean Delivery prior to 39 weeks	1	5	3; 2 NA
none done in hospital; NA; none; under review for formal guidelines; monitoring only; implemented ACOG guidelines few years ago			
7. Institutions with written policies or guidelines related to Elective Inductions and Cesarean Deliveries per the American College of Obstetricians and Gynecologists Guidelines	6	5	
developing; follow ACOG guidelines so do not have own P/P			
8a. Institutions with other guidelines, policies, or procedures related to Elective Inductions and Cesarean Deliveries	3	5	2
C-section policy; ACOG guidelines; inductions only none for C/S			
8b. Institutions willing to share other guidelines, policies, or procedures related to Elective Inductions and Cesarean Deliveries with the Department of Health	5	1	5 NA
C section policy; IHI guidelines; upon approval			
9. Institutions with a committee or department that is responsible for provider education and training	5	5	1
Perinatal safety committee; CME, Dept meetings; not for elective deliveries			
10a. Institutions with available training opportunities related to Elective Inductions and Cesarean Deliveries	2	9	
thru grand rounds; NAS; could use training especially for MDs; just education			
10b. Institutions willing to share training opportunities related to Elective Inductions and Cesarean Deliveries with the Department of Health	2		
can send schedule; none			
11. Institutions that would you like assistance in identifying training opportunities for staff regarding Elective Inductions and Cesarean Deliveries	5	6	
not at this time; not needed as do not do this			
12. Hospital Opinion: Elective Inductions and Cesarean Deliveries prior to 39 weeks are major factors contributing to the increased rate of late preterm births in the past decade	7	4	
not at this time; for the most part, military facilities abide by ACOG standards re: elective inductions only on or after 39 weeks. I would imagine that elective inductions performed prior to that gestational age have contributed to the increased rate of later preterm births noted over the past decade.			
13. Hospital Opinion: Major factors contributing to the increased rate of late preterm births in the past decade			
increase multiple gestation due to IVSX; increase pt acuity with co-morbidity-late or no prenatal care, language barrier, DM, Cardiac; choice - people are more informed about what is available and ask for it; inductions after 39 weeks; advanced medical technology for multiple implantations; lack of prenatal care; limited providers; physicians not following policy; improved neonatal care and surfactant (which has revolutionalized a lot for them); substance abuse, smoking, decreased prenatal care; factors for increased rate of late preterm births in the past decade (besides iatrogenic due to early elective induction) might include increased availability of assisted reproductive technology (increasing number of elderly gravitas with comorbid con ditions) limited access to care amongst underserved pregnant population, increase acquiescence to patient autonomy re: their care. Elective deliveries, diet, job stress, economical stress and smoking.			

Appendix IV

PHYSICIAN DEMOGRAPHICS:

The majority of physicians responding to the survey completed their residency between 10 to 29 years prior to completion of the survey (Chart 11).

Chart 11. MD Years Since Completion of Residency

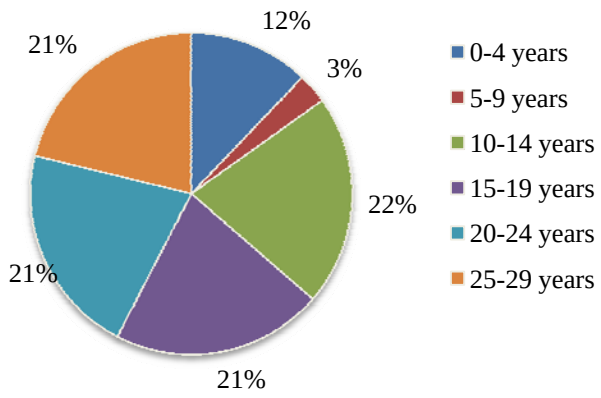
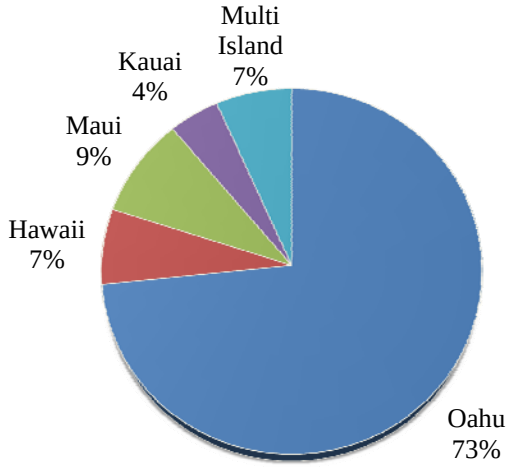


Chart 12. Island of Physician Practice



Island of physician practice ranged from 73% on Oahu, 7% on the big island, 9% on Maui, 4% on Kauai and 7% practice on two or more islands (Chart 12) with 59% of the respondents in solo practice (Chart 13). For physicians practicing in the neighbor isles/multi isles, the majority are in solo practice (Chart 14).

Chart 13. Clinical Practice Setting

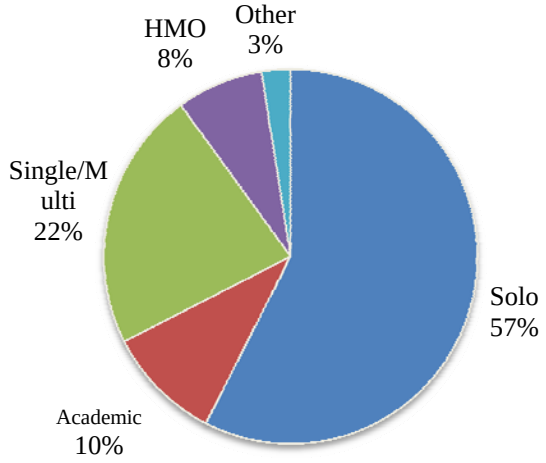
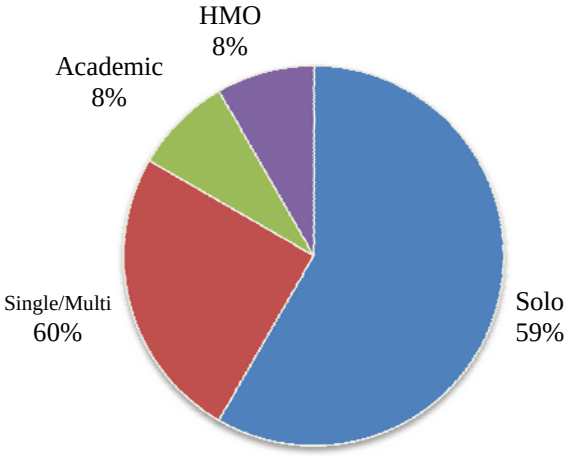


Chart 14. Neighbor Isle/Multi Isle MD Clinical Practice Setting



Of the 44 respondents that provided gender information, 59% were male and 41% female (Chart 15). Of the total number, gender of neighbor isle/multi isle physicians is 58% male and 42% female (Chart 16).

Chart 15. Physician Gender

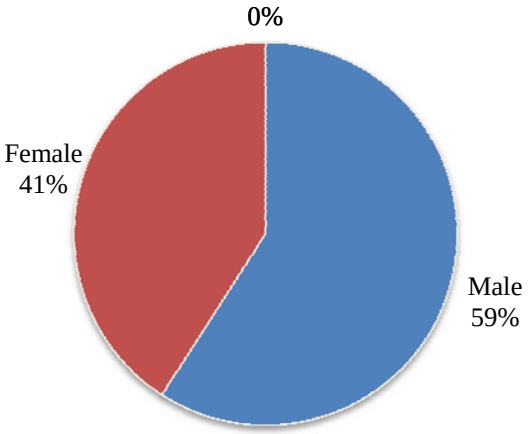
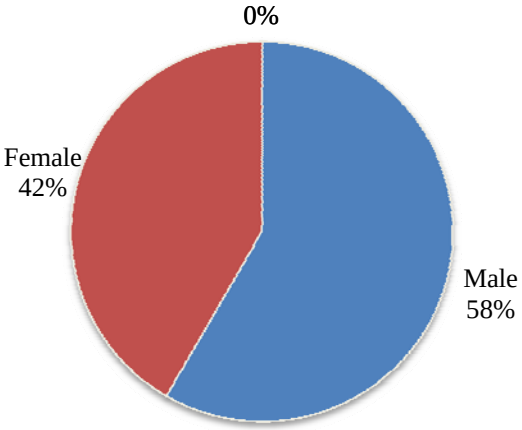


Chart 16. Neighbor Isle/Multi Isle MD Gender



Physician Survey:

Physician Survey
"Elective Inductions or Cesareans"

The 2009 Hawaii State Legislature passed a resolution requesting the Department of Health (DOH) to review and assess the policies and procedures implemented by hospitals to reduce elective cesarean sections and inductions of labor in response to rising rates of preterm births. The DOH convened a workgroup with the March of Dimes, Healthcare Association of Hawaii, and Healthy Mothers Healthy Babies Coalition of Hawaii to address this resolution. Workgroup discussions led to the development of this survey with consultation from Obstetricians with a background in public health. This survey will assist to concisely gather information to develop recommendations for the improvement of practices related to elective inductions and cesarean deliveries towards the goal of reducing the preterm birth rate in Hawaii. Survey respondents will remain anonymous.

1. Rates of cesarean delivery and inductions of labor have been increasing nationally as well as in Hawaii. Within your practice, have you seen an increase in inductions of labor? ☐Yes ☐No ☐Not sure
   in cesarean delivery? ☐Yes ☐No ☐Not sure

2. How concerned are you with the increasing rates of preterm births in Hawaii?
   ☐Very concerned ☐ Somewhat concerned ☐ Not concerned ☐Not sure

3. Please check the box that best describes your reaction to the following statements about obstetric practice.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Not Sure
a. Increases in infertility treatment are causing most of the increase in preterm births					
b. For low risk singleton pregnancies it is usually not a problem to schedule delivery prior to 37 weeks					
c. Patients wanting to schedule the date of their delivery is increasing					
d. I'm comfortable with a scheduled cesarean delivery on maternal request if she has a low risk pregnancy					
e. Most women who had a previous cesarean section opt for repeat cesarean delivery rather than vaginal birth after cesarean section					
f. Malpractice issues have a major impact on obstetrical practice (e.g. lack of tort reform, frivolous lawsuits and other issues)					
g. The causes of preterm delivery are complicated and multifactorial					

4. Based on ACOG practice guidelines, elective inductions (no medical or obstetrical indication) should not be performed until at least (how many) weeks of gestation. ☐34-36 ☐37-38 ☐ ≥39 ☐Not sure

5. At the primary hospital where you practice, are you aware of policies or protocols for the following issues?
   a. Elective cesarean delivery: ☐Yes ☐No ☐Not sure
   b. Elective induction of labor: ☐Yes ☐No ☐Not sure
   c. Preterm birth: ☐Yes ☐No ☐Not sure
6. If you practice at more than one hospital, for the second hospital, are you aware of policies or protocols for the following issues?
   a. Elective cesarean delivery: ☐Yes ☐No ☐Not sure
   b. Elective induction of labor: ☐Yes ☐No ☐Not sure
   c. Preterm birth: ☐Yes ☐No ☐Not sure
7. If you practice at more than two hospitals, for the third hospital, are you aware of policies or protocols for the following issues?
   a. Elective cesarean delivery: ☐Yes ☐No ☐Not sure
   b. Elective induction of labor: ☐Yes ☐No ☐Not sure
   c. Preterm birth: ☐Yes ☐No ☐Not sure

Please complete the other side →

8. Assuming your patient has a nulliparous, uncomplicated, low risk, singleton, cephalic pregnancy, and your patient requests:
   a. An elective cesarean, would you consider performing one? ☐Yes ☐No ☐Not sure
   b. An elective induction, would you consider performing one? ☐Yes ☐No ☐Not sure
   c. At what week of gestation would you want the delivery to occur? _____ weeks

The next questions are about you and your work.

9. Your clinical practice/practice setting is best described as:
   ☐Solo ☐Academic medical center/faculty practice ☐Hospital based (non-academic)
   ☐Single/multi-specialty group ☐HMO ☐Community Health Center
   ☐Other (please specify): _____

10. On which island(s) do you practice in Hawaii? (Check as many as apply)
    ☐Oahu ☐Big Island ☐Kauai
    ☐Maui ☐Molokai ☐Lanai

11. How long has it been since you completed residency training? _____ years
    How long have you practiced in Hawaii? _____ years

12. How many deliveries did you perform in 2008? _____deliveries
    For these deliveries, please estimate the rate for each of the following:
    Cesarean delivery: total C/S _____%
    Of those patients who had a previous C/S, what percentage undergo: Repeat C/S _____% VBAC _____%
    Induction of labor: total _____%

13. What is your gender: ☐Male ☐Female

Comments/suggestions: _____

_____

_____

_____

_____

_____

_____

_____

Thank you for taking the time to complete this survey, your participation is greatly appreciated.
Family Health Services Division, Hawaii Department of Health
March of Dimes Hawaii Chapter

If you have any questions or concerns, please contact
Dianne M. Okumura, R.N., M.P.H.
(808) 387-5939
(808) 485-2683 - fax

10/14/09

PHYSICIAN SURVEY DATA:

Physician Survey
"Elective Inductions or Cesareans"

1a. Incr in inductions of labor	1b. Incr in c-sect delivery	2. Concern w/ incr rates of preterm births in HI	3a. Curr of incr in infertility tx & preterm births	3b. Schd del <37 wks for low risk singl preg	3c. Incr in pts to schd date of del	3d. Comfort schd c-sect del on maternal req for low risk preg	3e. Prev c-sect opt for repeat c-sect del than vag birth after c-sect	3f. Malprac issues w/ mat impact on obstetrical pract	3g. Causes of preterm del complicated & multifactorial	4. Reform of elect inductions per ACOG pract guide	5a. Practice @ primary hosp: Aware of p&p for elect c-sect	5b. Practice @ primary hosp: Aware of p&p for elect induction of labor	5c. Practice @ primary hosp: Aware of p&p for preterm birth	6a. Practice @ > 1 hosp: 2nd hosp: Aware of p&p for elect c-sect	6b. Practice @ > 1 hosp: 2nd hosp: Aware of p&p for elect induction of labor	6c. Practice @ > 1 hosp: 2nd hosp: Aware of p&p for preterm birth	7a. Practice @ > 1 hosp: 3rd hosp: Aware of p&p for elect c-sect	7b. Practice @ > 1 hosp: 3rd hosp: Aware of p&p for elect induction of labor	7c. Practice @ > 1 hosp: 3rd hosp: Aware of p&p for preterm birth	8a. Perform a req elect c-section for pts w/ nulliparous, uncomp, low risk, singleton, cephalic preg	8b. Perform req elect induction for pts w/ nulliparous, uncomp, low risk, singleton, cephalic pregnancy	8c. Del to occur on gestation wk	9. Clinical practice/practice setting	10. Island of Physician practice	11a. Yrs since completion of residency/ train	11b. Years of practice in HI	12. # of del did you performed in 2008	12a. Estimated rate of C-sect deliveries	12b. % pts w/ prev c-sect del had repeat c-sect	12c. % pts w/ prev c-sect del had vaginal birth	13. Physician gender
21 #Y	22 #Y	18 #VC	4 #SA	2 #SA	7 #SA	2 #SA	6 #SA	27 #SA	32 #SA	1 #34-36	34 #Y	36 #Y	35 #Y	22 #Y	22 #Y	21 #Y	7 #Y	7 #Y	6 #Y	25 #Y	34 #Y	1 #38-39	23 #S	33 #O	4 #0-4	6 #0-4	6 <49	7 <10	4 <50	3 <5	8 <5	26 #M
22 #N	22 #N	24 #SC	22 #A	1 #A	19 #A	14 #A	30 #A	13 #A	10 #A	44 # ≥39	6 #N	6 #N	3 #N	5 #N	6 #N	4 #N	1 #N	1 #N	1 #N	12 #N	4 #N	35 39	4 #AMC/ FP	3 #BI	1 #5-9	2 #5-9	9 #50-99	8 11-19%	5 51-75%	5 #6-10	9 #6-10	18 #F
2 #NS	1 #NS	2 #NC	15 #D	5 #D	12 #D	15 #D	5 #D	0 #D	0 #D		5 #NS	3 #NS	7 #NS	3 #NS	2 #NS	5 #NS	0 #NS	0 #NS	1 #NS	7 #NS	5 #NS	0 40	1 #S/MSO	2 #K	7 #10-14	8 #10-14	10 #100-149	11 20-25%	13 76-90%	6 #11-20	5 #11-25	
		0 #NS	2 #SD	36 #SD	3 #SD	12 #SD	1 #SD	2 #SD	0 #SD														3 #HMO	4 #M	7 #15-19	8 #15-19	10 #150-199	6 #26-30%	14 91-100%	2 #21-30	2 #26-40	
			1 #NS	0 #NS	3 #NS	1 #NS	2 #NS	1 #NS	0 #NS														1 #O	3 #MUL	7 #20-24	5 #20-24	1 #200-249	3 35+%	0 >100	3 #31-49	1 #41-59	
																									7 #25-29	5 #25-29	4 >250			4 # >50	2 # >60	
																									9 # ≥30	6 # ≥30						

Comments:

1. thanks for hard work; recently QMC and now KCMC implementing when elective induction must be 39+; have done elective
2. C but disc risk/benefits, usually RN or MD very, very few pts request;
3. #8 - have done @ 32 1/2 primp unfavorable experience with floating UX at term
4. Need to target patients not MDs - smokers, teens, drug addicts, obesity. With the economy pts work 2 jobs, no access to care. Need Tort Reform
5. 37 or >37 Previous Classical cesarean section or high risk such as mild preeclampsia or elev BP or others. For repeat C-section helpful to have data per island' on BI do not do VBAC so repeat C/S rates are higher. Area of interest would be primary vs. repeat C/S ration; also data per hospital would be nice. thank you very much
6. Active management at term has been shown to prevent c-sections, fetal distress, meconium, birth trauma and NICU admissions. 65% of brain damaged babies are born at term and could be prevented. Delivery by 39 weeks should prevent 6000 still births in US every year. Every preg woman should be offered option of inductions with prostaglandins at term. All efforts should be made to get preg term to (38 wks by US)

Attachment A

ACOG PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN–GYNECOLOGISTS

NUMBER 10, NOVEMBER 1999

(Replaces Technical Bulletin Number 217, December 1995)

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins—Obstetrics with the assistance of Susan M. Ramin, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Reaffirmed 2006

Induction of Labor

The goal of induction of labor is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor. According to the National Center for Health Statistics, the overall rate of induction of labor in the United States has increased from 90 per 1,000 live births in 1989 to 184 per 1,000 live births in 1997 (1). Generally, induction of labor has merit as a therapeutic option when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy. The benefits of labor induction must be weighed against the potential maternal or fetal risks associated with this procedure. The purpose of this bulletin is to review current methods for cervical ripening and induction of labor and to summarize the effectiveness of these approaches based on appropriately conducted outcomes-based research. These practice guidelines classify the indications for and contraindications to induction of labor, describe the various agents used for cervical ripening, cite methods used to induce labor, and outline the requirements for the safe clinical use of the various methods of inducing labor.

Background

In 1948, Theobald and associates described their use of the posterior pituitary extract, oxytocin, by intravenous drip for labor induction (2). Five years later, oxytocin was the first polypeptide hormone synthesized by du Vigneaud and associates (3). This synthetic polypeptide hormone has since been used to stimulate uterine contractions. Other methods used for induction of labor include membrane stripping, amniotomy, and administering prostaglandin E (PGE) analogues.

Cervical Ripening

If induction is indicated and the status of the cervix is unfavorable, agents for cervical ripening may be used. The status of the cervix can be determined by the Bishop pelvic scoring system (Table 1) (4). If the total score is more than 8,

Table 1. Bishop Scoring System

	Factor				
Score	Dilation (cm)	Effacement (%)	Station*	Cervical Consistency	Position of Cervix
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	—	—

*Station reflects a –3 to +3 scale.

Modified from Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol 1964;24:267

the probability of vaginal delivery after labor induction is similar to that after spontaneous labor.

Acceptable methods for cervical ripening include mechanical cervical dilators and administration of synthetic prostaglandin E_1 (PGE_1) and prostaglandin E_2 (PGE_2) (5-9). Mechanical dilation methods are effective in ripening the cervix and include hygroscopic dilators, osmotic dilators (*Laminaria japonicum*), the 24-French Foley balloon, and the double balloon device (Atad Ripener Device) (10-15). Laminaria ripen the cervix but may be associated with increased peripartum infections (6, 16).

Misoprostol, a synthetic PGE_1 analogue, can be administered intravaginally or orally and is used for both cervical ripening and induction. It currently is available as a 100-mcg or 200-mcg tablet, and can be broken to provide 25-mcg or 50-mcg doses. Misoprostol currently is approved by the U.S. Food and Drug Administration (FDA) for the prevention of peptic ulcers, but not for cervical ripening or induction of labor.

Two PGE_2 preparations are commercially available: a gel available in a 2.5-mL syringe containing 0.5 mg of dinoprostone and a vaginal insert containing 10 mg of dinoprostone. Both are approved by the FDA for cervical ripening in women at or near term. The vaginal insert releases prostaglandin (PG) at a slower rate (0.3 mg/h) than the gel. Both the gel and the vaginal insert have been reported to increase the probability of successful initial induction, shorten the interval from induction to delivery, and decrease the total and maximal doses of oxytocin needed to induce contractions (17).

Other pharmacologic methods for cervical ripening include continuous intravenous oxytocin drip, extraamniotic saline infusion, vaginal recombinant human relaxin, and intracervical purified porcine relaxin. The safety and efficacy of these latter methods are unclear.

Methods of Labor Induction

In addition to oxytocin and misoprostol, other agents can be used for induction of labor. The progesterone antagonist mifepristone (RU 486) is one such suitable and effective induction agent (18). Nonpharmacologic methods of labor induction include stripping the amniotic membranes, amniotomy, and nipple stimulation.

Oxytocin

Oxytocin, an octapeptide, is one of the most commonly used drugs in the United States. The physiology of oxytocin-stimulated labor is similar to that of spontaneous labor, although individual patients vary in sensitivity and response to oxytocin. Based on pharmacokinetic studies of synthetic oxytocin, uterine response ensues after 3–5 minutes of infusion, and a steady state of oxytocin is achieved in plasma by 40 minutes (19). The uterine response to oxytocin depends on the duration of the pregnancy; there is a gradual increase in response from 20 to 30 weeks of gestation, followed by a plateau from 34 weeks of gestation until term, when sensitivity increases (20). Cervical dilation, parity, and gestational age are predictors of the dose response to oxytocin for labor stimulation (21).

Membrane Stripping

Stripping the amniotic membranes is commonly practiced to induce labor. However, several studies have yielded conflicting results regarding the efficacy of membrane stripping (22–24). Significant increases in phospholipase A_2 activity and prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$) levels occur from membrane stripping (25). Stripping membranes appears to be associated with a greater frequency of spontaneous labor and fewer inductions for postterm pregnancy. In a randomized trial of 195 normal pregnancies beyond 40 weeks of gestation, two thirds of the patients who underwent membrane stripping labored spontaneously within 72 hours, compared with one third of the patients who underwent examination only (26).

Amniotomy

Artificial rupture of the membranes may be used as a method of labor induction, especially if the condition of

the cervix is favorable. Used alone for inducing labor, amniotomy can be associated with unpredictable and sometimes long intervals before the onset of contractions. However, in a trial of amniotomy combined with early oxytocin infusion compared with amniotomy alone, the induction-to-delivery interval was shorter with the amniotomy-plus-oxytocin method (27).

Clinical Considerations and Recommendations

▶ *What are the indications and contraindications to induction of labor?*

Indications for induction of labor are not absolute but should take into account maternal and fetal conditions, gestational age, cervical status, and other factors. Following are examples of maternal or fetal conditions that may be indications for induction of labor:

- Abruptio placentae
- Chorioamnionitis
- Fetal demise
- Pregnancy-induced hypertension
- Premature rupture of membranes
- Postterm pregnancy
- Maternal medical conditions (eg, diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension)
- Fetal compromise (eg, severe fetal growth restriction, isoimmunization)
- Preeclampsia, eclampsia

Labor also may be induced for logistic reasons, for example, risk of rapid labor, distance from hospital, or psychosocial indications. In such circumstances, at least one of the criteria in the box should be met or fetal lung maturity should be established (28).

Generally, the contraindications to labor induction are the same as those for spontaneous labor and vaginal delivery. They include, but are not limited to, the following situations:

- Vasa previa or complete placenta previa
- Transverse fetal lie
- Umbilical cord prolapse
- Previous transfundal uterine surgery

Confirmation of Term Gestation

- Fetal heart tones have been documented for 20 weeks by nonelectronic fetoscope or for 30 weeks by Doppler.
- It has been 36 weeks since a positive serum or urine human chorionic gonadotropin pregnancy test was performed by a reliable laboratory.
- An ultrasound measurement of the crown–rump length, obtained at 6–12 weeks, supports a gestational age of at least 39 weeks.
- An ultrasound obtained at 13–20 weeks confirms the gestational age of at least 39 weeks determined by clinical history and physical examination.

However, the individual patient and clinical situation should be considered in determining when induction of labor is contraindicated. Several obstetric situations are not contraindications to the induction of labor but do necessitate special attention. These include, but are not limited to, the following:

- One or more previous low-transverse cesarean deliveries
- Breech presentation
- Maternal heart disease
- Multifetal pregnancy
- Polyhydramnios
- Presenting part above the pelvic inlet
- Severe hypertension
- Abnormal fetal heart rate patterns not necessitating emergent delivery

▶ *What criteria should be met before the cervix is ripened or labor is induced?*

Assessment of gestational age and consideration of any potential risks to the mother or fetus are of paramount importance for appropriate evaluation and counseling before initiating cervical ripening or labor induction. The patient should be counseled regarding the indications for induction, the agents and methods of labor stimulation, and the possible need for repeat induction or cesarean delivery.

Additional requirements for cervical ripening and induction of labor include cervical assessment, pelvic assessment, assessment of fetal size and presentation, and personnel familiar with the effects of uterine stimu-

lants on the mother and fetus because uterine hyperstimulation may occur with induction of labor. Monitoring fetal heart rate and uterine contractions is recommended as for any high-risk patient in active labor. Although trained nursing personnel can monitor labor induction, a physician capable of performing a cesarean delivery should be readily available.

▶ *What is the relative effectiveness of available pharmacologic methods for cervical ripening?*

Intracervical or intravaginal PGE_2 (dinoprostone) commonly is used and is superior to placebo or no therapy in promoting cervical ripening (29). Several prospective randomized clinical trials and a meta-analysis have demonstrated that PGE_1 (misoprostol) is an effective method for cervical ripening (30-34). Misoprostol administered intravaginally has been reported to be either superior to or as efficacious as dinoprostone gel (9, 32, 34, 35). It is difficult, however, to compare the results of studies on misoprostol because of differences in endpoints, including Bishop score, duration of labor, total oxytocin use, successful induction, and cesarean delivery rate. The rates of operative vaginal delivery and cesarean delivery are inconsistent between trials. The cesarean delivery rate has been reported to be higher with dinoprostone compared with misoprostol (31); however, further studies are needed. The results of cesarean delivery rate with dinoprostone use are inconsistent; some have shown a reduction but most have not shown a significant decrease.

▶ *How should prostaglandin be administered?*

If there is inadequate cervical change with minimal uterine activity after one dose of intracervical PGE_2, a second dose may be given 6–12 hours later. The manufacturers recommend a maximum cumulative dose of 1.5 mg of dinoprostone (three doses or 7.5 mL of gel) within a 24-hour period. A minimum safe time interval between PG administration and initiation of oxytocin has not been determined. According to the manufacturers' guidelines, after use of 1.5 mg of dinoprostone in the cervix or 2.5 mg in the vagina, oxytocin induction should be delayed for 6–12 hours because the effect of PG may be heightened with oxytocin. After use of dinoprostone in sustained-release form, delaying oxytocin induction for 30–60 minutes after removal is sufficient. One quarter of one 100-mcg tablet (approximately 25-mcg) of misoprostol should be considered for cervical ripening and labor induction.

▶ *What are the potential complications with each method of cervical ripening, and how are they managed?*

Hyperstimulation may occur with the use of the PGE analogues. There is no uniform definition of uterine hyperstimulation. In some studies hyperstimulation is never defined. In others, uterine hyperstimulation has been defined as either a series of single contractions lasting 2 minutes or more or a contraction frequency of five or more in 10 minutes (36). Another definition of hyperstimulation is uterine contractions lasting 2 minutes or more or a contraction frequency of 5 or more in 10 minutes with evidence that the fetus is not tolerating this contraction pattern, as demonstrated by late deceleration, or fetal bradycardia (37). Fortunately, most women and their fetuses tolerate uterine hyperstimulation without adverse outcome.

The intracervical PGE_2 gel (0.5 mg) has a 1% rate of uterine hyperstimulation, while the intravaginal PGE_2 gel (2–5 mg) or vaginal insert is associated with a 5% rate (29, 36–38). Uterine hyperstimulation typically begins within 1 hour after the gel or insert is placed but may occur up to 9 1/2 hours after the vaginal insert has been placed (36–38).

Removing the PGE_2 vaginal insert usually will help reverse the effect of hyperstimulation. Irrigation of the cervix and vagina is not beneficial. Maternal side effects from low-dose PGE_2 (fever, vomiting, and diarrhea) are quite uncommon (17). Prophylactic antiemetics, antipyretics, and antidiarrheal agents usually are not needed. The manufacturers recommend that caution be exercised when using PGE_2 in patients with glaucoma, severe hepatic or renal dysfunction, or asthma. However, PGE_2 is a bronchodilator, and there are no reports of bronchoconstriction or significant blood pressure changes after the administration of the low-dose gel.

In several studies of misoprostol, the term tachysystole was used to define hyperstimulation without corresponding fetal heart rate abnormalities in order to distinguish this complication from hyperstimulation with fetal heart rate changes. Data indicate that both tachysystole (defined in some studies as six or more uterine contractions in 10 minutes in consecutive 10-minute intervals) and hyperstimulation (with and without fetal heart rate changes) are increased with a 50-mcg or greater dose of misoprostol (9, 30, 39, 40). There seems to be a trend toward lower rates of uterine hyperstimulation with fetal heart rate changes with lower dosages of misoprostol (25 mcg every 6 hours versus every 3 hours) (40). Although in studies of misoprostol there were no differences in perinatal outcome, the studies have been insufficient in

size to exclude the possibility of uncommon serious adverse effects (40). The use of misoprostol in women with prior cesarean birth has been associated with an increase in uterine rupture (41). Misoprostol use for second-trimester pregnancy termination also has been associated with uterine rupture, especially when used with oxytocin infusion (40). An increase in meconium-stained amniotic fluid also has been reported with misoprostol use (34). Although misoprostol appears to be safe and effective in inducing labor in women with unfavorable cervices, further studies are needed to determine the optimal dosage, timing interval, and pharmacokinetics of misoprostol. Moreover, data are needed on the management of complications related to misoprostol and when it should be discontinued. If uterine hyperstimulation and a nonreassuring fetal heart rate pattern occur with misoprostol use and there is no response to routine corrective measures (maternal repositioning and supplemental oxygen administration), cesarean delivery should be considered. Subcutaneous terbutaline also can be used in an attempt to correct the nonreassuring fetal heart rate tracing or the abnormal contraction pattern or both.

Increased maternal and neonatal infection have been reported in connection with the use of laminaria and hygroscopic dilators when compared with the PGE_2 analogues (6, 12, 16).

▶ *What are the recommended guidelines for fetal surveillance for each type of prostaglandin preparation?*

The PG preparations should be administered at or near the labor and delivery suite, where uterine activity and fetal heart rate can be monitored continuously. The patient should remain recumbent for at least 30 minutes. The fetal heart rate and uterine activity should be monitored continuously for a period of 30 minutes to 2 hours after administration of the PGE_2 gel (42). The patient may be transferred elsewhere if there is no increase in uterine activity and the fetal heart rate is unchanged after this period of observation. Uterine contractions usually are evident in the first hour and exhibit peak activity in the first 4 hours (42, 43). Fetal heart rate monitoring should be continued if regular uterine contractions persist; maternal vital signs should be recorded as well.

Because uterine hyperstimulation can occur as late as 9 1/2 hours after placement of the PGE_2 vaginal insert, fetal heart rate and uterine activity should be monitored electronically from the time the device is placed until at least 15 minutes after it is removed (44). This controlled-release PGE_2 vaginal pessary should be removed at the onset of labor (37).

Patients treated with misoprostol should receive fetal heart rate and uterine activity monitoring in a hospital setting until further studies evaluate the safety of outpatient therapy.

▶ *Are cervical ripening methods restricted to inpatient use only?*

One small, randomized trial found that sequential outpatient administration of low-dose (2-mg) PGE_2 gel was no better than placebo in ripening the cervix in postterm patients (45). Larger controlled studies are needed to establish an effective and safe dose and vehicle for PGE_2 before application on an outpatient basis can be recommended. However, outpatient use may be appropriate in carefully selected patients.

▶ *What are the potential complications of various methods of induction?*

The side effects of oxytocin use are principally dose related; uterine hyperstimulation and subsequent fetal heart rate deceleration are the most common side effects. Hyperstimulation may result in abruptio placentae or uterine rupture. Fortunately, uterine rupture secondary to oxytocin use is rare even in parous women (46). Water intoxication can occur with high concentrations of oxytocin infused with large quantities of hypotonic solutions. The antidiuretic effect usually is observed only after prolonged administration with at least 40mU of oxytocin per minute (47).

Misoprostol appears to be safe and beneficial for inducing labor in a woman with an unfavorable cervix. Although the exact incidence of uterine tachysystole is unknown and the criteria used to define this complication are not always clear in the various reports, there are reports of uterine tachysystole occurring more frequently in women given misoprostol (30–32). There does not appear to be a significant increase in adverse fetal outcomes from tachysystole (31, 35); however, one also must consider the possibility of uterine rupture as a rare complication of induction of labor with misoprostol (40). The occurrence of complications does appear to be dose-dependent (9, 40). Oral misoprostol administration is associated with fewer abnormal fetal heart rate patterns and episodes of uterine hyperstimulation when compared with vaginal administration (48), but there are not yet enough data to support oral administration as an alternative method.

The potential risks associated with amniotomy include prolapse of the umbilical cord, chorioamnionitis, significant umbilical cord compression, and rupture of vasa previa. The physician should palpate for an umbili-

Table 2. Labor Stimulation with Oxytocin: Examples of Low- and High-Dose Oxytocin

Regimen	Starting Dose	Incremental Increase (mU/min)	Dosage Interval (min)
Low-Dose	0.5–1	1	30–40
	1–2	2	15
High-Dose	~6	~6	15
	6	6*, 3, 1	20–40

*The incremental increase is reduced to 3 mU/min in presence of hyperstimulation and reduced to 1 mU/min with recurrent hyperstimulation.

cal cord and avoid dislodging the fetal head. The fetal heart rate should be assessed before and immediately after amniotomy.

Stripping the amniotic membranes is associated with bleeding from undiagnosed placenta previa or low-lying placenta, and accidental amniotomy. Uterine hyperactivity and fetal heart rate decelerations have been reported in association with nipple stimulation (49).

▶ *When oxytocin is used for induction of labor, what dosage should be used and what precautions should be taken?*

Any of the low- or high-dose oxytocin regimens outlined in Table 2 are appropriate for labor induction (50–56). Most women attain normal progression of labor with 150–350 Montevideo units of uterine activity (50). Low-dose regimens and less frequent increases in dose are associated with decreased uterine hyperstimulation (52). High-dose regimens and more frequent dose increases are associated with shorter labor and less frequent cases of chorioamnionitis and cesarean delivery for dystocia, but increased rates of uterine hyperstimulation (52).

Each hospital's obstetrics and gynecology department should develop guidelines for the preparation and administration of oxytocin. Synthetic oxytocin generally is diluted 10 U in 1,000 mL of an isotonic solution for an oxytocin concentration of 10 mU/mL. Oxytocin should be administered by infusion using a pump that allows precise control of the flow rate and permits accurate minute-to-minute control. Bolus administration of oxytocin can be avoided by piggybacking the infusion into the main intravenous line near the venipuncture site. Oxytocin also can be administered by pulsatile infusion, which may better simulate spontaneous labor (53). The total amount of oxytocin given may be decreased by administering oxytocin in 10-minute pulse infusions (53, 57).

A numeric value for the maximum dose of oxytocin has not been established. The fetal heart rate and uterine contractions should be monitored closely. Oxytocin should be administered by trained personnel who are familiar with its effects.

▶ *How should complications associated with oxytocin use be managed?*

If hyperstimulation with a nonreassuring fetal heart rate occurs, intravenous infusion of oxytocin should be decreased or discontinued to correct the pattern. Additional measures may include turning the woman on her side and administering oxygen or more intravenous fluid. If hyperstimulation persists, use of terbutaline or other tocolytics may be considered.

Hypotension may occur following a rapid intravenous injection of oxytocin; therefore, it is imperative that a dilute oxytocin infusion be used even in the immediate puerperium. Although amniotic fluid embolism was once thought to be associated with oxytocin-induced labor, there is no causal relationship between oxytocin use or antecedent hyperstimulation and amniotic fluid embolism (58, 59).

▶ *Are the various methods of labor induction equally applicable to patients with intact or ruptured membranes?*

The same precautions should be exercised when prostaglandins are used for induction of labor with ruptured membranes as for intact membranes. Intravaginal PGE_2 for induction of labor in women with premature rupture of membranes appears to be safe and effective, although it has not been approved by the FDA for this indication (60). In a meta-analysis of labor induction in women with premature rupture of membranes at term, only one dose of intravaginal misoprostol was necessary

for successful labor induction in 86% of the patients (61). There is no evidence that use of either of these prostaglandins increases the risk of infection in women with ruptured membranes (60, 61).

▶ *What methods can be used for induction of labor with intrauterine fetal demise in the late second or third trimester?*

Intravenous oxytocin usually is a safe and effective method of inducing labor for a fetal death near term but is less effective remote from term (62). Laminaria or hygroscopic cervical dilators may be beneficial before the use of oxytocin or PGE for induction (63, 64). High-dose PGE_2 vaginal suppositories and more concentrated intravenous oxytocin are effective for achieving delivery, particularly when the gestational age is 28 weeks or less (62, 65, 66). Reported side-effects associated with higher doses of PGE_2 include nausea, vomiting, and diarrhea, which may be ameliorated with pretreatment medications. Although PGE_2 vaginal suppositories have been used safely in the third trimester (67), the risk of uterine rupture is increased. Vaginal misoprostol, intramuscular or extraamniotic infusion of $PGF_{2\alpha}$, and mifepristone also have been used safely and effectively; however, studies are few. In one study, mifepristone (600 mg per day for 48 hours) was effective in achieving delivery within 72 hours after the initial dose in 63% of women (68). In another study using intravaginal misoprostol, the mean time from induction to delivery was 12.6 hours, and all women delivered by 48 hours (69).

▶ *What is the cost effectiveness of these agents?*

There is a significant cost difference for induction of labor between misoprostol and dinoprostone. The approximate cost of a 100-mcg tablet of misoprostol ranges from $0.36 to $1.20, whereas a dinoprostone gel kit ranges from $65 to $75, and the dinoprostone vaginal insert is $165 (34, 35, 39, 70). The cost would be increased further if oxytocin augmentation were needed. Moreover, dinoprostone is an unstable compound that requires refrigeration to maintain its potency, whereas misoprostol is stable at room temperature.

Summary

The following recommendations are based on good and consistent scientific evidence (Level A):

- Prostaglandin E analogues are effective in promoting cervical ripening and inducing labor.
- Women in whom induction of labor is indicated may be appropriately managed with either a low- or high-dose oxytocin regimen.
- Fetal heart rate and uterine activity should be continuously monitored from the time the PGE_2 vaginal insert is placed until at least 15 minutes after it is removed.
- High-dose PGE_2 vaginal suppositories may be used in the management of intrauterine fetal demise in the second trimester of pregnancy.
- Although the optimal dose and timing interval of misoprostol is unknown, lower doses (25 mcg every 3–6 hours) are effective for cervical ripening and induction of labor.
- With term premature rupture of membranes, labor may be induced with prostaglandins.

The following recommendations are based on evidence that may be limited or inconsistent (Level B):

- Misoprostol use in women with prior cesarean birth should be avoided because of the possibility of uterine rupture.
- The use of higher doses of misoprostol (50 mcg every 6 hours) to induce labor may be appropriate in some situations, although there are reports of increased risk of complications, including uterine hyperstimulation.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- For women with third-trimester intrauterine fetal demise, intravaginal misoprostol can be used to induce labor.
- Fetal heart rate and uterine activity should be continuously monitored from 30 minutes to 2 hours after administration of PGE_2 gel.

References

1. Ventura SJ, Martin JA, Curtin SC, Mathews TJ. Births: Final data for 1997. National Center for Health Statistics, National Vital Statistics Reports, 1999;47(18):1–96 (Level II-3)
2. Theobald GW, Graham A, Campbell J, Gange PD, Driscoll WJ. The use of post-pituitary extract in physiological amounts in obstetrics. BMJ 1948;2:123–127 (Level III)
3. du Vigneaud V, Ressler C, Swan JM, Roberts CW, Katsoyannis PG, Gordon S. The synthesis of an octapeptide amide with the hormonal activity of oxytocin. J Am Chem Soc 1953;75:4879–4880 (Level III)

4. Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol 1964;24:266–268 (Level III)

5. Cross WG, Pitkin RM. Laminaria as an adjunct in induction of labor. Obstet Gynecol 1978;51:606–608 (Level I)

6. Krammer J, Williams MC, Sawai SK, O'Brien WF. Preinduction cervical ripening: a randomized comparison of two methods. Obstet Gynecol 1995;85:614–618 (Level I)

7. Fletcher HM, Mitchell S, Simeon D, Frederick J, Brown D. Intravaginal misoprostol as a cervical ripening agent. Br J Obstet Gynaecol 1993;100:641–644 (Level I)

8. Porto M. The unfavorable cervix: methods of cervical priming. Clin Obstet Gynecol 1989;32:262–268 (Level III)

9. Wing DA, Rahall A, Jones MM, Goodwin TM, Paul RH. Misoprostol: an effective agent for cervical ripening and labor induction. Am J Obstet Gynecol 1995;172: 1811–1816 (Level I)

10. Atad J, Hallak M, Ben-David Y, Auslender R, Abramovici H. Ripening and dilatation of the unfavourable cervix for induction of labour by a double balloon device: experience with 250 cases. Br J Obstet Gynaecol 1997;104:29–32 (Level III)

11. Blumenthal PD, Ramanauskas R. Randomized trial of Dilapan and Laminaria as cervical ripening agents before induction of labor. Obstet Gynecol 1990;75:365–368 (Level I)

12. Chua S, Arulkumaran S, Vanja K, Ratnam SS. Preinduction cervical ripening: prostaglandin E_2 gel vs. hygroscopic mechanical dilator. J Obstet Gynaecol Res 1997;23: 171–177 (Level I)

13. Gilson GJ, Russell DJ, Izquierdo LA, Qualls CR, Curet LB. A prospective randomized evaluation of a hygroscopic cervical dilator, Dilapan, in the preinduction ripening of patients undergoing induction of labor. Am J Obstet Gynecol 1996;175:145–149 (Level I)

14. Lin A, Kupferminc M, Dooley SL. A randomized trial of extra-amniotic saline infusion versus laminaria for cervical ripening. Obstet Gynecol 1995;86:545–549 (Level I)

15. Lyndrup J, Nickelsen C, Weber T, Molnitz E, Guldbaek E. Induction of labour by balloon catheter with extra-amniotic saline infusion (BCEAS): a randomized comparison with PGE_2 vaginal pessaries. Eur J Obstet Gynecol Reprod Biol 1994;53:189–197 (Level I)

16. Kazzi GM, Bottoms SF, Rosen MG. Efficacy and safety of laminaria digitata for preinduction ripening of the cervix. Obstet Gynecol 1982;60:440–443 (Level II-2)

17. Brindley BA, Sokol RJ. Induction and augmentation of labor: basis and methods for current practice. Obstet Gynecol Surv 1988;43:730–743 (Level III)

18. Frydman R, Lelaidier C, Baton-Saint-Mleux C, Fernandez H, Vial, M, Bourget P. Labor induction in women at term with mifepristone (RU 486): a double-blind, randomized, placebo-controlled study. Obstet Gynecol 1992;80: 972–975 (Level I)

19. Seitchik J, Amico J, Robinson AG, Castillo M. Oxytocin augmentation of dysfunctional labor. IV. Oxytocin pharmacokinetics. Am J Obstet Gynecol 1984;150:225–228 (Level III)

20. Caldeyro-Barcia R, Poseiro JJ. Physiology of the uterine contraction. Clin Obstet Gynecol 1960;3:386–408 (Level III)

21. Satin AJ, Leveno KJ, Sherman ML, McIntire DD. Factors affecting the dose response to oxytocin for labor stimulation. Am J Obstet Gynecol 1992;166:1260–1261 (Level II-3)

22. Crane J, Bennett K, Young D, Windrim R, Kravitz H. The effectiveness of sweeping membranes at term: a randomized trial. Obstet Gynecol 1997;89:586–590 (Level I)

23. Goldenberg M, Dulitzky M, Feldman B, Zolti M, Bider D. Stretching of the cervix and stripping of the membranes at term: a randomised controlled study. Eur J Obstet Gynecol Reprod Biol 1996;66:129–132 (Level I)

24. Wiriyasirivaj B, Vutyavanich T, Ruangsri RA. A randomized controlled trial of membrane stripping at term to promote labor. Obstet Gynecol 1996;87:767–770 (Level I)

25. McColgin SW, Bennett WA, Roach H, Cowan BD, Martin JN Jr, Morrison JC. Parturitional factors associated with membrane stripping. Am J Obstet Gynecol 1993;169: 71–77 (Level I)

26. Allott HA, Palmer CR. Sweeping the membranes: a valid procedure in stimulating the onset of labour? Br J Obstet Gynaecol 1993;100:898–903 (Level I)

27. Moldin PG, Sundell G. Induction of labour: a randomised clinical trial of amniotomy versus amniotomy with oxytocin infusion. Br J Obstet Gynaecol 1996;103:306–312 (Level I)

28. American College of Obstetricians and Gynecologists. Assessment of fetal lung maturity. ACOG Educational Bulletin 230. Washington DC: ACOG, 1996 (Level III)

29. Rayburn WF. Prostaglandin E_2 gel for cervical ripening and induction of labor: a critical analysis. Am J Obstet Gynecol 1989;160:529–534 (Level III)

30. Buser D, Mora G, Arias F. A randomized comparison between misoprostol and dinoprostone for cervical ripening and labor induction in patients with unfavorable cervices. Obstet Gynecol 1997;89:581–585 (Level I)

31. Sanchez-Ramos L, Kaunitz AM, Wears RL, Delke I, Gaudier FL. Misoprostol for cervical ripening and labor induction: a meta-analysis. Obstet Gynecol 1997;89: 633–642 (Meta-analysis)

32. Sanchez-Ramos L, Peterson DE, Delke I, Gaudier FL, Kaunitz AM. Labor induction with prostaglandin E_1 misoprostol compared with dinoprostone vaginal insert: a randomized trial. Obstet Gynecol 1998;91:401–405 (Level I)

33. Srisomboon J, Piyamongkol W, Aiewsakul P. Comparison of intracervical and intravaginal misoprostol for cervical ripening and labour induction in patients with an unfavorable cervix. J Med Assoc Thai 1997;80:189–194 (Level I)

34. Wing DA, Jones MM, Rahall A, Goodwin TM, Paul RH. A comparison of misoprostol and prostaglandin E_2 gel for preinduction cervical ripening and labor induction. Am J Obstet Gynecol 1995;172:1804–1810 (Level I)

35. Wing DA, Ortiz-Omphroy G, Paul RH. A comparison of intermittent vaginal administration of misoprostol with continuous dinoprostone for cervical ripening and labor induction. Am J Obstet Gynecol 1997;177:612–618 (Level I)

36. Rayburn WF, Wapner RJ, Barss VA, Spitzberg E, Molina RD, Mandsageer N, Yonekura ML. An intravaginal controlled-release prostaglandin E_2 pessary for cervical ripening and initiation of labor at term. Obstet Gynecol 1992;79:374–379 (Level I)

37. Witter FR, Rocco LE, Johnson TR. A randomized trial of prostaglandin E_2 in a controlled-release vaginal pessary for cervical ripening at term. Am J Obstet Gynecol 1992; 166:830–834 (Level I)

38. Witter FR, Mercer BM. Improved intravaginal controlled-release prostaglandin E_2 insert for cervical ripening at term. The Prostaglandin E_2 Insert Study Group. J Matern Fetal Med 1996;5:64–69 (Level I)

39. Magtibay PM, Ramin KD, Harris DY, Ramsey PS, Ogburn PL Jr. Misoprostol as a labor induction agent. J Matern Fetal Med 1998;7:15–18 (Level I)

40. Hofmeyr GJ. Vaginal misoprostol for cervical ripening and labour induction in late pregnancy. The Cochrane Library 1999; Issue 2:1–18 (Meta-analysis)

41. Wing DA, Lovett K, Paul RH. Disruption of prior uterine incision following misoprostol for labor induction in women with previous cesarean section. Obstet Gynecol 1998;91:828–830 (Level III)

42. Bernstein P. Prostaglandin E_2 gel for cervical ripening and labour induction: a multicentre placebo-controlled trial. CMAJ 1991;145:1249–1254 (Level I)

43. Miller AM, Rayburn WF, Smith CV. Patterns of uterine activity after intravaginal prostaglandin E_2 during preinduction cervical ripening. Am J Obstet Gynecol 1991; 165:1006–1009 (Level II-1)

44. American College of Obstetricians and Gynecologists. Monitoring during induction of labor with dinoprostone. ACOG Committee Opinion 209. Washington DC: ACOG, 1998 (Level III)

45. Sawai SK, Williams MC, O'Brien WF, Angel JL, Mastrogiannis DS, Johnson L. Sequential outpatient application of intravaginal prostaglandin E_2 gel in the management of postdates pregnancies. Obstet Gynecol 1991;78: 19–23 (Level I)

46. Flannelly GM, Turner MJ, Rassmussen MJ, Stronge JM. Rupture of the uterus in Dublin; An update. J Obstet Gynaecol 1993;13:440–443 (Level II-3)

47. Whalley PJ, Pritchard JA. Oxytocin and water intoxication. JAMA 1963:186;601–603

48. Toppozada MK, Anwar MY, Hassan HA, El-Gazaerly WS. Oral or vaginal misoprostol for induction of labor. Int J Gynaecol Obstet 1997;56:135–139 (Level I)

49. Schellpfeffer MA, Hoyle D, Johnson JWC. Antepartal uterine hypercontractility secondary to nipple stimulation. Obstet Gynecol 1985;65:588–591 (Level III)

50. Hauth JC, Hankins GD, Gilstrap LC III, Strickland DM, Vance P. Uterine contraction pressures with oxytocin induction/augmentation. Obstet Gynecol 1986;68: 305–309 (Level II-2)

51. Satin AJ, Leveno KJ, Sherman ML, Brewster DS, Cunningham FG. High- versus low-dose oxytocin for labor stimulation. Obstet Gynecol 1992;80:111–116 (Level II-1)

52. Crane JM, Young DC. Meta-analysis of low-dose versus high-dose oxytocin for labour induction. J Soc Obstet Gynaecol Can 1998;20:1215–1223 (Meta-analysis)

53. Cummiskey KC, Dawood MY. Induction of labor with pulsatile oxytocin. Am J Obstet Gynecol 1990;163: 1868–1874 (Level I)

54. Blakemore KJ, Qin NG, Petrie RH, Paine LL. A prospective comparison of hourly and quarter-hourly oxytocin dose increase intervals for the induction of labor at term. Obstet Gynecol 1990;75:757–761 (Level I)

55. Mercer B, Pilgrim P, Sibai B. Labor induction with continuous low-dose oxytocin infusion: a randomized trial. Obstet Gynecol 1991;77:659–663 (Level I)

56. Muller PR, Stubbs TM, Laurent SL. A prospective randomized clinical trial comparing two oxytocin induction protocols. Am J Obstet Gynecol 1992;167:373–380; discussion 380–381 (Level I)

57. Willcourt RJ, Pager D, Wendel J, Hale RW. Induction of labor with pulsatile oxytocin by a computer-controlled pump. Am J Obstet Gynecol 1994;170:603–608 (Level I)

58. Clark SL, Hankins GD, Dudley DA, Dildy GA, Porter TF. Amniotic fluid embolism: analysis of the national registry. Am J Obstet Gynecol 1995;172:1158–1169 (Level III)

59. Morgan M. Amniotic fluid embolism. Anaesthesia 1979; 34:20–32 (Level III)

60. Ray DA, Garite TJ. Prostaglandin E_2 for induction of labor in patients with premature rupture of membranes at term. Am J Obstet Gynecol 1992;166:836–843 (Level I)

61. Sanchez-Ramos L, Chen AH, Kaunitz AM, Gaudier FL, Delke I. Labor induction with intravaginal misoprostol in term premature rupture of the membranes: a randomized study. Obstet Gynecol 1997;89:909–912 (Level I)

62. Pitkin RM. Fetal death: diagnosis and management. Am J Obstet Gynecol 1987;157:583–589 (Level III)

63. Berkus MD, Laufe LE, Castillo M. Lamicel for induction of labor. J Reprod Med 1990;35:219–221 (Level II-2)

64. Sanchez-Ramos L, Kaunitz AM, Connor PM. Hygroscopic cervical dilators and prostaglandin E_2 gel for preinduction cervical ripening. A randomized, prospective comparison. J Reprod Med 1992;37:355–359 (Level I)

65. Kochenour NK. Management of fetal demise. Clin Obstet Gynecol 1987;30:322–330 (Level III)

66. American College of Obstetricians and Gynecologists. Diagnosis and management of fetal death. ACOG Technical Bulletin 176. Washington DC: ACOG, 1993 (Level III)

67. Kent DR, Goldstein AI, Linzey EM. Safety and efficacy of vaginal prostaglandin E_2 suppositories in the management of third-trimester fetal demise. J Reprod Med 1984;29: 101–102 (Level III)

68. Cabrol D, Dubois C, Cronje H, Gonnet JM, Guillot M, Maria B, et al. Induction of labor with mifepristone (RU 486) in intrauterine fetal death. Am J Obstet Gynecol 1990;163:540–542 (Level I)

69. Bugalho A, Bique C, Machungo F, Faaundes A. Induction of labor with intravaginal misoprostol in intrauterine fetal death. Am J Obstet Gynecol 1994;171:538–541 (Level III)

70. Chuck FJ, Huffaker BJ. Labor induction with intravaginal misoprostol versus intracervical prostaglandin E_2 gel (Prepidil gel): randomized comparison. Am J Obstet Gynecol 1995;173:1137–1142 (Level I)

The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and February 1999. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following catetories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

Copyright © November 1999 by the American College of Obstetricians and Gynecologists. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from the publisher.

Requests for authorization to make photocopies should be directed to Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, (978) 750-8400.

ISSN 1099-3630

The American College of Obstetricians and Gynecologists
409 12th Street, SW
PO Box 96920
Washington, DC 20090-6920

ACOG COMMITTEE OPINION

Number 394 • December 2007 (Replaces No. 386, November 2007)

Cesarean Delivery on Maternal Request

Committee on Obstetric Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

ABSTRACT: Cesarean delivery on maternal request is defined as a primary cesarean delivery at maternal request in the absence of any medical or obstetric indication. A potential benefit of cesarean delivery on maternal request is a decreased risk of hemorrhage for the mother. Potential risks of cesarean delivery on maternal request include a longer maternal hospital stay, an increased risk of respiratory problems for the baby, and greater complications in subsequent pregnancies, including uterine rupture and placental implantation problems. Cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity. Cesarean delivery on maternal request should not be motivated by the unavailability of effective pain management. Cesarean delivery on maternal request is not recommended for women desiring several children, given that the risks of placenta previa, placenta accreta, and the need for gravid hysterectomy increase with each cesarean delivery.

Cesarean delivery on maternal request is defined as a primary cesarean delivery at maternal request in the absence of any medical or obstetric indication. Cesarean delivery rates in the United States are at the highest levels ever, with more than 1.2 million cesarean deliveries (30.2% of live births) performed in 2005 (1). The incidence of cesarean delivery on maternal request and its contribution to the overall increase in the cesarean delivery rate are not known, but it is estimated that 2.5% of all births in the United States are cesarean delivery on maternal request (2).

Cesarean delivery on maternal request is not a well-recognized clinical entity, and there are no accurate means of reporting it for research studies, coding, or reimbursement. There are few studies that directly compare the intended mode of delivery (ie, cesarean delivery on maternal request or planned vaginal delivery). Most of the current knowledge is based on indirect analyses that compare elective cesarean deliveries without labor (instead of cesarean delivery on maternal request) with the combination of vaginal deliveries and unplanned and emergency cesarean deliveries (instead of planned vaginal deliveries) or outcomes of actual modes of delivery.

At the National Institutes of Health State-of-the-Science Conference on Cesarean Delivery on Maternal Request in 2006, a panel of experts was charged with reviewing the available literature and expert opinions on the subject (2). A systematic literature review of 1,406 recent articles was conducted to evaluate the relevance of existing studies on cesarean delivery on maternal request and the quality of evidence. The panel concluded that the available information comparing the risks and benefits of cesarean delivery on maternal request and planned vaginal delivery does not provide the basis for a recommendation for either mode of delivery. The panel identified the best information available on the short-term and long-term risks and benefits of cesarean delivery on maternal request and planned vaginal delivery for both the mother and her baby.

Benefits and Risks of Cesarean Delivery on Maternal Request Compared With Planned Vaginal Delivery

Maternal Outcomes

Potential short-term maternal benefits of planned vaginal delivery included a shorter maternal length of hospital stay, lower infection rates, fewer anesthetic complications, and higher breastfeeding initiation rates. However, at 3 months and 24 months after

The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

delivery, breastfeeding rates did not differ by mode of delivery (3, 4).

Potential short-term maternal benefits of planned cesarean delivery include a decreased risk of postpartum hemorrhage and transfusion, fewer surgical complications, and a decrease in urinary incontinence during the first year after delivery. Analysis of stress urinary incontinence at 2 years (3) and 5 years after delivery (5) showed no difference by mode of delivery. The benefit of a planned cesarean delivery may be eliminated by advanced maternal age and increased body mass index (5).

Maternal outcomes that favored neither delivery route include postpartum pain, pelvic pain, postpartum depression, fistula, anorectal function, sexual function, pelvic organ prolapse, subsequent stillbirth, and maternal mortality. Evidence for thromboembolism was conflicting. Potential risks of cesarean delivery on maternal request include greater complications in subsequent pregnancies, such as uterine rupture, placenta previa, placenta accreta, bladder and bowel injuries, uterine rupture, and the need for hysterectomy. A recent Canadian study of primiparous women with singleton pregnancies showed an increased risk of postpartum cardiac arrest, wound hematoma, hysterectomy, major puerperal infection, anesthetic complications, venous thromboembolism, and hemorrhage requiring hysterectomy in patients who had a planned primary cesarean delivery (6). These are also factors that may be influenced by parity and planned family size. Uterine scars put women at increased risk for uterine rupture in subsequent pregnancies. Although there is no difference between planned cesarean delivery or planned vaginal delivery in risk of peripartum hysterectomy in a woman's first delivery, there is a significant increased risk of placenta previa, placenta accreta, placenta previa with accreta, and the need for gravid hysterectomy after a woman's second cesarean delivery (Table 1). This emphasizes the need to consider the mother's total number of planned or expected pregnancies if cesarean delivery on maternal request is discussed during her first pregnancy, realizing that many pregnancies are unplanned.

Neonatal Outcomes

Potential neonatal benefits of planned vaginal delivery include a lower risk of respiratory problems, fewer problems with iatrogenic prematurity, and shorter length of hospital stay. There are limited studies on cesarean delivery on maternal request and neonatal outcomes, so literature on elective cesarean delivery without labor has been evaluated. The risk of respiratory morbidity, including transient tachypnea of the newborn, respiratory distress syndrome, and persistent pulmonary hypertension, is higher for elective cesarean delivery compared with vaginal delivery when delivery is earlier than 39–40 weeks of gestation (7, 8). The literature on elective cesarean delivery without labor also shows an increased rate of complications related to prematurity, including respiratory symptoms, other neonatal adaptation problems such as hypothermia and hypoglycemia, and neonatal intensive care unit admissions, for infants delivered by cesarean delivery before 39 weeks of gestation (2). Because of these potential complications, cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity.

Potential neonatal benefits of planned cesarean delivery include lower fetal mortality; lower newborn infection rate; reduced risk of intracranial hemorrhage diagnosis, neonatal asphyxia, and encephalopathy; and fewer birth injuries. In epidemiologic models, cesarean delivery on maternal request by 40 weeks of gestation would reduce fetal mortality because planned vaginal delivery could occur at up to 42 weeks of gestation, and there is a finite risk of stillbirth between 40 and 42 weeks of gestation. Rates of intracranial hemorrhage are similar for spontaneous vaginal deliveries and cesarean deliveries without labor but are higher in operative vaginal deliveries and cesarean deliveries with labor (2).

Table 1. Risk of Placenta Accreta and Hysterectomy by Number of Cesarean Deliveries Compared With the First Cesarean Delivery

Cesarean Delivery	Accreta [n (%)]	Odds Ratio (95% CI)	Hysterectomy [n (%)]	Odds Ratio (95% CI)
First	15 (0.2)	–	40 (0.7)	–
Second	49 (0.3)	1.3 (.7–2.3)	67 (0.4)	0.7 (0.4–0.97)
Third	36 (0.6)	2.4 (1.3–4.3)	57 (0.9)	1.4 (0.9–1.2)
Fourth	31 (2.1)	9.0 (4.8–16.7)	35 (2.4)	3.8 (2.4–6.0)
Fifth	6 (2.3)	9.8 (3.8–25.5)	9 (3.5)	5.6 (2.7–11.6)
Six or more	6 (6.7)	29.8 (11.3–78.7)	8 (9.0)	15.2 (6.9–33.5)

CI, confidence interval.

Silver RM, Landon MB, Rouse DJ, Leveno KJ, Spong CY, Thom EA, et al. Maternal morbidity associated with multiple repeat cesarean deliveries. National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network. Obstet Gynecol 2006;107:1226–32.

There is also weak quality evidence of a lower risk of neonatal encephalopathy and asphyxia with elective cesarean delivery without labor compared with the combined risks of spontaneous vaginal delivery, operative vaginal delivery, emergency cesarean delivery, and cesarean delivery with labor (9, 10). The incidence of brachial plexus injury is significantly lower for cesarean delivery than vaginal delivery, with the highest incidence for assisted vaginal delivery. The incidence of fetal laceration at the time of cesarean delivery is lower for elective cesarean delivery without labor (0.8%) than unscheduled cesarean delivery (1.4–1.5%) (11). Studies on neonatal mortality and long-term neonatal outcomes lacked statistical power and quality data to assess the effect of the planned delivery route.

Summary of Data

In summary, only five outcome variables have moderate quality evidence regarding delivery route: 1) maternal hemorrhage, 2) maternal length of stay, 3) neonatal respiratory morbidity, 4) subsequent placenta previa or accreta, and 5) subsequent uterine rupture. The remaining outcome assessments are based on weak evidence, which limits the reliability of the results. A potential benefit of cesarean delivery on maternal request as compared with planned vaginal delivery is a decreased risk of hemorrhage for the mother. Potential risks of cesarean delivery on maternal request include a longer maternal hospital stay, an increased risk of respiratory problems for the baby, and greater complications in subsequent pregnancies, including uterine rupture and placental implantation problems.

Other Factors

When a woman desires a cesarean delivery on maternal request, her health care provider should consider her specific risk factors, such as age, body mass index, accuracy of estimated gestational age, reproductive plans, personal values, and cultural context. Critical life experiences (eg, trauma, violence, poor obstetric outcomes) and anxiety about the birth process may prompt her request. If her main concern is a fear of pain in childbirth, then prenatal childbirth education, emotional support in labor, and anesthesia for childbirth should be offered.

Further research is needed to get direct evidence for better counseling in the future. This includes surveys on cesarean delivery on maternal request, modification of birth certificates and Current Procedural Terminology coding to facilitate tracking, prospective cohort studies, database studies, and studies of modifiable risk factors for cesarean delivery on maternal request versus planned vaginal delivery. Short-term and long-term maternal and neonatal outcomes as well as cost need further study.

Conclusions

The available data on cesarean delivery on maternal request compared with planned vaginal delivery is minimal and mostly based on indirect comparisons. Most of the studies of proxy outcomes do not adequately adjust for confounding factors and, thus, must be interpreted cautiously.

Recommendations

- Cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity.
- Cesarean delivery on maternal request should not be motivated by the unavailability of effective pain management.
- Cesarean delivery on maternal request is not recommended for women desiring several children, given that the risks of placenta previa, placenta accreta, and gravid hysterectomy increase with each cesarean delivery.

References

1. Hamilton BE, Martin JA, Ventura SJ. Births: preliminary data for 2005. Natl Vital Stat Rep 2006;55(11):1–18.
2. National Institutes of Health. NIH State-of-the-Science Conference statement on cesarean delivery on maternal request. NIH Consensus and State-of-the-Science Statements. Bethesda (MD): NIH; 2006. Available at: http://consensus.nih.gov/2006/CesareanStatement_Final053106.pdf. Retrieved July 20, 2007.
3. Hannah ME, Whyte H, Hannah WJ, Hewson S, Amankwah K, Cheng M, et al. Maternal outcomes at 2 years after planned cesarean section versus planned vaginal birth for breech presentation at term: the international randomized Term Breech Trial. Term Breech Trial Collaborative Group. Am J Obstet Gynecol 2004;191:917–27.
4. Hannah ME, Hannah WJ, Hodnett ED, Chalmers B, Kung R, Willan A, et al. Outcomes at 3 months after planned cesarean vs planned vaginal delivery for breech presentation at term: the international randomized Term Breech Trial. Term Breech Trial 3-Month Follow-up Collaborative Group. JAMA 2002;287:1822–31.
5. Rortveit G, Daltveit AK, Hannestad YS, Hunskaar S. Urinary incontinence after vaginal delivery or cesarean section. Norwegian EPINCONT Study. N Engl J Med 2003;348: 900–7.
6. Liu S, Liston RM, Joseph KS, Heaman M, Sauve R, Kramer MS. Maternal mortality and severe morbidity associated with low-risk planned cesarean delivery versus planned vaginal delivery at term. Maternal Health Study Group of the Canadian Perinatal Surveillance System. CMAJ 2007; 176:455–60.
7. Zanardo V, Simbi AK, Franzoi M, Solda G, Salvadori A, Trevisanuto D. Neonatal respiratory morbidity risk and mode of delivery at term: influence of timing of elective caesarean delivery. Acta Paediatr 2004;93:643–7.
8. Morrison JJ, Rennie JM, Milton PJ. Neonatal respiratory morbidity and mode of delivery at term: influence of timing of elective caesarean section. Br J Obstet Gynaecol 1995;102:101–6.

9. Badawi N, Kurinczuk JJ, Keogh JM, Alessandri LM, O'Sullivan F, Burton PR, et al. Intrapartum risk factors for newborn encephalopathy: the Western Australian case-control study. BMJ 1998;317:1554–8.

10. Towner D, Castro MA, Eby-Wilkens E, Gilbert WM. Effect of mode of delivery in nulliparous women on neonatal intracranial injury. N Engl J Med 1999;341:1709–14.

11. van Ham MA, van Dongen PW, Mulder J. Maternal consequences of caesarean section. A retrospective study of intraoperative and postoperative maternal complications of caesarean section during a 10-year period. Eur J Obstet Gynecol Reprod Biol 1997;74:1–6.

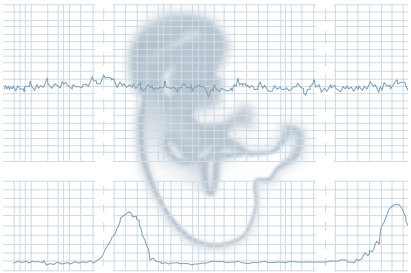
Copyright © December 2007 by the American College of Obstetricians and Gynecologists, 409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, posted on the Internet, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from the publisher. Requests for authorization to make photocopies should be directed to: Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, (978) 750-8400.

Cesarean delivery on maternal request. ACOG Committee Opinion No. 394. American College of Obstetricians and Gynecologists. Obstet Gynecol 2007;110:1501–4.

12345/10987 ISSN 1074-861X

Attachment B

INSTITUTE FOR HEALTHCARE IMPROVEMENT



Innovation Series 2005

Idealized Design of Perinatal Care

The Institute for Healthcare Improvement thanks Ascension Health and Premier, Inc., our colleagues in this important work to improve the safety and effectiveness of perinatal care.

PREMIER

ASCENSION HEALTH

9

We have developed IHI's Innovation Series white papers to further our mission of improving the quality and value of health care. The ideas and findings in these white papers represent innovative work by organizations affiliated with IHI. Our white papers are designed to share with readers the problems IHI is working to address; the ideas, changes, and methods we are developing and testing to help organizations make breakthrough improvements; and early results where they exist.

Copyright© 2005 Institute for Healthcare Improvement

All rights reserved. Individuals may photocopy all or parts of white papers for educational, not-for-profit uses. These papers may not be reproduced for commercial, for-profit use in any form, by any means (electronic, mechanical, xerographic, or other), or held in any information storage or retrieval system without the written permission of the Institute for Healthcare Improvement.

How to cite this paper:

Cherouny PH, Federico FA, Haraden C, Leavitt Gullo S, Resar R. *Idealized Design of Perinatal Care*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2005. (Available on www.IHI.org)

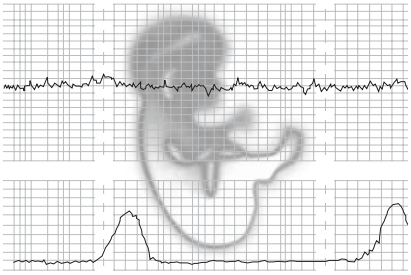
Acknowledgements:

Thanks are due to many Institute for Healthcare Improvement (IHI) faculty and staff for their advice and critical review of this paper, particularly Don Goldmann, MD, Senior Vice President, IHI, and Professor of Pediatrics, Harvard Medical School; Frank Davidoff, MD; Jane Roessner, PhD; and Val Weber.

For reprint requests, please contact:

Institute for Healthcare Improvement, 20 University Road, 7th Floor, Cambridge, MA 02138
Telephone (617) 301-4800, or visit our website at www.ihi.org

Institute for Healthcare Improvement



Innovation Series 2005

Idealized Design of Perinatal Care

Authors:

Peter H. Cherouny, MD: *Professor of Obstetrics and Gynecology, University of Vermont College of Medicine*
Frank A. Federico, RPh: *Director, Institute for Healthcare Improvement*
Carol Haraden, PhD: *Vice President, Institute for Healthcare Improvement*
Sue Leavitt Gullo, MS, RN: *Director, Institute for Healthcare Improvement*
Roger Resar, MD: *Senior Fellow, Institute for Healthcare Improvement, Luther Midelfort-Mayo Health System*

Editor:
Faith McLellan, PhD

Thank you to our colleagues in this important work:

Premier Healthcare Informatics and Insurance Management Services staff have provided invaluable leadership throughout the Idealized Design of Perinatal Care project. Premier's mission, to improve the health of communities, drove its involvement in the project. Through its clinical databases and risk management offerings, Premier's focus on improving health care quality and outcomes is well aligned with IHI. Premier thanks the ten Premier owner organizations that served as the participants in Phase I and the additional five Premier owners that joined the project in Phase II. Together, IHI and Premier are advancing the imperative for quality improvement.

Ascension Health (www.ascensionhealth.org) is the nation's largest Catholic and nonprofit health system, with more than 105,000 associates serving in 20 states and the District of Columbia. Consistent with its mission to serve all people with special attention to those who are poor and vulnerable, Ascension Health is an innovative leader in transforming health care through patient-centered, holistic care of the highest clinical quality. Ascension Health's Alpha Ministries have been involved in transforming care in perinatal safety for almost two years as part of the Clinical Excellence goal of no preventable deaths or injuries by 2008. The Perinatal Safety Alpha Ministries added the IHI innovation work in this area as part of a broad approach to develop high-reliability units and claims prevention strategies. With five new teams now participating in the IHI innovation project, Idealized Design of Perinatal Care, Ascension Health is pleased to continue to support important endeavors such as this.

The Institute for Healthcare Improvement also acknowledges the contributions made by **Kaiser Permanente** in the field of perinatal safety, especially in the areas of teamwork and communication training, including the SBAR technique, some of which is incorporated in the Idealized Design of Perinatal Care project.

© 2005 Institute for Healthcare Improvement

Executive Summary

Idealized Design of Perinatal Care is an innovation project based on the principles of reliability science and the Institute for Healthcare Improvement's (IHI's) model for applying these principles to improve care.[1] The project builds upon similar processes developed for other clinical arenas in three previous IHI Idealized Design projects. The Idealized Design model focuses on comprehensive redesign to enable a care system to perform substantially better in the future than the *best* it can do at present. The goal of Idealized Design of Perinatal Care is to achieve a new level of safer, more effective care and to minimize some of the risks identified in medical malpractice cases.

The model described in this white paper, Idealized Design of Perinatal Care, represents the Institute for Healthcare Improvement's best current assessment of the components of the safest and most reliable system of perinatal care. The four key components of the model are: 1) the development of reliable clinical processes to manage labor and delivery; 2) the use of principles that improve safety (i.e., preventing, detecting, and mitigating errors); 3) the establishment of prepared and activated care teams that communicate effectively with each other and with mothers and families; and 4) a focus on mother and family as the locus of control during labor and delivery.

Reviews of perinatal care have consistently pointed to failures of communication among the care team and documentation of care as common factors in adverse events that occur in labor and delivery. They are also prime factors leading to malpractice claims.[2]

Two perinatal care "bundles"—a group of evidence-based interventions related to a disease or care process that, when executed together, result in better outcomes than when implemented individually—are being tested in this Idealized Design project: the *Elective Induction Bundle* and the *Augmentation Bundle*. Experience from the use of bundles in other clinical areas, such as care of the ventilated patient, has shown that reliably applying these evidence-based interventions can dramatically improve outcomes.[3] The assumption of this innovation work is that the use of bundles in the delivery of perinatal care will have a similar effect.

The authors acknowledge that other organizations have also been working on improving perinatal care through the use of simulation training and teamwork and communication training. IHI's model includes elements of these methods.

The Idealized Design of Perinatal Care project has two phases. Sixteen perinatal units from hospitals around the US participated in Phase I, from February to August 2005. The goals of Phase I were identifying changes that would make the most impact on improving perinatal care, selecting elements for each of the bundles, learning how to apply IHI's reliability model to improve processes, and improving the culture within a perinatal unit. This white paper provides detail about the Idealized Design process and examines some of the initial work completed by teams.

© 2005 Institute for Healthcare Improvement

Phase II, which began in September 2005, expands on this work. This phase focuses particularly on managing second stage labor, including common interpretation of fetal heart monitoring, developing a reliable tool to identify harm, and ensuring that patient preferences are known and honored.

Introduction

Adverse events occurring during labor and delivery are rare relative to the number of births, but when they do occur they can result in significant harm. The effects of an adverse event—physical, psychological, and financial—take a heavy toll on the child, the family, and the clinicians involved. Families may be left to care for a child who has enormous needs, and their only recourse for obtaining financial assistance to meet these needs may be to pursue legal action.

Malpractice claims in obstetrics and gynecology are not uncommon. According to the American College of Obstetricians and Gynecologists (ACOG), obstetricians and gynecologists have an average of 2.6 claims filed against them during their career. Of these, 61 percent are obstetrics-related cases.[4] Claims related to a brain-damaged infant were among the top five conditions for which compensation was sought during the period from 1985 to 2003, with an average indemnity of $509,280.[5] According to the 2003 National Practitioner Data Bank report, obstetrics-related cases (totaling 1,255) generated 8.1 percent of all physician malpractice payment reports, had the highest median ($290,000) and mean ($475,880) payment amounts, and took the longest amount of time to resolve compared with anesthesia-related cases (the mean delay between incident and payment in obstetrics was 5.66 years, median 4.74 years; compared with 3.67 and 3.30 years, respectively, in anesthesia). The median malpractice award for a childbirth-related claim involving obstetricians and hospitals was $2.5 million for the period from 1997 to 2003.[6] In part because of these statistics, liability insurance premiums for obstetricians and hospitals with large OB services have risen dramatically.

The best defense against malpractice claims—and indeed for providing the best care for patients—is prevention or minimization of harm whenever possible, through adherence to evidence-based practice guidelines. Professional organizations such as ACOG and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) have developed a number of practice guidelines and position statements (Figure 1). The challenge is ensuring that these guidelines are used consistently. Guidelines also evolve, based on new research, and must be revisited periodically by clinicians to determine their impact on local practice. Further, the Idealized Design project recognizes that evidence-based care must be provided by a care team that works together smoothly and effectively (a high-functioning team, as described below), complemented by complete and accurate documentation of that care.[7]

© 2005 Institute for Healthcare Improvement

Figure 1. Examples of Position Statements and Bulletins Related to the Idealized Design of Perinatal Care

AWHONN Clinical Position Statements

- Fetal Assessment, Revised and Reaffirmed, April 2000
- Professional Nursing Support of Laboring Women, Approved by the Executive Board, April 2000

ACOG Practice Bulletins

- Induction of Labor, ACOG Practice Bulletin, Number 10, November 1999
- Intrapartum Fetal Heart Rate Monitoring, ACOG Practice Bulletin, Number 70, December 2005

Additional ACOG References

- ACOG Committee Opinion, Patient Safety in Obstetrics and Gynecology, Number 286, October 2003
- ACOG Practice Bulletin, Fetal Macrosomia, Number 22, November 2000
- ACOG Practice Bulletin, Shoulder Dystocia, Number 40, November 2002
- ACOG Practice Bulletin, Dystocia and the Augmentation of Labor, Number 49, December 2003

Poor documentation of care not only impedes communication among providers, but often complicates defense against malpractice claims. Incomplete or absent documentation may be interpreted as indicating a lack of planning for a particular course of action, and gaps in documentation make it difficult to determine the rationale behind a decision. Another potential problem with documentation can occur when the medical record contains contradictory statements, due to differences in interpretation, recorded by different providers. The wide variation in the way obstetricians and nurses interpret the fetal monitoring strip may be due to the absence of a common language for interpretation, lack of multidisciplinary training in teamwork and communication, and variability in processes of care.

Reviews of perinatal care (from individual cases and claims analysis) show that poor communication among providers and with patients contributes to care that is less than optimal and may increase the risk of a malpractice claim. In one study of closed claims in obstetrics and gynecology, more than one-third of adverse events were associated with communication problems ranging from basic miscommunication among providers, to misunderstanding because of a lack of common terminology, to delays in communication, and to a total absence of communication.[8]

The clinical processes in the Idealized Design project are designed to decrease the incidence of communication problems. The two perinatal care bundles are based on reliability science and provide a common language for team members, in order to improve teamwork and communication.

© 2005 Institute for Healthcare Improvement

The Idealized Design of Perinatal Care Model

Idealized Design of Perinatal Care is the fourth Idealized Design model developed by IHI. (The first three models are Idealized Design of Clinical Office Practices,[9] Idealized Design of Medication Systems, and Idealized Design of the Intensive Care Unit.) Each of these designs has resulted in improved outcomes in their respective clinical arenas.[10] The goal of Idealized Design is to develop the best possible "ideal" care system that its designers can conceive at that time. Furthermore, Idealized Designs are capable of being improved and of improving themselves.[11]

Idealized Design of Perinatal Care is based on reliability science (failure-free operation over time), including both *what* and *how* care is delivered. The *what* consists of the best science, the soundest evidence, upon which to base practice. This evidence spans a wide spectrum, from the results of randomized trials to expert opinion. The ACOG Practice Bulletins are examples of guidelines based on peer-reviewed research.

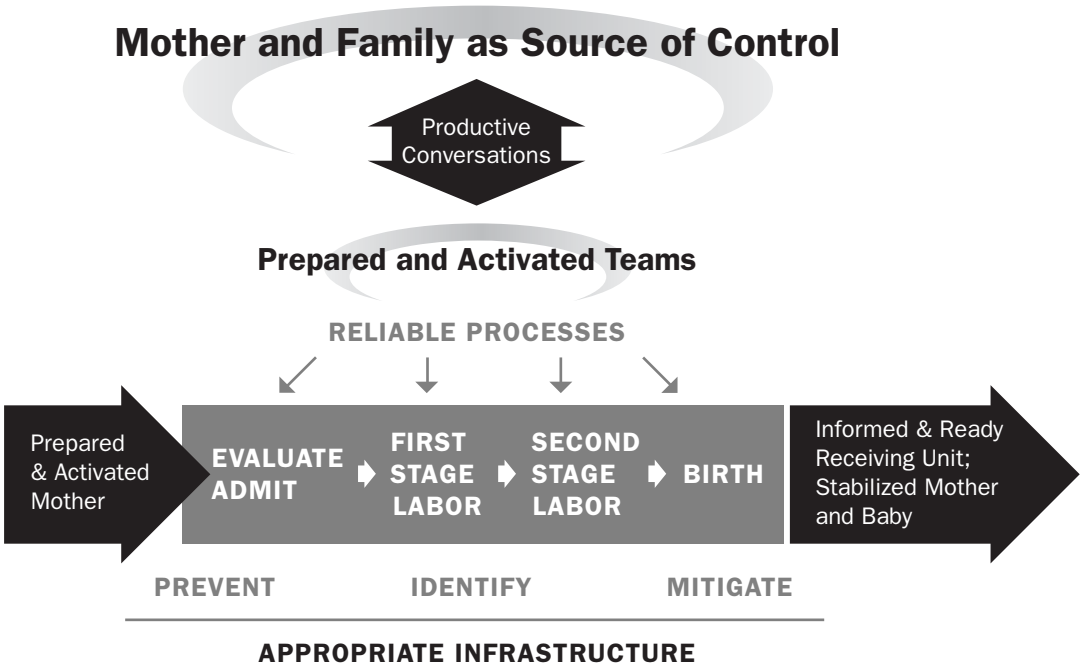
The *how* is the method by which that evidence-based care is delivered (e.g., by using standardized order sets). At present, the execution of best practices is highly variable, as demonstrated by chart review and malpractice claims analysis. To improve safety and reliability, *what* we do and *how* we do it must come together as the *way* we provide effective perinatal care.

The Model for Improvement[12] is an effective methodology to test changes in processes that result in the reliable delivery of the highest level of care. Delivering ideal care is based on reliable design and a specific goal for each process that will make the greatest difference in care.

Simply improving current processes cannot achieve acceptable levels of reliability.[13] Idealized Design is based instead on a comprehensive redesign of the care system: determining what the best perinatal care would look like, and how all the parts and players involved in its complex processes would best fit together, in a "best possible world" scenario. Components include clinical processes, communication and teamwork, and acknowledging and honoring the expressed preferences of the mother and the family. Idealized Design of Perinatal Care is a method of marrying these factors to produce a theory, an "educated best guess," about the best perinatal care system.

© 2005 Institute for Healthcare Improvement

Figure 2. Idealized Design of Perinatal Care



Components of the Model

The Idealized Design of Perinatal Care model (Figure 2) consists of eight basic components:

- A prepared and activated mother and family;
- The mother and family as the source of control (patient preferences);
- Productive conversations between the mother, family, and the care team;
- High-functioning care teams (prepared and activated);
- Reliable processes used to evaluate and manage labor and delivery (the perinatal care "bundles");
- Reliable processes to prevent, detect, and mitigate problems;
- An appropriate infrastructure that underlies the system of care; and
- A stabilized mother and baby, given into the care of an informed and ready patient care unit.

© 2005 Institute for Healthcare Improvement

The *mother and family as the source of control* means the mother has the information she needs to make informed decisions about her care, and is the source of control in the birth process. She, in collaboration with the care team, is able to make good decisions about the selection and delivery of her care. These shared goals create the conditions for delivering the safest and most reliable care. Mothers and partners are provided with information in a way that takes into account health and cultural literacy issues.

Productive conversations are defined as communications between the patient, her family, and the care team that honor *patient preferences* and emphasize the safety of both mother and fetus, and are continually evaluated and updated during the birth process. For example, patients have opportunities to list their preferences regarding delivery, pain management, and responses to their emotional needs.

A prepared and activated team that works together is a prerequisite for providing safe and reliable care. Effective communication among team members is critical for the team to be highly functional. SBAR (Situation-Background-Assessment-Recommendation)[14] is an effective tool to help team members communicate clearly and respectfully with each other in a focused and effective manner, especially in urgent or critical situations. All relevant facts are communicated in a cogent, methodical manner; concerns, recommendations, and requests are made specifically and clearly. Building on the work in crew resource management, communication training includes education in appropriate assertiveness and development of conflict resolution skills. Examples of applying these models can be found in Kaiser Permanente's work and in the Department of Defense/Agency for Healthcare Research and Quality (AHRQ) teamwork training curricula. Effective oral communication then translates into comprehensive written documentation that includes reasons for treatment decisions, monitoring information, and indications of treatment plans.

Reliable processes are used to evaluate the mother and fetus, and to manage the labor and delivery process. The Idealized Design of Perinatal Care bundles (described in more detail below) incorporate processes that help create a culture of patient safety, and processes that clinicians believe are important in contributing to good care for both the mother and the baby. By implementing the bundles and measuring their effect, IHI anticipates being able to reduce harm in labor and delivery, as well as being able to document that reduction.

These same reliable processes are also used to *prevent, detect, and mitigate* problems.[15] Prevention is, of course, preferable to anything else, but when problems cannot be prevented, providers must be able to detect them and mitigate their effects quickly. In labor and delivery, for example, this might mean collaborative interpretation of fetal monitoring based on common language and team response.[16] A common language is one in which descriptions of monitoring strips and desired actions are the same for both obstetricians and nurses, without inconsistencies or ambiguities. Once a problem is detected, action is taken based upon the results of detection. For example, the interpretation of fetal monitoring might mean the mother needs to be repositioned to improve

© 2005 Institute for Healthcare Improvement

oxygenation to the fetus, thereby mitigating the problem detected. This cycle — prevent, detect, mitigate — underpins the principles of safety in the Idealized Design.

An appropriate infrastructure in the perinatal unit is another prerequisite for providing safe and reliable care. This infrastructure includes standard elements of multidisciplinary staff education and preparation, ensuring staff competency, privileging, and adoption of common standards.

Finally, *a stabilized mother and baby are given into the care of an informed and ready patient care unit.*

Design Targets

To determine the effectiveness of the Idealized Design of Perinatal Care model, the expert faculty established specific design targets — measurable raise-the-bar goals that indicate a dramatic improvement in results for patients beyond the best known in health care today — that include the following:

1. Birth trauma (i.e., neonatal injury as defined in the AHRQ Patient Safety Indicators)[17] is reduced to a maximum of 3.3 adverse events per 1,000 live births. According to AHRQ, the national estimate of birth trauma per 1,000 live births was 7.358 in 2001.[18]
2. Patients (mothers) state that 95 percent of the time their wishes are known to the entire care team and respected.
3. Perinatal units report a 50 percent improvement in their culture survey scores. One example of a culture survey tool is AHRQ's Hospital Survey on Patient Safety Culture (HSOPSC).[19]
4. All claims or allegations may be defended because they meet each institution's internal standards for defense (e.g., consistent documentation, no lapses in documentation, no lapses in communication).

Implementation of the Perinatal Care Bundles

Idealized Design uses reliability principles to support the application of the "bundle" concept to clinical processes.[20] A bundle is a group of evidence-based interventions related to a disease or care process that, when executed together, result in better outcomes than when implemented individually. The selection of the evidence-based elements comprising the bundles is based on sound science and local knowledge, and an agreement among clinicians that patients should receive all elements of care unless medically contraindicated. Experience from the use of bundles in other clinical areas, such as care of the ventilated patient, has shown that reliably applying these evidence-based interventions can dramatically improve outcomes.[21] The assumption of this innovation work is that the use of bundles in the delivery of perinatal care will have a similar effect.

© 2005 Institute for Healthcare Improvement

Bundles themselves do not improve outcomes, but the ability of the team to reliably implement every element of the bundle for all patients, unless medically contraindicated, advances care in such a way as to achieve the improved outcomes. The most important idea underlying bundles is the "all or none" concept: A team gets credit for implementing the bundle only if *every* element of the bundle is delivered for each patient, unless medically contraindicated. This goal serves as a catalyst to move teams toward a design that achieves a 10^{-2} level of reliable performance (i.e., 95 percent of the time patients receive all elements of the bundle).[22] Providing care in the usual manner will not accomplish this goal.

Implementation of the two bundles, the Elective Induction Bundle and the Augmentation Bundle, is the focus of Phase I of the Idealized Design of Perinatal Care. Successful implementation requires that teams comply with all components of the respective bundle for each patient, establishing effective systems and a common language to ensure that obstetricians, nurses, and other caregivers interpret the same clinical scenario in the same way.

Elective Induction Bundle

Review of medical malpractice claims reveals that oxytocin, which stimulates uterine contractions and induces labor, is involved in more than 50 percent of the situations leading to birth trauma. To minimize the opportunity for harm, it is necessary to understand the pharmacology of the drug and its impact on the fetus, and to have protocols to guide its appropriate use. Based on findings from reviews of adverse events, medical malpractice claims, and guidelines provided by professional organizations, the expert faculty selected four elements that must be considered when using oxytocin for labor induction:

- Assessment of gestational age (ensuring that gestational age is greater than or equal to 39 weeks);
- Monitoring fetal heart rate for reassurance;
- Pelvic assessment; and
- Monitoring and management of hyperstimulation.

Before the elective induction of labor is initiated, it must be determined that the fetus has a gestational age of greater than or equal to 39 weeks, and this determination must be documented according to agreed upon standards. Determining which care team member is responsible for establishing gestational age and the method by which it is established are decisions that are left up to individual sites. Although babies have been delivered before 39 weeks of gestational age, ACOG guidelines[23] and other research report that the likelihood of harm to the baby from elective delivery is greater before 39 weeks. In the event of an adverse outcome, plaintiffs' attorneys may use non-compliance with this guideline as an indicator of poor care.

© 2005 Institute for Healthcare Improvement

Likewise, monitoring fetal heart rate for reassurance before induction, in accordance with specific definitions (detailed below), must be documented. Clinicians monitor fetal heart rate and the effects of uterine stimulants on the fetus, and ensure the availability of a physician capable of performing an emergency cesarean section, should it be necessary. For the first time, two major governing organizations, ACOG and AWHONN, have accepted the definitions of fetal monitoring developed by the National Institute for Child Health and Human Development (NICHD). This adoption is based on the goal of using a standard terminology to describe fetal heart rate monitoring and then developing an agreed upon plan of action to ensure compliance with this element of the bundle. According to ACOG, "The presence of fetal heart rate accelerations generally ensures that the fetus is not acidemic and provides reassurance of fetal status."[24,25] Because the positive predictive value of reassuring fetal assessment is high (>99 percent), it is vital that definitions are accepted and used by all members of the care team.[26]

Pelvic examination to determine dilation, effacement, station, cervical position and consistency (Bishop's Score), and fetal presentation should be performed and documented. This confirms the patient as a candidate for induction and allows a measure and evaluation of her progress in labor. Again, pelvic assessment should be performed and documented by pelvic examination before the induction is initiated.

Finally, because it is a frequent and potentially consequential occurrence during induced labor, hyperstimulation must be identified using a standard definition and documented, and a plan for a consensus response to the hyperstimulation must be made. The overall goal is to monitor for hyperstimulation and respond appropriately. In this Idealized Design project, teams worked together to develop a definition of hyperstimulation (generally agreed to be more than 5 contractions in 10 minutes), using information from the literature and guidelines from professional associations.[27]

Augmentation Bundle

Augmentation of labor is a coordinated effort to enhance uterine contractions for a woman who is already in labor. One reason to augment labor is inadequate contractions in terms of strength or frequency, resulting in inadequate progress of labor. Oxytocin is used to augment uterine contractions. As with induction, four critical elements must be considered:

- Estimated fetal weight;
- Monitoring fetal heart rate for reassurance;
- Pelvic assessment; and
- Monitoring and management of hyperstimulation.

© 2005 Institute for Healthcare Improvement

Estimation of fetal weight replaces gestational age in this bundle. It is important to know the size of the fetus to determine whether a continued attempt at vaginal delivery is appropriate. Monitoring for fetal reassurance and for uterine hyperstimulation and the teams' responses to both have the same implications as in the Elective Induction Bundle. Again, pelvic assessment should be performed and documented by pelvic examination before the augmentation is initiated.

Phase I: Lessons Learned

Of the perinatal/infant adverse events reported to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 84 percent cited poor or no communication among care providers as a common factor in those events.[28] The lack of a common language increases the chances of miscommunication among providers when they share information about maternal and fetal status and expected action. Nurses may have been trained using AWHONN language, and obstetricians trained using ACOG language. Further investigation has shown that even if a common language was adopted by both nurses and obstetricians, they continue to train independently. As a result, communication involving the description of the fetal heart rate tracings is not consistent among providers and this inconsistency may result in an action different from the one desired. Highly reliable perinatal teams have adopted a common language (the recently adopted NICHD language) and train nurses and obstetricians together. During the training, differences in interpretation are addressed and consensus is obtained regarding the desired action or response to specific interpretations.

A good example of the lack of consensus around nomenclature is "electronic fetal monitoring," or EFM. According to one study, "Complete consensus on EFM nomenclature has not been achieved within the United States and Canada and is dependent on the descriptive terminology of various researchers, authors, and equipment manufacturers. Since communication is the essence of quality and safety, common nomenclature should be established among the members of the same perinatal healthcare team. This assures that all members comprehend the meaning of pattern implication."[29] In another example, in AWHONN's Perinatal Nursing textbook (1996), Display 9-4, "Variability Nomenclature," lists seven different authors with differing definitions of "variability." The adoption by AWHONN and ACOG of the NICHD terminology has now supported one common language for pattern interpretation — something that has been missing since the first commercially available electronic fetal monitor was introduced in 1968. Another example of the need for one common language is the definition of "short- and long-term variability." Prior to the adoption of the NICHD terminology in 1997, each individual care provider, physician, or nurse used their own working definition, developed by researchers such as Parer, Schifrin, Tucker, and Murray.[30] The ACOG Technical Bulletin (Number 207), "Fetal Heart Rate Patterns: Monitoring, Interpretation and Management," was in place until May 2005, but did not provide a definition of short- or long-term variability in terms of beats per minute (bpm). Figure 3 illustrates various definitions and

© 2005 Institute for Healthcare Improvement

the evolution to the currently accepted NICHD guideline that no longer differentiates between short- and long-term variability, and instead uses baseline variability.[31]

Figure 3. Various Definitions of "Variability"

AWHONN Principles and Practices (1993)	
Short-term variability: • Absent • Present	**Long-term variability:** • Decreased/minimal (0–5 bpm) • Average/within normal limits (6–25 bpm) • Marked/saltatory (>25 bpm)
Murray et al. (1996)	
Short-term variability: • Absent • Present	**Long-term variability:** • Absent (0–2 bpm) • Decreased/minimal (3–5 bpm) • Average/within normal limits (6–25 bpm) • Marked/saltatory (>25 bpm)
NICHD (1997) [Currently accepted by ACOG and AWHONN]	
Baseline variability: Visually quantified as the amplitude of peak-to-trough in beats per minute	• Absent (amplitude range undetectable) • Minimal (amplitude range detectable but 5 bpm or fewer) • Moderate [normal] (amplitude range 6–25 bpm) • Marked (amplitude range >25 bpm)

Three elements of the two bundles proved difficult to adopt during Phase I: a policy of no elective deliveries before 39 weeks of gestational age, definition and management of hyperstimulation, and estimation and documentation of fetal weight. Teams will continue to test different processes to ensure reliable compliance with each of the bundle elements. In the case of limiting elective induction to instances in which gestational age is at least 39 weeks, teams in the Idealized Design project encountered issues related to physician preferences, workload and coverage issues, and demands from patients. To address these issues, teams presented guidelines and scientific information supporting the 39-week limit to the obstetricians practicing at the institutions to reinforce this element of the bundle. Some organizations set an expectation that there would be no elective inductions before 39 weeks. Once the expectation was set, staff at the hospital were instructed not to schedule elective inductions if the gestational age was determined to be less than 39 weeks.

Documentation of hyperstimulation proved more elusive, as the definition was more difficult to pin down. After consultation with expert faculty and internal discussions within their own organizations,

© 2005 Institute for Healthcare Improvement

teams agreed to use one definition for hyperstimulation. The next hurdle was to determine the clinical response to hyperstimulation. Physicians were reluctant to document estimated fetal weight, even when it was agreed that this was an estimate and could be listed as a range — LGA (large for gestational age), AGA (average for gestational age), and SGA (small for gestational age). The concern for some was the risk associated with estimating incorrectly. Some teams, however, were able to move ahead successfully by emphasizing that the estimated fetal weight is a range.

The role of leadership, both administrative and clinical, also proved to be essential to success. Adoption of the elements of the perinatal care bundles, especially the 39-week gestational age limit, was achieved more readily in organizations where leaders set the expectation that the bundles would be adopted.

Looking Ahead: Phase II

During Phase II, teams will continue to work on applying IHI's reliability model to the implementation of the perinatal care bundles. In addition, Phase II will focus on developing systems to ensure that a mother's preferences are known and honored. Teams will also focus on testing their response to crisis situations by simulating these situations and making changes to improve those processes. The Idealized Design project also focuses on improving the safety culture of the perinatal unit, which will be measured using available safety attitude survey tools.[32] A Perinatal Trigger Tool will be used to determine rate of perinatal harm. Another component of the model, the handoff to a receiving unit, is in development. Additional work in this project will focus on management of second stage labor and increasing the reliability of the selected processes.

IHI, Ascension Health, and Premier, Inc., remain committed to pursuing this valuable work to achieve improved outcomes.

© 2005 Institute for Healthcare Improvement

References

[1] *Improving the Reliability of Health Care*. IHI Innovation Series white paper. Boston, MA: Institute for Healthcare Improvement; 2004. Online information retrieved 14 September 2005. www.ihi.org

[2] White AA, Pichert JW, Bledsoe SH, Irwin C, Entman SS. Cause and effect analysis of closed claims in obstetrics and gynecology. *Obstet Gynecol*. 2005;105(5 Pt 1):1031-1038.

[3] Resar R, Pronovost P, Haraden C, Simmonds T, et al. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. *Joint Commission Journal on Quality and Patient Safety*. 2005;31(5):243-248.

[4] Medical Liability Survey Reaffirms More Ob-Gyns Are Quitting Obstetrics. ACOG News Release, 16 July 2004. Online information accessed 6 December 2005. www.acog.org/from_home/publications/press_releases/nr07-16-04.cfm

[5] Physician Insurers Association of America. Online information retrieved 14 September 2005. www.thepiaa.org

[6] Medical Malpractice: Verdicts, Settlements and Statistical Analysis Updated Edition. Horsham, PA: Jury Verdict Research; 2005:12.

[7] Simpson KR, Knox GE. Common areas of litigation related to care during labor and birth: Recommendations to promote patient safety and decrease risk exposure. *J Perinat Neonat Nurs*. 2003;17:110-125.

[8] White AA, Pichert JW, Bledsoe SH, Irwin C, Entman SS. Cause and effect analysis of closed claims in obstetrics and gynecology. *Obstet Gynecol*. 2005;105(5 Pt 1):1031-1038.

[9] For background, see: Berwick D, Kilo C. Idealized design of clinical office practice: An interview with Donald Berwick and Charles Kilo of the Institute for Healthcare Improvement. *Manag Care Q*. 1999 Autumn;7(4):62-69.

Also see: Vasquez L, Kancir S, Crede W, Schlosser JE. Using Idealized Design to improve access and clinical quality. Online information retrieved 13 November 2005. www.scientificsymposium.org/pdf/2004/Vasquez.pdf

[10] Radel SJ, Norman AM, Notaro JC, Horrigan DR. Redesigning clinical office practices to improve performance levels in an individual practice association model HMO. *J Healthc Qual*. 2001 Mar-Apr; 23(2):11-5; quiz 15, 52.

[11] Moen RD. A Guide for Idealized Design. Unpublished paper prepared for the Institute for Healthcare Improvement; 2002. Online information retrieved 13 November 2005. www.ihi.org

[12] Testing Changes. Online information retrieved 27 September 2005. www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/HowToImprove/testingchanges.htm

© 2005 Institute for Healthcare Improvement

[13] *Improving the Reliability of Health Care*. IHI Innovation Series white paper. Boston, MA: Institute for Healthcare Improvement; 2004. Online information retrieved 14 September 2005. www.ihi.org

[14] SBAR Technique for Communication: A Situational Briefing Model. Online information retrieved 14 September 2005. www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SBARTechniqueforCommunicationASituationalBriefingModel.htm

[15] Note that these are the three fundamental steps of applying the principles of reliability to health care. For details, see: *Improving the Reliability of Health Care*. IHI Innovation Series white paper. Boston, MA: Institute for Healthcare Improvement; 2004. Online information retrieved 14 September 2005. www.ihi.org

[16] Fox M, Kilpatrick S, King T, Parer JT. Fetal heart rate monitoring: Interpretation and collaborative management. *J Midwifery Women's Health*. 2000;45:498-507.

[17] AHRQ Patient Safety Indicator for "birth trauma": "The birth trauma PSI identifies cases of birth trauma per 1,000 liveborn births in a hospital. This is a patient safety indicator intended to flag preventable complications of full-term deliveries. The measure excludes preterm deliveries since birth trauma for these patients may be less preventable than for full-term infants. Risk adjustment beyond that possible using only administrative data is desirable. While not a definitive measure of quality, this measure can be used to identify potential opportunities for improvement." Online information retrieved 2 December 2005. www.qualityindicators.ahrq.gov/

[18] National Healthcare Quality Report 2004, AHRQ Publication No. 05-0013. Online information retrieved 2 December 2005. www.qualitytools.ahrq.gov/qualityreport/documents/nhqr2004.pdf

[19] Agency for Healthcare Research and Quality. Hospital Survey on Patient Safety Culture (HSOPC). Online information retrieved 2 December 2005. www.ahcpr.gov/qual/hospculture

[20] Bundle Up for Safety. Online information retrieved 27 September 2005. www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/ImprovementStories/BundleUpforSafety.htm

For a guideline that describes best practices in obstetrics, see: Clinical guidelines for the obstetrical services of the CRICO-insured institutions. Online information retrieved 26 September 2005. www.rmf.harvard.edu/reference/guidelines/obguide/obguide_03.pdf

Also see: ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists. Number 62, May 2005. Intrapartum fetal heart rate monitoring. *Obstet Gynecol*. 2005;105(5 Pt 1): 1161-1169.

[21] Resar R, Pronovost P, Haraden C, Simmonds T, et al. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. *Joint Commission Journal on Quality and Patient Safety*. 2005;31(5):243-248.

© 2005 Institute for Healthcare Improvement

[22] *Improving the Reliability of Health Care*. IHI Innovation Series white paper. Boston, MA: Institute for Healthcare Improvement; 2004. Online information retrieved 14 September 2005. www.ihi.org

[23] ACOG Practice Bulletin, Induction of Labor. Number 10, November 1999.

[24] ACOG Practice Bulletin, Intrapartum Fetal Heart Rate Monitoring. Number 70, December 2005.

[25] Intrapartum fetal heart rate monitoring. *Obstet Gynecol*. 2005;105(5 Pt 1):1165.

[26] Low JA, Victory R, Derrick EJ. Predictive value of electronic fetal monitoring for intrapartum fetal asphyxia with metabolic acidosis. *Obstet Gynecol*. 1999;93:285-291.

[27] ACOG, 1999, 2003; AWHONN, 2002.

[28] JCAHO. Preventing infant death during delivery. Sentinel Event Alert #30, 2004. Online information retrieved 21 October 2005. www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_30.htm

[29] Simpson KR, Creehan PA. AWHONN, Perinatal Nursing. Philadelphia: Lippincott-Raven; 1996:88.

[30] *Ibid*.

[31] ACOG Practice Bulletin, Intrapartum Fetal Heart Rate Monitoring. Number 70, December 2005.

[32] Helmreich RL. On error management: Lessons from aviation. *BMJ*. 2000;320:781-785.

Additional References

Miller LA. Patient safety and teamwork in perinatal care: Resources for clinicians. *Journal of Perinatal & Neonatal Nursing*. 2005;19(1):46-51.

Johnson CE, Handberg E, et al. Improving perinatal and neonatal patient safety: The AHRQ Patient Safety Indicators. *Journal of Perinatal & Neonatal Nursing*. 2005;19(1):15-23.

Simpson KR. Failure to rescue: Implications for evaluating quality of care during labor and birth. *Journal of Perinatal & Neonatal Nursing*. 2005;19(1):24-34.

Simpson KR, Atterbury J. Trends and issues in labor induction in the United States: Implications for clinical practice. *JOGNN*. 2003;32:767-779. 0

© 2005 Institute for Healthcare Improvement

White Papers in IHI's Innovation Series

1 Move Your Dot™: Measuring, Evaluating, and Reducing Hospital Mortality Rates (Part 1)

2 Optimizing Patient Flow: Moving Patients Smoothly Through Acute Care Settings

3 The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement

4 Improving the Reliability of Health Care

5 Transforming Care at the Bedside

6 Seven Leadership Leverage Points for Organization-Level Improvement in Health Care

7 Going Lean in Health Care

8 Reducing Hospital Mortality Rates (Part 2)

9 Idealized Design of Perinatal Care

All white papers in IHI's Innovation Series are available online at www.ihi.org and can be downloaded at no charge.

INSTITUTE FOR
HEALTHCARE
IMPROVEMENT

20 University Road, 7th Floor

Cambridge, MA 02138

(617) 301-4800

www.ihi.org

Institute for Healthcare Improvement
Perinatal Trigger Tool

July 2006

The use of triggers to identify adverse events during a manual chart review has been used extensively to measure the overall level of harm in a health care organization. Recent publications describe the process for the review and the history of triggers to identify events.

(Resar RK, Rozich JD, Classen D. Methodology and rationale for the measurement of harm with trigger tools. *Quality and Safety in Health Care*. 2003;12;Suppl 2:39-45.)

(Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: A practical methodology for measuring medication related harm. *Quality and Safety in Health Care*. 2003;12:194-200.)

The object of the review is to identify harm – not whether the event was preventable. In our experience, the discussion about the *preventability* of an adverse event is often a barrier to determining the *cause* of an adverse event. The Perinatal Trigger Tool defines an adverse event as *any physical harm to the infant or mother*. The tool limits the definition of adverse events to physical rather than emotional harm. The question that has been helpful is, "Would you be happy if the event in question happened to you or your loved one?" If the answer is no, then it probably is an adverse event.

This tool adapts the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors. NCC MERP brings together leading health care organizations to meet, collaborate, and cooperate to address the interdisciplinary causes of errors and to promote the safe use of medications. [See http://www.nccmerp.org/index.htm?http://www.nccmerp.org/main.htm]

Although originally developed for categorizing medication errors, these definitions can be easily applied to any type of error or adverse event.

This tool counts only adverse events: harm to the patient, whether or not the result of an error.

The tool includes categories E, F, G, H, and I of the NCC MERP Index, because these categories describe errors that do cause harm. (Note that NCC MERP's "An error that contributed to or resulted in…" has been deleted, because this tool is designed to find harm, whether or not it was the result of an error.)

Category E: Temporary harm to the patient and required intervention
Category F: Temporary harm to the patient and required initial or prolonged hospitalization
Category G: Permanent patient harm
Category H: Intervention required to sustain life
Category I: Patient death

© 2005 Institute for Healthcare Improvement

Rules and Methods for Using the Perinatal Trigger Tool

1. Review 20 randomly selected Labor & Delivery (L&D) charts per month. For the purpose of this work, a "chart" is considered a unit which includes both the mother and her infant/infants (this may mean a minimum of 40 charts with the mother and baby as a couplet). Randomization tools are available in Excel format at http://www.randomizer.org/form.htm.

2. Review only completed charts (including the discharge summary and all coding). Because of the time needed to complete coding, it may be best to select patients who were discharged more than 30 days ago. For example, if you are conducting a review in November, select patient records from those patients discharged in August or September.

3. Review each chart for no longer than 20 minutes so that reviews do not become time consuming. Tests showed that reviewing charts for longer than 20 minutes does not usually yield additional events. *Remember to look for triggers, not "read" the chart—a common error with new reviewers*.

4. Two reviewers with mid-level practice experience (for example, RN) should **independently** review each record and then agree on how to recognize harm.

5. Reviewers should examine charts looking for the following:
    a. Discharge codes (particularly infections, complications, or certain diagnoses; E-codes are found here)
    b. Discharge summary (look for the specifics of assessment and treatment during the hospital stay)
    c. Medications ordered from physician orders and the medication administration record
    d. Lab results
    e. Operative record
    f. Nursing notes
    g. Physician progress notes
    h. If time permits, any other areas of the chart (such as History & Physical, Consult notes, or Prenatal Record).

6. A positive trigger is the presence of that item (for example, administration of terbutaline). A positive trigger is not an adverse event in and of itself; it is just a clue that one may have occurred. When a positive trigger is found, then review that portion of the chart and determine if an adverse event has occurred. In the example of administration of terbutaline, the reviewer should look for hyperstimulation, a non-reassuring fetal heart rate, administration of oxygen to the mother, etc.

    The object is <u>not</u> to find every possible adverse event in every chart reviewed. The time limitation and random selection of charts are designed to produce a reliable sampling sufficient to use for the design of safety improvement efforts in the hospital.

7. If no adverse event is found, then move on and continue looking for other triggers. *At times, positive triggers will be found but no adverse events*. If an adverse event is identified, then assign a category of harm using the NCC MERP Index categories of E through I described above. Be sure to include every adverse event you find, even if not identified by a trigger. On occasion, you will come across an adverse event while looking for triggers or other details; all adverse events should be included.

© 2005 Institute for Healthcare Improvement

8. The two mid-level practitioner reviewers work together to reach a consensus on the type of event, number and severity. The goal is that all chart review must be completed by the mid-level practitioners and that they agree on everything before moving on to the physician reviewer. It is also possible to reach a consensus that "we need to discuss the finding with the physician reviewer." The physician should not be put in the position of deciding who is right. This obligation of consensus is critical at the level of the initial review. The consensus is then reviewed by the physician. If there was a question on an event (agreed on by both reviewers) then the final decision is made by the physician. The physician does not need to review the chart.

   The physician's decision on the event, number of events, and severity is final. The physician may ask to review a portion or the entire chart if a question has been raised. The decision to review the chart directly rests with the physician. There is no requirement for the physician to review the chart.

9. Experienced reviewers should train new users of the trigger tool whenever possible. Perform a double review of the first 20 charts to answer questions and ensure that the process is standardized.

   The **Perinatal Chart Review Tool** (below) lists triggers to assist in completing this review. You can use this worksheet during the chart review. If you find a trigger, check "Yes" in the column next to it. If you find an adverse event, note a description and category of harm in the appropriate column. In determining whether an adverse event has occurred, remember that an adverse event is harm to a patient *from the viewpoint of the patient*. Would you be happy if the event happened to you? If the answer is no, then there was harm. The next test is whether the event is a part of the natural progression of the birth process or a complication of the treatment related to the birth process. The decision is subjective at times.

10. Fill out the bottom of the Perinatal Chart Review Tool for each chart reviewed. *Only the most serious Adverse Event Category needs to be listed. When grading severity for a cascade of events the greatest severity is reported.* After all charts are reviewed, fill out the **Trigger Tool Review Summary Sheet** (below). Track the final data summary point of adverse events/total births in the sample on a run chart.

11. The specific events should be categorized both by harm category and type (modules or specific type) and used in the safety improvement efforts of the organization.

© 2005 Institute for Healthcare Improvement

INTERNAL USE ONLY
PERINATAL CHART REVIEW TOOL

Medical Record Number _____ **Patient Name** _____

Admission Date _____ **Patient's Age** _____

Discharge Date _____

TRIGGER	**Article I. Present in Review**		**Article II. Adverse Event Found**		**Article III. Harm Category and Description**
	YES	**NO**	**YES**	**NO**	
T1 Apgar < 7 at 5 min.					
T2 Admission to NICU and >24 hours					
T3 Maternal/Neonatal Transport					
T4Terbutaline					
T5 Naloxone					
T6 Infant Serum Glucose <50					
T7 3rd or 4th Degree Lacerations					
T8 Prolonged Decelerations					
T9 Blood Transfusion					
T10 Platelet count <50,000					
T11 Abrupt Medication Stop (e.g. epidural)					
T12 Hypotension/Lethargy (Mom e.g. OD on Mag SO4)					
T13 Transfer to a Higher Level of Care, including ICU in-house					
T14 Unplanned Return to Surgery					
T15 Estimated Blood Loss > 500 mL					
T16 Specialty Consult					
T17 Administration of Oxytocic Agents Post-delivery (such as oxytocin, ergonovine, methylergonovine, and 15-methyl-prostaglandin)					
T18 Instrumented Delivery					
T19 Administration of General Anesthetic for Delivery					
T20 Cord Gases Ordered					
T21 Gestational Diabetes					
T22 Other					

It is important to note that a review of both maternal and neonatal record is required.

COMMENTS: _____

_____

_____

_____

_____

Total Adverse Events for this Patient (ex: T3, T8):

_____

Harm Category for Adverse Event (most serious): _____

Reviewer: _____

Date: _____

Category E: Temporary harm to the patient and required intervention
Category F: Temporary harm to the patient and required initial or prolonged hospitalization
Category G: Permanent patient harm
Category H: Intervention required to sustain life
Category I: Patient death

© 2005 Institute for Healthcare Improvement

Perinatal Trigger Tool Review Summary Sheet

Chart #	Triggers	Adverse Event Description	Harm Category (as determined by MD)

Category E: Temporary harm to the patient and required intervention
Category F: Temporary harm to the patient and required initial or prolonged hospitalization
Category G: Permanent patient harm
Category H: Intervention required to sustain life
Category I: Patient death

© 2005 Institute for Healthcare Improvement

Description of Triggers

T1 Apgar < 7 at 5 min
Indicates that newborn may need continued life-sustaining support. May be the result of labor and delivery process or intrapartum harm.

T2 Admission to NICU > 24 hours
Admission of greater than 24 hours may be indicative of harm to the baby. May be the result of labor and delivery process or intrapartum harm.

T3 Maternal/Neonatal Transport
Any transport or transfer to another institution or a higher level of care in your own institution needs to be reviewed for an adverse event. May indicate harm to either mother or infant.

T4 Terbutaline
Found in the orders or the medication administration record; could indicate intrauterine resuscitation for non-reassuring fetal status or hyperstimulation. Look for complicating factors. *Use in preterm labor is not a positive trigger.*

T5 Naloxone
May indicate an opioid-related event. Review chart for documentation of somnolence lethargy, change in vital signs, respiratory depression, and confusion.

T6 Infant Serum Glucose < 50
May be indicator of problems with care or monitoring. *Use your institutional standard if lower than 50.*

T7 3rd or 4th Degree Lacerations
May indicate harm associated with instrumented delivery. Fourth degree lacerations may be an indicator for shoulder dystocia.

T8 Prolonged Deceleration (as defined by NICHD terminology)
Prolonged deceleration may be indicative of an adverse event associated with, for example, uterine rupture or hyperstimulation. Look for information in the L&D Flow Sheet or progress notes. We do not recommend reviewing the fetal monitoring strips. Documentation should be reflected in the medical record.

T9 Blood Transfusion
Any transfusion of packed red blood cells (RBCs) or whole blood should be investigated for causation, including excessive bleeding, unintentional trauma of a blood vessel, etc. Transfusion of many units within the first 24 hours of surgery or delivery, including intra-operatively and post-operatively, will commonly be related to a perioperative adverse event. Exceptions would be where excessive blood loss occurred pre-operatively. Fresh frozen plasma and platelets can reflect system problems that include failure to plan changes in anticoagulants prior to surgery and the necessity to reverse quickly in order to do the surgery.

T10 Platelet Count < 50,000
Look for adverse events related to bleeding such as strokes, hematomas, and hemorrhage requiring blood transfusions. Look for information about why the platelet count decreased to see if it was as a result of a medication. Usually, a platelet transfusion is an indication that the patient has a low platelet count. Events related to transfusions or bleeding may indicate that an adverse event may have occurred.

T11 Abrupt Medication Stop
In the order sets, whenever "hold" or "stop" all medication orders appear, look for the reason this was done. Frequently, it indicates an adverse event of some kind.

© 2005 Institute for Healthcare Improvement

T12 Lethargy/Hypotension
Review the physician progress, nursing or multidisciplinary notes for evidence of over-sedation and lethargy. Review vital signs records or graphics for episodes of hypotension related to the event and administration of a sedative, analgesic, or muscle relaxant. Intentional overdose resulting in sedation is not included. Example: ephedrine post-epidural insertion.

T13 Transfer to a Higher Level of Care
Transfers include either within the institution, to another institution, or to your institution from another. Transfer to an intensive care unit, cardiac care unit, or a neonatal ICU is a trigger that an adverse event may have occurred. The admission to intensive or critical care may have occurred when the mother's or the infant's clinical condition deteriorated perhaps secondary to an adverse event. When reviewing this trigger, look for the reasons for the transfer and the change in condition.

T14 Unplanned Return to Surgery
A return to surgery is a trigger that should prompt checking for whether an adverse event occurred during the previous surgery. An example of an adverse event would be a patient who had internal bleeding following the first surgery and required a second surgery to stop the bleeding. Patients who have a second surgery that is exploratory, but does not reveal anything (looking for bleeding, or a suspected retained surgical instrument) would be considered as an adverse event. A return to the operating room after a previous surgical procedure is sometimes planned.

T15 Estimated Blood Loss > 500 mL (vaginal delivery) or 1,000mL (cesarean delivery)
500mL remains the accepted limit for "normal" blood loss after vaginal delivery and a blood loss of 1,000 mL is considered within normal limits after cesarean birth.

T16 Specialty Consult
May be an indicator of shoulder injury or other harm. Severity may vary.

T17 Administration of Oxytocic Agents (such as oxytocin, methylergonovine, and 15-methyl-prostaglandin in the post-partum period)
Agents used to control post-partum hemorrhage. PPH was defined as blood loss greater than 500 mL in a vaginal delivery and greater than 1,000 mL in a cesarean. If standard administration of oxytocin occurs post-delivery, evaluate for administration amounts greater than 20 units in the immediate post-partum period.

T18 Instrumented Delivery
Instruments may cause injury to the baby or the mother. These include cephalohematomas, bruising, sub-galeal and intracranial hemorrhage, trauma, and perineal lacerations. Instrumented delivery may increase the risk for serum bilirubin elevation.

T19 Administration of General Anesthesia
May be an indicator of harm resulting from poor planning or other sources of harm.

T20 Cord Gases Ordered
If not routinely ordered, may be an indicator of an adverse event.

T21 Gestational Diabetes
Infants may be at increased risk for harm due to management of glucose control and the delivery process, such as earlier induction resulting in lung immaturity or shoulder dystocia.

T22 Other
Note any other trigger identified in the chart review that may indicate an adverse event has occurred. Example: positive GBBS status of mother not documented and infant did not receive appropriate treatment.

© 2005 Institute for Healthcare Improvement

Perinatal Bundle - Elective Induction Bundle Composite

Data Collection Tool

Elements:

□ **Gestational Age 39 weeks or >.** Documented prior to initiation of oxytocin. Per ACOG definition in ACOG Practice Bulletin Number 10, 1999{Induction of Labor}.

Team Definition_____

□ **Normal Fetal Status**: See NICHD September '08 Tier Recommendations. Assessed and documented prior to initiation of oxytocin *and* during administration.

Team Definition_____

□ **Pelvic Examination:** This element includes documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency; Bishop's Score), clinical pelvimetry (acceptable is "adequate pelvis") and an assessment of the fetal presentation.

Team Definition_____

□ **Tachysystole:** Recognized and management throughout the administration of oxytocin. NICHD September '08 Definition- >5 contractions in 10 minutes, averaged over a 30 minute window. If present, it is recognized and treated.

Team Definition: _____

Instructions: Review 5 charts each week where oxytocin was used to electively induce labor.

N: Total number of individual components in place (5 charts X 4 elements= 20)

D: Total number of elective induction components possible in 5 charts reviewed(20).

Month _____Week _____

Chart	**Gestational Age**	**Normal Fetal Status**	**Pelvic Examination**	**Tachysystole**	Total
#1					
#2					
#3					
#4					
#5					

→ When a rate of 95% or greater compliance is reached for at least _____data points, move to the All or Nothing Measure (Elective Induction Bundle).

INSTITUTE FOR HEALTHCARE IMPROVEMENT