



FOCUSED CLINICAL AUDIT: OBSTETRICS OUTURE CLINICAL PERFORMANCE & OUTCOMES MEASUREMENT ANALYTICS

FEATURED CLINICAL PERFORMANCE & OUTCOMES MEASUREMENT ENGAGEMENT

Outure International, Inc. ("Q") offers focused clinical audits in selected medical specialties for hospital departments and services. The overall goal of such audits is to first evaluate the performance level of the specialized department or service measuring complication rates relative from national databases. The second goal is then to identify the etiologies of complications and evaluate clinical variables for clinical processes and clinical performance improvements for optimal outcomes.

Elements of the Obstetrics Performance & Outcomes Measurement Engagement:

1. Determination of performance level as high, average or low-performing obstetrics service from HCUP database using Glance analytics process (structured machine learning);
2. Practitioner-specific performance determinations for both maternal and infant outcomes (with morbidity & mortality determinations) with complication rates (machine learning from structured and unstructured data);
3. Install QualOptima v1.7 with performance and outcomes database from #1 & 2 above, machine read (structured if available and unstructured peer review data, risk management data including claims, and medical staff committee minutes for Ob and Ob anesthesia committees or obstetrics service);
4. Machine learn from medical records designed first to identify specific complication etiology/root actionable insight;
5. Machine learn from medical records to identify clinical processes of obstetrical patient management, use analytics to identify clinical variables (against known evidence-based variables), then machine learn variation patterns and trends in standard deviation framework;
6. Review findings and actionable insight with the department/service to agree upon experience-based optimal clinical processes to reduce maternal and infant complications; and
7. Implement optimal clinical processes and continuously machine learn from data analytics and the QualOptima clinical intelligence system.

Optional adjunct consultation and technology services might also include working with the hospital medical malpractice insurer for open claims and actuarial analytics for reduction of premiums and/or credits for project costs. Return on investment studies can also be contracted to examine the financial impacts of the engagement. Development of data and information for selection by payers, use in ACO or other entity configurations, clinical process cost analysis, and additional financial analytics are also available to contract from Q's consulting subsidiary QualVal Solutions.

LOW-PERFORMING HOSPITAL OBSTETRICS SERVICES:

A recent startling study was recently published by Laurent Glance, M.D. and co-authors, "Fivefold Variation in Obstetrical Complications Among US Hospitals," Health Affairs 33(8): 1330-36 (August 2014). Analytics of a public federal database demonstrated that women undergoing C-section delivery at low-performing hospitals were nearly 5 times more likely to experience major complications (20.93%) than women undergoing C-section at high-performing hospital (4.37%). The major complications were post-partum hemorrhage, lacerations, infections and combinations of complications.

The authors noted significant correlations with vaginal deliveries and that their findings are consistent with three (3) previous studies of hospital variations in obstetrics using single state data.

The conclusion is that this information should spur clinicians, hospital administrators, and policy makers to develop comprehensive quality metrics and invest in the necessary data infrastructure to measure and publicly report hospital obstetrical outcomes.

RESPONSE OF ORGANIZED MEDICINE TO DR. GLANCE'S STUDY:

Dr. Glance and his co-authors noted the actions of the American Congress of Obstetricians & Gynecologists to begin building a framework for quality indicators. They urged ACOG to work with other medical specialty organizations and patient advocacy groups to further develop and operationalize a quality measurement platform for obstetrical patients.

On August 4, 2014, ACOG made the following announcement, which indicates the serious attention now being directed to new metrics for obstetrics outcomes in America. American Congress of Obstetricians and Gynecologists (ACOG) President John C. Jennings, MD, and American Society of Anesthesiologists® President Jane C.K. Fitch, MD, released the following statement today:

"The study published today in Health Affairs regarding variability in obstetrical complications demonstrates the need for constructive efforts to improve care for women and babies across America. Not surprisingly, the study found remarkable levels of variability between low-performing and high-performing hospitals. American women, and their families, deserve better.

"The American Congress of Obstetricians and Gynecologists (ACOG) and the American Society of Anesthesiologists (ASA) agree that an important way to improve care is by increasing our understanding of the causes of complications and other negative outcomes, as well as by emphasizing collaborative care among the obstetrical treatment team, including obstetricians, physician anesthesiologists, nurses, and hospital staff.

"This past spring, ACOG and ASA partnered to launch the Maternal Quality Improvement Program, a joint effort to develop a national obstetrical outcomes registry through ASA's affiliated Anesthesia Quality Institute. Our goal is to provide hospitals with the information they need to understand and improve their outcomes. The program will provide a framework for reporting performance and outcomes measures for obstetrical care. The information gathered through this registry will help to inform obstetrical care in the future, improving the care provided to women and their babies and paving the way for better patient outcomes.

“Importantly, this project will help to address the variations in care that currently exist among American hospitals. Similar programs supported by other medical specialties have demonstrated the ways in which clinical registries can guide care in a meaningful way, leading to important improvements for patients.

“Right now, no national system for reporting maternal complications exists. Although the article by Glance and colleagues provides important insight into obstetrical variations, the limitations in the survey demonstrate the need for clinical data to inform quality improvement efforts. The registry will be based on more accurate and comprehensive clinical data.

VARIANCE IN CESAREAN SECTION RATES ACROSS THE UNITED STATES:

Cesarean delivery is the most commonly performed surgical procedure in the United States, and cesarean rates are increasing. Variance in cesarean section rates were found to vary tenfold across hospitals in the U.S. from 7.1 percent to 69.9 percent. Even for women with lower-risk pregnancies, in which more limited variation might be expected, cesarean rates varied fifteen-fold, from 2.4 percent to 36.5 percent. These conclusions were published from a study by Katy B. Kozhimannil, Dr.P.H. and co-author “Tenfold Among US Hospitals; Reducing Variation May Address Quality And Cost Issues,” in *Health Affairs* 32(3): 527-35 (March 2013), working with 2009 data for 817,318 deliveries from 593 US hospitals.

Vast differences in practice patterns are likely to be driving the costly (\$12,739 versus 9,048 for private health insurance in 2010) overuse of cesarean delivery in many US hospitals. Because Medicaid pays for nearly half of US births, government efforts are focused on decreasing variation. In 2009, state Medicaid programs paid more than \$3 billion for cesarean deliveries.

Machine learning was used in a study published by Rich Caruana and his associates. Published in American Medical Informatics Association (AMIA) 2003 Symposium Proceedings “Evaluating the C-section Rate of Different Physician Practices: Using Machine Learning to Model Standard Practice”. The study determined a cesarean rate of 16.*% in a population of 22,175 expectant mothers. Remarkably, however, of the 17 physician groups serving these patients, they had a vastly different C-section rate ranging from 13% to 23%. Using machine learning, the study demonstrated that despite variance in intrinsic risk of patient populations, there was no significant correlation with the rate of C-sections. These results are similar to Q’s [Success Story Obstetrics Clinical Audits](#).

The Kozhirmannil study noted significantly that many data elements relevant to maternity care quality are not routinely or systematically collected. This observation echoes the “Blueprint for Action: Steps Toward a High-Quality, High-Value Maternity Care System,” The Transforming Maternity Care Symposium Steering Committee, *Women’s Health Issues* 20: S18-S49 (2010). The five (5) stakeholder groups determined that there are significant gaps in existing performance measures and that a nationally endorsed set of maternity care performance measures is needed to adequately assess outcomes, dimensions of quality and patient experience. “Many measures of interest for determining quality of maternity care cannot be implemented currently because the data needed for measurement are not routinely and systematically collected, and collection would impose an undue burden.”

Q’s technology is designed to reduce the burden anticipated from traditional manual data abstraction. As the new national performance and outcomes measure sets are developed

and endorsed, Q technology will continue to pioneer integration of electronically collected clinical data for analytics and improved outcomes.

NATIONAL CONCERNS FOR MORBIDITY & MORTALITY IN THE US:

The Centers for Disease Control (CDC) report "Infant Mortality Rates in U.S. Need Improvement" (September 24, 2104) findings recently determined that more infants are dying before they turn 1 year old in the United States than in most of Europe and several other developed countries. A greater proportion of premature births and deaths of full-term infants are driving the higher rate, which puts the United States below 25 other countries. Still, the U.S. rate is an improvement since 2005, when the rate was 6.87% and had not changed significantly for five years.

It has been known that the U.S. has a higher preterm birth rate; however, the higher infant mortality rate for full-term, big babies who should have really good survival prospects was neither expected nor explained.

Birth trauma resulting in a wide range of injuries drives medical malpractice insurance and litigation, and cesarean section rates reflect these concerns, not only for those damages but for the human toll that occurs as its result. Some of the more prominent birth trauma are head injury, cerebral palsy, Erbs palsy, brachial plexus palsy. The role of mechanical forces causing injury are well known, including compression, excessive or abnormal traction during delivery, use of forceps (especially mid-level), instrumental deliveries, vacuum measures, and vaginal breech deliveries. Perinatal asphyxia is reported to occur in 2 to 10 newborns out of every 1000 deliveries at term. This medical condition occurs as the result of oxygen deprivation with a drop in maternal blood pressure or interference with blood flow to the baby's brain during delivery.

Cerebral palsy has several causes, and one of them is infant brain damage due to lack of oxygen during delivery. The roles of the placenta and umbilical cord in birth injury are complex and significant. Evidence of oxygen deprivation includes severe pH abnormality in cord blood and neurologic abnormalities seen after birth. Sudden oxygen deprivation during labor may be seen on an electronic fetal monitor, very low Apgar scores at birth, and involvement of other organs such as kidneys within days after birth.

Meconium aspiration syndrome can cause severe illness, injury and death of newborns. Fetal stress during delivery causes meconium (first feces) which the infant breathes in with amniotic fluid into the lungs at time of delivery. In the United States, a reported 6 – 8 birth injuries occur in every 1000 births. A higher risk appears to be associated with larger infants, born with a weight of 4500 grams or more. And on the other end of the spectrum, pre-term small weight infants pose very significant issues for deliveries. The role of elective induction with Pitocin and delays in cesarean section are some of the factors that must be included in performance and outcomes measures sets in obstetrics.

IMPACT OF PUBLIC REPORTING:

Dr. Glance and his co-authors also concluded that public reporting with timely feedback to front-line clinicians could be a powerful tool to the effort to narrow and ultimately close the obstetrical quality gap across US hospitals and improve health of mothers and their newborn children.

The ACOG and ASA announcement emphasized not only creating metrics to identify low-performing hospitals but for them to be able to act on data insights to understand causes and to be able to improve outcomes. Improving outcomes will necessitate reducing complications. "Our goal is to provide hospitals with the information they need to understand and improve their outcomes. The program will provide a framework for reporting performance and outcomes measures for obstetrical care."

The net result is that hospitals must urgently identify whether they are low-performing, average or high-performing obstetrics programs. Inherent in the framework being developed is (1) timely feedback to front-line clinicians and (2) solving complications in low and average-performing obstetrics programs, and (3) preparing for public reporting in the coming era of transparency and public availability for women and their families to select high-performing hospitals for their deliveries as well as the physicians with privileges at these hospitals.

BIG DATA IMPACTS ON VARIANCE:

Harlan M. Krumholz, M.D. of Yale recently published an extraordinary study "Big Data and New Knowledge in Medicine: The Thinking, Training and Tools Needed for a Learning Health System," *Health Affairs* 33(7): 1163-70 (July 2014). "The analytic methods for big data typically depart from traditional statistics and hypothesis testing; they incorporate techniques such as machine learning, a form of artificial intelligence that employs advanced mathematical and computational systems to reveal information from the data, common for the purpose of prediction and discovery." "Medicine aspires to be a learning health care system, but it is failing to rapidly learn through data generated through individuals in clinical care and daily life."

Dr. Krumholz details the value of machine learning techniques and using these methods to phenotype hospitals, defining groups that have similar profiles and performance. He gives the example of one such study where his team evaluated the way in which hospitals abandoned an expensive medication that was found to be potentially harmful. They found very different patterns among hospitals, with some groups characterized by rapid change in practice in response to new information about the drug and others responding much more slowly.

Some of the big data tools for unsupervised learning (analyses that seek to find hidden patterns within data), graph analytics (analyses that use graphs to understand relationships and patterns), and natural language processing (analyses enabling computers to derive meaning from human language and thus to extract knowledge from documents) are discussed in the framework of health care becoming learning organizations.

David W. Bates, M.D., well-known for his leadership in population health, and his co-authors published another major article "Big Data in Health Care: Using Analytics to Identify and Manage High-Risk and High-Cost Patients," *Health Affairs* 33(7): 1123-31 (July 2014). The opportunities to use big data to reduce costs of health care are considered as six use cases, key examples of the clearest opportunities to reduce costs through use of big data: high-cost patients, readmissions, triage, decompensation (when a patient's condition worsens), adverse events, and treatment optimization for diseases affecting multiple organ systems.

QualOptima v1.7 is focused on reducing expensive adverse events and readmissions. Using big data to predict which patients are at risk for adverse events and readmissions of specific types are discussed with examples by Dr. Bates and his co-authors. Q and QualOptima

predictive modeling to reduce post-operative infections and other complications in patients with post-operative nausea and vomiting and body temperature maintenance issues are presented in Q's [Success Story: University of Miami QualOptima Clinical Trial](#).

QUALOPTIMA CONNECTIVITY & ANALYTICS PLATFORM

The Complete Solution for Clinical Intelligence in Learning Hospitals

Q has engineered the complete technology solution to what has been missing in health care quality and risk management; QualOptima is the connectivity and analytics system to



achieve optimal clinical, operational and financial outcomes. Healthcare organizations who commit to the IOH challenge to become learning organizations is best accomplished with the QualOptima strategic common data platform.

This discussion clearly emphasizes the need for new clinical performance and outcomes measure sets. The health data science inherent in QualOptima will become the standard for value-based health care quality. The science of measuring quality with cost implications is

embedded in QualOptima. Healthcare organizations committed to become learning enterprises urgently need the big data tools of QualOptima: machine reading and learning, natural language processing (analyses enabling computers to derive meaning from human language and thus to extract knowledge from documents), algorithmic performance and outcomes metrics measured in the context of personalized risk and fitness factors, unsupervised learning (analyses that seek to find hidden patterns within data), graph analytics (analyses that use graphs to understand relationships and patterns), root cause analytics and peer review drill-down functionality.

QualOptima creates the common data platform across boundaries of the enterprise for analytics of all constituents in value-based clinical performance and outcomes. Analytics tools not only embed clinical measure sets as they continue to be developed; QualOptima big data tools learn from experience within the unique ecosystem of the customer for optimal clinical processes with performance and outcomes metrics.

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