

Society of Critical Care Medicine



The Intensive Care Professionals

Toolkit to Enhance Medication Error (ME) and Adverse Drug Event (ADE) Surveillance in the Intensive Care Unit (ICU)

A. Patient Safety Surveillance Systems Methods of ME and ADE Detection

Use of an active voluntary reporting system is considered a baseline activity.

1. Family and Patient Involvement

Recommendation: Use patient/family reported outcome interviews at or soon after ICU discharge about possible medication errors or adverse drug events that occurred.

Description: Formalize a process for interviewing patients or family members about possible MEs or ADEs that occurred while the patient was in the ICU.

Process:

1. Develop a standardized questionnaire to detect potential MEs or ADEs that occurred during the patient's ICU stay. This questionnaire should be approved by an institutional patient safety committee or equivalent. Examples of published standardized interview tools include:
 - a. Kaboli PJ, Glasgow JM, Jaipaul CK, et al: Identifying medication misadventures: Poor agreement among medical record, physician, nurse, and patient reports. *Pharmacotherapy* 2010;30:529-538
 - b. van den Bemt PM, Egberts AC, Lenderink AW, et al: Adverse drug events in hospitalized patients. A comparison of doctors, nurses and patients as sources of reports. *Eur J Clin Pharmacol* 1999;55:155-158
2. Determine eligibility criteria for interviewing patients or family members. For example, determine if the patient is able to communicate in the ICU. If the patient is unable to participate, identify a family member or caregiver that has been involved in the patient's care. Ideally, all patients would be interviewed at discharge.
3. Establish a process for administering the standardized questionnaire to patients meeting the eligibility criteria including who will be trained and accept responsibility for conducting the interview.
4. Interview the patient, family member, or caregiver using the standardized questionnaire either close to the time of ICU discharge or shortly thereafter.
5. Document the results in a central location so that the information may be used by others for quality improvement and systematic changes within the institution.

2. Non-Targeted Chart Review

Recommendation: Perform non-targeted chart reviews for detecting ADEs as part of a surveillance system.

Description: A non-targeted chart review is a comprehensive review of the patient's entire medical record. It can be conducted concurrently, while the patient is in the ICU, or retrospectively, after the patient is discharged.

Process:

1. Establish multidisciplinary safety team to aid in executing the process for a non-targeted chart review including:
 - a. Advanced practice providers
 - b. Health system administrators
 - c. Beside nurses
 - d. Patient risk and/or safety personnel
 - e. Pharmacists
 - f. Physicians
2. Determine the goal for performing a non-targeted chart review at your institution. For example, increase in detection of ADEs by a specified metric.
3. Determine the area of focus, feasibility and utility of a non-targeted chart review as a part of an ADE surveillance system and consider the following:
 - a. Time constraints
 - b. Logistical barriers
 - c. Personnel and resources
4. Select a group of patients that non-targeted chart review is needed. For example, all ICU patients, patients in a specific ICU, a specific number of ICU patients or all ICU patients for a targeted duration (i.e., 2-weeks).
5. Establish a process for conducting the non-targeted chart review including information to be documented and determine who will be trained and accept responsibility for conducting the review.
6. Document the results in a central location so that the information may be used by others for quality improvement and systematic changes within the institution.

3. Targeted- Chart Review

Recommendation: Use trigger-initiated target chart reviews in addition to voluntary reports to increase the quantity of ADEs reported.

Description: A targeted chart review includes only evaluating a specific section of the patient's medical record (i.e. ICU discharge notes, progress notes on a specific day, medication administration times surrounding an abnormal lab value, etc.) or reviewing a medical record for a specific patient, based on a trigger alert. Trigger alerts are logic-based rules within clinical decision support software often involving pre-specified clinical criteria, which then generates an automated notification ("trigger alert") to healthcare providers for further investigation. Trigger alerts may involve logic-based rules including use of antidotes, diagnostic or billing codes, laboratory abnormalities, or serum drug

concentrations outside of therapeutic ranges. Targeted chart review can be conducted concurrently, while the patient is in the ICU providing an opportunity for immediate intervention, or retrospectively, after the patient is discharged allowing for systematic changes and prevention of future events. For consistency with the guideline recommendation, with the goal of increasing the quantity of ADE reports, the process will focus on retrospective reviews.

Process:

1. Establish multidisciplinary safety team to aid in the selection of specific sections of the medical chart or triggers that are appropriate for further investigation through a targeted chart review and to assist with the executing each step in the process including:
 - a. Advanced practice providers
 - b. Health system administrators
 - c. Beside nurses
 - d. Patient risk and/or safety personnel
 - e. Pharmacists
 - f. Physicians
2. Determine the goal for performing a targeted chart review at your institution. For example, increase in detection of ADEs by a specified metric or gaining knowledge about the occurrence of a specific ADE.
3. Determine the area of focus, feasibility and utility of a non-targeted chart review as a part of an ADE surveillance system and consider the following:
 - a. Time constraints
 - b. Logistical barriers
 - c. Personnel and resources
4. Determine if the targeted chart review will involve a section of the patient's medical record, a medical record review generated by a trigger or both. Focusing on a section of a medical record such as the ICU discharge notes will provide more general information about ADEs in the ICU, whereas the use of a trigger identifies a specific type of ADE. For example, the trigger could be used to identify drug induced bleeding events with logic based knowledge for patients receiving an anticoagulant and having a decrease in hemoglobin of $>2\text{gm/dL}$.

Step 5-10 guides a targeted chart review focusing on the use of triggers.

5. Evaluate clinical decision support software technology with trigger alert capabilities to determine which will aid in the identification of ADEs from a targeted chart review.
 - a. Identify proprietary logic-based rules already developed and provided in clinical decision support software
6. Develop trigger alert process
 - a. Identify healthcare professionals receiving trigger alerts
 - i. Advanced practice provider
 - ii. Bedside nurse
 - iii. Pharmacist

- iv. Physician
 - v. Combination of above
 - b. Evaluate the contents of the trigger alert information sent to the clinician for targeted chart review
 - i. Patient identifier (name, medical record number, etc)
 - ii. Potential causal medication
 - iii. Rationale or criteria for trigger alert generated
 - 1. Abnormal laboratory value
 - 2. Serum drug concentration outside therapeutic range
 - 3. Administration of antidote
 - 4. ICD-10 code
 - iv. Date/time of trigger alert generation
 - c. Develop a mechanism for trigger alert delivery system
 - i. Email
 - ii. Text
 - iii. Paper printout report
 - iv. Electronic medical record
 - v. Combination of above
- 7. Establish a process for conducting the targeted chart review including information to be documented and determine who will be trained and accept responsibility for conducting the review.
 - a. Healthcare professional reviews chart surrounding time of event to determine if it is drug-induced
 - b. Use a reliable and valid adverse drug reaction instrument
- 8. Document the results of the evaluation including severity of the event and clinician response in a central location so that the information may be used for quality improvement and systematic changes within the institution.
- 9. Monitor alert performance characteristics through quality improvement initiatives
 - a. Evaluate the positive and negative predictive values to ensure alerts are firing when they should with a high probability that the event is actually drug-induced
 - b. Identify potential trigger alert changes based on logic-based criteria to improve performance ensuring optimal use of resources for the detection of events.
- 10. Suggested resources for trigger alert development and implementation:
 - a. https://www.ismp.org/newsletters/acutecare/articles/20050310_2.asp
 - b. https://www.ismp.org/Newsletters/acutecare/articles/20000906_3.asp
 - c. <http://www.ihl.org/resources/Pages/Tools/TriggerToolforMeasuringAdverseDrugEvents.aspx>
 - d. <https://www.ismp.org/newsletters/acutecare/articles/20050310.asp>

4. Direct Observation

Recommendation: Include direct observation as a component of an active medication surveillance system to identify the MEs.

Description: Direct observation includes having a trained observer watch a subject's performance in their usual clinical environment and document the subject's activities so that it may be later evaluated for MEs. This is usually done in the context of nurses administering drugs and pharmacists dispensing medications

Process:

1. Establish multidisciplinary safety team to aid in executing the process for direct observation including:
 - a. Advanced practice providers
 - b. Health system administrators
 - c. Beside nurses
 - d. Patient risk and/or safety personnel
 - e. Pharmacists
 - f. Physicians
2. Determine the goal for performing direct observation at your institution. For example, increase in detection of MEs by a specified metric.
3. Determine the area of focus, feasibility and utility of direct observation as a part of an ADE surveillance system and consider the following:
 - a. Medication process node for focus (prescribing, dispensing, administration phase)
 - b. Time constraints
 - c. Logistical barriers
 - d. Personnel and resources
 - e. Acceptance and understanding of administrators and healthcare staff members being observed
4. Develop standardized data collection tool for consistency and reliability among observers
 - a. Data points for evaluation and recording
 - b. List of items or processes to observe
 - i. Reconstitution of IV medications using the correct diluent, volume, etc.
 - ii. Administration of IV medications for compatible IV medication and fluids, rate of infusion, etc.
 - iii. Compliance of institution/department policy and procedures when reconstituting chemotherapy agents
5. Identify observation group and frequency
 - a. Determine who and how many clinicians will be observed. Examples:
 - i. All new hires
 - ii. Random sample
 - iii. Healthcare specialty (ICU nurse, chemotherapy pharmacy technician, etc.)
 - b. Determine the time (morning, afternoon, evening) and frequency of observations
6. Train observers on proper technique (non-interruptive) and data collection.
7. Often the observer is not intended to perform the evaluation of MEs since their purpose is to observe and collect data. A group of experienced patient safety clinicians should

use the information to conduct an assessment of errors. This assessment would include comparing documented, observed data to actual medication orders.

8. Document the results in a central location so that the information may be used for quality improvement and systematic changes within the institution.
9. Suggested resources for direct observation method:
 - a. Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. *Arch Intern Med* 2002;162:1897-903.
 - b. Barker KN, Flynn EA, Pepper GA. Observation method of detecting medication errors. *Am J Health Syst Pharm* 2002;59:2314-6.

B. Evaluating a Possible ADE After Suspicion

Recommendation: Use a reliable and valid ADE causality assessment instrument can aids in the evaluation of suspected ADEs.

Description: An algorithm or questionnaire should be designed to assist with the determination of causality between drug administration and a patient-related event (i.e. bleeding, mental status changes, dysrhythmia). Assessment with a causality instrument offers a more objective assessment approach and more consistency in clinician assessment than not using an instrument. An ADE causality instrument is also useful in the evaluation process of a non-targeted and targeted chart review.

Process:

1. Select an instrument that is reliable and valid for aiding in the assessment of causality. Several instruments are available. Refer to reference for possible instrument options.
 - a. Agbabiaka TB, Savovic J, Ernst E. Methods of causality assessment of adverse drug reactions. *Drug Safety* 2008;31:21-37.
2. Educate clinicians on the availability of the ADE causality instrument and make the instrument widely available to the clinicians.
3. Identify a location in the electronic medical record where the results of an ADE assessment using the instrument can be documented.