

Identifying, Predicting, and Preventing Adverse Drug Events (ADEs): The Need for Standardized ADE Terminology, Coding, Documentation, and Consistent Clinical Usage in Electronic Health Records

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**Pharmacy Health Information
Technology Collaborative**



Table of Contents

- 1. INTRODUCTION 3
- 2. PURPOSE..... 3
- 3. ISSUES 3
- 4. RECOMMENDATIONS 4
- 5. BACKGROUND..... 4
- 6. DISCUSSION 6
- 7. CONCLUSION..... 14
- 8. REFERENCES..... 14
- 9. ADDITIONAL RESOURCES..... 15
- 10. APPENDIX 17
- 11. ACKNOWLEDGMENTS31



1. INTRODUCTION

Adverse drug events (ADEs) and adverse drug reactions (ADRs) are medical categories pertinent to all health care professionals, particularly pharmacists, involved in medication management. ADEs and ADRs are detectable and possibly preventable with appropriate measures. Predicting ADEs and ADRs through the use of clinical decision support systems (CDSS) and electronic health records (EHRs), however, is failing because of certain fundamental reasons.

As indicated through environmental scanning of ADE/ADR processes, specific reasons for not being able to predict ADEs and ADRs surfaced:

- ADE and ADR terms are being used interchangeably and not consistently.
- The impact of the inconsistent usage of standardized codes.
- Clinical workflow steps as related to documentation, the use of inconsistent (non-standard) terminology, and the exchange of patient-specific ADE/ADR reporting.

These variables, as well as the issues surrounding them, are the primary focus of the discussion throughout this paper.

2. PURPOSE

This paper is intended to raise awareness about the health care void that exists because of the lack of structured data sets to code medication response information for the purpose of data management, automated intake, and electronic exchange. It will not address nor endorse any specific drug side effect categorization hierarchy. Discussions presented will show how the reasons for not being able to predict ADEs/ADRs and their underlying issues have contributed to the lack of structured data sets needed to code medication response information affect patient care.

3. ISSUES

- Non-consistent definitions for terms pertaining to ADEs/ADRs are being used throughout health care.
- ADE/ADR information is not codified to make it usable and exchangeable.
- EHR workflow for providers to correctly code allergy and ADE information using diagnostic codes is lacking.
- Manual capture of ADE/ADR data and subsequent transcription to electronic data is inconsistent, especially concerning the correction of existing paper and electronic forms and data set structures within the EHR's terminology for ADE/ADR data capture.



4. RECOMMENDATIONS FOR ACTION

- The health care industry needs to develop and adopt consistent definitions for ADEs/ADRs for use across all segments of health care.
- The health care industry must enhance the ability to correctly interpret and capture data regarding ADEs.
- To resolve the issues surrounding the clinical support decision (CDS) workflow process, ADE data should be further broken into potential, observed, confirmed, and reported ADEs.
- Documentation workflow of ADE/ADR in the patient electronic health record must be improved.
- Health systems must be able to capture codes that can be imported and exported across both pharmacy systems and external systems (e.g., registries).

Significant negative outcomes directly attributable to the current lack of uniformity around documenting ADEs have created a major gap in the provision of high-quality health care. This includes not only proper use of terminology during verbal communications but also on paper forms and in IT systems. It is crucial that pharmacists take a significantly more active role and ownership of this responsibility. The pharmacy profession needs to establish standards for how this is to be achieved in both electronic health record (EHR) user interfaces and the functionality that systems will require to document a clinician's actions, as well as making them interoperable with systems used by other health care professionals.

5. BACKGROUND

For many years, pharmacy has struggled with controlling the identification and reporting of ADEs. ADEs cause approximately 1.3 million emergency department (ED) visits and 350,000 hospitalizations each year. Based on data from 42,585 cases, an estimated four ED visits (95% CI, 3.1-5.0) for adverse drug events occurred per 1000 individuals annually in 2013 and 2014 and 27.3% (95% CI, 22.2%-32.4%) of ED visits for adverse drug events resulted in hospitalization. (Sahab 2016).

In 1988, in a bibliography of 250 selected references, Kraynak and Kier described 14 distinct categories of literature, emphasizing the complex scope of the field of reporting ADEs. (Kraynak 1988) Among these, the authors cited work from individuals whom they identified as pioneers in this area of research from the two decades prior. Their earliest citation, from 1965, is part of a collection of studies by Cluff and Seidl that led to an early proposed architecture for categorizing and documenting ADEs. Pertinently, their paper includes an early definition ("An Adverse Reaction: Any Adverse Response to a Medication Undesired or Unintended by the Prescribing

Physician"); a categorization structure consisting of probability (of the drug being the cause), severity, and mechanism; and a statement regarding deficiencies in being able to capture the information accurately and consistently. They noted a need for greater uniformity of reporting and detection. (Seidl 1965) Several additional citations covered by the bibliography further highlight the many difficulties associated with correctly documenting and reporting ADEs and provide additional considerations for a practitioner or software engineer involved in ADE monitoring and ADR diagnoses.

The health care industry needs to develop and adopt consistent definitions for ADEs/ADRs for use across all segments of health care.



In the report on medication safety by the Institute of Medicine National Resource Council (IOM NRC), the issue concerning the need for greater uniformity, reporting, and detection of ADEs was further emphasized: “Significant confusion exists about the most fundamental issue in quantifying medication errors. One broad definition of medication errors is any inappropriate use of a drug, regardless of whether that use resulted in harm.” (Nebeker et al., 2004). Other definitions include only medication errors that have the potential to produce harm, or “clinically significant medication errors.” (IOM NRC 2007)

It is also important to consider transmission methods of ADE information into organized collection systems, known as registries. The electronic transfer of this information enhances the ability of organizations, such as the U.S. Food and Drug Administration (FDA), to process, review, store, and analyze this information. As summarized by the FDA, electronic submission improves collection, aggregation and analysis of ADEs. This promotes more rapid review of ADE data (identifies and evaluates emerging safety problems) for the dissemination of safety information.)

The FDA Adverse Event Reporting System (FAERS) has long been regarded as a model for ADE documentation and tracking. Since the inception of FAERS in 1969, the application of the 14 million recorded ADE reports have been used on an aggregate data repository level. FAERS clinical relevance from a patient-specific perspective, however, is limited because

- data is from spontaneous reporting;
- data includes duplicate reports;
- reports may be missing information;
- existence of a report does not establish causation or definitive association;
- information is not verified or medically confirmed;
- rates of occurrence cannot be established – there is no denominator; and
- a definitive association cannot be established. (U.S. Food and Drug Administration, FAERS Public Dashboard)

To harmonize ADE reporting, the U.S. Department of Health and Human Services (HHS) Office of Disease Prevention and Health Promotion (ODPHP), with 13 government agencies and subject matter experts, published the National Action Plan for Adverse Drug Event Prevention (ADE Action Plan). (U.S. Department of Health and Human Services 2014) Because ADEs represent a large portion of hospital readmissions and deaths, the ADE Action Plan was established to address two key objectives: (1) identify common, preventable, and measurable adverse drug events (ADEs) that may result in significant patient harm, and (2) align the efforts of Federal health agencies to reduce patient harms from these specific ADEs nationally. They also expanded the scope of data to be documented, stored, analyzed, and reported by pharmacy IT systems.

“Significant confusion exists about the most fundamental issue in quantifying medication errors.”



6. DISCUSSION

Pharmacists are often responsible for ADE/ADR/allergy/medication error identification, investigation, documentation, and intervention. Documentation forms a basis for tracking and reducing recurrence. However, this documentation can be missed in medical charts where such information is not readily apparent to all members of the care team. Thus, medication errors and ADEs records that may contribute to the success of patient care are regularly missed.

The health IT industry continues the march toward full interoperability between disparate systems. A primary goal of this interoperability is to have patient information available to all appropriate care providers, including ADE information. However, ADE terminologies are inconsistent, making ADE information from another system effectively unavailable for patient care (the various ADE terms used are defined and presented in Table 1, Appendix). The lack of consistency and accuracy of ADE information also impacts the ability to analyze ADE information from multiple systems to derive important insights on ADEs and patient care. Greater use of new technologies, such as machine learning (ML) and artificial intelligence (AI), will provide further insights into each patient's needs and help with the inconsistency in terminology.

Terminology surrounding medication events across the national and international landscapes remain widely inconsistent, contributing to the confusion around the establishment of a standardized approach to structured data collection and exchange. In order for ADE information to be electronically transmitted, a common language or codified language is needed. The codification of health diagnosis has been established by ICD-10 (International Classification of Diseases) codes. (Hohl 2014) In like manner, ADE information will need to apply a same or similar set of codes so that the information can be documented, stored, transferred, interpreted, and made actionable irrespective of the system platform used. Therefore, it becomes important to establish a common set of standards for ADE definitions and capture. Tightly controlled ADE data capture, when embedded into an EHR, will then exist as an interoperable dataset that can follow a patient to other EHR systems.

Figure 1 provides a visual model showing relationships between the various medication response categories: medical errors, side effects, ADE, ADR, and allergies. Each grouping represents a result that may evidence itself after a medication is administered and is often an unintended outcome from that which the drug was originally prescribed. Regardless of the manner that individual health care providers interpret the most logical hierarchy of prescription drug side effects, simply stated, they represent varying degrees of response to medication and thereby can collectively be referred to as medication response information.

When an individual patient experiences a serious negative response to a medication, such as drug-induced thrombocytopenia or acute renal compromise, it is important that the outcome be attributed to a specific, causative medication where possible, but also (and possibly more importantly) that the medication-response event be retained via a standardized data format similar to ICD-10 or other unique transferable format for reproducibility upon future patient encounters.

Because of the lack of a codified nomenclature, as illustrated by the varying definitions and categorizations in Table 1 (see Appendix), the Pharmacy HIT Collaborative (PHIT) recommends a consistent set of definitions and hierarchy for all aspects of ADEs, including each drug or drug product administered to a patient, as well as signs and symptoms – and diagnoses – associated with an ADE. Most importantly, it is imperative that pharmacists take a leadership role in the application of these definitions consistently and accurately in an effort to reduce the existing lack of clarity regarding cause-and-effect relationships. This should diminish today's inconsistency exhibited by practitioners in all health care professions when diagnosing and documenting an ADE and the drug or drug product which may have caused it.

It is imperative that all ADE terminology be properly positioned within health care, in general, and pharmacy, in particular. Using relational algebra – a common mathematical foundation conceptually utilized by most relational database management systems (RDMS) throughout a large number of technology platforms – will achieve proper positioning of ADE terminology. Relational algebra was

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developed by Edgar “Ted” Codd and others and was built on a set-based mathematical model using logic theory. (Association for Computing Machinery)

Relational algebra is a commonly used categorization scheme in pharmacy informatics, as well. (Butler 2012) This logic is easily illustrated using a Venn diagram (Figure 1) to show the relationship of the drug therapy entities associated with the terms drugs, drug products, ADEs, ADRs, drug allergies, and medical errors used throughout this document.

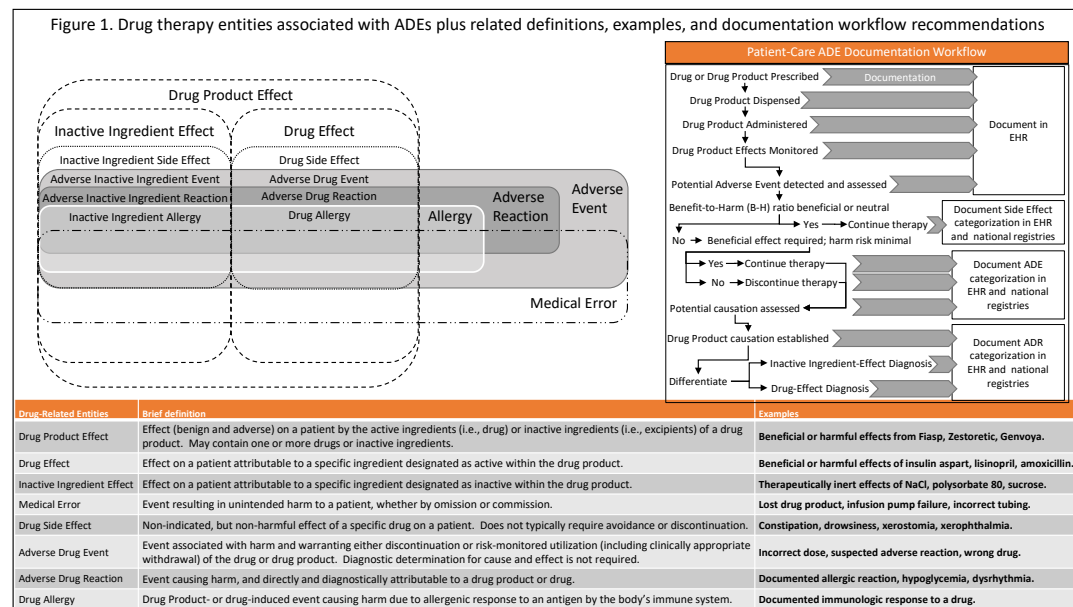


Figure 1 created by Pharmacy HIT Collaborative

THE SIGNIFICANCE SURROUNDING THE LACK OF ADE/ADR DATA SETS AND STANDARDIZED TERMINOLOGY

With the sophistication and specificity applied to the structured data exchange of coded information for medical diagnosis (ICD-10), outpatient services and procedures (CPT, CPT II), clinical concepts (SNOMED CT), laboratory (LOINC), medical equipment/supplies (HCPCS), pharmacy products (NDC), clinical drugs (RxNORM), CCD, C-CDA (XML) and ORU (HL7), all patient-specific medication response information should be coded in a similar fashion.

When EHR and provider level data are transferred to health plans, pharmacies, and institutions, the clinical medication outcome documentation is absent from clinical decision support and machine learning. The reason the data are absent is because the standard coding of medication response data (ADE and ADR information) is not included as recognized categories within EHRs. Codification of ADEs, ADRs, and medication response data represents an underrecognized and critical component of data intelligence needed to drive appropriate medication use.

Unfavorable response, adverse reaction, and medication intolerance information is traditionally documented under the “Allergy” section of the EHR. This causes unstructured text or natural



language processing (NLP) to generate unusable data content for the purpose of exchange. Medication response information remains trapped within the EHR and held dormant at the individual health care encounter level. To be usable, this information needs to be transformed into a structured data format with a structured data model for system consumption. ADE and ADR data are not usable when measuring quality measures such as adherence.

EXAMPLE

Statin prescribing and medication adherence are a significant focus of medication quality measures under the CMS Medicare Part-D Stars program. The benefit of statin therapy is based upon population statistics that have shown an overall lower incidence of cardiac risk in patients with diabetes or atherosclerotic cardiovascular disease (ASCVD). The strong emphasis for the national recommendation to promote statin prescribing is premised on population-wide statistics that reference overall population percentages as a justification for statin benefit without accounting for statin allergy, intolerance, and side effect data that are collected and documented in pharmacy systems. CMS does not have access to statin allergy data (it is not coded for exchange) that is found only within the pharmacy system or EHR. This data void perpetuates a vicious cycle where CMS contracts with insurance companies to further communicate back to provider groups about patient gaps where a statin is found to be missing from the patient's medication regimen. The recommendation is then made by the payer group to promote statin use by patients, wherein statin intolerance may have been previously confirmed by the provider but documented as an allergy.

CLINICAL DECISION SUPPORT WORKFLOW FOR ADE, ADR, AND ALLERGIES

This section covers the health care provider CDS workflow for capturing, documenting, and using ADE, ADR, and drug allergy information in text-field or NLP format. Inconsistent non-standardized terminology affects CDS documentation, as will be shown in the example that follows.

The power of ADE information in an EHR comes when structured ADE documentation is made actionable through CDSS. More accurate and consistent ADE and ADR integration into CDSS would allow CDS functionality to become more sophisticated by increasing specificity and sensitivity. CDSS can incorporate ADE information with other aspects of the patient's medical record to predict potential (or recurrent) ADEs prior to manifestation. CDSS can also recommend methods to mitigate an ADE. Aside from critical medical response to an adverse event (e.g., managing anaphylaxis), CDSS can take into account the lifetime patient record, including prior ADEs, to recommend immediate (post-critical) management. If long-term ADE management is needed, CDSS augmented with ADE information can refine that management.

A concern is when integrating ADE and CDS workflow relates to the granularity of the ADE information. ADE information at the drug class level forces the CDSS to produce recommendations based on the entire drug class. This can lead to recommendations that, while valid for medications in that class, are not relevant to the situation at hand, particularly with regard to investigating an ADR.

EXAMPLE

The EHR system populated an alert to a patient-reported, potential allergy to the drug lisinopril, stat-



To resolve the issues surrounding the CDS workflow process, ADE data should be further broken into potential, observed, confirmed, and reported ADEs.

ing reaction of angioedema. While the patient was admitted to the hospital, the practitioner placed an order for enalaprilat (Vasotec IV). Although the event/reaction to lisinopril was documented as an allergy, the allergic reaction (angioedema) was not listed anywhere as a previous medical diagnosis. The reaction was serious enough to warrant alternative therapy; however, in this case, had the ADE/ADR been coded at the time of occurrence and standard data terminology applied, confirming the ADR and outcome, the patient may not have needed to self-report the serious medication event to their provider.

Medication ADE/ADR, allergy, and intolerance documentation is critical historical information that is entered into a system's CDS workflow that triggers notifications, flags, or medication prescribing alerts that are programmed to prevent a repeat adverse event (AE) from occurring. Issues surrounding this process are that these alerts contribute to alert fatigue, do not have functionality that extends beyond the ordering and pharmacy verification process, and are safety notifications that can be easily overridden.

The standards development organization, Health Level 7 (HL7), established an AE workflow within the HL7 Fast Healthcare Interoperability Resources (FHIR) that includes standardized data sets for capturing AEs. HL7 FHIR focuses on potential or avoidable events and actual events causing unintentional injury requiring treatment, hospitalization, or death. (HL7 FHIR Release 4.0.1). HL7 Medical History could include information from these FHIR resources to track an adverse event:

- "AdverseEvent – These would be filtered to only extract issues that would not qualify as 'adverse events', but were still potentially study-relevant (perhaps having occurred prior to the study).
- "AllergyIntolerance – captures both the propensity to reaction as well as specific reaction occurrences.
- "Condition – used to capture healthcare problems as well as other conditions (e.g., pregnancy).
- "Observation – captures symptoms, assessments, non-study pertinent lab results (e.g., blood type), etc." (HL7 FHIR to CDISC)

Although HL7 AE workflow captures standardized data sets, if standardized terminology is not consistently used, then the clinical workflow and exchange to other systems using HL7 is a problem. The HL7 AE workflow does not capture a complete AE process capturing potential and the investigation leading to a confirmed ADE:

RECOMMENDATIONS TO IMPROVE ADE WORKFLOW

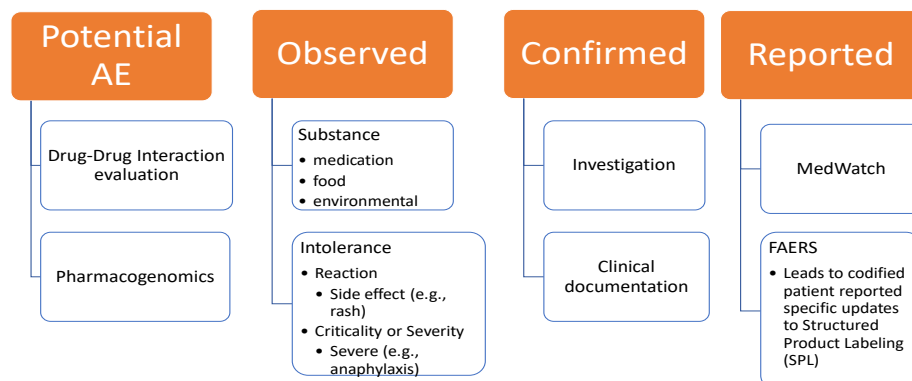
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Pharmacists use potential ADE information to prevent an ADE.

ADE Provider Workflow



Created by Pharmacy HIT Collaborative

POTENTIAL AND OBSERVED ADE WORKFLOW

Potential AEs are events that may not be drug related. Potential ADEs may or may not have reached the patient and did not result in harm to the patient. Observed ADEs are events that reached the patient and caused harm. An observed ADE refers to an outcome that may be directly observed or noted to be occurring while the suspected causative agent was consumed by the patient.

Current ADE documentation does not differentiate a potential ADE from an observed or confirmed ADE. Differentiating the type of ADE is important to informing clinical management decisions while avoiding misdirected care. Pharmacists use potential ADE information to prevent an ADE (e.g., evaluation of potential drug-drug interactions or using pharmacogenomics to predict ADE).

In order to have a complete ADE/ADR workflow, where clinical decision support algorithms can be used, each of the recommended categories should be interconnected in the EHR documentation process. Currently, the documentation is separated and not interconnected.

As a uniform language is established for ADE/ADR, the clinical documentation should allow the integration into the workflow of elements such as:

- Diagnosis – identifying potential ADEs and determining whether an ADR has occurred.
- Observation – monitoring of and documenting ADEs and initiating clinical interventions, including care and diagnostic procedures.
- Outcomes – population health, pharmacovigilance, and cost analyses to determine the ADE impact on care and best practices.

Historical ADEs are another possible classification that are not reflected in the workflow. Historical ADEs refer to adverse outcomes that have reportedly occurred in the past but no longer require intervention. Documentation of historical ADEs assists in better continuity of care. One common example of a historical ADE is when a patient experienced an allergic reaction to penicillin in their childhood but no longer responds with a drug allergy as an adult.

Events also may be further subdivided into preventable and non-preventable ADEs. Preventable ADEs are typically associated with a medication error, which indicates a flaw is present in the current verification process. Preventable ADEs, as medical errors, must also be evaluated according to the principle of ethical malfeasance. (Blumenthal 2011) Nonpreventable medication errors are not

associated with a medication error, indicating that the event would not have been preventable no matter the number of refinements that go into a verification process. Unintentional drug overdoses



(such as starting a patient on a dose appropriate to the patient's presentation but resulting in too strong of a response) and allergic reactions can fall into either category, depending on documentation of the prior history.

INVESTIGATION TO CONFIRM ADES

In order to have a complete picture of an AE, an investigation should occur to determine if the event was drug related. If it is drug related, then it gets documented as an ADR.

EHR and pharmacy IT systems should codify medication reactions to be specific enough to document the intolerance (reaction) to the medication. Current systems use a medication therapeutic class within CDS to investigate the reaction to the specific ingredient or product. This leads to inaccurate documentation of adverse drug and allergy reporting, which may cause alert fatigue and prescribing errors.

Desired functionality should include the capability to capture documentation that accounts for the severity of the reaction, including the specificity pertaining to the clinical manifestation (symptom) of the patient's physiologic reaction (e.g., immunological response, environmental response) along with the level of criticality (e.g., rash, hives, anaphylaxis). This creates a process to route medication response information through a triage pathway where potential and observed response are investigated and confirmed. Once an AE investigation is identified as an ADE, the clinical documentation should be updated to appropriately impact clinical decision support tools and reporting.

REPORTING ADES

MedWatch is the FDA's adverse event reporting program that interacts with the FDA [FAERS, though it has some limitations, as previously noted](#). FAERS is a database that includes reported ADEs identified in clinical trials and is one resource for the development of standardized information structure for ADEs. There are elements in FAERS, which have discrete values (e.g., an associated set of terms), that can be considered a resource for AE data elements or standardized terminology. If the AE investigation is severe enough to be reported through MedWatch, having standardized codified data documented in the EHR about the ADE helps make the electronic reporting into FAERS more efficient.

FAERS sets a baseline for standardizing ADE information, though it does not drive further standardization within its system and has its own distinct definition for an ADE. FAERS defines ADE as "Adverse Event - drug reaction is also known as a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death, or are birth defects." (U.S. Food and Drug Administration)

In terms of the submission process, an EHR user must go to the FDA MedWatch data entry page to enter the ADE information. Alternatively, a paper form can be submitted.

The FDA MedWatch system utilizes and recommends the following categories for data collection and EHR ADE documentation:

- Patient Information: age, sex, weight, ethnicity, race



- Event or problem encountered
 - Outcome: death, life-threatening; hospitalization (initial or prolonged, other serious; disability or permanent damage; congenital anomaly/birth defect)
 - Relevant tests/laboratory data
 - Relevant history and preexisting conditions
 - Suspected products (up to two)
 - Product name, strength, NDC, manufacturer; lot #
 - Dates of use
 - Indication for use
 - Compounded/over the counter
 - Event abated when product stopped
 - Event recurred if product restarted
- Device Information
 - Brand name, common name, device class code
 - Model #, catalog #, serial #, lot #, expiration date, UDI
 - Manufacturer
 - Device operator
 - Implant date, explant date
- Single use device reprocessed/reused; reprocessor
- Reporter information

CHANGING PHARMACY PRACTICE RELATED TO ADES

Whether in community, outpatient clinics, or acute care settings, the use of various technologies from pharmacy IT vendors must enable pharmacists to routinely interview and assess patients for potential ADEs and document those actions and their outcomes as a key component in their routine practices. In some pharmacy situations, this may include routine physical exams and laboratory tests to evaluate and reduce therapeutic risk any time a prescription is newly dispensed, refilled, or administered.

Pharmacists must be able to alert other practitioners to the need for routine assessment of patients for potential adverse events with concomitant documentation. Pharmacists must be vigilant in safeguarding a correct and proper designation for an ADR assigned to a component of drug products, whether a drug or an inactive ingredient, during the assessment, investigation, and documentation process. Pharmacists and pharmacy IT vendors must also ensure vigilant, ongoing, and accurate reporting of ADEs to agencies and organizations involved in the surveillance, prevention, and research focus areas for the National ADE Action Plan. (U.S. Department of Health and Human Services)

For example, patients are often asked by a provider, “do you have a history of any allergic reactions to a medication,” and the patient may state a reaction of nausea from codeine. The fields on forms themselves that both patients and providers complete are commonly labelled as “Drug Allergies”



The vast majority of documentation on adverse effects is incorrectly documented as a drug allergy when it should be documented or coded as an ADE.

rather than “Adverse Drug Events.” Thus, the vast majority of documentation on adverse effects is incorrectly documented as a drug allergy when it should be documented or coded as an ADE. The problem with coding codeine intolerance as an allergy is that the system will alert the clinician with a drug class notification stating the patient is allergic to opioids which requires clarification in order to provide opioid medication for pain management.

EHR and pharmacy IT systems must also be able to capture a chemical description or therapeutic drug class category that allows alerts, including smart alerts, based on the drug product, drug, or inactive ingredient that specifically triggers the ADE based on the risk and applicability to a patient against multiple drugs or an entire drug class. EHRs must overcome the lack of functionality to capture and account for clinical severity and any manifestation pertaining to a patient’s physiologic reactions, including an immunological response and other environment factors. There should be an appropriate categorization of potential and observed allergic or adverse drug events, as well as intolerances.

Current deficiencies among clinical systems cause barriers to the transfer and use of these important sets of safety data. They also reduce usability by providers for appropriately assessing, monitoring, and responding to the physiologic effects of a potential ADE, regardless of the category (whether a drug allergy or other pharmacologic action).

Extensive effort must be made to incorporate full health care team feedback to develop this new model and process for collecting, documenting, validating, grouping, and subgrouping all ADEs in a standardized fashion, so data integrity may be maintained and applied to a patient’s care as it is transferred and communicated between systems. In addition, a long-term objective should be to eventually allow near real-time transfer of data in a manner that can recognize changes, and then simultaneously alert providers and other systems to those changes, as well as transmit an ADE event reporting.

In order to change pharmacy practices, pharmacy IT system vendors are encouraged to build systems supporting the following initiatives for pharmacy:

- Consistent and accurate categorizations and hierarchies must be standardized and codified so that pharmacists do not inappropriately call a drug product a drug, an ADR a drug allergy, or an ADE an ADR.
- Pharmacists must advocate for health-system-wide programs to relabel all forms where the term “drug allergy” is used inappropriately to capture ADE information, and the term “drug” is inappropriately used to capture drug product information. Pharmacists must also educate all practitioners of the importance of this differentiation for improving patient care and safety.
- Pharmacists in all practice settings must enhance ADE monitoring when filling and refilling prescriptions, as well as during any patient encounter involving a pharmacist’s authority and responsibility for drug therapy, plus correctly applying drug product, drug, inactive ingredient, ADE, ADR, and drug allergy terminology.

7. CONCLUSION

Although drug safety researchers, many years ago, coined the term “adverse drug event” as a way to identify and categorize possible harm to patients caused by prescription drugs, pharmacists and



other health care professionals continue to struggle with standardized identification, documentation, and reporting of ADEs. Over time, ADEs evolved to include various subsets (e.g., ADR, side effect), each with different meanings and inconsistent usage not only among individual health care practitioners, but also among the various health care organizations and government agencies who also use these terms (see Appendix (Table 1) for detailed information as to how these same terms are defined differently by various groups).

As noted throughout this paper, in some cases, ADEs are identifiable, preventable, and in many instances predictable. If ADE terminology is standardized, coded, used consistently, and documented accurately, this can be leveraged to improve patient safety, reducing potential and actual harm caused by medications prescription drugs.

This paper identifies specific areas where challenges exist and provides recommendations to move ADE prevention forward. These areas also provide the pharmacy profession opportunities to collaborate with other health care professionals and government agencies to standardized terminology, coding, and usage to bring about consistency in identifying and preventing ADEs. This paper is the first step in that direction.

The pharmacy profession not only has a shared responsibility with other health care professionals and organizations for appropriately overseeing use and classification of ADEs, but it must also embrace a leadership role in overcoming today's many discrepancies and inconsistencies that encumber the correct categorization of ADEs.

ADE terminology is standardized, coded, used consistently, and documented accurately; this can be leveraged to improve patient safety, reducing potential and actual harm caused by medications prescription drugs.

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10. APPENDIX

Table 1. Standards Organizations and Governmental Agencies' Variances in Definitions Applicable to



Drug, Drug Product, Ingredient, Adverse Drug Event , Adverse Drug Reaction, Drug Allergy, and Side Effect

Agency	Term	Definitions
FDA	Drug	• A substance recognized by an official pharmacopoeia or formulary. • A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. • A substance (other than food) intended to affect the structure or any function of the body. • A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device. • Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)
	Drug Product	• The finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients
	Biologic Product	Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies. In general, the term “drugs” includes therapeutic biological products.



Agency	Term	Definitions
	Active Ingredient	An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.
	Inactive Ingredient	An inactive ingredient is any component of a drug product other than the active ingredient. Only inactive ingredients in the final dosage forms of drug products are included in this database.
	Side Effect	Side effects, also known as adverse events, are unwanted or unexpected events or reactions to a drug. Side effects can vary from minor problems like a runny nose to life-threatening events, such as an increased risk of a heart attack.
FDA GMP	Component	Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.
	Drug	Has the same meaning as “drug” listed for FDA Drug on page 18.
	Drug Product	Drug product means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.



Agency	Term	Definitions
	Active Ingredient	Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.
	Inactive Ingredient	Inactive ingredient means any component other than an active ingredient.
	In-process material	In-process material means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the drug product.
FDA PET GMP	PET Component	Component means any ingredient intended for use in the production of a PET drug, including any ingredients that may not appear in the final PET drug product.
	Positron Emission Tomography (PET) Drug	PET drug means a radioactive drug that exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for providing dual photon positron emission tomographic diagnostic images. The definition includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of a PET drug. "PET drug" includes a "PET drug product" as defined in this section.
	PET Drug Product	PET drug product means a finished dosage form of a PET drug, whether or not in association with one or more other ingredients.



Agency	Term	Definitions
	PET Active Pharmaceutical Ingredient	Active pharmaceutical ingredient means a substance that is intended for incorporation into a finished PET drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis or monitoring of a disease or a manifestation of a disease in humans, but does not include intermediates used in the synthesis of such substance.
	PET Inactive Ingredient	Inactive ingredient means any intended component of the PET drug other than the active pharmaceutical ingredient.
	PET in-process material	In-process material means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and is used in, the preparation of a PET drug.
NRC IOM	Error	The failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). An error may be an act of commission or an act of omission (IOM, 2004).
	Medication error	Any error occurring in the medication-use process (Bates et al., 1995a). Examples include wrong dosage prescribed, wrong dosage administered for a prescribed medication, or failure to give (by the provider) or take (by the patient) a medication.
	Adverse Event	An adverse event is an injury caused by medical management rather than the underlying condition of the patient.
	Adverse drug event	Any injury due to medication (Bates et al., 1995b). Examples include a wrong dosage leading to injury (e.g., rash, confusion, or loss of function) or an allergic reaction occurring in a patient not known to be allergic to a given medication.
	Injury	An injury includes physical harm (for example, rash), mental harm (for example, confusion), or loss of function (for example, inability to drive a car).



Agency	Term	Definitions
	Medication Error, ADE, ADR	The terms medication error, adverse drug event, and adverse drug reaction denote related concepts (see Figure 1-1) and are often used incorrectly.
	Medication	Medication encompasses three broad categories of products—prescription and nonprescription drugs and dietary supplements—all regulated by the FDA
	Biologic Product	Biologic products (including vaccines, blood, and blood products) are a subset of. Biologics are distinguished from other drugs by their manufacturing process—biological as opposed to chemical. Some biologics, principally vaccines (excluding their long-term effects), are within the scope of this study; blood and blood products and tissues for transplantation are excluded.
	Drug	drug is defined as a substance that is recognized by an official pharmacopeia or formulary; intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; intended to affect the structure or any function of the body (excluding food); and intended for use as a component of a medicine, but not a device or a component, part, or accessory of a device. Drugs include both those that require a prescription and those that do not. Nonprescription drugs are usually termed over-the-counter (OTC).



Agency	Term	Definitions
	Dietary Supplement	often called complementary and alternative medications, are another group of products often used for medicinal or general health purposes. The Dietary Supplement Health and Education Act of 1994 (P.L. 103-147) defined a dietary supplement as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient cited above.
HHS National Action Plan for ADE Prevention	ADE	An adverse drug event (ADE) is an injury resulting from medical intervention related to a drug. This includes medication errors, adverse drug reactions, allergic reactions, and overdoses. ADEs also may be caused by a medication error, intentional overdose, or other inappropriate use (of an otherwise appropriate drug)."
	ADR	A subtype of an ADE that stems directly from taking an appropriate dose of the drug.
CDC Medication Safety Program	ADE	Adverse drug events are harms resulting from the use of medication and include allergic reactions, side effects, overmedication, and medication errors.



Agency	Term	Definitions
ODPHP	ADE	Preventable or amenable ADEs include medication errors (e.g., errors in the dose of drug administered) or adverse events that are outcomes resulting from harm caused by medical care that could have been mitigated in duration or severity by heightened monitoring or better health care management. An adverse drug event has been defined by the Institute of Medicine as “an injury resulting from medical intervention related to a drug”. This broad term encompasses harms that occur during medical care that are directly caused by the drug including but are not limited to medication errors, adverse drug reactions, allergic reactions, and overdoses.
	ADR	...an adverse drug reaction (ADR) is “harms directly caused by a drug at normal doses”. A subtype of an ADE that stems directly from taking an appropriate dose of the drug. ADEs also may be caused by a medication error, intentional overdose, or other inappropriate use (of an otherwise appropriate drug).
	Medication Error	A medication error is defined as “inappropriate use of a drug that may or may not result in harm;” such errors may occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring of a drug.
NCI	Adverse Event	An Adverse Event (AE) is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure. An AE is a term that is a unique representation of a specific event used for medical documentation and scientific analyses. Each CTCAE v4.0 term is a MedDRA LLT (Lowest Level Term).



Agency	Term	Definitions
FAERS	Adverse Event	Adverse Event - drug reaction is also known as a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death, or are birth defects.



Agency	Term	Definitions
AHRQ	Adverse Drug Event	See Primer. An adverse event (i.e., injury resulting from medical care) involving medication use. Examples: anaphylaxis to penicillin; major hemorrhage from heparin; aminoglycoside-induced renal failure; agranulocytosis from chloramphenicol. As with the more general term adverse event, the occurrence of an ADE does not necessarily indicate an error or poor quality of care. ADEs that involve an element of error (either of omission or commission) are often referred to as preventable ADEs. Medication errors that reached the patient but by good fortune did not cause any harm are often called potential ADEs. For instance, a serious allergic reaction to penicillin in a patient with no prior such history is an ADE, but so is the same reaction in a patient who has a known allergy history but receives penicillin due to a prescribing oversight. The former occurrence would count as an adverse drug reaction or non-preventable ADE, while the latter would represent a preventable ADE. If a patient with a documented serious penicillin allergy received a penicillin-like antibiotic but happened not to react to it, this event would be characterized as a potential ADE. An ameliorable ADE is one in which the patient experienced harm from a medication that, while not completely preventable, could have been mitigated. For instance, a patient taking a cholesterol-lowering agent (statin) may develop muscle pains and eventually progress to a more serious condition called rhabdomyolysis. Failure to periodically check a blood test that assesses muscle damage or failure to recognize this possible diagnosis in a patient taking statins who subsequently develops rhabdomyolysis would make this event an ameliorable ADE: harm from medical care that could have been lessened with earlier, appropriate management. Again, the initial



Agency	Term	Definitions
	Adverse Drug Reaction	Adverse effect produced by the use of a medication in the recommended manner -(e.g., a drug side effect). These effects range from nuisance effects (e.g., dry mouth with anticholinergic medications) to severe reactions, such as anaphylaxis to penicillin. Adverse drug reactions represent a subset of the broad category of adverse drug events - specifically, they are non-preventable ADEs.



Agency	Term	Definitions
EMA Pharmacovigilance Practice Guidelines	Adverse Event	Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product (see GVP Annex IV, ICH-E2D Guideline). The following will apply when Regulation (EU) No 536/2014 becomes applicable (see ** on page 3): In the context of a clinical trial: any untoward medical occurrence in a subject to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment. In the context of pharmacovigilance and outside a clinical trial: any untoward medical occurrence in a patient to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment (based on ICH-E2D Guideline, see GVP Annex IV). An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product (see GVP Annex IV, ICH-E2D Guideline).
	Adverse Event Following Immunization	



Agency	Term	Definitions
	Adverse Reaction	Adverse reaction; synonyms: Adverse drug reaction (ADR), Suspected adverse (drug) reaction, Adverse effect, Undesirable effect. A response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility (see GVP Annex IV, ICH-E2A Guideline). An adverse reaction, in contrast to an adverse event, is characterised by the fact that a causal relationship between a medicinal product and an occurrence is suspected. For regulatory reporting purposes, if an event is spontaneously reported, even if the relationship is unknown or unstated by the by healthcare professional or consumer as primary source, it meets the definition of an adverse reaction. Therefore all spontaneous reports notified by healthcare professionals or consumers are considered suspected adverse reactions, since they convey the suspicions of the primary sources, unless the primary source specifically state that they believe the event to be unrelated or that a causal relationship can be excluded. Adverse reactions may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure. Use outside the marketing authorisation includes off-label use, overdose, misuse, abuse and medication errors. See also Adverse event, Serious adverse reaction, Unexpected adverse reaction, Off-label use, Overdose, Misuse of a medicinal product, Abuse of a medicinal product, Medication error, Occupational exposure to a medicinal product



Agency	Term	Definitions
	Vaccine Product-Related Reaction	An adverse event following immunisation that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product (see CIOMS-WHO21). In this definition immunisation means the usage (handling, prescribing and administration) of a vaccine for the purpose of immunising individuals (see CIOMS-WHO21), which in the EU is preferably referred to as vaccination (in the report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance the terms immunisation and vaccination are used interchangeably21).
WHO	Adverse Drug Event	Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment
	Adverse Drug Reaction	Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function
WHO Guidelines for Pharmacovigilance	Adverse Event	Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with this treatment.
	Adverse Drug Reaction	A response to a medicine, which is noxious and unintended, and which occurs at doses normally used in humans.
	Serious Reaction	A serious reaction is an adverse drug reaction which involves any of the following: death or a life-threatening experience; hospitalization or prolongation of hospitalization; persistent significant disability; congenital anomaly.



Agency	Term	Definitions
Veterans Administration	Adverse Drug Event	An adverse drug event (ADE) is an injury resulting from the use of a drug. This umbrella term encompasses all harms caused by a drug, including those intrinsic to the active pharmaceutical product (e.g., adverse drug reactions [ADRs], allergies) or due to the manner in which the drug is used, whether appropriate or inappropriate (e.g., overdoses).
	Adverse Drug Reaction	Various adverse effects, including allergic and pharmacologic reactions, that typically occur when a drug product is prescribed at doses normally used for treatment (the types of ADEs most likely to be encountered in clinical practice).
ASHP	Adverse Drug Reaction	Any unexpected, unintended, undesired, or excessive response to a drug that: 1. Requires discontinuing the drug (therapeutic or diagnostic) 2. Requires changing the drug therapy 3. Requires modifying the dose (except for minor dose adjustments) 4. Necessitates admission to a hospital 5. Prolongs stay in a health care facility 6. Necessitates supportive treatment 7. Significantly complicates diagnosis 8. Negatively affects prognosis, or 9. Results in temporary or permanent harm, disability, or death
	Side Effect	An expected, well-known reaction resulting in little or no change in patient management (e.g., drowsiness or dry mouth due to administration of certain antihistamines or nausea associated with the use of antineoplastics). An effect with a predictable frequency and an effect whose intensity and occurrence are related to the size of the dose.



Agency	Term	Definitions
	Allergic Reaction	An immunologic hypersensitivity, occurring as the result of unusual sensitivity to a drug.
ICD9	800-999: Injury and Poisoning; 990-995: Other and Unspecified Effects of External Causes; 995: Certain adverse effects not elsewhere classified; 995.20: Unspecified adverse effect of unspecified drug, medicinal and biological substance	Approximate Synonyms: Adverse drug reaction; Adverse effect of drug; Adverse reaction to drug; Central sleep apnea, due to drug or substance; Drug induced central apnea (disorder); Drug intolerance; Lichenoid drug eruption; Lichenoid drug reaction; Medication side effects present; Side effect of medication; Sleep apnea, central, due to drug or substance; Applies To; Unspecified adverse effect of unspecified medicinal substance properly administered.
ICD10	S00-T88: Injury, poisoning and certain other consequences of external causes: T36-50: Poisoning by, adverse effect of and underdosing of drugs, medicaments and biological substances	Includes: adverse effect of correct substance properly administered; poisoning by overdose of substance; poisoning by wrong substance given or taken in error; underdosing by (inadvertently) (deliberately) taking less substance than prescribed or instructed.

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