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# ONC HITECH Electronic Clinical Quality Measures (CQM) Development

# Options Paper – MU-2 Adverse Drug Events (ADE)

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## 1.0 SITUATION

The Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology Policy Committee proposed the development of an adverse drug event (ADE) reporting measure that would be calculated by ONC-certified electronic health record (EHR) technology and would be available as a clinical quality measure for use in the Centers for Medicare and Medicaid Services (CMS) EHR Incentive Program. The ONC asked a team led by Booz Allen Hamilton to continue the development of this ADE reporting measure as part of a contract for development of new clinical quality measures for the EHR Incentive Program. The goals of such a measure would be to measure the rate of ADE occurrence and track improvement over time.

In this document, the Booz Allen team provides a summary of evidence provided by ONC-identified subject matter experts, other related resources, and relevant experience of the team members. Based on this summary and on how ADE reporting aligns with clinical quality measurement, the Booz Allen team presents several options for developing an ADE reporting measure.

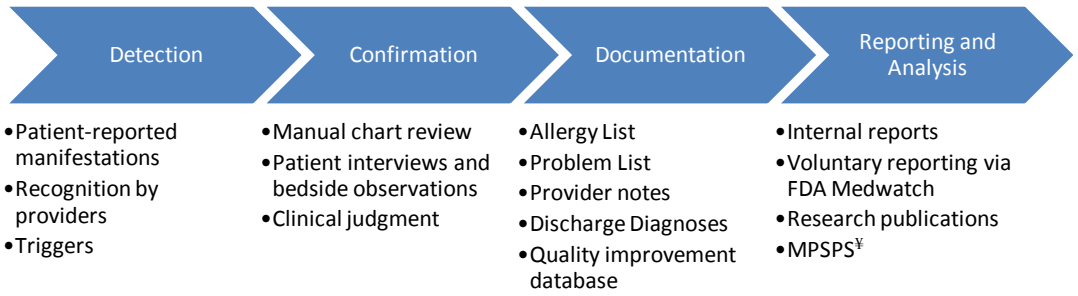
## 2.0 BACKGROUND

Adverse drug events are the most frequent type of adverse event experienced by patients. The World Health Organization, US Food and Drug Administration (FDA), and the Joint Commission have advocated for the establishment of hospital-based drug safety programs. In order to assess the prevalence of ADEs and to identify opportunities for their prevention, these drug safety programs include ADE surveillance and reporting. In order for the results of surveillance efforts to be comparable, standards must be used for case definitions, surveillance protocols, and data elements for reporting.

In the US, the FDA coordinates post-marketing surveillance of pharmaceuticals via its MedWatch program. Voluntary reporting by health care providers is the current mainstay of this program. The FDA maintains a database of ADEs that are spontaneously, voluntarily reported through its MedWatch program and collected in the FDA Adverse Event Reporting System (AERS). FDA AERS has a mechanism for electronically submitting individual case reports; however, the technical standards required to submit reports to FDA AERS are not currently included in the ONC Standards and Certification Criteria for EHR Technology.

Computerized voluntary ADE reporting systems have aimed to encourage providers to report ADEs. However, when compared to other valid methods of ADE surveillance (e.g., manual chart review and computerized detection), voluntary reporting by providers has been shown to underestimate the true prevalence of ADEs. Thus, the use of voluntary reports for clinical quality measurement may lead to inaccurate ADE rates. There is also concern that having a clinical quality measure for reporting to CMS could inhibit reporting because the rate may be perceived as reflecting negatively on performance.

**Figure 1 – ADE surveillance workflow and the data that supports each activity**




¥ MPSPS = Medicare Patient Safety Monitoring System

However, ADE detection and measurement is improved in routine surveillance. In general, the workflow of ADE surveillance is similar to that of other surveillance programs (Figure 1). The steps are: detection, confirmation, documentation, reporting and analysis. This process is described in several peer-reviewed journal articles on ADE surveillance and typically involves manual chart review by a trained clinician or researcher in at least one step of the process. Triggers (e.g., alerts or signals based on patient data) are used to indicate that an ADE may have occurred (Table 1). Specifically trained clinical or research personnel investigate the cases identified by these triggers, through manual review of the information contained in the medical record. In some studies, ADE triggers were built into the logic of EHR systems, which enhances the detection of ADEs. However, presence of a trigger alone is insufficient evidence of an ADE. Additional data is required to confirm an ADE, such as the use of a suspected causative agent, specific signs/symptoms consistent with the ADE, and the indication for use of an antidote or rescue medication (i.e., intervention to treat the ADE). This investigation also includes the exclusion of underlying medical conditions that may have been the actual cause of the abnormal sign or symptom.

**Table 1 – IHI Global Triggers (from the medication module of the IHI Global Trigger Tool)**

| Trigger | Causative Drug | EHR Location | Vocabulary | Additional Data Required† |
|---|---|---|---|---|
| Clostridium difficile-positive culture | Antimicrobials | Laboratory result | LOINC or SNOMED CT | • Recent antibiotic use |
| Partial thromboplastin time greater than 100 seconds | Anticoagulants | Laboratory result | LOINC | • Bleeding<br>• Drop in Hgb/Hct<br>• Bruising |
| International normalized ratio greater than 6 | Anticoagulants | Laboratory result | LOINC | • Bleeding<br>• Drop in Hgb/Hct<br>• Bruising |
| Glucose less than 50 mg/dL | Hypoglycemics | Laboratory result | LOINC | • Lethargy or shakiness<br>• Administration of glucose |
| Rising BUN or serum creatinine greater than 2 times baseline | Antimicrobials and radiocontrast agents | Laboratory result | LOINC | • Non-medical cause of acute renal failure |
| Vitamin K administration | Anticoagulants | Pharmacy order or medication administration | RxNorm | • Bleeding<br>• Drop in Hgb/Hct<br>• Bruising |
| Benadryl (diphenhydramine) use | Various classes | Pharmacy order or medication administration | RxNorm | • Indication for use (e.g., allergic reaction) |
| Romazicon (Flumazenil) use | Sedatives/ benzodiazepines | Pharmacy order or medication administration | RxNorm | • Hypotension<br>• Sedation<br>• Indication for use |

| Trigger | Causative Drug | EHR Location | Vocabulary | Additional Data Required† |
|---|---|---|---|---|
| Antiemetic use | Various classes | Pharmacy order or medication administration | RxNorm | • Indication for use (e.g., medication-associated reaction) |
| Naloxone use | Analgesics/narcotics | Pharmacy order or medication administration | RxNorm | • Hypotension<br>• Sedation |
| Oversedation/hypotension | Analgesics/ narcotics | Signs/symptoms or vital signs | SNOMED CT | |
| Abrupt medication stop | Various classes | Pharmacy order | RxNorm | • Reason for stopping medication |

† Confirmation of all triggers requires the identification of the suspected causative agent.

Source: Griffin FA, Resar RK. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2009. (Available on www.IHI.org)

In order to develop an EHR-based measure, we considered the list of desirable attributes of a clinical quality measure. These attributes are relevance, scientific soundness and feasibility. Based on review of the literature provided by ONC and additional references, a clinical quality measure for inpatient ADEs fulfills the relevance attribute because this measure would be meaningful, important, and would support health care systems' efforts to improve their performance. In terms of scientific soundness, a clinical quality measure for ADEs would fulfill the criterion of clinical evidence and validity in certain instances where action can be taken to prevent ADEs and where there is high agreement that an ADE has occurred. However, an EHR-based ADE measure would not fulfill the criteria of accuracy and comparability of data sources, since ADE surveillance methods and reporting practices vary across health care settings due to the lack of a universally accepted protocol. For the attribute of feasibility, precise specifications of an EHR-based ADE measures can be created. However, the resources needed to implement a formal ADE surveillance program – which includes time and personnel to confirm ADE triggers – may prevent an organization from implementing and/or acting upon an ADE measure. Since EHRs are not currently required to support the ADE surveillance and reporting workflow, EHR-based measures may not be logistically feasible until EHR system and vocabulary standards are established.

There are several barriers to the development of a clinical quality measure of ADE rates that can be calculated automatically by an EHR system. At this time, there is no widely accepted gold standard for either ADE detection or reporting. ADE triggers are indicators of the occurrence of ADEs and require confirmation by specifically trained personnel. While many ADE triggers may be available in EHR systems, they are not intended to be used alone to estimate the occurrence of ADEs. The confirmation of an ADE detected by a trigger is inherently subjective, which leads to decreased inter-rater reliability (Classen 2008). ADE triggers can be found in several parts of a patients' EHR, including narrative notes. However, current methods for clinical quality measures rely on the availability of data that is discrete, represented using standard vocabulary codes, and stored in structured fields. These barriers are

challenges that need to be addressed in order to create valid, reliable and comparable measures of ADE occurrence.

Fortunately, an initial set of standards – established or recommended – are available to support the creation of an EHR-based clinical quality measure for ADEs. In September 2011, the ONC Health IT Standards Committee's Clinical Quality Measures Workgroup and the Vocabulary Task Force jointly recommended vocabulary standards for the clinical concepts needed in an ADE measure. These are listed in the column "Vocabulary" found in Table 1 above. The standards include:

- RxNorm for medications that caused the adverse [drug] effect
- LOINC for laboratory test names and results that indicate the occurrence of an adverse [drug] effect
- SNOMED CT for the adverse [drug] effect itself and, if applicable, for applicable test result values.

Using these standard terminologies and the clinical categories provided by the NQF Quality Data Model, a limited-function clinical quality measure can be developed initially as a building block for future, more robust versions. In order to achieve this within the timeframe for Meaningful Use Stage 2, the ADE measure needs to be focused on a narrow scope, such as a particular drug class, type of manifestation, type of provider action, or source of information.

# 3.0 Analysis and Options for Meaningful Use Stage 2 (MU-2)

## 3.1 Option 1: Development of a structural measure of ADE documentation in EHR systems

The act of documenting in the EHR the occurrence of an ADE is not a measure of Meaningful Use for Stage 1. Creation of a Stage 2 Measure of Meaningful Use would create a standard for EHR capabilities, clinical documentation workflow, and representation of ADEs using standard vocabulary terms and codes. This would address important barriers to the development of a clinical quality measure.

- Advantages:
  - Establish EHR system capabilities needed for future development of an clinical quality measure for ADEs (e.g., location in EHR to document ADEs)
- Disadvantages
  - Would not provide a clinical quality measure for ADEs in Stage 2

## 3.2 Option 2: Develop a Trigger-Based Clinical Quality Measure Focused on a Specific Manifestation or Type of Reaction (e.g. drug allergies or abnormal lab result)

The clinical quality measure of *potential* ADEs would assess the percentage of patients with an inpatient admission during the measurement year who had at least one lab result-based trigger that occurred during the inpatient admission. Since triggers require clinical confirmation using additional data and information that is potentially not available discretely in the EHR system, the accuracy of this measure would vary according to the predictive test characteristics of each trigger.

We would need to decide whether or not an abnormal lab result alone would fulfill the case definition of an ADE. For instance, the IHI Global Trigger Tool protocol indicates that a patient on the anticoagulant

Warfarin who has an INR value greater than 6 would not have experienced an ADE unless the patient had signs of bleeding. In contrast, a patient who had received antibiotics and has a positive result for Clostridium difficile would have experienced a true ADE as per the IHI Global Trigger Tool protocol.

- Advantages
  - If focused on drug allergies, a clinical quality measure would utilize an EHR component established by the ONC Standards and Certification Criteria: patient Allergies
  - If focused on laboratory result-based trigger, a clinical quality measure's the trigger and the additional data required to detect and confirm the ADE is more likely to be available in the EHR system as per ONC Standards and Certification Criteria than symptom-based triggers (e.g., over sedation) and medication-based triggers that are not antidotes (e.g., abrupt medication stop).
- Disadvantages
  - The patient Allergies list may not consistently differentiate between historic allergies and newly occurring allergies.
  - Not all data needed to confirm a laboratory-based trigger may be available discretely in the EHR system. This would include signs, symptoms, and underlying medical causes of the abnormal lab value.

If additional data were not available, the false positive ADE rate may be unacceptably high for use in a CMS program.

### 3.3 Option 3: Develop a Trigger-Based Clinical Quality Measure Focused on the Use of an Antidote or Reversal Agent

The use of an antidote (aka reversal agent or rescue drug) indicates that an adverse event may have occurred, was recognized and action had been taken. A clinical quality measure of *potential* ADEs would assess the percentage of patients with an active inpatient order for a particular drug (e.g., Warfarin or narcotic pain medication) who had received an antidote (e.g., vitamin K or naloxone) during that inpatient stay.

- Advantages
  - The triggers based on antidotes or reversal agents (e.g., vitamin K or naloxone) may be more specific to ADEs than other medication-based and laboratory-based triggers. This is due to the assumption that the use of an antidote indicates that the provider is taking some action in response to an ADE.
- Disadvantages
  - Antidotes and reversal agents can be administered for reasons other than ADEs. For example, vitamin K may be given to a patient about to undergo a surgical procedure. These situations would need to be excluded from the calculation of the measure, which would be difficult without knowing the indication for administering the medication. Exclusions may not reliably be stored as discrete, coded data in an EHR-system.
  - Reversal agents may be given at the bedside from floor stock without explicit entry as a Medication order or administrated medication.

## 3.4 Option 4: Develop a Clinical Quality Measure that Relies on ADEs Explicitly Documented in the EHR System

ADEs that are explicitly documented as Problems or Discharge Diagnoses during an inpatient stay indicate that a provider recognized and acknowledged the occurrence of an ADE. An EHR-based clinical quality measure would assess the percentage of patients with an active inpatient order for a targeted medication who had an ADE documented in their EHR record during the same inpatient stay.

- Advantages
  - Both Meaningful Use Stage 1 and the ONC Standards and Certification Criteria for EHR Systems provide technical standards for the use and maintenance of the Problem List. The Problem List is a likely place to detect ADEs documented by providers.
  - This measure can be focused on a particular drug class for which documentation by providers in the EHR system is likely (e.g., narcotic over sedation).
  - Triggers for the specific type of ADE may be included in the measure logic as confirmatory evidence to improve the accuracy of the measure.
- Disadvantages
  - As with voluntary reporting, rates of ADEs based on provider documentation are lower than rates based on manual chart review or formal ADE surveillance programs.
  - Without explicit training and education, the inter-rater agreement between providers may affect the accuracy and comparability of ADE rates.
  - No specific ADE documentation standards exist for EHR systems, such as which specific concepts to use for ADEs or in which part of the EHR system to store them.

## 3.5 Option 5: Develop a Clinical Quality Measure of Outpatient Medication Monitoring for Patients on Chronic Medications

We identified one outpatient measure concept for the prevention of ADEs, which is based on a recommendation made by the ONC HITPC Patient Safety Tiger Team. This process measure would assess appropriate lab tests ordered at reasonable intervals for patients on any of the following medications: Warfarin, ACE inhibitors, ARBs, diuretics, Metformin, and atypical neuroleptics. The clinical quality measure would assess the percentage of patients with active orders for these targeted medications who had orders for appropriate laboratory orders at the expected intervals during the measurement year.

- Advantages
  - This measure focuses on ADE prevention for Meaningful Use Stage 2
  - If future ONC Standards and Certification Criteria support explicit documentation of ADEs, then this initial process measure can serve as a building block for an ADE outcomes measure for Meaningful Use Stage 3.
- Disadvantages
  - This process measure would not generate an ADE rate

## 4.0 RECOMMENDATIONS

Based on the discussion above, we recommend either *Option 3: Develop a trigger-based clinical quality measure focused on the use of an antidote or reversal agent for Meaningful Use Stage 2* for the inpatient setting or *Option 5: Develop a clinical quality measure of outpatient medication monitoring for patients on chronic medications* for the outpatient setting. For either option, the time available from the present until the June 2012 delivery date would allow only feasibility testing for this measure. Additional testing (e.g., reliability) would occur after June 2012. The results of testing and updates to the measure would be available in future versions of the measure.