

FOCUS**INNOVATIONS IN HEALTH IT**

Using Intelligent Electronic Fetal Monitoring Software to Reduce Iatrogenic Complications of Childbirth

A Case Study

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OXYTOCIN (OFTEN referred to by the brand name Pitocin®) is a drug used in more than half of all U.S. births to enhance labor by inducing or augmenting uterine contractions.¹ Conditions that may necessitate induction include (but are not limited to) hypertensive disorders of pregnancy, preeclampsia or eclampsia, maternal medical conditions such as diabetes mellitus or chronic hypertension, severe intrauterine fetal growth restriction, and post-term

pregnancy.²

Oxytocin is used to induce labor when the benefits of earlier delivery outweigh the risks of continuing the pregnancy for either the woman or the fetus. Oxytocin is also used to augment a labor when inadequate uterine contractions have failed to result in progressive cervical dilation or descent of the fetus.² In these cases, the goal is to avoid a costly and risk-prone cesarean section by enabling a lower-risk vaginal birth.

Whether used for induction or augmen-

tation, oxytocin is normally administered without incident and its labor-enhancing properties are generally beneficial. However, more than one of five women will develop uterine tachysystole (UT), which is defined as 5 or more contractions in a 10-minute window, averaged over 30 minutes.³ These overly frequent contractions can decrease the flow of oxygen to the fetus due to long contractions and inadequate relaxation time between contractions.⁴

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ABSTRACT

Oxytocin, a drug that stimulates uterine contractions, is used in over half of U.S. births to induce or augment labor. Despite its widespread use, however, it is critical to note that more than one in five women who receive oxytocin will develop uterine tachysystole (UT)—overly frequent contractions that can decrease oxygen delivery to the fetus. Although many babies can tolerate brief episodes of UT, longer durations and/or more frequent occurrences increase the risk of permanent brain injury. Therefore, it is especially critical to vigilantly monitor a baby's tolerance to labor in compliance with national guidelines when the mother has been administered labor-inducing drugs.

Electronic fetal monitoring (EFM) technology has been used for many years to monitor maternal contractions and the fetal heart rate—critical factors in determining the baby's tolerance to labor. Yet these factors can be challenging for humans to monitor consistently and in a standardized fashion. The assessment of fetal heart rate patterns is subjective, and repetitive calculation of contraction rates is tedious and time-consuming. Additionally, it is easy to become complacent with high-frequency issues such as UT because the incidence of adverse outcomes associated with it is low. However, when that adverse outcome is a birth-related brain injury with lifelong disability, hospitals risk multimillion-dollar lawsuits because appropriate administration of oxytocin is presumed to have been their responsibility.

Understanding that lowering the incidence of UT in women receiving oxytocin reflects better care and should lead to better outcomes, MedStar Franklin Square Medical Center launched an IT initiative aimed at providing reliable, automated detection of UT, making it clear to clinicians when oxytocin should be discontinued.

Oxytocin management policies had been in place for many years at this institution. Later, in 2011, they introduced next-generation fetal monitoring software with real-time pattern recognition that calculates contraction rates at any point in time and identifies key fetal heart rate parameters.

The following improvements were observed in women receiving oxytocin after introducing the software:

- Rate of UT fell from 22.7 percent to 17.3 percent ($P < 0.0001$).
- Average duration of UT fell from 64 minutes to 54 minutes ($P = 0.004$).
- Total time spent in UT fell by 36.5 percent ($P < 0.0001$).

These substantial improvements provide evidence of the synergy of an IT intervention providing clinicians with the information they need, instantly and at the bedside, using real-time pattern recognition and useful data visualization techniques.

KEYWORDS

Uterine tachysystole, obstetrics, oxytocin, electronic fetal monitoring, labor and delivery.

incidences of UT, a very small number will develop permanent brain injury from oxygen deprivation during labor.

CLINICAL RISKS AND MALPRACTICE CLAIMS CONSEQUENCES

Problems resulting from UT occur when an unintended reaction to oxytocin is coupled with a failure by clinicians to recognize and act on it. This scenario is driven in part by the nature of oxytocin and the variation in how mothers and babies respond to it. While there are well-established protocols for the administration of oxytocin during labor, they often form only a starting point; individual reactions vary widely. As

a result, administration of oxytocin must be watched and managed more closely than most other drugs, such as antibiotics, where there is fixed dosage for all. In a hectic labor and delivery (L&D) environment, when nurses are tending to multiple patients at various stages of labor, it can be difficult to quickly spot these non-reassuring trends using conventional EFM technology.

Although the actual number of injuries incurred with UT is small, the consequences for families, clinicians, and hospitals are severe. Of all the legal claims related to labor induction or augmentation with oxytocin opened by the Canadian Medical

Protective Association between 2002 and 2012, 75 percent of those were closed with a settlement. More than 70 percent showed a failure to appreciate and act on severity of EFM abnormalities with or without UT.⁵

Other studies point to similar findings. Excessive use of contraction-simulating drugs was found to be the underlying problem in 45 percent of hypoxic brain injury claims.⁶ Incautious use of oxytocin was shown in 71 percent of births where legal action was sought after severe asphyxia,⁷ and oxytocin misuse was found in 47 percent of babies born with metabolic acidosis.⁸

Overall, obstetrics claims represent the

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first or second highest-risk department in terms of dollar amounts as well. A 2010 study published by CRICO, a medical malpractice company owned by and serving the Harvard medical community, shows OB claims costing twice as much as those in other departments, with an average of \$980,000.⁹ This same study estimates that approximately 1 in 1,000 U.S. births (a total of more than 4,000 annually) involve a preventable adverse outcome, most of which occurred in the active stage of labor. In short, when birth-related injury occurs, it is devastating to families, costly to all, and questionable oxytocin management is often a factor.

Oxytocin is used frequently because it has many benefits. Induction of labor for genuine medical indications can save lives. Augmentation of slow labor with oxytocin can reduce the need for cesarean delivery. One of the largest reviews concluded that one cesarean was avoided for every 50 patients treated by high-dose oxytocin augmentation.¹⁰

The medical challenge is clear – improve the risk/benefit ratio with oxytocin usage. The situation is analogous to reducing excessive speeds on the highway to reduce the rates of accidents with serious injury or fatality. Lowering the incidence of UT across all births as a preventative measure should improve patient safety and improve hospital vulnerability in litigation. No one would consider driving without a speedometer. However until recently no fetal monitoring software provided clinicians with an automated way of measuring con-

traction rates.

This article examines how MedStar Franklin Square Medical Center, a 377-bed hospital in Baltimore, is using IT technology at the bedside to increase early recognition of UT during labor and improve communication between nurses and physicians without developing alarm fatigue.

PeriGen's PeriCALM Patterns™ (Cranbury, NJ) is software that identifies and measures fetal heart rate parameters including baseline, baseline variability, decelerations and uterine contractions. Markings are superimposed on the displays on the familiar views of the fetal heart rate and contraction recordings. Additional long-term displays summarize the data in graphical format so that clinicians can instantly see important trends and the degree of abnormality in contraction rates or fetal heart rate responses.

MEDSTAR'S RESEARCH FOCUS ON UT AND QUALITY OF CARE

MedStar Franklin Square Medical Center is a not-for-profit, general medical and surgical hospital that is part of the MedStar Health organization. It is one of the top 25 community teaching hospitals in the United States, with a professional staff that includes more than 1,000 nurses and 400-plus staff physicians.

MedStar Franklin Square has earned some of the nation's most prestigious quality awards and recognitions, including Magnet Designation for excellence in nursing, the Delmarva Foundation Award

for Quality Excellence, and inclusion in the *U.S. News and World Report's* Best Hospital specialty ranking for three consecutive years. It is known for offering leading-edge levels of care, treatment and technology in several specialty areas, including obstetrics and neonatology.

Hospital-sponsored research into UT and its effect on babies during labor has been a noteworthy area of research focus over the past few years.¹¹ Thousands of electronic tracings stored and analyzed were used to identify patterns and determine correlations between features in the tracings and birth outcomes. This was not feasible with naked eye examination of miles of paper tracings.

MedStar Franklin Square already had well-defined clinical protocols in place for the management of oxytocin that included and even extended the most up-to-date recommendations. Most importantly, nurses were empowered to stop the infusion of oxytocin or reduce the dosage any time they recognized a non-reassuring trend.

Although their baseline rates of UT were half the rates reported by some others in the literature,¹² and their outcomes were excellent in more than 97% of cases in which UT occurred, the hospital embarked on this study to determine if automated detection of UT reduced these rates even further.

UNDERSTANDING UT MANAGEMENT

To comprehend the significance of this initiative, it is first imperative to understand

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FIGURE 1: Basic EFM Recordings (blue labels) Available During “Before” period and Additional Color-Coded Visual Markers and Long-Term Displays (orange labels) in the “After” Period

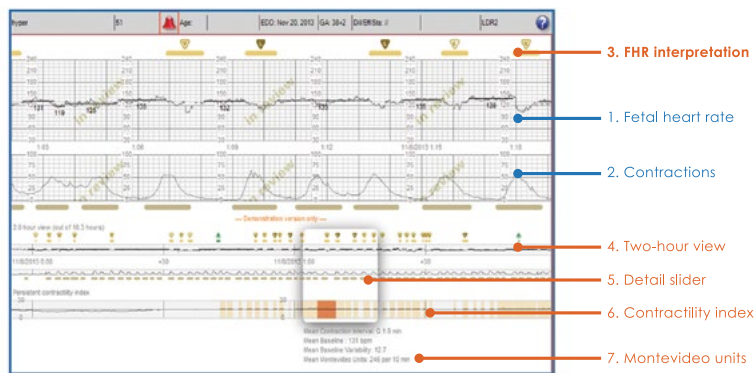


FIGURE 2: Findings in the “Before” and “After” Periods

	Before 2006-2010	After 2012-2013	P value
Number of Births	6728	3790	
Induced or Augmented Labor	3869 57.5%	1988 52.5%	<0.0001
CS	1628 24.2%	1044 27.5%	0.0002
CS in induced or augmented	742 19.2%	421 21.2%	0.0749
CS in not induced or augmented	886 31.0%	623 34.6%	0.0102
PIs with UT	1422 21.1%	613 16.2%	<0.0001
Neonatal Depression	183 2.7%	96 2.5%	0.61
Births with Induction or Augmentation	3869	1988	
With UT	880 22.7%	344 17.3%	<0.0001
Average duration of UT	64 min	54 min	0.0039
% Tracing hours spent in UT	935.5/22792 4.1%	312/11792 2.6%	<0.0001

the effect UT has on the baby. Each time the mother has a contraction, the flow of oxygen to the baby is reduced. Oxygen flow returns to normal once the uterus relaxes. This is a normal part of the birthing process and can be likened to holding one’s breath while under water for many seconds, then surfacing and breathing normally.

In UT, the contractions become more frequent and longer which is akin to holding one’s breath longer and more frequently.

The more UT is present, and the longer it persists, the more stressful it becomes for the baby, especially if the baby is compromised by another complication of

pregnancy. Reducing the frequency and duration of UT is viewed as a marker of higher quality care because fewer babies are placed in jeopardy.

FACTORS CONTRIBUTING TO PROBLEMATIC OXYTOCIN MANAGEMENT

As previously discussed, in rare cases where UT is associated with adverse outcomes, oxytocin management that does not adhere to well-established protocols for safest use is frequent. This is not surprising given human nature and other factors at play.

1. Oxytocin shortens labor, increasing productivity of units and convenience for families and clinicians. Thus in general, clinicians experience many benefits to oxytocin use and few adverse outcomes. To use the speeding analogy again, on balance, a little extra speed is often beneficial and rarely causes harm.

2. Careful and frequent adjustment of the rate of medication administration is required because of potentially rapid changes in how the mother and baby respond to it.

3. It is tedious to calculate contraction rates every 10 minutes. When rates fluctuate, it is easy to focus on the “snapshot” in time where rates were satisfactory and ignore the periods of time when they were not. Thus one may not always recognize the degree and duration of UT.

4. Finally, it is often challenging for nurses to convey their assessments of conventional EFM’s to physicians. Physicians may focus on different aspects or different portions of the tracing or disagree with their assessments.

THE IT INTERVENTION

Computerized displays of fetal monitor tracings typically display a snapshot of approximately 10 minutes of the fetal heart rate and maternal contractions. Traditionally, all the parameters of interest to the clinicians are estimated visually by comparing the tracings to the gridlines in the background. Although this allows clinicians to see minute details of the tracing, it does not provide a long-term overview nor any summary measurements. The very definition of UT requires an assessment over 30 minutes, and significant trends in fetal heart rate perturbations often develop over hours.

The IT application introduced in 2011 addresses these deficiencies by providing a zoomed or enlarged view simultaneously with an overview of the last 2 hours. The pattern recognition module measures and marks the features clinicians use to assess the mother and baby, and provides a summary of their measurements on screen. The Detail slider window selects the portion of the 2-hour view for magnification as shown

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in the upper panel. The screen capture in **Figure 1** displays the basic EFM recordings (blue labels) available during the “Before” period, as well as the additional color-coded visual markers and long-term displays (orange labels) added in the “After” period. The Contractility Index provides an instantaneous, color-coded visual indicator of the degree and duration of uterine tachysystole.

The lowest colored bar, entitled Contractility Index, summarizes the mother’s contraction rates over the past two hours. When those rates exceed the desirable range of 5 contractions per 10 minutes, the display becomes lightly colored. When this condition persists beyond a configurable limit, the intense coloration appears. Thus, at a glance clinicians can see the state of maternal contractions, the mother’s response to changing oxytocin levels and, most critically, the response of the baby’s heart at this point in time.

The Detail slider window can be dragged or snapped to any portion of the long-term view, allowing the clinician to quickly see details within that portion. Finally, the pattern recognition markers are interactive, allowing the clinicians to drill down for further details about them.

Clinician can focus on any point in time and/or the trends over the last 2 hours. The markings and summaries provide a common language and an efficient quantitative basis for ongoing discussion between physicians and nurses.

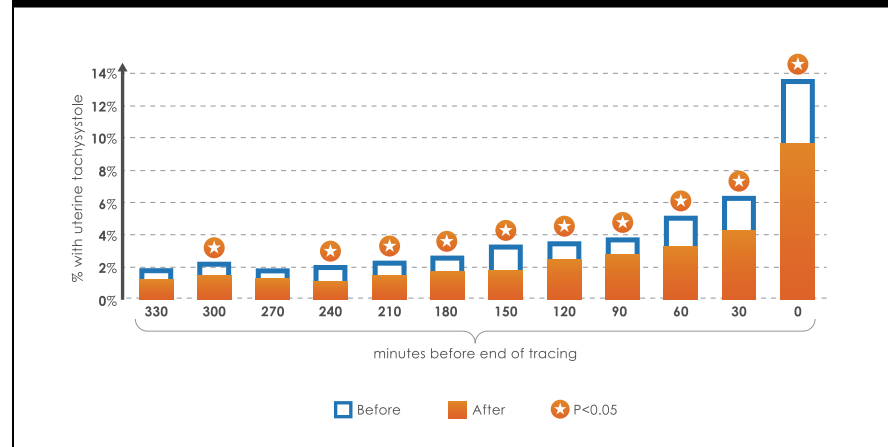
METHODS

The “Before” group consisted of 6,728 singleton labors from February 2006 to February 2010. The “After” group consisted of 3,790 singleton labors between January 2012 and December 2013.

Induction or augmentation status for both periods was ascertained by automated review of the electronic medical record database, searching for any evidence of oxytocin use to induce or enhance labor.

Digital tracings equivalent to 23 miles of paper tracings were analyzed electronically. Contractions rates were calculated every 30 minutes. The percentage of mothers experiencing UT in each 30-minute segment was calculated.

FIGURE 3: Percentage of Women with Induced or Augmented Labor who Experienced UT in Each 30-Minute Time Segment as Labor Advanced



RESULTS: SIGNIFICANT REDUCTION IN UT

Figure 2 compares overall findings in the Before and After periods. Note the use of oxytocin in more than half of labors and the overall reduction in UT rates from 21.2 percent to 16.2 percent. The lower half of the table shows findings specifically for women with labor induction or augmentation. Note the significant fall in incidence, duration and total amount of time spent in UT.

Figure 3 shows the rates of UT in each 30-minute segment in women with induced or augmented labor. Note the significant reduction in the incidence of UT at almost every time slice.

DISCUSSION

This institution saw a highly statistically significant improvement in UT measures. In labors that were induced or augmented, the incidence of UT declined (from 22.7 percent to 17.3 percent—a 23.5 percent reduction), the average duration of UT declined (from 64 minutes to 54 minutes) and consequently the total amount of time their babies were subjected to UT declined (a 36.5 percent reduction).

Furthermore, it indicated a real behavior change with respect to regulating oxytocin. This is remarkable because human behavior is hard to change, especially when an ingrained behavior has some benefits and is seldom associated with adverse conse-

quences. It is also an achievement for an IT solution because the risk of alarm fatigue is high under these conditions.

We speculate that several IT considerations contributed to this success.

1. Efficiency – Clinicians could see if UT was present at a glance.
2. Consistency and Objectivity – Contractions were counted all the time without bias.
3. Distinguished the degree of UT – Color indicators distinguished mildly elevated/transient versus severely elevated/persistent.
4. Transparency – Computerized markings were superimposed allowing the reader to accept or reject them; additional measures were available on demand.
5. Quantitative measurements facilitate communication and lessen fear of criticism of personal judgment.

Finally, the collective commitment to improve the quality of care, by bedside clinicians and hospital leadership, must be emphasized. Technology provided assistance but it was human intervention that ultimately changed the rates of UT.

DRIVING ADDITIONAL CONTINUOUS IMPROVEMENT

In addition to reducing UT, this project produced numerous comments from the staff regarding other perceived beneficial

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ALTHOUGH THEY ARE RARE, complications resulting from UT can be devastating and expensive. The more the incidence of UT can be reduced, and any remaining occurrences mitigated, the more the likelihood of adverse consequences can be lowered.

aspects of the software. For example, it was a valuable training tool for new or less-experienced clinicians. They could turn off the decision support component, evaluate the readings, then turn it back on to see if their evaluation of the situation concurred with the technology. They could learn under real-life conditions without risk to the patients, and the training process was not dependent on the availability of specific personnel.

The technology, particularly its ability to aggregate data easily across thousands of births, gives MedStar Franklin Square the ability to test new EFM theories in a way that would not be practical by manually counting or measuring in 30 minute segments on a paper grid. This increased knowledge will be used to further refine protocols and communication between clinicians in order to deliver safer care and better outcomes for mothers and babies.

CONCLUSION

Although they are rare, complications resulting from UT can be devastating and expensive. The more the incidence of UT can be reduced, and any remaining occurrences mitigated, the more the likelihood of adverse consequences can be lowered.

Earlier recognition of problematic or modifiable conditions where intervention can resolve them is a basic goal of all clinicians. Technology that provides visual notification of developing trends, automates repetitive tasks and delivers decision support at the bedside can simplify and speed this process and facilitate communication between clinicians. This study

demonstrates the power of providing committed clinicians with useful tools to complement their knowledge and skills. **JHIM**

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