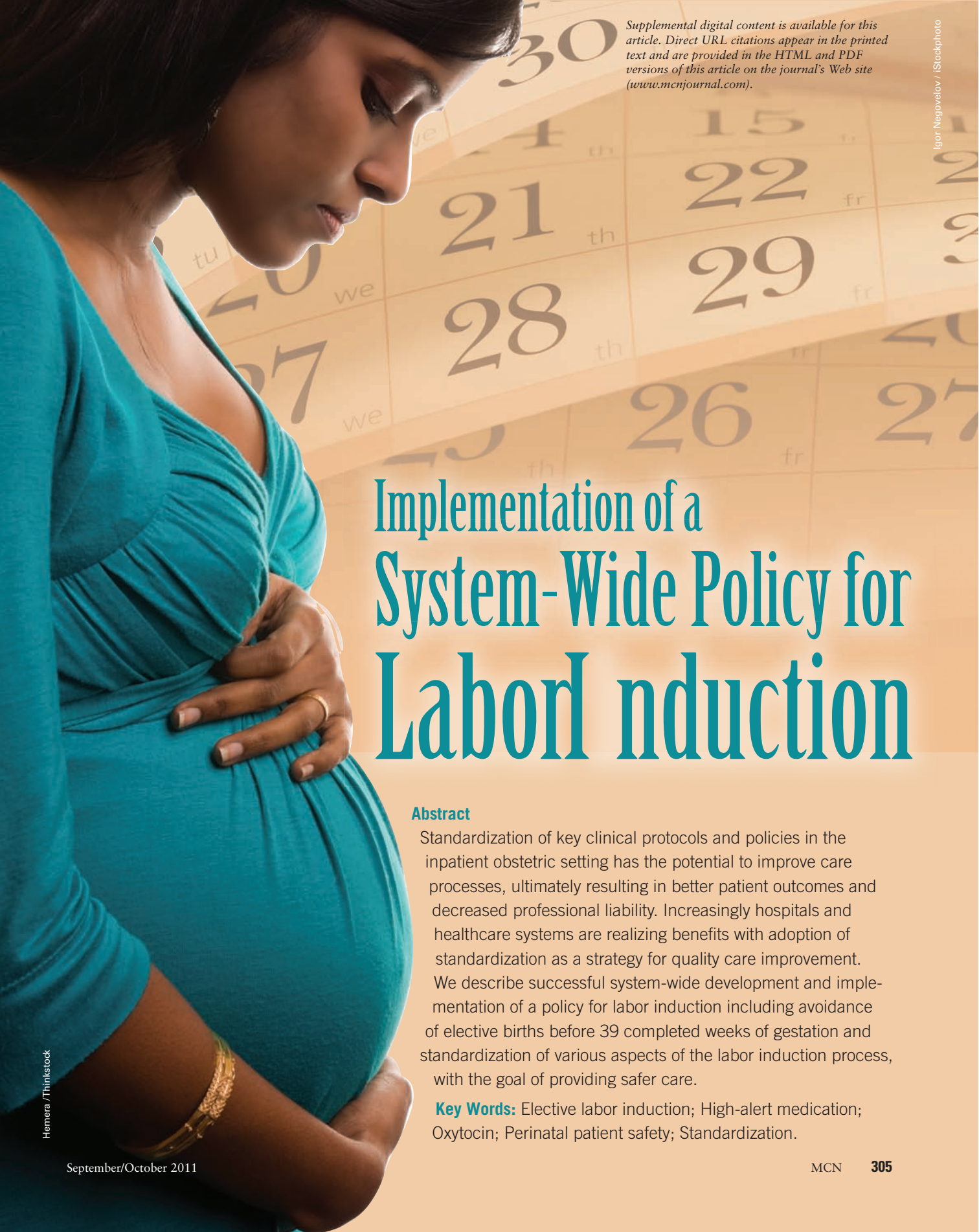


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Implementation of a System-Wide Policy for Labor Induction

Abstract

Standardization of key clinical protocols and policies in the inpatient obstetric setting has the potential to improve care processes, ultimately resulting in better patient outcomes and decreased professional liability. Increasingly hospitals and healthcare systems are realizing benefits with adoption of standardization as a strategy for quality care improvement. We describe successful system-wide development and implementation of a policy for labor induction including avoidance of elective births before 39 completed weeks of gestation and standardization of various aspects of the labor induction process, with the goal of providing safer care.

Key Words: Elective labor induction; High-alert medication; Oxytocin; Perinatal patient safety; Standardization.

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There is a growing body of evidence that standardization of key clinical protocols and practices has the potential to promote a safer clinical environment. In the inpatient obstetric setting these areas of practice include fetal assessment, labor induction, second stage labor care, management of shoulder dystocia, administration of high-alert medications, and care for women during a trial of labor attempting a vaginal birth after cesarean birth (VBAC) (Clark, Belfort, Dildy, & Meyers, 2008; Pettker et al., 2009; Simpson & Knox, 2006, 2009). These areas of obstetrical practice offer substantial opportunities for standardization as there are related standards and guidelines from professional organizations and cumulative evidence, they are often subject to wide variations among clinicians and within individual perinatal units and healthcare systems, and they are associated with risk of potential harm to mothers and babies during labor and birth (Clark, Belfort, Byrum, Meyers, & Perlin, 2008; Clark, Belfort, Dildy, et al., 2008; Simpson & Knox, 2006).

Review of the Evidence

Data from high-reliability organizations and the aviation industry demonstrate the benefits of standardization. Well-designed, agreed-upon operational plans and expectations have been shown to consistently produce reliable results and lead to improvements in processes and outcomes (Pronovost et al., 2006; Riley, 2009). High-reliability organizations are organizations with hazardous conditions in which an error could have potentially devastating consequences that experience a record of consistent safety over long periods of time (Roberts, 1990). These include the nuclear power industry, the space agency, aircraft carrier ships, and chemical plants. Although the complexity of hospital structure, operations, fiscal barriers, multiple care providers, and a variety of patient encounters can sometimes produce hazardous conditions for patients, hospitals and healthcare systems can be highly reliable in the perinatal care they deliver (Knox, Simpson, & Townsend, 2003). Organizational characteristics identified that substantially limit accidents and “failures” and simultaneously result in high levels of performance include prioritization of both safety and performance, consensus about management of competing goals across the organization, promotion of a “culture of reliability”, use of organization knowledge that maximizes learning from accidents, incidents, and near misses, redundancy, and extensive use of standardization as appropriate (Weick & Sutcliffe, 2001). This organizational model has been applied to the practice of inpatient obstetrics over the past several years.

In 2008, Clark, Belfort, Byrum, et al. found that a few key aspects of care done well in obstetrics could minimize risk of most patient harm and professional liability. Contrary to widely held beliefs, in an evaluation of 189 closed claims, Clark, Belfort, Dildy, et al. (2008) noted that 70% of obstetric malpractice claims actually involved substandard care. Other healthcare systems have found that adherence to established evidence-based protocols is

less likely to result in obstetric malpractice claims (Ransom, Dombrowski, Mello, & Brennan, 2003). The Hospital Corporation of America (HCA) implemented a comprehensive redesign of patient safety processes including standardized processes and procedures, the premise that every member of the obstetric team should be required to stop any process that is deemed to be dangerous and that malpractice loss is best avoided by decreasing adverse outcomes and development of unambiguous practice guidelines (Clark, Belfort, Byrum, et al., 2008). The HCA program resulted in improvements in patient outcomes, a dramatic decline in litigation claims, and a decrease in the primary cesarean birth rate.

Other healthcare systems have found similar benefits of standardization. The Seaton Family of Hospitals used the principles of high reliability to apply a series of standardized practices and protocols related to cervical ripening, labor induction, fetal monitoring interpretation, and operative vaginal birth, which resulted in a reduction in birth trauma rates to virtually zero (Mazza et al., 2008). Catholic Healthcare Partners (CHP) implemented a perinatal patient program based on an agreement among administrators, the perinatal leadership team, and front-line clinicians to provide care in the context of the best evidence and standards and guidelines from professional organizations. The CHP program included standardization of key clinical practices including fetal assessment, labor induction, and second stage labor care. Over a 4-year period, there was a 96% decrease in birth trauma rates, a 65% decrease in potentially compensable events, and an approximate 50% decrease in average costs per obstetrical claims and number of new claims reported (Simpson, Kortz, & Knox, 2009). Yale New Haven Hospital’s perinatal patient safety program included protocol standardization, creation of a patient safety nurse position and interdisciplinary patient safety committee, and interdisciplinary training in team skills and fetal monitoring interpretation. As a result, adverse outcomes were significantly reduced and there were significant improvements in safety climate by validated safety attitude surveys (Pettker et al., 2009).

Elective labor induction requires careful assessment of gestational age (American College of Obstetricians and Gynecologists [ACOG], 2009). Although perceived by some clinicians as a “new standard”, in 1983, the American Academy of Pediatrics (AAP) and ACOG in their first edition of *Guidelines for Perinatal Care* indicated that elective births should not be performed before 39 completed weeks of gestation. This recommendation has been ongoing for many years and is supported by evidence of increased risk of neonatal morbidity, admission to the special care nursery or neonatal intensive care nursery, and longer neonatal lengths of stay when elective births occur too early (Clark et al., 2009; Oshiro, Henry, Wilson, Branch, & Warner, 2009; Tita et al., 2009).

Recent attention to avoiding elective births before 39 completed weeks by the March of Dimes, the National Quality Forum, the Institute for Healthcare Improvement, and the Joint Commission (TJC) has further de-



Well-designed, agreed-upon operational plans and expectations have been shown to consistently produce reliable results and lead to improvements in processes and outcomes.

fined and highlighted the issue. The Joint Commission has developed perinatal quality measures to monitor appropriate gestational age for elective birth (TJC, 2010). Articles in the lay press and media coverage have increased public awareness. Therefore, in addition to risk of iatrogenic prematurity with potential adverse sequelae, elective birth before 39 completed weeks of gestation poses a professional liability risk. If care during labor induction and/or cesarean section of a woman having elective birth before 39 completed weeks of gestation leads to an adverse outcome and subsequent litigation, the plaintiffs have readily available evidence that there was a breach of the standard of care before any other aspects of the clinical situation are reviewed.

Labor induction usually involves use of oxytocin, a high-alert medication (Institute for Safe Medication Practices [ISMP], 2007). High-alert medications are drugs that have a heightened risk of causing significant patient harm when they are used in error (ISMP, 2007). Errors with high-alert medications may or may not be more common than with other drugs; however, patient injury and consequences of associated errors may be more devastating. Thus, special considerations and precautions are required prior to and during administration (ISMP, 2007). As with other high-alert medications, standardization and administration of the lowest dose of oxytocin possible to achieve the desired clinical effect is recommended. A standard oxytocin protocol that includes starting at 1 milliunit/minute (mU/min) and increasing by 1 to 2 mU/min no more frequently than every 30 minutes based on the maternal-fetal response has numerous benefits to mothers and babies including decreased risk of: oxytocin-induced uterine tachysystole, fetal hypoxemia and acidemia, maternal pain, placental abruption, uterine rupture, unnecessary cesarean birth for indeterminate/abnormal fetal heart rate patterns, postpartum hemorrhage, and infection (ACOG, 2009; Clark et al., 2007; Crane & Young, 1998; AWHONN [Simpson, 2009]). Therefore, this type of conservative, standardized approach to oxytocin administration is recommended.

Patient injury from drug therapy is the single most common type of adverse event that occurs in the inpa-

tient setting (Agency for Healthcare Research and Quality, 2001). Patient harm resulting from use of a drug is defined as an *adverse drug event* (ADE). Other terms used include *potential adverse drug event*: circumstances that could result in patient harm by the use of the drug, but did not harm the patient; and *medication error*: inappropriate use of a drug that may or may not cause patient harm. Oxytocin-induced tachysystole can be classified as one or more of these conditions. Tachysystole is a major feature in successful obstetrical malpractice cases (ACOG, 2004a) and makes them challenging to defend. Although tachysystole can occur even with the most vigilant care (Crane, Young, Butt, Bennett, & Hutchens, 2001); processes to minimize the risk of tachysystole together with processes designed for timely identification and treatment can reduce risk of patient harm and professional liability. Clinical disagreements related to use of oxytocin often occur, including what constitutes tachysystole and how to handle tachysystole when it occurs (Simpson, James, Knox, 2006; Simpson & Lyndon, 2009). A standard definition of tachysystole and algorithm for treating tachysystole that does not require calling the provider for additional orders can be beneficial in minimizing these types of clinical disagreements and ensuring timely appropriate treatment before fetal harm occurs (Clark et al., 2007; Simpson & Knox, 2009).

Trinity Health

Trinity Health is a Catholic healthcare system with 36 acute care hospitals (ministry organizations) in ten states (California, Idaho, Oregon, Nebraska, Iowa, Illinois, Indiana, Michigan, Ohio and Maryland) with annual births ranging from 50 to 8,750. The healthcare system includes one hospital ranking in the top 10 in the United States based on birth volume (of the approximately 3,265 US hospitals with a perinatal service) along with several critical access hospitals (critical access hospitals must be located in a rural area and meet the following criteria: 25 beds or less and over 35-mile distance from another hospital or 15 miles from another hospital in mountainous terrain or areas with only secondary roads) with very small birth volumes. Twenty-six of the ministry organizations have perinatal services, 10 of which are level I,

8 level II, and 8 level III. The ministry organizations are located in rural, midsized, and urban areas serving diverse patient populations with a variety of payer mixes. In addition to the perinatal nurses, care providers include nurse midwives, obstetricians, family medicine physicians, and resident physicians in training. Some of the ministry organizations have employed physicians, some have obstetrical hospitalist programs with 24/7 in-house coverage, and some are level III referral centers. Thus, based on these multiple factors, Trinity Health is representative of the variety of practice settings seen in contemporary perinatal care in the United States.

Implementation of Standard Protocols and Policies at Trinity Health

In 2008, Trinity Health began the process of implementing system-wide policies and protocols that were supported by the best available scientific evidence and consistent with national standards and guidelines, with the objective of minimizing risk of preventable harm to mothers and babies and decreasing professional liability. The first system-wide policy implemented involved VBAC care. The goal was not to encourage or discourage providing VBAC care but rather to insure that this care was provided in the context of existing evidence and the guidelines in the practice bulletin and committee opinion on this topic from ACOG (2004b, 2006). Careful scrutiny of existing resources in each ministry organization followed. The obstetric leadership team in some of the hospitals decided that they did not have the resources to provide immediate availability of a full surgical team during VBAC labor and elected to discontinue providing planned VBAC care, whereas others tightened their policies and protocols to ensure adequate in-house resources to be able to respond in a timely manner to an obstetrical emergency related to uterine rupture. Full adoption of the system-wide VBAC policy took several months and involved multiple discussions with obstetrical providers, nurses, and hospital administrators; however, eventually success was achieved. The most recent ACOG practice bulletin on VBACs (2010) was incorporated into the policy. Ongoing monitoring supports sustainability and accountability.

Labor Induction

Given the success of the implementation of the system-wide VBAC policy, attention was directed at another source of potential patient harm and professional liability: induction of labor. Expert stakeholders from the ministry organizations were invited to participate in a Perinatal Patient Safety Initiative Collaborative Team. These included clinicians from medicine, nursing, and midwifery and members of the leadership team. Some of the experts who participated in the VBAC initiative were also part of this team. A collaborative charter was developed that included guiding behaviors, a vision, purpose, team accountability, guiding principles for decision-

Expert stakeholders from the ministry organizations were invited to participate in a Perinatal Patient Safety Initiative Collaborative Team.

making, membership, expectations of members, communication processes, and reporting to stakeholders. The group revised and approved the charter. The purpose was stated as: The Perinatal Patient Safety Initiative Collaborative provides feedback and makes recommendations regarding the identification and implementation of key care processes in perinatal care in an effort to improve perinatal patient safety. Recommendations are made to the Perinatal Safety Initiative Steering Team. The Perinatal Safety Initiative Steering Team is a workgroup within the Unified Clinical Enterprise and reports to the Clinical Leadership Council.

A subgroup, the Perinatal Patient Safety Initiative Steering Team began the process of developing a standardized oxytocin policy that could be shared among the members of the collaborative team for feedback and potential revisions. The goal was to cover all areas of labor induction (Table 1). A preoxytocin and during oxytocin checklist was developed and adapted from the work of Clark et al. (2007). Standards and guidelines from ACOG (2009), AAP (AAP & ACOG, 2007), the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN [Simpson], 2009), the Joint Commission (2010), and ISMP (2007) along with pertinent research articles were provided and reviewed by the steering committee to facilitate development of an evidence and standards-based policy for induction of labor.

There was ongoing discussion about key aspects of the policy under consideration. The steering committee met by telephone conferences monthly and the collaborative team met on a quarterly basis. Email communication and conversations continued between meetings. Experts from the pharmacy team and the risk management team participated as members of the committee as needed. Once the steering committee developed a working draft, this draft was shared with the collaborative team. Suggestions for revisions were made through an iterative process until the group was in agreement with the components of the policy.

Areas of potential controversy such as oxytocin concentration, the intravenous (IV) solution, the dosing regimen, and how to assure avoidance of elective inductions before 39 weeks gestation were discussed in detail over the course of several meetings. When questions arose, further review of available evidence and existing stan-

dards and guidelines assisted decision-making. However, resolution of some of these issues was at times a challenging process. As expected, some clinicians were resistant to change and this resistance covered nearly all aspects of the standardized policy. For example, in some ministry organizations, the interval between oxytocin increases was every 15 to 20 minutes rather than every 30 minutes. In others, there was no standard protocol; oxytocin administration was based on individual provider orders. There were variations in the frequency of maternal-fetal assessment during oxytocin administration from every 15 minutes to 30 minutes. Many of the hospitals did not have an agreed-upon definition of tachysystole and/or a standardized protocol to treat tachysystole when it occurred. The concentration of oxytocin varied between 30 units in 500 mL of IV solution to 20 units in 1 liter of IV solution. The IV solution varied as well, with normal saline and lactated Ringer's solution being used. The expert pharmacists from the Trinity system developed a standardized solution for the IV diluent and oxytocin concentration. Several ministry organizations had not focused on elective births before 39 completed weeks of gestation; thus, elective births at 37 and 38 weeks were occurring at times. Some providers were unaware or disbelieving of the evidence of neonatal morbidity for early term elective births. Some ministry organizations had relied on retrospective peer review to minimize elective births before 39 completed weeks of gestation rather than processes for prevention at time of scheduling before the woman arrived at the hospital for care. Local practices and "the way we've always done it" were preferred by some clinicians. In summary, reaching agreement was not a quick or easy process. However, in the end, consensus was reached and system-wide implementation proceeded. The standardized process for labor induction was supported by the Trinity Health administrative team with expert clinicians in each ministry organization serving as leaders to promote adoption.

In addition to the policy, several forms were developed to facilitate ease of implementation and compliance with the policy in each of the ministry organizations including an elective induction scheduling form (See Figure 1, Supplemental Digital Content 1, <http://links.lww.com/MCN/A2> and Figure 2, Supplemental Digital Content 2, <http://links.lww.com/MCN/A3>) and a preoxytocin and during oxytocin checklist. The goal of the scheduling form was to insure that women having elective induction were at least 39 completed weeks of gestation and that women requiring medically indicated induction were given priority. The scheduling form offered the ability

Table 1. Aspects of Labor Induction That Were Standardized

Elective and medically indicated inductions
Documentation of the indication for induction
Documentation of patient consent and discussion of potential risks and benefits
Scheduling procedures with medically indicated inductions being given priority
Avoidance of elective induction before 39 completed weeks of gestation
Roles and responsibilities of providers and staff nurses
Electronic medical record cues and documentation options
Provider order set
Concentration of oxytocin in a standard intravenous (IV) solution (20 units in 1 liter of normal saline)
Dosing regimen (start at 1 milliunit per minute [mU/min] and increase by 1 to 2 mU/min no more frequently than every 30 minutes until adequate progress of labor is established and/or contractions are every 2 to 3 minutes; once adequate labor is established, maintain or decrease oxytocin to baseline rate necessary for continued labor progress)
Preoxytocin and during oxytocin checklist
Definition of tachysystole (more than 5 contractions in 10 min (averaged over 30 min), contractions lasting 2 min or more, contractions of normal duration occurring within 1 min of each other or insufficient return of uterine resting tone between contractions via palpation or intraamniotic pressure above 25 mmHg between contractions via IUPC
Algorithm for treatment of tachysystole and associated indeterminate or abnormal fetal heart rate patterns based on the fetal response (Oxytocin-Induced Tachysystole (Normal [Category I] FHR): Maternal repositioning [either left or right]; IV fluid bolus of lactated Ringer's solution; if uterine activity has not returned to normal after 10 min, decrease oxytocin rate by at least half; if uterine activity has not returned to normal after 10 more min, discontinue oxytocin until uterine activity is less than 5 contractions in 10 min; Oxytocin-Induced Tachysystole (Indeterminate [Category II] Abnormal [Category III] FHR): discontinue oxytocin; maternal repositioning [either left or right]; IV fluid bolus of lactated Ringer's solution; consider oxygen at 10 L/min via nonrebreather facemask if the first interventions above do not resolve the indeterminate/abnormal FHR pattern. Discontinue as soon as possible. If no response, consider 0.25 mg terbutaline SQ. Notify primary provider of actions taken and maternal-fetal response.)
Process for clinical disagreements (There will be some situations in which alterations in management from that described in the protocol are clinically appropriate. If, after reviewing the fetal heart rate strip during a bedside evaluation, the responsible physician feels that in his or her judgment, use of oxytocin is in the best interest of the mother and baby, the physician should write or dictate a note to that effect and order the oxytocin to begin. Labor nurses may refuse to administer oxytocin if in their best judgment it is contraindicated, or if the needs of the service make it difficult or impossible to adequately monitor maternal-fetal status.)

Clinical Implications

- Standardization of labor induction processes has the potential to promote safer care for mothers and babies by eliminating elective births before 39 completed weeks of gestation, minimizing risk of tachysystole through use of a physiologic dosing regimen for oxytocin and encouraging use of a protocol for management of tachysystole if it occurs.
- Despite variations in settings, areas of the country, types of care providers, and levels of service, system-wide standardization of labor induction processes is possible with committed clinicians with knowledge of current evidence and standards and encouragement and support from the healthcare system leadership team.

to note the woman's consent to the procedure after being informed regarding potential risks and benefits. The oxytocin checklists were developed to assist clinicians in assessment and documentation of maternal and fetal status before and during oxytocin administration. The purpose of the checklists was to establish fetal well-being prior to the procedure, promote ongoing fetal well-being, avoid tachysystole, and treat tachysystole in a timely manner if it occurred. As these tools were shared with front-line clinicians, more suggestions for revisions were made and incorporated in the forms and the policy. Changes were made to the system-wide electronic medical record to be consistent with new policy and facilitate incorporation into clinical practice. Implementation in all ministry organization began in the summer of 2010. Trinity Health developed an audit process to insure ongoing consistency with the standardized provider order sets, policies, and protocols.

Clinical Implications

Although we have not yet been able to collect outcome data, we are confident that standardization of the process for labor induction will promote safer care for mothers and babies in our ministry organizations. As others have found (Clark et al. 2010), standardization with "hard stop" hospital policies on labor induction, especially related to avoidance of elective inductions before 39 completed weeks of gestation, is more effective than solely physician education and encouragement of the adoption of policies backed only by peer review. We believe this approach will work in a similar manner to the HCA (Clark et al. 2010) process of standardizing labor induction practices with adoption by all members of the perinatal team in all ministry organizations as this is the expectation of the Trinity Health leadership team and ongoing consistency will be monitored.

Summary

Standardization has the potential to improve care and decrease risk of preventable harm and professional liability. Other healthcare systems have found success with this approach and associated benefits in terms of better patient outcomes, less adverse events, and fewer malprac-

Trinity Health developed an audit process to insure ongoing consistency with the standardized provider order sets, policies, and protocols.

tice claims. This system-wide oxytocin policy adopted by our 25 ministry organizations providing perinatal services is one step in the efforts of Trinity Health to make care as safe as possible for mothers and babies. ❖

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