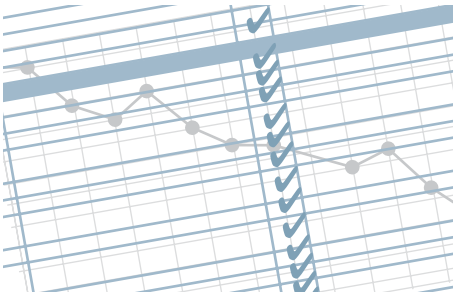
Institute for Healthcare Improvement



Innovation Series 2009

IHI Global Trigger Tool

for Measuring Adverse Events

Second Edition

The Institute for Healthcare Improvement (IHI) is a not-for-profit organization leading the improvement of health care throughout the world. IHI helps accelerate change by cultivating promising concepts for improving patient care and turning those ideas into action. Thousands of health care providers participate in IHI's groundbreaking work.

We have developed IHI's Innovation Series white papers as one means for advancing our mission. The ideas and findings in these white papers represent innovative work by IHI and organizations with whom we collaborate. Our white papers are designed to share the problems IHI is working to address, the ideas we are developing and testing to help organizations make breakthrough improvements, and early results where they exist.

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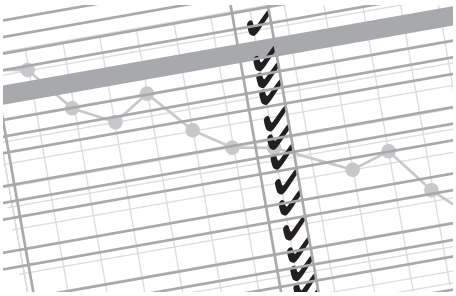

Innovation Series 2009

IHI Global Trigger Tool

for Measuring Adverse Events

Second Edition

Authors:

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Executive Summary

Traditional efforts to detect adverse events have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients in order to quantify the degree and severity of harm, and to select and test changes to reduce harm.

The IHI Global Trigger Tool for Measuring Adverse Events provides an easy-to-use method for accurately identifying adverse events (harm) and measuring the rate of adverse events over time. Tracking adverse events over time is a useful way to tell if changes being made are improving the safety of the care processes. The Trigger Tool methodology is a retrospective review of a random sample of inpatient hospital records using "triggers" (or clues) to identify possible adverse events. Many hospitals have used this tool to identify adverse events, to assess the level of harm from each adverse event, and to determine whether adverse events are reduced over time as a result of improvement efforts. It is important to note, however, that the IHI Global Trigger Tool is not meant to identify every single adverse event in an inpatient record. The methodology, recommended time limit for review, and random selection of records are designed to produce a sampling approach that is sufficient to determine harm rates and observe improvement over time.

The Institute for Healthcare Improvement (IHI) formed the Idealized Design of the Medication System (IDMS) Group in May 2000. This group of 30 physicians, pharmacists, nurses, statisticians, and other professionals established an aim to design a medication system that is safer by a factor of 10 and more cost effective than systems currently in use. The Trigger Tool for Measuring Adverse Drug Events was initially developed by this group to assess progress on this safety goal and provided the basis for development of subsequent Trigger Tools.

This white paper is designed to provide comprehensive information on the development and methodology of the IHI Global Trigger Tool, with step-by-step instructions for using the tool to measure adverse events in a hospital.

Foreword to Second Edition

Since its development in late 2003, use of the IHI Global Trigger Tool has spread from collaborative projects to large-scale improvement efforts, including IHI's 5 Million Lives Campaign. The IHI Global Trigger Tool has become a tool that hundreds of hospitals in multiple countries now use to monitor adverse event rates while working to improve patient safety. In 2008, the US Department of Health and Human Services Office of Inspector General completed a pilot study to measure adverse events in Medicare beneficiaries and used the IHI Global Trigger Tool as one method of detection.[1] This extensive use of the IHI Global Trigger Tool has provided the opportunity to collect feedback from those using the tool and identify opportunities to clarify definitions and update material.

This Second Edition of the *IHI Global Trigger Tool for Measuring Adverse Events* white paper contains no substantive changes to the overall methodology or process for review. Clarifications have been made to some text and trigger definitions. References have been added based on recent publications related to Trigger Tools. Experienced reviewers will note that there are changes to the list of triggers. A number of triggers have been removed, particularly in the Surgical module, as these triggers were found over time to not be very useful. The development of a Perinatal Trigger Tool provided the opportunity to update the Perinatal module with additional triggers that will be useful to identify possible adverse events.

Changes to the triggers in the Second Edition will not affect data for organizations that have been using the prior version of the IHI Global Trigger Tool because triggers are not measured; only adverse events are measured. Organizations with months or years of adverse event data from IHI Global Trigger Tool reviews can continue to conduct reviews using the modified trigger list and incorporate the results into the same data set. The triggers listed in the IHI Global Trigger Tool are recommendations only and organizations are encouraged to modify them as needed.

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I. Background

A. History

Conventional attempts to quantify adverse events have included voluntary incident reports, retrospective or concurrent record reviews (sometimes supplemented by "bedside" surveillance), and abstraction of events from observational databases. The concept of a "trigger" (or clue) to identify adverse events in the medical record was introduced by Jick in 1974.[2] Classen refined and automated the approach by using electronic triggers with an integrated hospital information system to identify patient records and review the same records for adverse events.[3] The use of triggers with manual record reviews was initially developed by the Institute for Healthcare Improvement (IHI) in 1999 to identify only adverse medication events; adaptation of the methodology for other areas of the hospital, such as intensive care, followed. Recent publications describe the use and development of Trigger Tools.[4-10] Subsequently, IHI developed the IHI Global Trigger Tool for Measuring Adverse Events to identify adverse events in adult inpatients, with some exclusions, throughout the hospital.

B. Harm versus Error

The overall goal of improved safety in health care is to reduce patient injury or harm, which underscores the importance of distinguishing between errors and harm. Although detection and analysis of errors is important in understanding failure-prone aspects of health care delivery systems and designing strategies to prevent and mitigate these failures, there is special value in quantifying actual harm. Medical errors are failures in processes of care and, while they have the potential to be harmful, numerous reports have shown they are often not linked to the injury of the patient.[11] Because events of harm are clear clinical outcomes, they are particularly likely to engage both clinicians and administrators in a thorough review of the system factors that led to the adverse event, with a clear focus on improving patient outcomes. By concentrating on the events actually experienced by patients, a hospital can begin to foster a culture of safety that shifts from individual blame for errors to comprehensive system redesign that reduces patient suffering. To address the clear need to quantify adverse patient outcomes, the IHI Global Trigger Tool focuses on the identification of harm or injury to the patient.

C. Definition of an Adverse Event

Any effort to identify harm requires a clear definition of an adverse event. The World Health Organization (WHO) Collaborating Centers for International Drug Monitoring defines an adverse drug event as follows:

> *"Noxious and unintended and occurs at doses used in man for prophylaxis, diagnosis, therapy, or modification of physiologic functions."* [12]

The IHI Global Trigger Tool includes these types of events, but goes beyond medications to include any noxious or unintended event occurring in association with medical care.

In the IHI Global Trigger Tool, the definition used for harm is as follows: *unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death.*

D. Commission versus Omission

The IHI Global Trigger Tool focuses on and includes only those adverse events related to the active delivery of care (commission) and excludes, as much as possible, issues related to substandard care (omission). While adverse events due to omission of evidence-based treatments commonly occur and should be a focus in quality improvement efforts, they are not the focus of measurement with the IHI Global Trigger Tool. For example, a patient not appropriately treated for hypertension who subsequently experienced a stroke certainly has had a medical catastrophe related to poor care, but would not be considered to have suffered an adverse event using the IHI Global Trigger Tool definition because the event is related to omission of evidence-based care. However, a patient to whom anticoagulants were administered who subsequently suffered a stroke from an intra-cerebral bleed would be considered to have suffered an adverse event with the IHI Global Trigger Tool because the use of the anticoagulant (commission) caused the event. During reviews, acts of omission may be noticed and can be referred to others as improvement opportunities.

E. Preventability

The IHI Global Trigger Tool includes all adverse events—that is, events which are *unintended* consequences of medical care, whether preventable or not. There should be no attempt by the reviewers to determine preventability during a review with the IHI Global Trigger Tool. If an adverse event occurred it is, by definition, harm. One could argue that today's "unpreventable events" are only an innovation away from being preventable. The IHI Global Trigger Tool is designed to be a method for measuring harm over time. If the definition of included events constantly changed depending on what was preventable, the measure over time would become meaningless.

F. Severity Ratings

The IHI Global Trigger Tool adapts the classification from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors.[13] Although originally developed for categorizing medication errors, these definitions can be easily applied to any type of error or adverse event.

The IHI Global Trigger Tool counts only adverse events: harm to the patient (as defined above), whether or not the result of an error. Accordingly, the tool excludes the following categories from the NCC MERP Index because these categories describe errors that do not cause harm:

Category A: Circumstances or events that have the capacity to cause error

Category B: An error that did not reach the patient

Category C: An error that reached the patient but did not cause harm

Category D: An error that reached the patient and required monitoring or intervention to confirm that it resulted in no harm to the patient

This tool utilizes categories E, F, G, H, and I of the NCC MERP Index because these categories describe harm. (Note that NCC MERP's "An error that contributed to or resulted in…" has been deleted, since Trigger Tools do not focus on 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

G. Trigger Selection

IHI developed the triggers used in the IHI Global Trigger Tool by reviewing the literature on adverse events in various areas of the hospital. IHI then tested these prioritized triggers in hundreds of hospitals using various Trigger Tools (Adverse Drug Event, Surgical, Perinatal, Intensive Care).[14] IHI developed the IHI Global Trigger Tool using modules that correspond to these antecedent Trigger Tools and has added, deleted, and adjusted triggers over time to reflect changes in treatments and types of adverse events being identified in the field.

II. Rules and Methods

The IHI Global Trigger Tool requires manual review of closed inpatient records (records with completed discharge summaries and coding). This section of the tool explains the processes for selecting and reviewing records and determining whether adverse events have occurred.

A. Review Team

The review team should consist of, at a minimum, three people:

1) *Two primary record reviewers who have clinical backgrounds and knowledge about the contents and layout of the hospital's record, as well as about how care is generally provided in the hospital.* Hospitals using the IHI Global Trigger Tool have typically used nurses, pharmacists, and respiratory therapists on their review teams. Experienced nurses have been the best reviewers, but other combinations of team members can be used since each person brings unique expertise.

2) *A physician who does not review the records, but authenticates the consensus of the two primary record reviewers.* The physician authenticates the findings of the adverse events and the rating of severity, and provides answers to questions the record reviewers have about findings in a specific record.

Using two or more primary record reviewers raises the issue of consistency (intra- and inter-rater reliability) among the reviewers: the greater the number of reviewers on the team, the greater the potential inconsistency. IHI does not recommend that individual hospitals conduct exhaustive studies to measure reliability, but does encourage teams to continually promote consistent, standard record review procedures, use of triggers, and interpretation of events. The review team should remain consistent over time whenever possible. Many hospitals have found that a practical approach is to have a one-year assignment for both primary record reviewers and the physician, with overlapping team members to ensure adequate training of new reviewers. In addition, teams should meet approximately monthly to review all the adverse events identified for that month to detect and resolve variation between the reviewers in adverse event identification and severity rating. This continuous approach to training has been shown to achieve high inter-rater consistency.[10] (See section IV for further information regarding training of the review team to enhance consistency.)

B. Sampling Patient Records

The IHI Global Trigger Tool is designed for use with a sampling methodology that utilizes small samples over time.

The recommendation is to sample 10 patient records from the entire population of discharged adult patients (with some exclusions noted below) every two weeks (for example,

patients discharged between the 1st and 15th of the month for the first two-week sample and between the 16th and end of the month for the second two-week sample), for a total of 20 records per month. Some hospitals may elect to review all 20 records at one time monthly, but this generates only one data point per month versus the two data points with the two-week samples. Organizations that have the resources to do so may elect to choose a larger sample size, such as 40 records per month, but reviewing more than 40 records per month accrues little additional benefit.

IHI recommends sampling every two weeks and generating two data points each month. Data from these small samples may show wide variation from sample to sample. However, aggregating these samples over time will increase precision, and plotting this data on control charts will give you useful information about trends and special causes of variation in harm in your organization. (Note that hospitals should use the IHI Global Trigger Tool as one part of a learning system that includes other component measures, such as voluntarily reported errors, surgical site infections, and other outcome measures.)

Because readmission within 30 days is a trigger, select records of patients who were discharged more than 30 days prior to the review date so that readmissions can be checked for the sample. For example, if conducting a review in December, select patient records from those discharged in October.

Use the following guidelines when selecting the records:

- Select 10 patient records for each two-week sampling period, plus a few extra records in case a record is discovered that does not meet review criteria.
- Do not select 20 records for the entire month and divide these 20 records into two 10-record samples; draw each two-week sample independently.

The selection criteria are:

- Closed and completed record (discharge summary and all coding is complete)
- Length of stay at least 24 hours and formally admitted to the hospital
  (Note: This is a sampling strategy to avoid outpatient cases. Some hospitals include patients with a one-day stay; however, selected records for review should always be patients that have been classified as inpatient.)
- Patient age 18 years or older
- Excluding inpatient psychiatric and rehabilitation patients
  (Note: Triggers are not defined for these populations in this tool.)

If a record does not meet these criteria, do not use it; instead, select one of the "extras." The team will review only 10 records, so the extra records will not be used unless this occurs.

Because the review is based on sampling to discover adverse events, it is critical to use a truly random process for selecting the records. Use any selection method, as long as it is random (i.e., every patient record has an equal opportunity of being chosen). Some valid methods are:

- Generate random numbers between 1 and 9, and select 10 records with record numbers ending in the random number.
- Print out all admissions or discharges (as long as deaths are included), and select every 10th record for review.

If a record selected for review is not available, select the next record in the random list.

In small rural hospitals that have fewer than 10 inpatients per two-week interval, review all records for the interval.

If possible, records of hospital admissions before and after the index record (i.e., the record selected for review) should be made available. The team can consult these to determine cause for admission or readmission. A complete review with the IHI Global Trigger Tool should not be done on these records, only the record identified in the random sample; use the additional records only to investigate the trigger associated with readmission, which should take less than 5 minutes.

C. Review Process

The two primary record reviewers should each review all records independently. During the review, the physician should be available to answer questions that may arise.

Use the following process for the review:

1) The IHI Global Trigger Tool contains six "modules," or groupings of triggers. Four of the groupings are designed to reflect adverse events that commonly occur in a particular unit; the Cares and Medication groupings are designed to reflect adverse events that can occur anywhere in the hospital. The six modules are:
   - Cares
   - Medication
   - Surgical
   - Intensive Care
   - Perinatal
   - Emergency Department

   All patient records should be reviewed for the triggers in the Cares and Medication modules. The other modules should only be used if applicable; for example, the Intensive Care module should be used when reviewing a record for a patient who spent any part of the hospital stay in an intensive care unit.

2) The record should only be reviewed to look for the presence of triggers, not to read the record from front page to back page. Experienced reviewers have found the following sections of the record most useful when reviewed in this order:
   - Discharge codes, particularly infections, complications, or certain diagnoses (E-codes, which are used by trained coders to note the presence of certain events and complications, can be found here)
   - Discharge summary (look for the specifics of assessment and treatment during the hospital stay)
   - Medications administration record
   - Laboratory results
   - Prescriber orders
   - Operative record (operative report and anesthesia record, if applicable)
   - Nursing notes
   - Physician progress notes
   - If time permits, any other areas of the record (such as History & Physical, Consult notes, or Emergency Department notes)

3) Set a 20-minute limit for review of each patient record, once the training period for reviewers has been completed. The "20-minute rule" applies to all records regardless of size. The 20-minute rule was developed in the initial tests of the Trigger Tool because there was a propensity to review the smaller, "easier" patient records (i.e., those with shorter lengths of stay). However, if only shorter stay patient records are reviewed, the sample is no longer random and there will be "selection bias" in the results. It is unlikely that all the events in the larger record will be identified since 20 minutes will not be sufficient time to adequately review the entire record using the Trigger Tool technique. It is important to note that the IHI Global Trigger Tool is not meant to identify every single adverse event in a record. The review time limitation and random selection of records are designed to produce a sampling approach that is sufficient for the design of safety work in the hospital.

4) If a trigger is identified in a record, the "positive trigger" indicates only the presence of a trigger, not necessarily an adverse event. When a positive trigger is found, review only the pertinent portions of the record. The focused review will determine whether an adverse event has occurred (refer to section II-D regarding the Determination of an Adverse Event). If no adverse event is found, the reviewer should then move on and look for other triggers. Reviewers will find many positive triggers, but will identify many fewer adverse events. Occasionally, reviewers will find adverse events with no antecedent trigger. Include these events. Some triggers (nosocomial infections, 3rd- or 4th-degree laceration) are also adverse events by definition. However, a positive trigger most often is not an adverse event in and of itself; rather, it is just a clue that one may have occurred.

D. Determination of an Adverse Event

When a reviewer identifies a positive trigger, the reviewer should check other relevant portions of the record such as progress notes and orders that were documented in close proximity to the occurrence of the trigger. Documentation that the patient experienced harm from medical care should be present for an adverse event. For example, an INR level greater than 6 would be a positive trigger. The reviewer should look for documentation of bleeding or decreased hemoglobin with need for transfusion and other adverse events that can result from over-anticoagulation.

In determining whether an adverse event has occurred, consider that an adverse event is defined as unintended harm to a patient *from the viewpoint of the patient*. There are several important aspects:

- Would you be happy if the event happened to you? If the answer is no, then likely there was harm.
- Was the event part of the natural progression of the disease process, or a complication of the treatment related to the disease process? The harm identified should be the result of some medical treatment (review section I-D on Commission versus Omission). The decision is subjective at times and physician input will be critical.
- Was the event an *intended* result of the care (e.g., a permanent scar from surgery)? If so, then this is not considered harm.
- Psychological harm by definition has been excluded as an adverse event.

It is important to emphasize that reviewers may occasionally discover an adverse event without a trigger, while looking for triggers or other details. These events should be included when recording findings, regardless of whether a trigger led the reviewer to the adverse event.

An adverse event that is present on admission to the hospital should be included, provided that it meets the definition of being harm related to medical care. All such adverse events are counted because the measure is *what the patient experienced*, not what happened within the hospital. Field experience has shown that fewer than 10 percent of all harms that are detected by the IHI Global Trigger Tool will be present on admission. It is useful to keep track of which events occurred outside the hospital so that this can be noted when reporting data. Such data may indicate an opportunity to collaborate with others—office practices, clinics, long-term care facilities—to improve patient safety, even if the events did not result from hospital care itself.

Once reviewers have determined that an adverse event has occurred, assign a category of harm (as defined previously in section I-F on Severity Ratings) as follows:

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

These categories are not progressive (i.e., an event does not have to first meet the definition of E and F before it can be categorized as G). For category E, some intervention is required. For category H, experienced reviewers have found it helpful to define "lifesaving intervention" as that which must be provided in one hour or less in order to prevent death. For example, a patient with a surgical site infection requires antibiotic treatment and one could argue that failure to provide it could lead to sepsis and death. While this may be true, it is unlikely that the antibiotic would need to be provided within one hour to prevent death. However, a patient who develops respiratory depression and arrest from a narcotic requires immediate intervention, such as non-invasive or invasive ventilation; this would be an intervention required to sustain life, even if it was only needed for a few hours. For category I, the event needs only to be contributory to the death.

Primary reviewers should record information on findings while reviewing the patient records. The IHI Global Trigger Tool Worksheet (Appendix B) lists all triggers, categorized into their modules, for use during the review. When a primary reviewer identifies a trigger, the reviewer places a check in the column next to it (the column with +). If the primary reviewer then identifies an adverse event associated with this trigger, the reviewer notes a description and category of harm in the appropriate column. The reverse side of the Worksheet is blank, and reviewers often use this space to make notes for discussion with other members of the review team or to capture questions that need to be reviewed with the physician.

The two primary record reviewers should meet after completing their separate reviews to compare findings and come to consensus, which they record on the IHI Global Trigger Tool Review Summary Sheet (Appendix C).

The physician should review the consensus with the two record reviewers and reach a final agreement on the type, number, and severity of events. The physician does not review the patient records, only the Summary Sheet (Appendix C). Individual Worksheets, notes, and the patient records should be available for the physician's reference and clarification, if necessary. Adjust the number of adverse events or harm categories, if needed, after review with the physician. The physician is the final arbitrator.

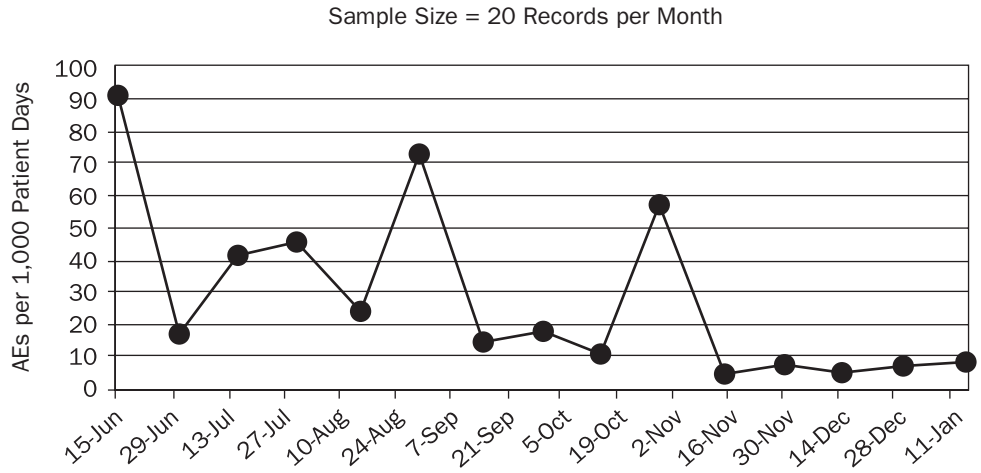
E. Data Collection

Present the two-week data collections initially in three ways:

- Adverse events per 1,000 patient days (see the example in Figure 1);
- Adverse events per 100 admissions; and
- Percent of admissions with an adverse event.

Each method has certain advantages. "Adverse events per 1,000 patient days" is the traditional measure and is the recommended measure to track the harm rate over time. Data should be presented in a run chart with "adverse events per 1,000 patient days" on the Y-axis and time in two-week increments on the X-axis.

Figure 1. Sample Run Chart of Adverse Events (AEs) per 1,000 Patient Days

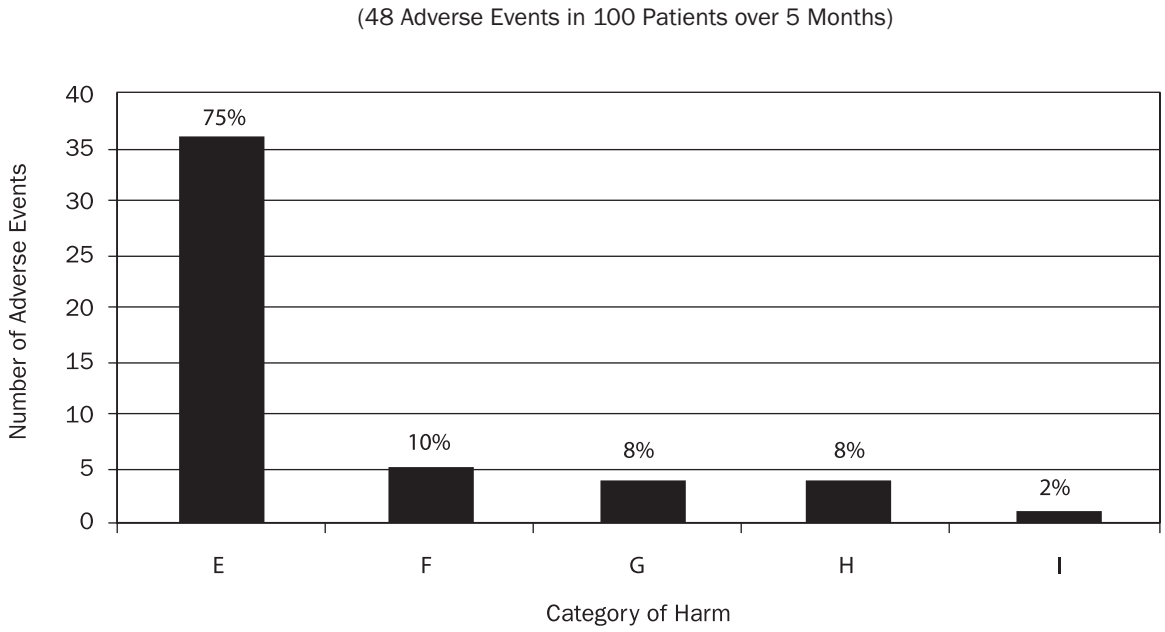


"Adverse events per 100 admissions" is an alternative presentation of rate. It provides a more easily understood representation of harm for leadership. Data should be presented in a run chart similar to "adverse events per 1,000 patient days." Note that the conversion from "adverse events per 1,000 days" to "adverse events per 100 admissions" simply entails a switch from number of patient days (1,000) to records reviewed (admissions).

"Percent of admissions with an adverse event" is a convenient way to present the information to lay leadership, although it diminishes the number of events because some patients may have more than one adverse event during a hospital stay. Thus it is less sensitive to improvement than the two rate measurements.

In addition to the run chart representations, the team should present categories of harm in a bar chart (see Figure 2) depicting the volume of harm in each category (E through I).

Figure 2. Distribution of Harm by Category



Data is also often presented by type of adverse events. The types of events have commonly been defined as infections, medications, and procedural complications. Hospitals have found this categorization to be useful in prioritizing areas for improvement work.

It is also helpful to include a category in the bar chart of those events that occurred prior to admission and were present on arrival. These should not be excluded from the rate or percentage data in run charts, but it will be important to leadership to see the occurrence of these events.

III. Triggers and Definitions

This section lists all of the triggers contained in the IHI Global Trigger Tool by module, with descriptions of each trigger and what reviewers should look for to determine the presence of an adverse event.

IMPORTANT NOTE: If a trigger is identified in a record, the "positive trigger" indicates only the presence of a trigger, not necessarily an adverse event. The reviewer must investigate the details to determine whether an adverse event has actually occurred. (For more detail, see section II-C, #4, on the Review Process.)

A. Cares Module Triggers

C1–Transfusion of Blood or Use of Blood Products

Procedures can require intra-operative transfusion of blood products for replacement of estimated blood lost, but this has become less common with "bloodless surgery." Any transfusion of packed red blood cells or whole blood should be investigated for causation, including excessive bleeding (surgical or anticoagulant-related), unintentional trauma of a blood vessel, etc. Transfusion of many units or beyond expected blood loss within the first 24 hours of surgery, including intra-operatively and post-operatively, will likely be related to a peri-operative adverse event. Cases in which excessive blood loss occurred pre-operatively are typically not adverse events. Patients receiving anticoagulants who require transfusion of fresh frozen plasma and platelets have likely experienced an adverse event related to the use of anticoagulants.

C2–Code, Cardiac or Pulmonary Arrest, or Rapid Response Team Activation

All "codes," cardiac or pulmonary arrests, and activation of Rapid Response Teams need to be carefully reviewed as this may be the culmination of an adverse event (check for medication-related issues). However, not all codes/arrests/team responses are adverse events as some may be related to progression of a disease process. For example, cardiac or pulmonary arrest intra-operatively or in the post anesthesia care unit should always be considered an adverse event. In the first 24 hours post-operatively, it is also very likely to be an adverse event. Conversely, a sudden cardiac arrhythmia resulting in cardiac arrest may not be an adverse event, but related to cardiac disease. Failure to recognize signs and symptoms would be an example of an error of omission and would not be counted as an adverse event unless the changes in patient condition were the result of some medical intervention.

C3–Acute Dialysis

A new need for dialysis may be the course of a disease process or the result of an adverse event. Examples of adverse events might be drug-induced renal failure or reaction to the administration of a dye for radiological procedures.

C4–Positive Blood Culture

A positive blood culture at any time during the hospitalization must be investigated as an indicator of an adverse event, specifically a hospital-associated infection. Generally, adverse events associated with this trigger will include infections that are diagnosed 48 hours or more after admission, such as bloodstream line infections, sepsis from other device infections (e.g., catheter-associated urinary tract infection), or any other hospital-associated infection. Patients with positive blood cultures related to other disease (such as community-acquired pneumonia progressing to sepsis) would not be considered to have adverse events.

C5–X-Ray or Doppler Studies for Emboli or Deep Vein Thrombosis

Development of a deep vein thrombosis (DVT) or pulmonary embolism (PE) during a hospital stay in most cases will be an adverse event. Rare exceptions may be those related to disease processes such as cancer or clotting disorders. However, in most patients this is harm related to medical care, even if all appropriate preventive measures appear to have been taken. If the hospitalization occurs due to a DVT or embolism, look for causation prior to admission that could be attributed to medial care such as a prior surgical procedure. The lack of prophylaxis with no DVT or PE is not an adverse event; it is an error of omission.

C6–Decrease in Hemoglobin or Hematocrit of 25% or Greater

Any decrease of 25 percent or greater in hemoglobin (Hg) grams or hematocrit (Hct) should be investigated, especially when occurring in a relatively short period of time such as 72 hours or less. Bleeding events are commonly identified by this trigger and may be related to use of anticoagulants or aspirin or a surgical misadventure. The decrease in Hg or Hct in itself is not an adverse event unless related to some medical treatment. A decrease associated with a disease process is not an adverse event.

C7–Patient Fall

A fall in a care setting represents a failure of care and may be the result of medications, equipment failure, or failure of adequate staffing. Any fall in the care setting that causes injury, regardless of cause, is an adverse event; a fall without injury is not an adverse event. Falls resulting in injury and admission to the hospital should be reviewed for causation. A fall that is the result of medical treatment (such as from medications) should be considered an adverse event, even if the fall occurred outside the hospital.

C8–Pressure Ulcers

Pressure or decubitus ulcers are adverse events. Chronic decubiti are adverse events if they occurred during a hospitalization. If the ulcers occurred in the outpatient setting, consider the etiology (over-sedation, etc.) to assess if an adverse event occurred.

C9–Readmission within 30 Days

Any readmission, particularly within 30 days of discharge, could be an adverse event. An adverse event may not manifest itself until after the patient has been discharged from the hospital, especially if the length of stay is minimal. Examples of adverse events may include surgical site infection, deep vein thrombosis, or pulmonary embolism.

C10–Restraint Use

Whenever restraints are used, review the documented reasons and evaluate the possible relationship between the use of restraints and confusion from drugs, etc., which would indicate an adverse event.

C11–Healthcare-Associated Infections

Any infection occurring after admission to the hospital is likely an adverse event, especially those related to procedures or devices. Infections that cause admission to the hospital should be reviewed to determine whether they are related to medical care (e.g., prior procedure, urinary catheter at home or in long-term care) versus naturally occurring disease (e.g., community-acquired pneumonia).

C12–In-Hospital Stroke

Evaluate the cause of the stroke to determine whether it is associated with a procedure (e.g., surgical procedure, conversion of atrial fibrillation) or anticoagulation. When procedures or treatments have likely contributed to a stroke, this is an adverse event.

C13–Transfer to Higher Level of Care

Transfers to a higher level of care within the institution, to another institution, or to your institution from another must be reviewed. All transfers are likely to be the result of an adverse event and a patient's clinical condition may have deteriorated secondary to an adverse event. Look for the reasons for the transfer. For example, in the case of admission to intensive care following respiratory arrest and intubation, if the respiratory arrest was a natural progression of an exacerbation of chronic obstructive pulmonary disease (COPD), then it would not be an adverse event; if it was caused by a pulmonary embolism that developed post-operatively or resulted from over-sedation of a patient with COPD, it would be an adverse event. A higher level of care may include telemetry, intermediate care, or a step-down unit if the patient is transferred from a general medical or surgical nursing unit.

C14–Any Procedure Complication

A complication resulting from any procedure is an adverse event. Procedure notes frequently do not indicate the complications, especially if they occur hours or days after the procedure note has been dictated, so watch for complications noted in coding, the discharge summary, or other progress notes.

C15–Other

Frequently when the record is reviewed, an adverse event is uncovered that does not fit a trigger. Any such event can be placed under this "Other" trigger. An event does not require a listed trigger to be counted as an event.

B. Medication Module Triggers

M1–*Clostridium difficile* Positive Stool

A positive *C. difficile* assay is an adverse event if a history of antibiotic use is present.

M2–Partial Thromboplastin Time (PTT) Greater than 100 Seconds

Elevated PTT measurements occur when patients are on heparin. Look for evidence of bleeding to determine if an adverse event has occurred. Elevated PTT in itself is not an adverse event—there must be manifestation such as bleeding, drop in Hg or Hct, or bruising.

M3–International Normalized Ratio (INR) Greater than 6

Look for evidence of bleeding to determine if an adverse event has occurred. An elevated INR in itself is not an adverse event.

M4–Glucose Less than 50 mg/dl

Review for symptoms such as lethargy and shakiness documented in nursing notes, and the administration of glucose, orange juice, or other intervention. If symptoms are present, look for associated use of insulin or oral hypoglycemics. If the patient is not symptomatic, there is no adverse event.

M5–Rising BUN or Serum Creatinine Two Times (2x) over Baseline

Review laboratory records for rising levels of either BUN or serum creatinine. If a change of two times greater than baseline levels is found, review medication administration records for medications known to cause renal toxicity. Review physician progress notes and the history and physical for other causes of renal failure, such as pre-existing renal disease or diabetes, that could have put the patient at greater risk for renal failure; this would not be an adverse event, but rather the progression of disease.

M6–Vitamin K Administration

If Vitamin K was used as a response to a prolonged INR, review the record for evidence of bleeding. An adverse event has likely occurred if there are laboratory reports indicating a drop in hematocrit or guiac-positive stools. Check the progress notes for evidence of excessive bruising, gastrointestinal (GI) bleed, hemorrhagic stroke, or large hematomas as examples of adverse events.

M7–Diphenhydramine (Benadryl) Administration

Diphenhydramine is frequently used for allergic reactions to drugs but can also be ordered as a sleep aid, a pre-op/pre-procedure medication, or for seasonal allergies. If the drug has been administered, review the record to determine if it was ordered for symptoms of an allergic reaction to a drug or blood transfusion administered either during the hospitalization or prior to admission—these are adverse events.

M8–Romazicon (Flumazenil) Administration

Romazicon reverses the effect of benzodiazepine drugs. Determine why the drug was used. Examples of adverse events are severe hypotension or marked, prolonged sedation.

M9–Naloxone (Narcan) Administration

Naloxone is a powerful narcotic antagonist. Usage likely represents an adverse event except in cases of drug abuse or self-inflicted overdose.

M10–Anti-Emetic Administration

Nausea and vomiting commonly are the result of drug administrations both in surgical and non-surgical settings. Anti-emetics are commonly administered. Nausea and vomiting that interferes with feeding, post-operative recovery, or delayed discharge suggests an adverse event. One or two episodes treated successfully with anti-emetics would suggest no adverse event. Reviewer judgment is needed to determine whether harm occurred.

M11–Over-Sedation/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 administration of a sedative, analgesic, or muscle relaxant. Intentional overdose is not considered an adverse event.

M12–Abrupt Medication Stop

Although the discontinuation of medications is a common finding in the record, abruptly stopping medications is a trigger requiring further investigation for cause. A sudden change in patient condition requiring adjustment of medications is often related to an adverse event. "Abrupt" is best described as an unexpected stop or deviation from typical ordering practice; for example, discontinuation of an intravenous antibiotic for switch to oral is not unexpected.

M13–Other

Use this trigger for adverse drug events detected but not related to one of the Medication triggers listed above.

C. Surgical Module Triggers

S1–Return to Surgery

A return to the operating room can either be planned or unplanned, and both can be a result of an adverse event. An example of an adverse event would be a patient who had internal bleeding following the first surgery and required a second surgery to explore for the cause and to stop the bleeding. Even if the second surgery is exploratory but reveals no defect, this should be considered an adverse event.

S2–Change in Procedure

When the procedure indicated on the post-operative notes is different from the procedure planned in the pre-operative notes or documented in the surgical consent, a reviewer should look for details as to why the change occurred. An unexpected change in procedure due to complications or device or equipment failure should be considered an adverse event, particularly if length of stay increases or obvious injury has occurred.

S3–Admission to Intensive Care Post-Operatively

Admission to an intensive care unit can be either a normal post-operative journey or it may be unexpected. The unexpected admissions frequently are related to operative adverse events. For example, admission to intensive care following aortic aneurysm repair may be expected, but admission following knee replacement would be unusual. The reviewer needs to determine why intensive care admission occurred.

S4–Intubation or Reintubation or Use of BiPap in Post Anesthesia Care Unit (PACU)

Anesthesia, sedatives, or pain medications can result in respiratory depression requiring the use of BiPap or reintubation post-operatively, which would be an adverse event.

S5–X-Ray Intra-Operatively or in Post Anesthesia Care Unit

Imaging of any kind that is not routine for the procedure requires investigation. An x-ray taken due to suspicion of retained items or incorrect instrument or sponge count would be a positive trigger. The identification of a retained item necessitating an additional procedure is an adverse event. If the retained item is identified and removed without any additional evidence of harm or re-operation to the patient, this is not considered an adverse event.

S6–Intra- or Post-Operative Death

All deaths that occur intra-operatively should be considered adverse events unless death is clearly expected and the surgery was of a heroic nature. Post-operative deaths will require review of the record for specifics, but in general all post-op deaths will be adverse events.

S7–Mechanical Ventilation Greater than 24 Hours Post-Operatively

Short-term mechanical ventilation post-operatively for cardiac, major thoracic, and certain abdominal procedures is planned. If the patient requires mechanical ventilation beyond 24 hours, an intra-operative or post-operative adverse event should be considered. Patients with pre-existing pulmonary or muscular disease may experience more difficulty in quickly weaning from a ventilator post-operatively, but this should not automatically exclude the possibility of an adverse event. Reviewers must use clinical judgment to determine whether the intra-operative and post-operative care was event free or part of the disease process.

S8–Intra-Operative Administration of Epinephrine, Norepinephrine, Naloxone, or Romazicon

These medications are not routinely administered intra-operatively. Review anesthesia and operative notes to determine the reason for administration. Hypotension caused by bleeding or over-sedation are examples of adverse events that might be treated with these medications.

S9–Post-Operative Increase in Troponin Levels Greater than 1.5 Nanogram/ml

A post-operative increase in troponin levels may indicate a cardiac event. Reviewers will need to use clinical judgment as to whether a cardiac event has occurred.

S10–Injury, Repair, or Removal of Organ During Operative Procedure

Review operative notes and post-operative notes for evidence that the procedure included repair or removal of any organ. The removal or repair must be part of the planned procedure or this is an adverse event and likely the result of surgical misadventure such as an accidental injury.

S11–Occurrence of Any Operative Complication

This refers to any of a number of complications, including but not limited to PE, DVT, decubiti, MI, renal failure, etc.

D. Intensive Care Module Triggers

I1–Pneumonia Onset

Any pneumonia diagnosed in the ICU needs to be looked at carefully. If the evidence suggests the pneumonia started prior to admission to the hospital, there is no adverse event; but if the review suggests initiation in the hospital, it is an adverse event. In general, any infection starting in not only the intensive care unit but in any hospital unit will be considered nosocomial. Readmissions either to the hospital or the intensive care unit could represent a nosocomial infection from a previous hospitalization.

I2–Readmission to the Intensive Care Unit

Refer to trigger S3–Admission to Intensive Care Post-Operatively.

I3–In-Unit Procedure

Any procedure occurring on a patient in the intensive care unit requires investigation. Look at all the bedside procedures and other procedures done while the patient was in the ICU. Complications will commonly not be on the dictated procedure note, but may be evident by the care required, which might indicate an event has occurred.

I4–Intubation/Reintubation

Refer to trigger S4–Intubation or Reintubation or Use of BiPap in Post Anesthesia Care Unit.

E. Perinatal Module Triggers

Only maternal records will be selected for review when using the IHI Global Trigger Tool; thus, only triggers related to documentation in the maternal record are included. Adverse events to neonates are not measured with this tool.

P1–Terbutaline Use

Use of terbutaline could result in an unnecessary intervention of a cesarean section that is created by the administration of a medication. Look for complicating factors. Use of terbutaline in pre-term labor is not a positive trigger.

P2–3rd- or 4th-Degree Lacerations

By definition a 3rd- or 4th-degree laceration is an adverse event. Also look for additional events to the mother or child associated with the laceration as part of a cascade so appropriate severity can be assessed.

P3–Platelet Count Less than 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.

P4–Estimated Blood Loss Greater than 500 ml for Vaginal Delivery, or Greater than 1,000 ml for Cesarean Delivery

The accepted limit for "normal" blood loss after vaginal delivery is 500 ml, and a blood loss of 1,000 ml is considered within normal limits after cesarean birth.

P5–Specialty Consult

May be an indicator of injury or other harm.

P6–Administration of Oxytocic Agents (such as oxytocin, methylergonovine, and 15-methyl-prostaglandin in the post-partum period)

Agents used to control post-partum hemorrhage, defined as blood loss greater than 500 ml for a vaginal delivery and greater than 1,000 ml for a cesarean delivery. If standard administration of oxytocin occurs post-delivery, evaluate for administration amounts greater than 20 units in the immediate post-partum period.

P7–Instrumented Delivery

Instruments may cause injury to the mother, including bruising, trauma, and perineal lacerations.

P8–Administration of General Anesthesia

May be an indicator of harm resulting from poor planning or other sources of harm.

F. Emergency Department (ED) Module Triggers

E1–Readmission to the ED within 48 Hours

Look for drug reactions, infections, or other reasons that events may have brought the patient back to the ED and then required admission.

E2–Time in ED Greater than 6 Hours

Long ED stays in some cases can represent less than optimal care. Look for complications arising from the ED such as falls, hypotension, or procedure-related complications.

IV. Training

Experienced reviewers should train new users of the IHI Global Trigger Tool whenever possible.

A. General Considerations

1) The primary record reviewers and the physician should be trained as a team. Ideally, the training should be provided by someone skilled in using the tool. If that is not possible, the next best option is to follow these instructions as closely as possible and use the discussion groups on the IHI website for questions, particularly if the adverse event rates are either much higher or lower than numbers typically seen in other hospitals. Although the review team could consist of more than three individuals to accomplish some distribution of the work load, too many reviewers and physicians can introduce variability in adverse event identification, particularly in the E category.

2) During training, all patient records should be reviewed by both trainers and trainees. This will enable the trainer to answer questions and ensure that the process is standardized.

3) If there are more than two reviewers, it might be beneficial to stagger the assignments for individual reviewers, for example, by alternating who reviews each month (but ensure that pairs of reviewers are not always together—mix up the team). This ensures that the knowledge acquired in the organization is not lost in transitions if a reviewer leaves or new ones are brought in.

B. Read the IHI Global Trigger Tool White Paper

All primary and physician reviewers should read this white paper as a first step, except for the answers to the training records located in Appendix D.

C. Phase 1: Training Records

IHI provides five sample patient records for training of reviewers. The first phase of training should be conducted using these training records. The sample records were purposely chosen to highlight key learning points. These are real, but not complete, patient records from which all identifiers have been removed. The pages that are not necessary for identifying a positive trigger or adverse event have also been removed to make the file size easier to use, whether printed or viewed on screen. These training records can be accessed on IHI's website at http://www.ihi.org/knowledge/Pages/Tools/TrainingRecordSetforIHIGlobalTriggerTool.aspx.

1) All training records should be reviewed by each of the primary reviewers ***and*** the physician.

2) Trainers will have reviewed these records previously, but should refresh their knowledge of the content.

3) The "20-minute rule" should not be applied during training so that reviewers can focus on learning the methodology without time pressure.

4) Schedule a session for all trainees and trainers to debrief findings and discuss the answers provided in Appendix D, as well as to review the key points contained in each of the sample records.

Discuss every trigger and adverse event identified by each reviewer and the physician, including the validity of the identification and the severity of the event. It may be necessary to reinforce the difference between a positive trigger and an adverse event.

If any adverse events were missed by all reviewers, these should be reviewed. It is helpful to have a copy of the training records available for reference.

During this debriefing session, the review team should agree on rules for reviewing individual events and making determinations of harm in that organization. Consider whether all events would be considered an adverse event and, if so, the severity. This is often a subjective

process. For example, how much vomiting is considered an adverse event: one time or over four hours?

The team should decide on the local definition using the guidelines described in this white paper.

Review the entire IHI Global Trigger Tool white paper with the review team at the end of the training session to ensure common understanding of the process and all definitions.

D. Phase 2: Practice Review

After reviewing the answers and understanding the specific training points, the team should complete a practice review using patient records from the organization.

1) Select a set of inpatient records from the hospital using the sampling process described in section II-B.

2) The primary record reviewers should each review all of the records selected. Just as in Phase 1, the 20-minute rule should not be applied.

   The physician does not review the records, only the Summary Sheet (Appendix C). Follow the process described in sections II-A through II-C.

   Remember that the role of the physician is to be the final arbitrator and to provide the link between the adverse events identified and the collegial acceptance of these findings in the organization.

3) Do not use the data collected during the practice review as a data point on the subsequent run charts. Consider this as true "practice."

After these two review sessions, the team will have the needed experience to start real record review and data collection for the hospital.

V. Tips for Leadership

- When selecting the primary reviewers (seasoned nurses, pharmacists, or others) and the physician reviewers, identify individuals available to do the reviews on an ongoing basis. At least a one-year assignment should be the goal, because having the same individuals involved in the process over a substantial period of time will help ensure consistency.
- Carve out dedicated time for these individuals to be trained and then actually complete the record reviews. Total time for primary reviewers should be at least three hours per reviewer every two weeks. The physician reviewer should need about 30 minutes every two weeks.

- Each hospital needs to define the process for selecting randomly pulled records for the review. The process should be well understood and teams should use the same random process for each record pull.
- Identify a lead person responsible for each step in the process.
- Identify a resource/time in the information or medical records department to "randomly" identify the required number of records from the discharged patients (making sure deaths are also included as possible record pulls).
- Identify an area where the review team can meet to carry out the record review. Make sure this area has a place where the records can be stored confidentially.
- Do not draw conclusions from the record review rates until the team has generated at least 12 data points.
- After a team has generated a number of appropriate data points, have a clear process for distributing the information.

VI. Stories from Experienced Organizations

A. Florida Hospital[15]

Florida Hospital (FH) in Orlando comprises eight campuses (50 to 1,000 beds per hospital) and is part of Adventist Health System (AHS). FH implemented the IHI Global Trigger Tool methodology across seven campuses (pediatric hospital excluded) starting in December 2006. Patient harm data was collected from over 3,000 medical records. The goal for 2009 is to expand to all remaining acute care hospitals in its parent company, AHS. The FH Board of Trustees reviews adverse event rates at quarterly meetings and considers it a key whole system measure[16] that reflects safety performance.

Initially, two nurses and one physician were trained, with subsequent training of other reviewers (nurses, pharmacists, and respiratory therapists) at each campus to ensure cross-coverage and mentoring. The current process includes one to two trained reviewer(s) examining a minimum of 10 patient records each (total 20 records per month per campus). In addition an experienced reviewer independently checks for triggers and harms. This promotes organizational consistency across seven campuses. Following physician authentication, the harm and triggers identified are entered into a database for analysis. Monthly reports are forwarded to the Patient Safety Officers (PSOs), who are accountable to senior hospital leaders and safety and quality committees. PSOs distribute relevant harm information (e.g., pressure ulcers, falls, and medication events) to respective performance teams for continuous improvement cycles.

FH has found that it is vital to engage the board of trustees, medical staff, and senior leaders to promote understanding of the implementation, methodology, and value of the IHI Global Trigger Tool. Using harm identification helps the board and senior leadership to prioritize resource allocation to optimize impact of patient safety initiatives and meet the organization's mission and values. For example, since 55 percent of harms identified were due to medication-related events, FH is targeting specific harms due to *C. difficile* infections, fluid or electrolyte overload, glycemic events, over-sedation from pain medication, and anticoagulant-related bleeding. The hospital is also performing a system-wide medication safety infrastructure gap and risk analysis.

B. Mayo Clinic

The Mayo Clinic (Rochester, Minnesota) started using the IHI Global Trigger Tool in August 2004 to measure baseline adverse event occurrence and determine whether safety in the organization actually improved over time. Although the Mayo Clinic was devoting considerable resources to improving patient safety with many new and ongoing safety improvement projects in the organization, they had no macro-level measurement of the effectiveness of those efforts. The IHI Global Trigger Tool would provide such a measure. Three sites (Rochester, Arizona, and Jacksonville) selected record reviewers and physician reviewers, and used the IHI Global Trigger Tool practice records to train the reviewers. The teams review 10 records every two weeks. The three sites conduct quarterly conference calls to compare notes among reviewers, discuss difficult cases, and share learning about how best to utilize the tool.

After the first year of data was collected and graphed in a run chart, the results were presented to Mayo's senior Quality Committee. The Committee now reviews the rate of harm regularly; for the first time, Mayo has a credible measure of the reduction in harm as its patient safety program has matured. Reviews of the root causes of adverse events detected by the IHI Global Trigger Tool have provided the Committee with a tangible sense of the impact of harms on patients and the systems problems that caused them.

C. OSF Healthcare System

OSF Healthcare System (Peoria, Illinois) started using the IHI Global Trigger Tool in their six hospitals early in 2004. Every month, the team chooses 20 records at random for review by designated nurses. During the first year, reviewers across the system met periodically to discuss how results were being interpreted in order to improve inter-rater reliability. Sharing among the six hospitals continues, both to continuously improve the review procedures and to inform patient safety efforts.

OSF found value in using the IHI Global Trigger Tool at two levels. First, while the organization has other inputs regarding errors and adverse events, the IHI Global Trigger Tool provides accurate data over time so that the quality and safety program, as well as institutional leadership, can gauge the impact on harm and patient outcomes of the

organization's extensive efforts to improve safety. OSF sees this as a vast improvement over voluntary reporting, which was an unreliable measure of actual trends in the rate of harm. Second, teams use the results of the reviews using the IHI Global Trigger Tool to discover where to direct improvement activities. For example, one hospital noted readmissions in patients who had been discharged on warfarin. The inquiry sparked by these unnecessary rehospitalizations catalyzed the hospital's implementation of an anticoagulation clinic.

D. Tayside Healthcare System

The Tayside Healthcare System (Scotland) relied on voluntary incident reporting to detect adverse events—a reactive and unreliable way to monitor harm and prioritize improvement efforts. The System found that the IHI Global Trigger Tool was easy to implement and sustain. A multidisciplinary review team now meets monthly to identify actual harms using the IHI Global Trigger Tool. Many of these events would go undetected by relying only on voluntary reporting. The team prepares regular summaries on these adverse events and trends results over time for senior leadership and all relevant departments.

E. Missouri Baptist Medical Center

Missouri Baptist Medical Center in St. Louis was very interested in the concept, development, and use of the IHI Global Trigger Tool based on their prior experience with the IHI Trigger Tool for Measuring Adverse Drug Events. Missouri Baptist has used the IHI Global Trigger Tool on 20 patient records per month since October 2003. The tool has allowed Missouri Baptist to demonstrate a reduction in harm by identifying opportunities related to systems and processes, and to direct the actions of multiple safety and quality improvement teams. In 2004, the adverse event rate per 1,000 patient days was over 90 and has decreased significantly to 29.1 in 2005, 22.0 in 2006, and 20.5 in 2007. In 2008 there was an increase to 31 adverse events per 1,000 patient days; it was determined that this increase was due to a change in events occurring prior to admission.

The adverse events rate per 100 admissions was 35 in 2004; in 2006, it was 9.5. The review team has been composed of the same clinicians since its inception in 2003; having a stable review team is a key contributor to providing a consistent and reliable outcome measure.

Missouri Baptist also uses a modified version of the IHI Global Trigger Tool for monthly mortality review meetings and chart review. More than 16 physicians and physician assistants have been trained using the IHI Global Trigger Tool Training Records for their Mortality Review Board. The data results in a richer review of mortality; focused improvement teams then address the information identified.

The IHI Global Trigger Tool outcome data provide a longitudinal record of the results of the actions of these teams; the Performance Improvement Committee of the Board of

Trustees reviews the data quarterly. They view this as a key, high-level monitor of the outcomes related to the organization's safety and quality initiatives.

VII. Frequently Asked Questions

Q: Will I be able to use the data collected to compare my organization to other organizations within my system or to other hospitals in the country?

A: No. The IHI Global Trigger Tool is meant to be used as a mechanism to track your organization's progress over time. Although efforts are made to maintain a standard of training and process for the IHI Global Trigger Tool, organizations will vary in the skill of reviewers and other aspects of the IHI Global Trigger Tool process. We assume this bias is relatively stable over time in a given organization. The stability over time allows comparison to your own organization over time, but is not as useful in comparing between organizations. You can use national data to determine if your rates are in the general range of others. Organizations that have decreased adverse event rates should also be contacted to learn how this was achieved, even if the data is not exactly the same as yours.

Q: There seems to be some argument about the validity of the IHI Global Trigger Tool. How do I defend our time investment in the tool?

A: There certainly is healthy discussion in the safety community regarding the IHI Global Trigger Tool. It is important to understand there is no gold standard for adverse event identification. The time commitment to apply the IHI Global Trigger Tool is relatively small and requires no highly technical investment. It certainly is more sensitive than voluntary reporting and provides a better method for tracking actual harm over time in an individual hospital.

Q: If we use the IHI Global Trigger Tool, how reasonable is it to expect we will identify all adverse events that occur as a result of medical care?

A: The IHI Global Trigger Tool was never intended to identify all adverse events. Experienced reviewers familiar with the IHI Global Trigger Tool will identify almost all events greater than category E in a patient record that can be reviewed completely within the 20-minute time limit. Events in the E category of harm involve more judgment and at times are not as obvious, so these are less easily identified and may be missed. When the 20-minute time limit is enforced not all adverse events are expected to be identified.

Q: How should the training records be used?

A: The training records should be reviewed by all members of the team—physicians and primary record reviewers. No 20-minute limit should be imposed during training. After the records are reviewed, the whole team should then debrief using the answer sheets in Appendix D.

Q: If a patient has an adverse event that occurred prior to coming to our institution, does this count?

A: Yes, provided that it meets the definition of being harm related to medical care. All such adverse events are counted because the measure is what the patient experienced, not what happened within the hospital. It is useful, though, to keep track of which events occurred outside the hospital so that this can be noted when reporting data. Such data may also indicate an opportunity to collaborate with others—office practices, clinics, long-term care facilities—to improve patient safety.

Q: Our hospital is a referral center and if we count all the outside adverse events, are we not penalizing ourselves?

A: When measured as a separate item in tertiary medical centers, the event rate for those out-of-hospital occurrences is less than 10 percent of all adverse events identified.

Q: What are the approximate levels of harm that organizations are finding when using the IHI Global Trigger Tool?

A: Organizations are finding approximately 90 adverse events per 1,000 patient days or 40 adverse events per 100 admissions. Approximately 30 to 35 percent of all admissions are
found to have adverse events.

Q: If there is more than one trigger found and two different manifestations of adverse drug events from the same drug, is this two adverse events or one (e.g., vomiting and thrombocytopenia from allopurinol)? What if there is vomiting that can be attributed to two drugs; is it one or two?

A: In both cases, we would count it as one event, but an important determination here is whether treatment or intervention was required. Vomiting on one or two occasions, even with treatment, is usually not considered harm; but protracted nausea and vomiting that requires treatment, reduces oral intake, or limits recovery would be an adverse event. Thrombocytopenia by itself is not an adverse event; you need to look for clinical manifestations of it and treatment.

In the first example, we would call it one event because both manifestations were likely related to the same medication. In the second example, it is considered as one event because there is no way to determine which medication caused the vomiting (unless the vomiting ceased when one medication was discontinued, which might make it clear). This is clearly harm from medication, which for the purposes of the Trigger Tool is all you need to know.

Q: When an INR is above 6, this is unintended because it is out of the therapeutic range and noxious (part of the WHO definition of harm) because the patient is in coagulopathy; even without bleeding or any kind of physical complications, should it not be considered an adverse event? What about glucose less than 50? Even without clinical presentation, it is still unintended because with the use of any anti-diabetic drug, the aim would be to achieve normoglycemia. Should it be classified as an adverse drug event (ADE) in the absence of symptoms?

A: A key point for using Trigger Tools is distinguishing between a positive trigger and an adverse event, as these are not the same thing.

For example, INR greater than 6 is a positive trigger and nothing more. When this trigger is found, one must investigate the record for evidence of harm. Some patients are fortunate and do not experience any harm (such as bleeding or bruising) even at such a level, while other patients do experience harm. That is the determination of an adverse event.

In the WHO definition of "unintended and noxious," while an elevated INR to this degree is unintended, it may not be noxious. Simply being in a state where there is the potential for harm is not harm itself.

The same applies for glucose less than 50. This is only a trigger. Some patients may drop below 50 and have no symptoms at all. If so, what is the harm in that case? We define it as none. However, if the patient becomes dizzy, has a syncopal episode, and must receive glucose, then we would call it harm.

Our definition of an adverse event, including an ADE, is that it was unintended physical injury resulting from or contributed to by medical care.

Q: We have done two reviews using our own records and are not finding any adverse events. Are we doing something wrong?

A: This is not uncommon and there are two primary reasons why you may see this:

1) You are using a small random sample, so it is possible that there were no adverse events in the small record set selected. On your next review, you may find many. This is the wide variation that can occur from sample to sample and why you need at least 12 data points before you will have a sense of your baseline.

2) Another possibility is that some category E events were missed. This is not unusual with new reviewers because many events in this category have been traditionally viewed as non-preventable or known risk of treatment. If you found positive triggers but no adverse events, consider reviewing those records again to see if perhaps there were some category E events.

Q: We do not use diphenhydramine (Benadryl) in our organization, so how do we use this trigger?

A: If there is a medication trigger that does not match your hospital formulary, the trigger should be revised. Consider the intent behind this trigger and the harm it identifies: allergic reactions. What medication is administered in your hospital for these reactions? If it is not Benadryl, then simply rename the trigger to match your formulary.

Q: Is there a specific reason that certain items are not listed as a trigger, such as Protamine, which is used to counteract another drug?

A: When the IHI Global Trigger Tool was developed, we realized that it would not be realistic to develop a comprehensive trigger list that included every possible trigger for every possible adverse event. Such a tool would be incredibly large and nearly impossible to use for record review. The list of triggers is based on those adverse events that occur most frequently and, when they do occur, cause the most harm to patients. The areas included in the current IHI Global Trigger Tool represent many for which there are known improvement strategies.

Q: What is the average time to complete an IHI Global Trigger Tool record review?

A: Time to manually review a record averages about 10 to 15 minutes for an experienced primary reviewer and should not exceed 20 minutes. If a reviewer is spending more time than that, usually it is because the reviewer starts reading the record rather than just looking for triggers or is doing an analysis of events.

Q: Can the Trigger Tool be automated and used with our computer system?

A: Many of the triggers can easily be captured from information systems. This is especially true for the medication and laboratory value triggers. If you have a system that captures these electronically and reports can be generated, this can save time during the review.

The recommended process for selection of records should be followed first. Once the records have been identified, generate a report from the information system based on the triggers for each patient. If none are identified, then you do not need to look in the record for them; however, if a positive trigger is found, then you will need to review the record for the details as to whether an adverse event occurred.

Not all of the triggers can be automated, so some record review will still be required. For example, evidence of over-sedation is often noted in progress notes indicating lethargy or inability to complete therapy due to fatigue.

Q: Do you have any examples of organizations that have actually decreased their adverse events by using the IHI Global Trigger Tool? If so, how did they identify which events to focus on, and how did they implement a change that resulted in a decrease in adverse events related to that particular issue?

A: First, the IHI Global Trigger Tool is a measurement tool, so using it will do nothing to your adverse event rate. An easy analogy: You can't lose weight by getting on a scale every day. The same is true with the IHI Global Trigger Tool: You can't decrease adverse events by measuring them; you have to implement change.

You may use a Pareto chart categorizing the events that you find (medications, surgery, etc.) to help you decide where to start your improvement efforts. However, when first using the tool, you may not have enough data for this. Small samples will vary in findings. If you want to know where to start your improvement efforts, talk to front-line staff (perhaps using Patient Safety Leadership WalkRounds[17]). They will tell you where safety work should be done. In order to decrease harm across the organization, you will need to have work in multiple areas, not just one.

The organizations referenced in section VI of the white paper as experienced with the IHI Global Trigger Tool are good places to contact for learning about use of the tool and improving patient safety.

Q: We understand that the IHI Global Trigger Tool is a measurement tool, not an improvement tool; we struggle with the cost-versus-value of a measurement tool. How has use of the tool impacted patient safety at other institutions?

A: Currently, how do you decide which improvement projects to choose? Most organizations either follow someone's advice (The Joint Commission, Centers for Medicare and Medicaid Services, etc.) or "grease the squeaky wheel" that presents itself with sentinel events. The IHI Global Trigger Tool is an organized way to gain information about your organization's progress and where you want to target your resources. The review of 10 patient records every two weeks takes at least three hours per primary reviewer and 30 minutes of physician reviewer time every two weeks to obtain the data point. This is a small investment for the information being gained. The tool has been in use around the US and in Europe. Experienced organizations are recommending that a minimum of 24 data points need to be present to establish a good baseline. The tool itself does not impact safety. Teams should use the tool to direct resources and measure trends over time.

Q: We are formalizing our process for IHI Global Trigger Tool reviews. Should we have a review by two people with confirmation by a physician for the first 20 records only, or is the requirement for review by two people ongoing?

A: Ideally, you should always have at least two primary reviewers review each record. The separate reviewers will pick up different events at times. The reviewers should get together, discuss their findings and come to consensus, then have the physician review the findings of the consensus for the final determination.

If you only have one person reviewing the records, the data will be a bit skewed, as that person will catch about 75 percent of the adverse events. We have found that many of the category E and F events have a greater chance of being detected with more than one reviewer.

Q: How many records need to be reviewed to establish a baseline rate of adverse events?

A: We recommend 10 records every two weeks or 20 per month, randomly selected. Because this is a small, random sample, you need a minimum of 12 data points before you can establish a baseline, and experienced organizations are recommending 24 data points. If you would like to obtain this baseline data sooner, consider reviewing 10 records every two weeks and plotting data for each set of records rather than monthly. A note of caution: Don't get hung up on the baseline and delay starting on improvement. It takes a long time to move the adverse event rate, so you should start improvement efforts while collecting data. This won't adversely affect your results.

VIII. Conclusion

The IHI Global Trigger Tool is a measurement strategy only and its use alone will not make your organization safer. Changes must be implemented to increase patient safety and decrease adverse events. You do not need to wait until you have 12 or more data points in order to start making changes—it will take time to test and successfully implement multiple types of changes to impact the adverse event rate. Examples of changes that have been successful for improving patient safety with medications, in surgical patients, in intensive care units and other areas can be found in the Patient Safety Topic section of IHI's website (http://www.ihi.org/explore/PatientSafety/Pages/default.aspx). "An Introduction to Trigger Tools" on IHI's website provides a useful overview of the various Trigger Tools that are also available for download.[14]

IX. Appendices

Appendix A: References

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	Cares Module Triggers	+	Event Description and Harm Category (E-I)
C1	Transfusion or use of blood products		
C2	Code/arrest/rapid response team		
C3	Acute dialysis		
C4	Positive blood culture		
C5	X-ray or Doppler studies for emboli or DVT		
C6	Decrease of greater than 25% in hemoglobin or hematocrit		
C7	Patient fall		
C8	Pressure ulcers		
C9	Readmission within 30 days		
C10	Restraint use		
C11	Healthcare-associated infection		
C12	In-hospital stroke		
C13	Transfer to higher level of care		
C14	Any procedure complication		
C15	Other		
	Surgical Module Triggers		
S1	Return to surgery		
S2	Change in procedure		
S3	Admission to intensive care post-op		
S4	Intubation/reintubation/BiPap in Post Anesthesia Care Unit (PACU)		
S5	X-ray intra-op or in PACU		
S6	Intra-op or post-op death		
S7	Mechanical ventilation greater than 24 hours post-op		
S8	Intra-op epinephrine, norepinephrine, naloxone, or romazicon		
S9	Post-op troponin level greater than 1.5 ng/ml		
S10	Injury, repair, or removal of organ		
S11	Any operative complication		

	Medication Module Triggers	+	Event Description and Harm Category (E-I)
M1	*Clostridium difficile* positive stool		
M2	Partial thromboplastin time greater than 100 seconds		
M3	International Normalized Ratio (INR) greater than 6		
M4	Glucose less than 50 mg/dl		
M5	Rising BUN or serum creatinine greater than 2 times baseline		
M6	Vitamin K administration		
M7	Benadryl (Diphenhydramine) use		
M8	Romazicon (Flumazenil) use		
M9	Naloxone (Narcan) use		
M10	Anti-emetic use		
M11	Over-sedation/hypotension		
M12	Abrupt medication stop		
M13	Other		
	Intensive Care Module Triggers		
I1	Pneumonia onset		
I2	Readmission to intensive care		
I3	In-unit procedure		
I4	Intubation/reintubation		
	Perinatal Module Triggers		
P1	Terbutaline use		
P2	3rd- or 4th-degree lacerations		
P3	Platelet count less than 50,000		
P4	Estimated blood loss > 500 ml (vaginal) or > 1,000 ml (C-section)		
P5	Specialty consult		
P6	Oxytocic agents		
P7	Instrumented delivery		
P8	General anesthesia		
	Emergency Department Module Triggers		
E1	Readmission to ED within 48 hours		
E2	Time in ED greater than 6 hours		

Patient Identifier _____ Total Events _____ Total LOS _____ Write descriptions of the events in greater detail on reverse of Worksheet.

[Photocopy Worksheet single-sided. Leave opposite side blank for notes.]

Appendix C: IHI Global Trigger Tool for Measuring Adverse Review Summary Sheet

Record #	LOS	Triggers	Events (Note trigger identifying event)	Event present on admission?
Totals				

Measure #1: Adverse events per 1,000 patient days

Total number of adverse events/Total length of stay (LOS) for all records reviewed x 1,000=_____

Adverse events per 1,000 patient days

Events _____/ Total LOS for all records reviewed _____x 1,000=_____

Measure #2: Adverse events per 100 admissions

Total number of adverse events/Total records reviewed x 100=Adverse events per 100 admissions

Events _____/ Total records reviewed_____x 100=Adverse events per 100 admissions

Measure #3: Percent of admissions with an adverse event

The number of admissions with at least one adverse event

Total number of records with at least one event/Total records reviewed x 100=Percent of admissions with an adverse event

Records with at least one adverse event_____/Total records reviewed_____

x 100=_____

Appendix D: Answers to Training Records for IHI Global Trigger Tool

The IHI Global Trigger Tool for Measuring Adverse Events is best utilized when personnel have been trained as reviewers for this methodology. IHI provides five sample patient records for training of reviewers. These training records can be accessed on IHI's website at http://www.ihi.org/knowledge/Pages/Tools/TrainingRecordSetforIHIGlobalTriggerTool.aspx.

The first phase of training uses actual patient records (with identifiers removed) that IHI has selected to emphasize key learning points for using the IHI Global Trigger Tool. Each record has been reviewed by experienced reviewers and answers on findings are included below.

Note that the training records, like all records, will look different to different reviewers. The following are the most common answers, but others are possible. The answer sheets reflect real life. The aim is not to find every possible adverse event, but to sample those events to a fairly high degree of dependability by reasonable reviewers in short periods of time.

Training Record #1

The patient is a 51-year-old female admitted to the hospital for an ovarian cyst. The triggers commonly identified are:

- C1 Transfusion
- M10 Anti-emetic use
- C6 Abrupt drop of hematocrit
- C14 Any procedure complication

Two adverse events are identified:

1. A large hematoma occurring post-operatively and requiring a longer length of stay for the hospitalization. Due to extension of the hospitalization, the event was classified as a category F.

2. Nausea lasting about 2 days. Since the event was temporary and was not felt to have substantially increased the length of stay due to the other adverse event, it was classified as a category E.

The key learning points from this record are:

- All post-operative complications, whether or not the patient was advised of risk prior to surgery, are adverse events. Even if the complication was clearly unpreventable it is counted as an adverse event because it was unintended. The question of "would you be happy if it happened to you" sometimes puts these complications in perspective. The issue is not whether there was an error or not. The prime concern is the identification of harm as a result of some medical intervention or treatment.

- A minor event such as nausea needs to be looked at carefully. One or two episodes of nausea adequately treated should not be considered an event. But when nausea lasts a day or more in spite of treatment, or when the nausea interferes with post-operative progress, it is almost always considered an event. Most reviewers over a short time will get a pretty good concept of how much of a small or minor occurrence has to happen before it becomes an event. It is true there might be different definitions from organization to organization, but within one hospital the definition will become reasonably consistent. Each hospital team must decide what constitutes an event versus a minor episode not to be considered an event. Admittedly, this loose definition will cause some people to question the validity of this measurement, but experience has shown that record reviewers with the physician oversight will make the identification reasonable.

Training Record #2

A 48-year-old male was admitted with a pulmonary embolism. The positive trigger is C5 X-ray studies for emboli. The adverse event was a pulmonary embolus and because it required admission to the hospital the severity of the event was rated as category F. By definition if an adverse event causes hospitalization it is an F. Severity of category F can be attained either by prolonging a hospital stay or causing a hospitalization.

The key learning points from this record are:

- Events occurring outside the hospital, whether or not initiated in your hospital, are still unintended harm experienced by the patient and should be counted in your data. This means that if you are a referral hospital and a patient is transferred to your hospital and you identify an adverse event as the reason for transfer and subsequent admission, then this is counted as an event in your hospital data. In this particular case the patient previously had prostate surgery. It is not relevant in which hospital the surgery took place. The hospital where the patient ended up with the event counts the event. Many hospitals will place a marker on these types of events so they can keep track of this as a percentage of events or admissions. In major referral centers the adverse event rate attributable to outside caused events is less than 10 percent. Lastly, if your organization is a major referral center and event trends are noted from referring physicians or hospitals, this might well provide an opportunity for your outreach education efforts.

- The time interval between initial medical treatment and subsequent event does not have to be fixed. The duration of time from the initial surgery and the presentation of the pulmonary embolus might well require input from the physician reviewer to decide the relationship. Most would agree that the relationship between prostate surgery and subsequent pulmonary embolus exists, but the relationship may require physician-based knowledge to make the final decision. There is not a predetermined amount of time beyond which events are not counted, but in general only events occurring within one year of the procedure are included.

Training Record #3

A 74-year-old woman was admitted with a fractured vertebra.

Review of this record reveals no clear trigger. The approach should be to use trigger M13 Other. The patient had an adverse event related to confusion from medications. There is mention in the notes of the confusion, and there was indecision as to whether it was from the Robaxin, Somax, or Xanax. The exact cause is not necessary to identify an adverse event. Clearly someone thought it was drug-related. Most reviewers feel this event is a category E as there was no permanent harm and it was not responsible for extending the patient's hospital stay.

The key learning points from this record are:

- Not all adverse events have to have a trigger. Events count if they have no trigger and many triggers have no events. If events are found just as the result of the trigger review, even though there is no identified trigger, it must be counted.
- In this case the caregivers suggested the confusion was related to a medication. When a statement is made in the record that suggests an adverse event, this is taken at face value. Do not try to make your own judgments as to whether the nurses or physicians were right in their assessments.

Training Record #4

A 59-year-old woman was admitted for surgery for a prolapsed vagina.

Most reviewers will identify the trigger as S10 Removal/injury of an organ. In this record review, the trigger identified a perforation of the bladder during surgery. In this event the reviewers felt the complication extended the hospital stay and graded the severity as category F.

The key learning points from this record are:

- A complication of surgery is always an adverse event. Even though this is a known complication, it requires classification as an adverse event.

- Because the principal diagnosis is vaginal prolapse after hysterectomy, the question is sometimes raised whether the prolapse is a consequence of that surgery leading to admission (a category F event). However, documentation indicates that the patient had a grade II cystocele with rectocele, neither of which is a result of the hysterectomy and the prolapse was likely due to this.
- Some reviewers, when looking at the discharge summary, identified atelectasis and there have been discussions as to whether this represents an adverse event or just a minor episode. Most agree that in certain body configurations (patient was 5-feet-6-inches in height and weighed 226 pounds) this will commonly occur. When treated appropriately it appeared to have no effect on the case. In this record most suggest this is just a minor episode and not an event. Reviewers will need to come to a consensus on these types of episodes and then use the physician reviewer as not only the final decision maker, but also the educator about some of these episodes. The aim is to find adverse events, not minor episodes.

Training Record #5

A 45-year-old male underwent surgery for aortic valve insufficiency. Positive triggers identified include:

- S3 Admission to the ICU post procedure
- M10 Anti-emetic use
- M11 Over-sedation and hypotension

The adverse events identified were reintubation and significant nausea. The reintubation was classified as category H and the nausea as category E.

The key learning points from this record are:

- The patient was extubated when the effects of drugs were obviously still affecting the patient. Increasing somnolence occurred and the patient became quite acidotic with significant CO2 retention. In order to save this person's life an intervention needed to take place. The intervention must be necessary within about one hour to classify the severity as category H (Intervention required to sustain life). In the extreme, almost all interventions could be construed as lifesaving. For example, over longer periods of time antibiotics for an infection are "lifesaving," but are certainly not considered so within one hour.

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