

➤ Trigger Tool for Measuring Adverse Drug Events

The use of “triggers,” or clues, to identify adverse drug events (ADEs) is an effective method for measuring the overall level of harm from medications in a health care organization. The Trigger Tool for Measuring Adverse Drug Events provides instructions for conducting a retrospective review of patient records using triggers to identify possible ADEs. This tool includes a list of known ADE triggers and instructions for collecting the data you need to measure the number of ADEs per 1,000 doses and the percentage of admissions with an ADE.

NOTE: You can use this tool in conjunction with the interactive Trigger Tool for Measuring ADEs in the Workspace area on IHI.org. Enter your detailed data from all of your ADE Patient Record Review Sheets into the interactive Trigger Tool for Measuring ADEs. The Tool will automatically calculate and graph two measures: ADEs per 1,000 Doses and Percent of Admissions with an ADE.

This tool contains:

- Background
- List of ADE Triggers
- General Instructions
- Case Studies
- ADE Patient Record Review Sheet
- Pediatric ADE Patient Record Review Sheet
- ADE Monthly Summary Sheet (*Use interactively on IHI.org)



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Background

The Institute for Healthcare Improvement formed the Idealized Design of the Medication System (IDMS) Group in May 2000. The group of 30 physicians, pharmacists, nurses, and statisticians 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.

What Is an Adverse Drug Event?

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 WHO definition includes ADEs caused by medication errors. Medication errors can occur at any stage in the medication system — from ordering through administering the drug to the patient. Some medication 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).

Measuring Only Harm from Medications

Adverse drug events present the single greatest risk of harm to patients in hospitals. Traditional efforts to detect ADEs 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. This tool provides an easy-to-use method for accurately identifying ADEs (harm from medications) and measuring the rate of ADEs over time. Tracking ADEs over time is a useful way to tell if changes the team is making are improving the safety of the medication system.

This tool adapts the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors. NCC MERP brings together leading health care organizations to meet, collaborate, and cooperate to address the interdisciplinary causes of errors and to promote the safe use of medications.

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*This tool counts only ADEs: harm to the patient from medications, whether or not the result of an error. Harm is defined as "temporary or permanent impairment of physical or psychological body function or structure." 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 medication 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 hospitalization
- Category G:** Permanent patient harm
- Category H:** Intervention required to sustain life
- Category I:** Patient death

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List of ADE Triggers

Before you conduct the review of patient records to identify adverse drug events, your team needs to agree on a list of triggers, clues that an ADE may have occurred, such as certain drugs or lab tests/results. The following is a list of triggers that organizations have found to be the most useful clues that an ADE has occurred.

Your organization may choose to add some triggers to the list and delete others. For example, the Pediatric ADE Patient Record Review Sheet at the end of this tool contains a list of triggers customized for the pediatric population (patients under 18 years of age).

T1 Diphenhydramine (Benadryl)

Diphenhydramine is frequently used for allergic reactions to drugs. Benadryl may signal a possible ADE, but can also be ordered as a sleep aid, a pre-operative or pre-procedure medication, or for seasonal allergies. If Benadryl has been administered, review the chart to determine if it was ordered for symptoms of an allergic reaction to a drug administered either during the hospitalization or prior to admission.

T2 Vitamin K (Aqua-mephyton)

If Vitamin K was used as a response to a prolonged prothrombin time or elevated International Normalized Ratio (INR) levels, it may signal an ADE. If either lab value is high, review the chart for evidence of bleeding. Look in the lab reports for a drop in hematocrit or for guiac-positive stools. Check the progress notes for evidence of excessive bruising or gastrointestinal bleeding. Less likely, a hemorrhagic stroke or other internal bleeding may have occurred. If any of these is found, it is likely that an ADE has occurred.

T3 Flumazenil (Romazicon)

This drug reverses benzodiazepine drugs. Determine why the drug was used. If hypotension or marked, prolonged sedation occurred following benzodiazepine administration, an ADE may have occurred.

T4 Anti-emetics (Droperidol (Inapsine); Ondanestron (Zofran); Promethazine (Phenergan); Hydroxyzine (Vistaril); Trimethobenzamide (Tigan); Prochlorperazine (Compazine); or Metoclopramine (Reglan)

Nausea and vomiting can be the result of drug toxicity or overdose, particularly in patients with impaired renal function. Drugs such as theophylline preparations frequently cause nausea and vomiting when levels get high. Anti-emetics are also commonly administered to patients postoperatively or to patients receiving chemotherapy. Chart reviewers must use professional judgment in these situations to determine if an ADE may have occurred.

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T5 Naloxone (Narcan)

This is a powerful narcotic antagonist. Use of Narcan frequently indicates overdosage of narcotics. If Narcan was used and the patient's condition changed, excessive narcotic administration, which is an ADE, probably has occurred.

T6 Anti-diarrheals

Look for antibiotic-caused infections of *Clostridium difficile*. If the *C. difficile* was not ordered and significant diarrhea occurred in a patient receiving multiple antibiotics, it is likely that an ADE has occurred.

T7 Sodium Polystyrene (Kayexalate)

Sodium polystyrene sulfonate is used in the treatment of hyperkalemia. The drug aids in the removal of excess potassium from the body. Look for the reason for hyperkalemia and whether the patient had been receiving potassium. Administration of Kayexalate may be in response to an overdose of potassium, which would be an ADE.

T8 Glucose < 50

Low serum glucose does not necessarily mean an ADE occurred. Look for evidence of symptoms and administration of glucose (orally or IV). Not all patients will be symptomatic. In addition, look for signs or symptoms in the nursing notes about lethargy, shakiness, etc., to determine if an ADE has occurred.

T9 *Clostridium difficile* Positive Stool

If a patient is on multiple antibiotics, a stool positive for *Clostridium difficile* is a likely complication and an indication of an ADE.

T10 Partial Thromboplastin Time (PTT) > 100 seconds

As with Vitamin K, look for evidence of bleeding to determine if an ADE has occurred. High PTT is not an infrequent occurrence when patients are on heparin. Use professional judgment for patients with high PTTs receiving heparin during a surgical procedure.

T11 International Normalized Ratio (INR) Level > 6

Again, an elevated INR is not an infrequent occurrence when patients are on warfarin (Coumadin). Look for evidence of bleeding to determine if an ADE has occurred.

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T12 White Blood Cell (WBC) Count < 3,000

In some cases, a low WBC count will occur in response to drug administration. Follow the WBC counts throughout the admission and see what has happened. If leukopenia is related to drugs such as Indocin, a drop in WBC should be evident. Don't include patients currently receiving chemotherapy. If a drop in WBC occurs in the absence of medications that may cause this, an ADE has not occurred.

T13 Platelet Count < 50,000

Certain medications can cause platelet counts in the blood to drop, placing patients at greater risk for bleeding. 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 ADE may have occurred.

T14 Digoxin Level > 2 ng/ mL

This heart medication provides benefits within a continuous therapeutic range depending on the patient and the condition. When the level exceeds this range, some patients get benefits, but in others, toxicity may occur. The toxicity frequently manifests itself as arrhythmias or bradycardia, but may also include nausea, vomiting, anorexia, and vision changes even without cardiac symptoms. If the level is greater than the therapeutic range, look for evidence that the patient had complications related to this drug or required other interventions as signs that an ADE may have occurred.

T15 Rising Serum Creatinine

Certain medications, especially aminoglycosides, diuretics, and anti-hypertensive medications can cause renal toxicity, which may become evident when serum creatinine levels start rising. Look at several sequential results to see if levels rose. If they did, check to see if the patient received medications that are known to be nephrotoxic. If interventions were required to correct renal problems, an ADE may have occurred.

T16 Over-sedation, Lethargy, Falls

Look in the physician progress notes, nursing notes, or multidisciplinary notes for evidence of over-sedation, lethargy, and falls. If any of these triggers appears, look for a relationship between the event and administration of a sedative, analgesic, or muscle relaxant. If over-sedation, lethargy, or falls occurred as a result of administration of a sedative, analgesic, or muscle relaxant, an ADE has occurred. Include falls related to an ADE and resulting in the admission. Do not include intentional overdose resulting in sedation.



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T17 Rash

There are many causes for a rash. To determine if an ADE has occurred, look for evidence that the rash is related to drug administration. For example, a yeast infection may indicate overuse of antibiotics.

T18 Abrupt Cessation of Medication

In the order sets, whenever "hold" or "stop" medication orders appear, look for the reason. These orders frequently indicate that an ADE has occurred.

T19 Transfer to a Higher Level of Care

Transfer to a higher level of care includes transfers within the institution, to another institution from yours, or to your institution from another. Transfer of a patient to a higher level of care is only a trigger, a clue that an ADE may have occurred. A higher level of care is indicated when a patient's clinical condition deteriorates or becomes more serious. This is a result of a change in clinical condition or sometimes following a major procedure. However, in some cases an adverse drug event is the cause of the change in condition. When reviewing this trigger, look for the reasons for the transfer and the change in condition. If the clinical condition can be linked to any medications, this may be an indication that an ADE has occurred. For example, in the case of transfer to intensive care following respiratory arrest and intubation, if the respiratory arrest was a complication of chronic obstructive pulmonary disease (COPD), it would not be an ADE, but if it was caused by use of a narcotic or sedative, it would be an ADE.

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Identifying and Measuring ADEs in Your Organization

Once your team has decided on the list of triggers, the next step is to review a sample of patient records. Recruit a multidisciplinary team to conduct the ADE patient record review. Ideally, the team should include at a minimum one physician, one nurse, and one pharmacist. All members of the team should review this tool so they understand how to conduct the patient record review.

Edit the list of triggers at the top of the ADE Patient Record Review Sheet per your team's decision. Distribute the ADE Patient Record Review Sheet to all team members, either electronically or on paper. Each patient record in the review requires its own copy of the form, whether or not the record turns out to contain triggers and ADEs.

The patient record review has two major components: First, review in a systematic way the portions of the chart where the triggers are most likely to be found. For example, an elevated INR would be found in the Laboratory Values portion of the chart. The important point is not to read through the entire patient record, but to read very selectively; this is how the trigger tool review differs from a standard chart review. If a trigger is found, then go to whatever portion of the chart that will reveal the occurrence of an ADE. If a harmful event is found, determine the level of harm using the NCC MERP Index Categories E through I (those that cause harm).

Measuring ADEs: A Sampling Plan

Measuring the number of ADEs in your organization over time tells you whether or not the changes you are making result in improvement. Instead of reviewing all patient records to detect triggers and investigate them to determine if an ADE has occurred, we suggest using the following sampling plan:

1. Get the list of discharges for the month (minimum two-day hospital stay).
2. Select a random sample of 20 patient records (each record has an equal chance of being selected).
3. Obtain those 20 patient records from the Medical Records Department.
4. Review each patient record, paying particular attention to the following sections:
 - a. Discharge summary: Look for ADEs or hints at ADEs.
 - b. Laboratory reports: Look for trigger lab results.
 - c. Physician orders or Medication Administration Records (MARs): Look for trigger medications.

Note: Generally allow only 20 minutes for a patient record review by an experienced person (allow a little more for someone just learning the process). Any time left after

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the review should then be devoted to the notes, in the following order. (In general, physician admission and consult notes as well as daily progress notes are not very helpful.)

- d. Nursing flow sheets: Look for altered level of consciousness, skin rash.
 - e. Nursing/Multidisciplinary progress notes: Look for over-sedation, lethargy, falls, hypotension, rash, nausea/vomiting, or other adverse events.
5. List all triggers found on the ADE Patient Record Review Sheet.
 6. For each trigger found, read through the appropriate parts of the patient record to determine if an ADE has occurred. Sometimes professional judgment will be required to make this determination. For example, if a patient received an anti-emetic (T4) an hour after receiving a narcotic; list T4 on the ADE Patient Record Review Sheet. If the patient continued to receive the narcotic without further anti-emetic, the incidents are probably unrelated (= No ADE Found). However, if the patient continued to require anti-emetics after narcotics, an ADE probably occurred (= ADE Found). Some ADEs will result in more than one trigger; use your best judgment in determining the number of ADEs that occurred in this situation.
 7. If an ADE occurred, assign a category of harm (E through I) and provide a brief description of the ADE.
 8. Examine the financial department's record of charges to the patient, if there is a charge for each dose administered, or just count up the doses administered, to determine the total number of medication doses received. This is not essential, so if financial data does not provide total doses and manually counting is too cumbersome, you can skip this step.

NOTE: You can use the interactive Trigger Tool for Measuring ADEs to complete the next three steps. [LINK to Trigger Tool/Data Manager page]

9. After you have completed the ADE Patient Record Review Sheet for the 20 patient records in the sample, summarize your findings in the ADE Monthly Summary Sheet. For each patient record reviewed, document the following: whether an ADE occurred; the number of ADEs; and (if you collected data on doses) the total number of medication doses received.



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10. Use the data in the ADE Monthly Summary Sheet to calculate one or both of these important measures:

a. Percent of Admissions with an ADE

The total number patients identified as having experienced any ADEs from a sample of patient records, divided by the total number of records in the sample; multiplied by 100 to express as a percentage.

b. ADEs per 1,000 Doses

The total number of ADEs identified in a sample of patient records, divided by the total number of medication doses administered to those patients. Multiply the result by 1,000.

11. Track the measures (Percent of Admissions with an ADE, ADEs per 1,000 Doses) over time in a run chart, to see if changes you are testing are making the medication system safer. You can use the Improvement Tracker on IHI.org to automatically track and graph these measures over time.



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Case Studies: Using the Trigger Tool to Identify ADEs

The following two scenarios show how a reviewer used this tool to identify ADEs in the patient record.

Following the instructions in the Trigger Tool for Measuring ADEs, the reviewer completed the following:

- Reviewed the physician's orders looking for any of the identified triggers, especially the medication triggers.
- For each trigger found, reviewed progress notes, nursing notes, and multidisciplinary notes for evidence of an ADE. If an ADE was found, then determined the harm category.
- Reviewed laboratory findings for any of the lab triggers. If triggers were found, reviewed progress notes, nursing notes, and multidisciplinary notes for evidence of an ADE. If an ADE was found, then determined the harm category.
- Obtained financial data in order to count total doses of medications.

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Scenario 1

While reviewing the patient's record, reviewer finds an order to discontinue Levaquin. The patient had only received two doses of the IV Levaquin. Reviewer notes T18, Abrupt Cessation of Medication, on the ADE Patient Record Review Sheet. Further in the record, on the same day, reviewer finds an order for Benadryl 25 mg IV now. Reviewer notes T1 on the ADE Patient Record Review Sheet. Next, the reviewer examines the physician progress notes to see if an ADE occurred. The physician's notes do document that patient has developed a rash in response to the Levaquin. Reviewer notes third trigger (T17). Also, in the nurse's notes, reviewer finds documentation stating that a red, itchy rash developed, physician notified, and antibiotic is stopped. Nurse's notes later on the same day document that the rash is still present and patient is complaining of itching; physician notified and order for Benadryl received.

Reviewer examines the rest of the chart, including labs, and identifies no additional ADEs.

Reviewer counts one ADE with a harm category of E, because the patient did require discontinuation of therapy and treatment with another drug.

Reviewer reviews a report from the organization's finance department listing all medication doses that the patient was charged for, which is the total number of doses recorded.

Triggers Found:	ADE Found?		Harm Category*	Description of ADE
	Yes	No		
T18				
T1	X		E	Patient required discontinuation of therapy and treatment with another drug.
T17				
Total ADEs for this patient:	1			
Total number of doses of medications for this patient (if available):	75			

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Scenario 2

While examining the patient record, reviewer identified no triggers from the physician orders. While examining laboratory values, reviewer found a glucose level of 33 (T8). Reviewer listed T8 on the ADE Patient Record Review Sheet, and then investigated the physician progress notes to determine if an ADE occurred. Nothing was documented regarding low glucose levels or any changes in insulin orders. In nurse's notes, reviewer found documentation of patient being very shaky, lethargic, and slightly confused. Glucose level was 33. Physician was notified and orange with sugar was prescribed, with follow-up glucose levels. Later that day, there was a physician order to change the sliding scale insulin.

Reviewer examined the Medication Administration Record (MAR) and found that regular insulin on a sliding scale had been given approximately 90 minutes prior to the low glucose level.

No other triggers were identified.

Reviewer identified one ADE and assigned a harm category of E, due to the increased monitoring and the change of the medication.

Triggers Found:	ADE Found?		Harm Category*	Description of ADE
	Yes	No		
T8	X		E	Increased monitoring and change of medication.
Total ADEs for this patient:	1			
Total number of doses of medications for this patient (if available):	125			

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ADE Patient Record Review Sheet

Patient Identification Number _____

Admission Date _____ **Patient's Age** _____

Discharge Date _____ **Date** _____

(Two-day minimum hospital stay required)

- | | |
|---|--|
| T1 Diphenhydramine (Benadryl) | T10 PTT > 100 seconds |
| T2 Vitamin K (Aqua-mephyton) | T11 INR > 6 |
| T3 Flumazenil (Romazicon) | T12 WBC < 3,000 |
| T4 Anti-emetics (Inapsine, Zofran, Phenergan, Vistaril, Compazine, Reglan) | T13 Platelet Count < 50,000 |
| T5 Naloxone (Narcan) | T14 Digoxin Level > 2 |
| T6 Anti-diarrheals (diphenoxylate/Lomotil, loperamide/Imodium, Kaopectate) | T15 Rising Serum Creatinine |
| T7 Sodium Polystyrene (Kayexalate) | T16 Over-sedation/lethargy/fall/hypotension |
| T8 Serum glucose < 50 | T17 Rash |
| T9 C. difficile positive | T18 Abrupt Cessation of Medication |
| | T19 Transferred to a Higher Level of Care |

Triggers Found:	ADE Found?		Harm Category*	Description of ADE
	Yes	No		
Total ADEs for this patient:				
Total number of doses of medications for this patient (if available):				

*Harm Category (adapted from NCC MERP Index; Categories A–D do not cause harm):
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



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Pediatric ADE Patient Record Review Sheet

Patient Identification Number _____

Admission Date _____ **Patient's Age** _____

Discharge Date _____ **Date** _____

(Two-day minimum hospital stay required)

- T1 Diphenhydramine (Benadryl)
- T2 Anti-emetics
- T3 Naloxone (Narcan)
- T4 Sodium Polystyrene (Kayexalate)
- T5 PTT > 100 seconds
- T6 Rising Serum Creatinine
- T7 Over-sedation/lethargy/fall/hypotension
- T8 Rash
- T9 Abrupt Cessation of Medication

Triggers Found:	ADE Found?		Harm Category*	Description of ADE
	Yes	No		
Total ADEs for this patient:				
Total number of doses of medications for this patient (if available):				

*Harm Category (adapted from NCC MERP Index; Categories A–D do not cause harm):
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



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NOTE: You can use the interactive Trigger Tool for Measuring ADEs to complete the ADE Monthly Summary Sheet and automatically calculate and graph Percent of Admissions with an ADE and ADEs per 1,000 Doses. [LINK to Trigger Tool/Data Manager page]

ADE Monthly Summary Sheet

Date _____

Patient	ADE Found? (Yes/No)	Total number of ADEs for this patient	Total number of doses of medications for this patient (if available):
Pt #1			
Pt #2			
Pt #3			
Pt #4			
Pt #5			
Pt #6			
Pt #7			
Pt #8			
Pt #9			
Pt #10			
Pt #11			
Pt #12			
Pt #13			
Pt #14			
Pt #15			
Pt #16			
Pt #17			
Pt #18			
Pt #19			
Pt #20			
	Total:	Total:	Total:

Percent of Admissions with an ADE

The total number patients identified as having experienced any ADE from a sample of patient records (Column 1 Total), divided by the total number of records in the sample; multiplied by 100 to express as a percentage.

ADEs per 1,000 Doses

The total number of ADEs identified in a sample of patient records (Column 2 Total), divided by the total number of medication doses administered to those patients (Column 3 Total). Multiply the result by 1,000.