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Systematic approaches to adverse events in obstetrics, Part I: Event identification and classification

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ABSTRACT

Despite our best intentions to improve health when a patient presents for care, adverse events are ubiquitous in medical practice today. Known complications related to the course of a patient's illness or condition or to the characteristics of the treatment have been an openly stated part of taking care of patients for centuries. However, it is only in the past decade that preventable adverse events, instances of harm related to error and deviations in accepted practice have become a primary part of these conversations. Human and system errors are an innate part of working in a complex environment like health care and we are now well aware of this burden in medicine. Now, we are building ways to react to adverse events from error in systematic ways. A systematic approach to identifying and classifying events is a critical part of any safety program, let alone an obstetric safety program. This article reviews the various systems that are used to identify adverse events, in particular sentinel events, state reportable events, and the significant local adverse "trigger" events in obstetrics. These events typically become identified through robust reporting systems where staff can report adverse, near-miss events, or precursor safety events. After events are reported, a system for classifying events, including a structured tracking and reporting system with built in accountability, is necessary. The concept of the "serious safety event," and how these differ from known complications or unpreventable events, and how this is classified are also reviewed.

Despite our best intentions to improve health when a patient presents for care, adverse events are ubiquitous in medical practice today. Known complications related to the course of a patient's illness or condition or to the characteristics of the treatment have been an openly stated part of taking care of patients for centuries. However, it is only in the past decade that preventable adverse events, instances of harm related to error and deviations in accepted practice have become a primary part of these conversations. Human and system errors are an innate part of working in a complex environment like health care and we are now well aware of this burden in medicine. Now, we are building ways to react to adverse events from error in systematic ways.

The true burden of errors in medicine is challenging to quantify. There is no literature that estimates the frequency of a medical error occurrence over a single hospitalization, though if given a broad definition of error it would be hard to argue that every hospitalization is not associated with at

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least one error. The impact of error on adverse events and harm is better established. Serious preventable adverse events are estimated to complicate up to 15% of all hospitalizations.[1] Further, it is estimated that approximately 0.7–0.9% of preventable adverse events will lead to a death in the general hospitalized population. This leads to an estimate that medical error could be the third leading cause of death, behind cancer and heart disease, in the United States, though this is highly controversial.[2] The total cost of measurable medical errors in the United States in 2008 is approximately $17.1 billion, which is about 0.72% of health care spending that year.[3]

The burden of preventable errors and mistakes in obstetrics is not well characterized at this time either. There is no reason to believe that human error is less prevalent in obstetrics, however, given the healthier patients and the paradigm of supporting normal and physiologic processes (rather than illnesses), errors are less likely to lead to harm and adverse events. Adverse events likely complicate 1–4% of patients on an obstetric unit, with up to 2/3 of those could be considered preventable.[4,5]

The basic theme, however, is striking: adverse events are common enough that they impact substantially on patients, families, and health care workers. Preventable adverse outcomes represent a large proportion of these cases, making the impact even more appalling. It is thus incumbent on our health care systems to provide support for systematic approaches to classifying, investigating, and managing adverse events. This article (Part I and Part II) reviews these approaches with respect to obstetrics. Part I focuses on the identification and classification of serious adverse events.

Systematic identification: Sentinel events, state reportable events, and local reporting systems

A systematic approach to adverse events begins with identifying the events where the health care team or environment *contributed* to harm, rather than avoided or alleviated it. Safety measurement in health care takes its lead from other high-risk industries, in particular transportation. Transportation industries like aviation and rail have monitored safety for many decades by quantifying injuries and deaths according to passenger journeys, travel hours, or distance. In industries like this that do not encounter illness or death, these outcomes are easily defined and measured. It is obvious that in medicine, where deterioration of health and death are a part of the natural course of events in many cases, defining these outcomes is not so easy. This points out why a system for defining and classifying adverse events is necessary.

"Sentinel events" are the first place to start, as they represent the most serious and significant events and they are often required for reporting by regulatory agencies. The Joint Commission (TJC; formerly known as JCAHO) defines a sentinel event as a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm or severe temporary harm and intervention required to sustain life.[6] (Severe temporary harm is defined as critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.)[7] Since 1996 The Joint Commission (TJC) has issued formal policies and procedures for the handling of sentinel events, which are followed as conditions of accreditation for health facilities.

Box 1–: Obstetric- and neonatology-related sentinel events.

Any intrapartum maternal death
Severe maternal morbidity resulting in permanent harm or severe temporary harm
Unanticipated death of a full-term neonate
Discharge of a neonate to the wrong family
Abduction of any patient receiving care
Wrong-site surgery
Unintended retention of a foreign object in a patient after an invasive procedure
Hemolytic transfusion reaction
Severe neonatal hyperbilirubinemia
Others (suicide, abductions, rape, fire, etc.)

In addition to patient safety events that lead to death, permanent harm, and severe temporary harm, TJC lists other specific events that would qualify as sentinel events. The sentinel events listed by TJC that apply specifically to obstetrics and neonatology are listed in Box 1.[7] A severe maternal morbidity is deemed a sentinel event when it is not primarily related to the natural course of the patient's illness or underlying condition and when it reaches a patient and results in permanent or severe temporary harm. Thus, a case of placenta accreta that could not have been reasonably predicted (such as in a nulliparous low-risk patient) but led to massive transfusion, hysterectomy, repeat surgery, and prolonged critical care unit admission would probably not be a sentinel event.

Sentinel events are named this because they signal a need for immediate investigation and corrective action. Importantly, under their terms of accreditation, these cases and investigations are required to be reviewed by the hospital and are subject to review by TJC, who defines very specific criteria for what makes an appropriate response[7]:

- A formalized team response that stabilizes the patient, discloses the event to the patient and family, and provides support for the family as well as staff involved in the event.
- Notification of hospital leadership (such as the Chief Medical Officer, Chief Safety/Quality Officer, Chief Nursing Officer, and Risk Management).
- Immediate investigation.
- Completion of a comprehensive systematic analysis for identifying the causal and contributory factors.
- Identification of corrective actions to eliminate or control system hazards or vulnerabilities directly related to causal and contributory factors.
- Timeline for implementation of corrective actions.
- Systemic improvement.