

ADVERSE DRUG EVENTS: Understanding the Basics Improves Patient Safety

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Adverse drug events (ADEs) have become one of the greatest threats to patient safety with the ever-increasing number of drugs available on the market. Sharing information through ADE reporting is an essential first step in identifying system issues and reducing potential patient harm. Unfortunately, confusion over the different types of ADEs such as adverse drug reactions (ADRs) and medication errors can often hinder reporting. Healthcare providers may not be aware of their reporting responsibilities or the appropriate way to report an ADE. In their 2009 review of determinants of under-reporting of adverse drug reactions, Lopez-Gonzalez et al. found that provider lack of knowledge about ADRs and the ADR reporting process was present in over 90% of published studies analyzed.¹ The purpose of the following article is to provide basic information about the different types of ADEs and to review the importance of ADE reporting.

DEFINITIONS:

- An **adverse drug event (ADE)** is a negative consequence of medication use encompassing both mistakes that result in harm to the patient (preventable ADEs) and adverse drug reactions (unavoidable ADEs).²
- An **adverse drug reaction (ADR)** is an unintended and undesired side effect of a drug that occurs when the drug is used in a manner appropriate for the patient's clinical condition. ADRs can be predictable or unpredictable.^{2,3}
- A **medication error** is a mistake in any part of the medication use process (prescribing, transcribing, dispensing, administering, or monitoring) that may or may not result in harm to the patient.³ (See Table 1)

THE IMPORTANCE OF REPORTING ADVERSE DRUG EVENTS

ADEs have been associated with prolonged hospital stays, increased healthcare costs, and a higher risk of death.⁴ The Adverse Drug Event Prevention Study Group determined that ADEs occur in 6.5 of every 100 hospital admissions, with 42% of events being either serious or life-threatening.^{5,6} In 2000, the number of patient deaths attributable to ADRs was reported to be approximately 218,000 annually.⁷ The average cost of an ADE has been estimated to be more than \$2,000, amounting to an excess cost of over \$5.6 million per year for an average-sized teaching hospital.⁸ Research has determined that excessive dosage (42%), drug interactions (4.6%), patient identification errors (3.5%), and cases of known drug allergies (1.5%) are the leading causes of preventable ADEs.^{9,10}

Medication error reporting is vital to the detection of medication error trends and patient safety. Data trending and benchmarking are used for staff education and development of risk reduction strategies. Institutions rely on frontline reporting to understand where vulnerabilities exist and improve the medication use process. Understanding the importance of reporting and a safe and nonpunitive culture is imperative in promoting reporting. In addition to institutional reporting systems, there are nonprofit and federal organizations devoted to medication error prevention and safe medication use. The Institute for Safe Medication Practices (ISMP) (www.ismp.org) is a nonprofit national organization devoted to medication error prevention and safe medication use. Data extracted from voluntary confidential medication error reports submitted to the ISMP Medication Errors Reporting Program (MERP) may be used to identify medication error trends and alert healthcare providers to the risks via ISMP-generated case studies or medication safety briefs. Organizations such as ISMP rely on information from the healthcare community in order to fulfill their mission to improve patient safety.

What reporting responsibilities does a UWMC/HMC healthcare provider have if a patient experiences an adverse drug event?

- Providers are strongly encouraged to report all ADEs via PSN.
- All providers should consider it their responsibility to report any serious ADE they encounter in practice to MedWatch.
- In addition, medication errors can be reported to the ISMP Medication Errors Reporting Program (MERP), a confidential national voluntary web-based reporting program.

WAC 246-873-080 on Hospital Standards requires:

“All adverse drug reactions shall be appropriately recorded in the patient’s record and reported to the prescribing practitioner and to the pharmacy.”

Reportable ADRs at UWMC/HMC include those that are serious enough to require a change in therapy (i.e., drug discontinuation, dosage reduction, or initiation of an additional therapeutic intervention to manage the reaction).

To report ADRs (including allergies) at UWMC, providers may also call:

ADR phone line: 206-598-6837

Allergy phone line: 206-598-0333

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Clinical trials do not always capture the full range and severity of a drug’s side effect profile. Post-marketing surveillance that includes healthcare provider and patient reporting of adverse drug reactions to the Food and Drug Administration (FDA) MedWatch program facilitates better understanding of drug safety profiles. Information from such reports allows FDA to keep healthcare providers updated on the potential adverse effects of drugs via safety alerts, and may result in mandated changes to drug labeling. Important decisions on product changes and recalls are oftentimes based on voluntary reporting of adverse drug reactions.

HOW AND WHERE TO REPORT ADVERSE DRUG EVENTS

- 1) **Patient Safety Net (PSN)** is a web-based reporting tool accessible from any UW Medicine computer terminal. UW healthcare providers are strongly encouraged to report all ADEs via PSN. PSN is easy to use and prompts the user to enter specific information about an event. Providers should be as specific as possible when filling out a PSN report. PSN reports are used to identify patient safety concerns within the institution and are reviewed by departmental and ancillary managers. The PSN reporting system is accessible at: <https://www.uhc.edu/home.htm>.
- 2) **MedWatch** is the FDA’s web-based reporting tool for reporting ADEs and product problems. All reports are confidential. All healthcare providers should consider it their responsibility to report any serious ADE they encounter in practice to MedWatch. FDA mandates reporting of the following medication-related problems:
 - **Serious ADEs:** Includes those that result in death, hospitalization (initial or prolonged), disability, congenital anomalies, are life-threatening, or require intervention to prevent permanent impairment or damage.
 - **Product problems:** Includes possible counterfeit products, product contamination, poor packaging or product mix-up, questionable stability, device malfunctions, and labeling concerns.

The MedWatch online reporting form is accessible at:
<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.
- 3) **The Vaccine Adverse Event Reporting System (VAERS)** is the FDA’s web-based tool for reporting adverse vaccine-related events. Only certain adverse vaccine reactions are considered reportable. These are listed in the Table of Reportable Events Following Vaccination at the VAERS website. The VAERS online reporting form can be found at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.
- 4) **ISMP Medication Errors Reporting Program (MERP)** is a confidential national voluntary web-based reporting program. Providers are encouraged to report medication errors at the following URL: <https://www.ismp.org/orderforms/reporterrortoISMP.asp>.
- 5) **Patient medical record:** Under Washington state law, all adverse drug reactions should be documented in the patient’s medical record. This documentation is critical to prevent inadvertent medication rechallenges and to ensure patient safety. (See Table 2)

References are available on request.

TABLE 1: Drug Therapy Complication Definitions ^{2,3}

TERM	DEFINITION	PREVENTABLE?	EXAMPLE
Adverse Drug Event (ADE)	A negative consequence of medication use encompassing both errors that result in harm to the patient (preventable ADEs) and adverse drug reactions (unavoidable ADEs).	Sometimes	Either example A or C below.
Adverse Drug Reaction (ADR)	An unintended and undesired side effect of a drug that occurs when the drug is used in a manner appropriate for the patient's clinical condition. ADRs can be predictable or unpredictable.	No	A) Development of a first-time allergic reaction to a penicillin.
Medication Error	A mistake in any part of the medication use process (prescribing, transcribing, dispensing, administering, or monitoring) that may or may not result in harm to the patient.	Yes	B) An order for digoxin 0.25mg misinterpreted or mistakenly ordered as 2.5mg. Error caught before drug is administered . OR C) Error not caught, the wrong dose of digoxin is administered, and patient suffers harm

TABLE 2: Adverse Drug Event Reporting Summary

<p>If an adverse drug event occurs at UWMC/HMC, it is essential to:</p> <ul style="list-style-type: none"> • Report the event to the patient's medical team, the pharmacy, and file a PSN report. • Reportable ADRs at UWMC/HMC include those that are serious enough to require a change in therapy (i.e., drug discontinuation, dosage reduction, or initiation of an additional therapeutic intervention to manage the reaction). Document reportable ADRs in the patient's medical record. Reportable ADRs should be entered in the patient's allergy profile in ORCA and in the outpatient pharmacy medical record to allow appropriate systems allergy checking. • Where appropriate, file a FDA MedWatch report, a VAERS report, or an ISMP MERP report.

P&T COMMITTEE BRIEF SUMMARY July 21, 2009 through September 15, 2009

FORMULARY ADDITIONS (click here for monograph)

Clevidipine (Cleviprex®) Added 09/15/09	
CLASS	Calcium channel blocker
PLACE IN THERAPY	For rapid control of blood pressure when oral therapy is not a feasible or desirable option.
DOSAGE FORMS	0.5mg/mL (50mL, 100mL) vial
USUAL STARTING DOSE	1-2mg/hr IV infusion
UW RESTRICTIONS	Use restricted to anesthesia providers in the OR.

OTHER ACTIONS

09/15/09	Docusate products	An AUTO-SUBSTITUTION was approved that allows pharmacy to interchange the following products based on availability: docusate sodium 200mg = docusate sodium 250mg = docusate calcium 240mg.
09/15/09	Erythromycin ophthalmic ointment	Due to current limited availability, this product will be RESTRICTED to use in neonates as it is the only commercially available product approved for prophylaxis of ophthalmia neonatorum due to <i>N. gonorrhoeae</i> or <i>C. trachomatis</i> .

- ADVERSE DRUG EVENTS: Understanding the Basics Improves Patient Safety, p1-p3
- P&T Committee Brief Summary, p3
- UWMC/HMC Adverse Drug Reaction Summary, back cover



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UWMC/HMC ADVERSE DRUG REACTION SUMMARY

FISCAL YEAR 2008/2009 • 4TH QUARTER (APRIL 2009-JUNE 2009)

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- A total of 72 adverse drug reactions (ADRs) were reported at UWMC this quarter.
- Nurses, pharmacists, and technicians reported these ADRs.
- The drug class for which the largest numbers of ADR reports were filed was anticoagulants - 26.
- The ADR reaction types[†] reported were: augmented - 3, hypersensitivity - 26, idiosyncratic - 19.
- Total number of ADRs with a harm score^{††} of F or greater - 5.
- Three ADR reports were submitted to FDA this quarter.

HARBORVIEW MEDICAL CENTER

- A total of 16 adverse drug reactions (ADRs) were reported at HMC this quarter.
- Nurses, pharmacists, and technicians reported these ADRs.
- The drug class for which the largest numbers of ADR reports were filed was antibiotics - 5.
- The ADR reaction types[†] reported were: augmented - 2, hypersensitivity - 9, idiosyncratic - 5.
- Total number of ADRs with a harm score^{††} of F or greater - 6.
- Four ADR reports were submitted to FDA this quarter.

[†] ADR reaction type definitions — **Augmented:** reactions consistent with the pharmacology of the drug; **Idiosyncratic:** unusual reaction independent of the pharmacology of the drug; **Hypersensitivity:** newly identified allergy or one previously identified; **False Alarm:** reaction deemed not related to drug therapy.

^{††} Harm score definitions — **D:** The event reached the individual and required additional monitoring or treatment to prevent harm; **E:** The individual experienced temporary harm and required treatment or intervention; **F:** The individual experienced temporary harm and required initial or prolonged hospitalization; **G:** The patient experienced permanent harm; **H:** The individual experienced harm and required intervention to sustain life (e.g., transfer to ICU); **I:** The patient died.

ERRATA: VOL. 38 NO.3

The following were accidentally omitted from the pharmacy phone number list on page 1:

HMC Medication Safety:
Jennifer Chang
744-6043

HMC Medication Utilization
and Quality Improvement:
Steve Riddle
744-6045