



Identification of Adverse Drug Events via “TRIGGERS”

Predefined computerized triggers are utilized to identify potential adverse events previously unidentified or reported/classified as an event. The use of these triggers to identify events involving patient harm, as opposed to other methods, which tend to identify medication errors.

Background:

As part of an effort to target Adverse Drug Events in our hospitalized patients, OhioHealth hospitals are launching an Adverse Drug Events / Triggers Project on September 1st.

All patient charts with the triggers defined below will undergo chart review for a 3-month period to develop a baseline and determination of frequency of events. After this baseline period, one (or more) of the following triggers will be chosen by each facility to focus improvement and intervention efforts over a 6-9 month period. The monitoring of the chosen trigger(s) should continue over this intervention period for trending purposes.

Study design:

This project is designed as a retrospective study. Trigger events, as defined below, will be identified and charts will be reviewed after patient discharge if a potential adverse drug event occurred.

Inclusion:

All inpatient admissions, with the following exclusions, will be screened for the defined trigger events.

Exclusions:

Where possible, SAS programming using UB 92 administrative dataset may be used to narrow the required chart review.

- OB patients (DRG 370-384)
- Mental health admissions (DRG 429-430)
- Patients < 18 yrs
- < 48 hrs
- A trigger would be negative if
 - there is no evidence in the chart that the patient received the medication that triggered the review. (Narcan, D50W, or Romazicon)
 - if the patient did not receive the medication suspected to cause the trigger (example: a patient in liver failure with an elevated PT receiving vitamin K)
 - if it is utilized to reverse anticoagulation for a procedure
 - If it is utilized to reverse sedation at the end of surgery
- Outpatients: Differentiate inpatient occurrences from those that caused the admission (patient arrived in ED with glucose of 25 would count as an outpatient (OP) occurrence. The event must occur while the patient is an inpatient.

METHODOLOGY:

1. CHART IDENTIFICATION via triggers – This can be automated through the lab and/or pharmacy computer systems, or manually monitored and reviewed according to each institution’s capabilities.
 - a. Lab triggers:
 - i. PTT > 100 (exclude elevated PTT within 24 hrs post-op/procedure)
 - ii. INR > 5
 - iii. Serum glucose < 50 mg/dL
 - b. Medication triggers – administration of...
 - i. D50W
 - ii. Vitamin K

- iii. Narcan (or other similar narcotic antagonist)
- iv. Romazicon

2. CHART REVIEW – Each chart containing one of the listed triggers shall be reviewed, looking for documentation to determine whether an adverse event occurred. Multiple triggers may be identified in a single patient. Abstract all triggers regardless of number per patient. If a trigger is identified from the automated system but not present in the medical record, it is excluded.

A pharmacist or nurse will review the medical record collecting the following information at minimum:

- a. Patient account number (unique number identifying patient admission)
- b. Admit date
- c. Discharge date
- d. Type of trigger
 - i. Note whether the trigger was identified in the outpatient arena or
 - ii. Inpatient occurrence as a result of medication use within the hospital
 - iii. No trigger identified in the medical record after review.
- e. Severity ranking:
 - i. Patient level of harm: symptoms/adverse event
 - ii. Treatment given
 - iii. Level of care
 - iv. Resolution of event
 - v. Lab monitoring needed after the trigger

Outcome (use attached definitions to determine category)	Drug therapy required to treat	Level of care (LOC)	Resolution	Lab monitoring after trigger
1. None 2. Minor injury 3. Moderate injury 4. Serious injury 5. Permanent injury 6. Death	1. None 2. One prescription med 3. 2 prescription meds 4. > 2 prescription meds	1. No change 2. Add precautions 3. Elevated level of care 4. Elevated to critical care 5. Elevated to critical care and resuscitation required	1. 24-48 hrs 2. 49-72 hrs 3. > 72 hrs – 1 wk 4. > 1 wk-1 mth 5. > 1 mth – 3 mths	1. None or once 2. Monitor x 24-72 hrs 3. > 72 hrs – 1 wk 4. > 1 wk – 1 mth 5. > 1 mth

3. CHART REVIEW METHODOLOGY

- a. Review the physician orders and Medication Administration Record (MAR)
 - i. Look for sudden discontinuation of medications signaling a potential adverse drug event
 - ii. Use of Narcan , Romazicon, D50W, Vitamin K (FFP, PRBC)
 - iii. Timing and amount of doses in relation to adverse events (amount of narcotics within 12-24 hrs prior to need for Narcan, dosing of warfarin, potentially interacting medications, etc)
- b. Review discharge summary
 - i. Identify
- c. Review the Progress Notes
 - i. Looking for documentation/discussion of hypoglycemia, oversedation, etc.
 - ii. Looking for calls to residents/interns regarding issues needing attention
 - iii. Transfers to higher level of care
- d. Review laboratory results to document trends

- e. Review procedure notes (diagnostic, surgical) looking at narrative sections for adverse events
- f. Review nursing notes, diabetic flow sheets, heparin flow sheets – signs of hypoglycemia, oversedation, etc. and treatment
- g. Review surgery, anesthesia, and PACU documents
- h. Duration of review:
 - i. Hypoglycemic episode: monitor until insulin duration of action has passed.
 - ii. Vitamin K, PTT > 100, and INR > 5: Monitor patient until discharge for bleeding episodes
 - iii. Narcan/Revex, and Romazicon: Monitor until narcotic duration of action has passed

4. DATA SUBMISSION FORM – Data will be submitted on a monthly basis. The actual # of events will be reported to the “Balanced Scorecard”.

MR#	Name	Admit date	DC date	Trigger	Event	Treatment	Severity				
							Outcome	Drug tx	LOC	Resol'n	Labs

5. SPECIFIC DRUG CLASS INFORMATION

INSULIN

1. Primary/secondary diagnosis of diabetes mellitus, serum glucose < 50 mg/dL, administration of D50W, and receiving insulin
2. Signs and symptoms of hypoglycemia: diaphoretic, confused, unconscious or unresponsive, tremor, sharking, agitation, seizures, hunger
3. Note the medications they received that may have contributed to this event (insulin, oral anti-diabetic meds, beta-blockers, etc)
4. Note the difference between a documented “no symptoms” and when you cannot find documentation “no documentation re: symptoms”.

WARFARIN

1. Evidence of bleeding: hematuria, Ecchymosis, bruising, Epistaxis, retroperitoneal bleed, GI hemorrhage, intracranial hemorrhage, hematemesis, Guaiac positive stools, drop in H/H of > 4 points from baseline or highest value, bleeding at cath site, hemoptysis, etc.
2. Concomitant medications which may contribute to bleeding: aspirin, Plavix, Integrilin, Aggrastat, Reopro, thrombolytics, heparin, warfarin, NSAIDS, etc.
3. Interacting medications with warfarin:
 - a. “Azoles” (fluconazole, itraconazole, metronidazole, etc)
 - b. Quinolones
 - c. Any antibiotics (Bactrim, “mycins”, clarithromycin, erythromycin)
 - d. Amiodarone
 - e. Fluoxetine or fluvoxamine
 - f. Verapamil, diltiazem, mexiletine
 - g. Thyroid medications
4. Use of FFP, PRVC, cryoprecipitate
5. Repeated elevated INRs still count as one occurrence due to the half life of the drug and expected resolution of lab abnormality.

HEPARIN

1. Evidence of bleeding: hematuria, Ecchymosis, bruising, Epistaxis, retroperitoneal bleed, GI hemorrhage, intracranial hemorrhage, hematemesis, Guaiac positive stools, drop in H/H of > 4 points from baseline or highest value, bleeding at catheter site, hemoptysis

2. Concomitant medications which may contribute to bleeding: aspirin, Plavix, Integrilin, Aggrastat, Reopro, thrombolytics, heparin, warfarin, NSAIDS, etc
3. Use of FFP, PRBC, cryoprecipitate
4. An elevated PTT is expected to be reversed after a dosage change within 3 hrs. Additional elevated PTT's count as separate occurrences if beyond this time frame.

NARCOTICS/SEDATIVES

1. Excessive sedation (decreased respiratory rate, decreased O2 sats, lethargy, unresponsiveness)
2. Not sedating medications the patient received in the previous 12-24 hr period potentially contributing to the event.
3. Note co-morbidities (obesity, obstructive sleep apnea, COPD, sepsis, etc)
4. Exclude doses administered at the end of a surgical procedure exclusively for rapid reversal
5. Include doses administered in PACU related to medications given in PACU or surgery.

6. DENOMINATORS:

Insulin:

- All patients who get any dose of insulin (TPN, sliding scale, infusion)
- Problems with development: inconsistent pharmacy charges for insulin

Warfarin

- All patients who received any dose of warfarin
- Problems with development: doses ordered on a daily basis

Heparin

- All patients who received any dose of heparin
- During procedures, dialysis doses

Narcotics:

- All patients who received any dose of a narcotics
- Charges for morphine, diazepam, midazolam, meperidine, lorazepam, hydromorphone, fentanyl)



