IHI Global Trigger Tool for Measuring Adverse Events (UK version)

Institute for Healthcare Improvement

Developed in Cooperation with
The Pursuing Perfection, Innovation & Knowledge Group
NHS Modernisation Agency

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Background

Traditional efforts to detect adverse events (AEs) 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 select and test changes to reduce harm. The use of triggers to identify adverse events during a manual record review has been used extensively to measure the overall level of harm in a health care organisation. Recent publications describe the process for the review and the history of triggers to identify events (Resar RK, Rozich JD, Classen D. Methodology and rationale for the measurement of harm with trigger tools. *Quality and Safety in Health Care*. 2003; 12; Suppl 2:39-45. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: A practical methodology for measuring medication related harm. *Quality and Safety in Health Care*. 2003; 12:194-200. Resar RK, Rozich JD, Simmonds T, Haraden CR. A Trigger Tool to Identify Adverse Events in the Intensive Care Unit. *Jt Comm J Qual Saf* 32:585-90, Oct. 2006*.)* Recently, the IHI has developed the IHI Global Trigger Tool, meant to be ***used to identify all categories of adverse events*** including, but not limited to, those related to medications.

Definition of an “adverse event”

The IHI Global Trigger Tool (UK version) builds upon the work of the IHI Global Trigger Tool and the Trigger Tool for Measuring Adverse Drug Events, developed by IHI and Premier in 2000. The World Health Organization (WHO) Collaborating Centers for International Drug Monitoring defines an adverse drug event (ADE) as follows:

“Noxious and unintended and occurs at doses used in man for prophylaxis, diagnosis, therapy, or modification of physiologic functions.” WHO Publication DEM/NC/84.153 (E), June 1984.

The IHI Global Trigger Tool (UK version) includes these types of events, but goes beyond medications to include any noxious or unintended event occurring in association with medical care. The WHO definition of “adverse events” includes events caused by errors. Some errors are harmless, some cause injury, and some are “near misses” (that is, they do not cause injury to the patient, either by chance or because they are intercepted before the medication is administered). **The object of the review is to identify harm** – not whether the event was preventable. In our experience, the discussion about the *preventability* of an adverse event is often a barrier to determining the *cause* of an adverse event. The IHI Global Trigger Tool (UK version) defines an adverse event as ***any physical harm to the patient***. (The tool limits the definition of adverse events to physical rather than emotional harm.)

The question that has been helpful is, “Would you be happy if the event in question happened to you?” If the answer is no, then it probably is an adverse event.

This tool adapts the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors. However, this tool counts only AEs: harm to the patient, whether or not the result of an error.

Accordingly, the tool **excludes** the following categories in NCC MERP Index because these categories describe medication 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

The tool includes categories E, F, G, H, and I of the NCC MERP Index, because these categories describe errors that do cause harm. (Note that NCC MERP’s “An error that contributed to or resulted in…” has been deleted, because this tool is designed to find harm, whether or not it was the result of an error.)

Category E: Temporary harm to the patient and required intervention
Category F: Temporary harm to the patient and required initial or prolonged hospitalisation
Category G: Permanent patient harm
Category H: Intervention required to sustain life
Category I: Patient death

Use of Sampling

Conduct small samples over time. The IHI Global Trigger Tool (UK version) uses the measurement methodology of sampling small numbers of records every two weeks over several months or even years. From a statistical viewpoint, small numbers of records suffer from the problem of wide variation from sample to sample. However, when ten records are reviewed every two weeks, after approximately twelve sample points, the mean number of adverse events will vary from a much larger statistical sample by only 4% or less.

Use random sampling for record review. Because we are using sampling to discover adverse events, it is critical to select the initial records using a truly random fashion. Use any chart selection method, as long as it is random. A selection process is random as long as every chart has an equal opportunity of being chosen. For example, one such method might include generating random numbers between 1 and 9 and selecting ten charts with record numbers ending in the random number. Use only 20 minutes to review any one chart, after the training period has been completed. The experience of hundreds of organisations has shown there is a propensity to review the easier (less thick) case notes. However, reviewing only the short-stay patients will affect the random nature of the sampling. The tool has been built to allow only 20 minutes for each record, regardless of its “thickness.” Each

adverse event in the larger case notes will have the same likelihood of being identified, since 20 minutes will not be sufficient to adequately review the entire record using the trigger tool technique.

Reviewer Selection

The IHI Global Trigger Tool (UK version) requires manual case note review. The review team should consist of two reviewers and a physician. The two initial case note reviewers could be anyone knowledgeable about the case notes and care provided in the hospital, including nurses and pharmacists. Experienced nurses are probably the best initial reviewers, but other combinations can be used. The physician is needed to concur with the identification and severity of the adverse event, and to provide the link between the adverse events identified and the other physicians in the organisation.

Performing the Review

1- Patient records need to be selected in a random fashion and must have a LOS (Length of Stay) of at least 24 hours. This would exclude the short hospital admission. One method of random chart selection is to print out all admissions or discharges (if deaths are included) and select every 10th case note for review. A good strategy is to pull all prior case notes for that patient including the case notes for the admission to be reviewed. This allows the reviewer to determine readmissions.

2- General instructions: Review a minimum of 50 random case notes for baseline and 20 records per month thereafter. These reviews can be split into two sessions to be more resource friendly.

3- Review “completed” case notes (those that have been processed and include the discharge summary and all diagnosis and procedure coding).

4- Each case note should be reviewed for a maximum review time of 20 minutes. Fewer than 20 minutes can be used, but never more than 20 minutes).

5- An independent review of the first 20 patient records should be performed by two separate reviewers to establish inter reviewer reliability and assure that the process is standardized for your organisation as well as to provide a common platform to discuss the findings and answer questions.

6- The case note review process should take the following path:
   - Discharge diagnoses (looking particularly for infections, complications or certain diagnoses)
   - Discharge summary (Look for specifics of the assessment and treatment during the hospital stay)
   - Medication orders and the medication administration documentation form
   - Laboratory results
   - Operative theatre documentation
   - Nursing documentation
   - Physician case notes

- If time permits any other areas of the case notes

7- *Use only the triggers in the modules that apply to the patient record being reviewed.* All reviews should include the General Care, Laboratory test, and Medication modules. The other modules should only be used if applicable; for example, the Intensive Care module should be used when reviewing a chart for a patient who spent any days in an intensive care unit.

8- A positive trigger is the presence of that item; for example, an *INR level greater than 5* would be a positive trigger. A positive trigger is not an adverse event in and of itself; it is just a clue that one may have occurred. When a positive trigger is found, then review that portion of the chart and determine if an adverse event has occurred. In the example of INR greater than 5, the reviewer should look for bleeding, decreased haemoglobin, haematoma, and other adverse events that can result from over-anticoagulation. The object is not to find every possible adverse event in every chart reviewed; the time limitation and random selection of charts are designed to produce a reliable sampling sufficient to use for the design of safety work in the hospital.

9- If no adverse event is found, then move on and continue looking for other triggers. At times, positive triggers will be found, but no adverse events. If an adverse event is identified, then assign a category of harm using the NCC MERP index categories of E-I described previously. Be sure to include every adverse event you find, even if not identified by a trigger. On occasion, you will come across an adverse event while looking for triggers or other details; all AEs should be included.

10- Complete a separate copy of the trigger worksheet (located on page 4) for each case note reviewed. After all case notes are reviewed; complete the Excel summary sheet (separate attachment).

11- Specific events should be categorized both by severity and type and used in the safety improvement efforts of the organization.

12- Adverse events are best defined from the viewpoint of you as a patient. *Would I be happy if the event happened to me?* If the answer is no, then answer the question of whether or not harm occurred. **An adverse event is harm to a patient from the viewpoint of the patient.** The next question to be answered is whether or not this a part of the natural progression of the disease process or a complication of the treatment related to the disease process. Admittedly the decision at times will be difficult and subjective, but experience with the use of the trigger tool has found the process to be reasonable.

13- Assign a severity to each adverse event using the following guide:

Category E: contributed to or resulted in temporary harm to the patient and required intervention
Category F: contributed to or resulted in temporary harm to the patients and required initial or prolonged hospitalization

Category G: contributed to or resulted in permanent patient harm
Category H: required intervention to sustain life
Category I: contributed to the patient's death

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Category E: contributed to or resulted in temporary harm to the patient & required intervention
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Trigger		+	Event Description and Severity E-I
	General care module		
G 1	Lack of early warning score or early warning score requiring response		
G 2	Any patient fall		
G 3	Decubiti		
G 4	Readmission to hospital within 30 days		
G 5	Shock or cardiac arrest		
G 6	DVT/PE following admission evidenced by imaging +/or D dimmers		
G7	Complication of procedure or treatment		
G8	Transfer to higher level of care		
	Surgical care module		
S 1	Return to theatre		
S 2	Change in planned procedure		
S3	Removal/Injury or repair of organ		
	Intensive care module		
I 1	Readmission to ICU or HDU		
I 2	Unplanned transfer to ICU or HDU		
	Patient identifier		
	Total events		
	Total length of stay		

Trigger		+	Event Description and Severity E-I
	Medication module		
M 1	Vitamin K		
M 2	Naloxone		
M 3	Flumazenil		
M 4	Glucagon or 50% glucose		
M5	Abrupt medication stop		
	Lab test module		
	Haematology		
L1	High INR (>5)		
L 2	Transfusion		
L3	**Abrupt drop in Hb or Hct (>25%)**		
	Biochemistry		
L4	Rising urea or creatinine (>2x baseline)		
L5 L6	Electrolyte abnormalities Na^+ <120 or >160 K^+ <2.5 or >6.5		
L7	Hypoglycaemia (<3mmol/l)		
L8	Raised Troponin (>1.5 ng/ml)		
	Microbiology		
:L9	MRSA bacteraemia		
L10	C. difficile		
L11	VRE		
L12	Wound infection		
L13	Nosocomial pneumonia		
L14	Positive blood culture		

General care module

Early warning score
If an early warning scoring risk assessment system is in use, then the lack of an early warning score or an early warning score requiring a response may be a precursor to an adverse event.

Patient fall
A fall represents a failure of care. A fall that causes no harm may be the result of medications or failure to assess risk. Any fall that causes harm regardless of cause is an adverse event by definition. Review the physician progress notes, nursing or multidisciplinary notes for evidence of over sedation, lethargy or other conditions that may have contributed to a fall. Falls resulting in admission to the hospital need should be reviewed for causation and attributed as an adverse event if appropriate.

Decubiti
Decubitus ulcers are adverse events. Chronic decubiti are events if they occurred during a hospitalisation. If they occurred in the outpatient setting consider the aetiology (over sedation, etc.) to assess if an adverse event occurred.

Readmission within 30 days
An adverse event may not manifest until after the patient has been discharged from the hospital, especially if the length of stay is minimal. As the chart is reviewed look to see if this admission was within a 30 days from a previous hospitalisation. Or did the current admission result in another future hospitalisation? Examples of adverse events may include surgical site infection, deep vein thrombosis or pulmonary embolism. This is particularly easy to detect if all the records are pulled along with the current chart being reviewed.

Shock or cardiac arrest / crash calls
All cardiac arrests need to be carefully reviewed as the end event of a flawed care process. Not all crash calls are adverse events. Cardiac or pulmonary arrest occurring intra-operatively or in the post anaesthesia care unit should always be considered as an adverse event. In the first 24 hours post-operatively, it is also very likely to be an adverse event. A sudden cardiac arrhythmia with a resulting crash call may well be associated with no adverse event, but failing to rescue a patient due to lack of recognition of physiological change in signs and symptoms would be an adverse event.

X-Ray or Doppler studies for emboli or Deep Vein Thrombosis (DVT)
Development of a DVT or pulmonary embolism (PE) during a hospital stay should be considered as an adverse event. Even if all appropriate preventive measures appear to have been taken, from a patient's perspective this is a harmful event. If the hospitalisation occurs due to a DVT or emboli look for drug related or other outside of the hospital.

Complication of Procedure or Treatment
Evaluate the reason for the procedure. The procedure itself may be required due to an adverse event. Look for complications from any procedures. Procedure notes do

not always note the complications especially if the complication occurs hours or days after the procedure note has been documented.

Transfer to higher level of care
Transfers include either within hospital, to another hospital, or to your hospital from another. Transfer to an intensive care unit or high dependency unit is a trigger that an adverse event may have occurred. Admissions to intensive care or HDU may have occurred when a patient's clinical condition deteriorated perhaps secondary to an adverse event. When reviewing this trigger, look for the reasons for the transfer and the change in condition. 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), it would mot be an adverse event, but if it was caused by a pulmonary embolism that developed post-operatively, or over-sedation of a patient with COPD it would be an adverse event.

Surgical care module

Return to theatre
A return to surgery is a trigger to check whether an adverse event occurred during the previous surgery.

An example of an adverse event is a patient who had internal bleeding following the first surgery and required a second surgery to stop the bleeding. Patients who have a second surgery that is exploratory, but does not reveal anything (looking for bleeding, or a suspected retained surgical instrument) would be considered as an adverse event.

Sometimes a return to theatre after a previous surgical procedure is planned and is therefore not an adverse event. For example a procedure that must be completed in stages or a procedure that is completely unrelated to the first procedure and the result of another diagnosis, such as pacemaker insertion after a bowel resection. It is important to distinguish whether the additional procedure was planned.

Change in planned procedure
An unexpected change in surgical procedure can be the result of unexpected findings after the procedure has started, a change in clinical condition during the procedure or due to an adverse event occurring during the procedure. When the procedure on the post-operative note is different from the procedure planned in the pre-operative note 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 equipment failure or missing equipment is an adverse event if the patient experienced additional pain, time in the hospital or other harm as a result of the different procedure.

Removal / Injury/ repair of organ
Review theatre notes and postoperative notes for evidence that the procedure included repair, injury or removal of any organ. Except in cases of trauma, where

organ injury or suspicion thereof is the reason for surgery, this may indicate an operative event damaging the organ.

Intensive care module

Readmission to Intensive Care or High Dependency Care
Any readmission to the ICU has a high probability of an event occurring on the floor or outside the hospital. Look for a relationship to a precipitating adverse event. Examples might be pulmonary oedema secondary to excess fluid administration or an aspiration.

Unplanned transfer to intensive care or high dependency care
Transfer to an intensive care unit or cardiac care unit is a trigger that an adverse event may have occurred. The admission to intensive or critical care may have occurred when a patient's clinical condition deteriorated perhaps secondary to an adverse event. When reviewing this trigger, look for the reasons for the transfer and the change in condition. 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), it would not be an adverse event, but if it was caused by a pulmonary embolism that developed post-operatively, or over-sedation of a patient with COPD it would be an adverse event.

Medication module

Vitamin K
If Vitamin K was used as a response to a prolonged INR, review the chart for evidence of bleeding. The laboratory reports should indicate a drop in haematocrit or guiac-positive stools. Check the progress notes for evidence of excessive bruising gastrointestinal (GI) bleed, hemorrhagic stroke, large haematomas or other bleeding episodes.

Naloxone
Naloxone is a powerful narcotic antagonist. If it has been used, over dosage of narcotics is a frequent finding.

Flumazenil (Romazicon)
Flumazenil reverses benzodiazepine drugs. Determine why the drug was used. If hypotension or marked, prolonged sedation occurred following benzodiazepine administration, an adverse event has occurred.

Glucagon or 50% glucose
The administration of glucagons or 50% dextrose the patient may have experienced an adverse event related to hypoglycaemia. The chart should be reviewed for associated use of insulin or oral hypoglycemics with evidence of symptoms which are commonly followed by and administration of glucose (oral or intravenous).

Abrupt medication stop

While some medication courses such as antibiotics are of limited duration, the cessation of several medications at once or cessation of a long term medication, such as an antihypertensive is a trigger requiring further investigation and may indicate an adverse drug reaction, drug interaction or sudden change in the patients' condition.

Lab test module

Haematology

High INR (>5)

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

Transfusion

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 (RBC's) or whole blood should be investigated for causation including excessive bleeding, unintentional trauma of a blood vessel, etc. Transfusion of many units within the first 24 hours of surgery, including intra-operatively and post-operatively, will commonly be related to a peri-operative adverse event. Exceptions would be where excessive blood loss occurred pre-operatively. Fresh frozen plasma and platelets can reflect system problems that include failure to plan changes in anticoagulants prior to surgery and the necessity to reverse quickly in order to do the surgery.

Abrupt drop in Hb or Hct (>25%)

Any drop of 25% or greater in Hg grams or Hematocrit (Hct) requires an explanation. All bleeding associated events might commonly see this as a trigger. Smaller "drops" obviously can also be associated with adverse events, but the question as to whether harm occurred needs to be subjectively answered. Anticoagulant use is frequently observed to be associated with this particular trigger.

Biochemistry

Rising urea or creatinine (>2x 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 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.. Subjective judgment may be needed to determine whether renal failure was event induced if multiple factors are identified.

Electrolyte abnormalities (Na+ <120 or >160 K+ <2.5 or >6.5)

Electrolyte imbalance can either precede or be associated with adverse events. Not all patients with electrolyte abnormalities will be symptomatic. Review the case notes for evidence of symptoms.

Hypoglycaemia (<3mmol/l)
Not all patients will be symptomatic; if the patient is not symptomatic there is probably no adverse event. Review for associated use of insulin or oral hypoglycemics with evidence of symptoms and commonly followed by and administration of glucose (oral or intravenous). Often the signs and symptoms description will be noted by nursing where lethargy, shakiness, etc. will be described.

Raised Troponin (>1.5 ng/ml)
A post-operative increase in troponin levels may indicate a cardiac event. Reviewers will need to use clinical judgement as to whether a cardiac event has occurred.

Microbiology

MRSA bacteraemia
Review for any positive MRSA bacteraemia.

C. difficile
If a patient is on or has been on multiple antibiotics this adverse event can be observed. A positive C. difficile assay is an adverse event.

VRE
Review for any nosocomial infections, central line infection, and surgical site infection or urinary tract infections. Any infection occurring in hospital is an adverse event. Exceptions might be the urinary tract infection from outside the hospital, or infection being treated but not contracted in hospital.

Wound infection
Review for any nosocomial infections, central line infection, and surgical site infection or urinary tract infections. Any infection occurring in hospital is an adverse event. Exceptions might be the urinary tract infection from outside the hospital, or infection being treated but not contracted in hospital.

Nosocomial pneumonia
Any pneumonia diagnosed in the ICU needs to be looked at carefully. Any infection starting in hospital needs to be considered nosocomial unless clearly from outside the hospital. Readmissions could also represent a pneumonia from a previous hospitalisation, particularly if antibiotic resistant.

Positive blood culture
A positive blood culture at any time during hospitalisation must be investigated as an indicator of an adverse event. A surgical site infection, sepsis, infected lines or any other hospital-acquired infection is an adverse event.