

**University of Michigan Health System  
Department of Pharmacy Services**

**Competency in Medication Safety**

Medication safety is the responsibility of all members of the healthcare team. As a valuable asset to our pharmacy staff, you should be able to appreciate the significance of medication errors. The purpose of this competency assessment is to help you appreciate the vital role that pharmacy plays in reducing the potential for medication error and the systems that have been implemented at UMHS to improve patient safety.

**What are the facts about adverse drug events and medication errors?**

1. Between 1993 and 1998, the FDA Adverse Event Reporting System recorded 5307 medication error reports (an additional 59 were classified as duplicate reports or intentional overdoses)<sup>1</sup>
  - **Medication errors were fatal in 9.8%** (N=469) of cases
  - 48.6% of deaths occurred in patients greater than 60 years of age
  - The **three most common causes of death were improper dose, wrong drug, and wrong route of administration**; collectively these represented approximately 66% of all deaths associated with medication errors.
  
2. The Institute of Medicine<sup>2</sup> reported that in the US
  - **7000 deaths occur yearly** due to medication errors
  - Medication errors account for one out of 131 outpatient deaths and one out of 854 inpatient deaths
  - **More than 100,000 deaths may occur yearly due to ADRs**
  - **The cost of preventable ADEs**
    - Approximately \$2.8 million yearly for a 700-bed teaching hospital
    - At a yearly salary of \$80,000, this is the equivalent of 35 full-time pharmacists
    - \$2 billion for the nation
  
3. Bates et al.<sup>3</sup> reported that 42% of ADE were judged as life-threatening (12%) or serious (30%)
  - **Of these ADEs, 42% were preventable** and were caused by:
    - Ordering errors (56%)
    - Administration errors (34%)
    - Transcription errors (6%)
    - Dispensing errors (4%)

References:

1. Phillips J, Beam S, Brinker A, et al. Retrospective analysis of mortalities associated with medication errors. *Am J Health-Syst Pharm.* 2001;58:1824–1829.
2. Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system.* Washington, DC: Committee on quality of health care in America, Institute of Medicine. National Academy Press. 1999.
3. Bates DW, Cullen DJ, Laird N. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *JAMA.* 1995;274:29–34.

### What initiatives have been implemented for medication safety?

1. **Standard Administration Times** - working with the Medication Safety Committee, we developed standardized medication administration times. This synchronizes the pharmacy records with nursing.
2. **New Medication Administration Record (MAR) Format** - new MARs were introduced in July 2000. The MAR provides much more information and allows the nurse to better check the order with the drug that is being administered. The new MAR was developed in conjunction with the recommendation of the Institute of Safe Medication Practice (ISMP).
3. **New Medication Labels** - new labels were implemented in all inpatient units. The new labels are larger, clearer and contain much more information.
4. **Drug Name Standardization** - the pharmacy department has been standardizing the names of medications on the MARs, labels and packaging. For many drugs, the department is printing both common drug trade names and generic names to increase recognition and improve safety.
5. **Improved pharmacy clinical coverage** - pharmacy services is working to improve pharmaceutical care for our patients. Our efforts include advanced clinical training for our pharmacists and assigning more pharmacists to the floors to work with patients, physicians and nurses.

### What initiatives are planned for the future?

1. **Physician order entry** – The medication use system has been identified as the initial focus for the clinical information system. Pharmacy Services is playing an active role in helping to develop a comprehensive system including physician order entry of medications and electronic charting of administration.
2. **MedSafe Committee** – previously called MUPIC, the Medication Safety (MedSafe) Committee is co-chaired by John Mitchell, PharmD and Maureen Thompson, BSN. This committee will concentrate its efforts on reducing the potential of medication misadventures and promote a culture of patient safety relative to the drug delivery process. They will examine key sources of medication errors within UMHS, analyze literature to proactively reduce the likelihood of similar errors in our environment, educate staff, and encourage a non-punitive reporting of medication errors and near misses.
3. **MOC** – The Medication Operations Committee (MOC) is co-chaired by Stephanie Newland, MBA and Louise Grondin, RN, CNS. This committee will address operational issues that affect the day-to-day, staff level work of the nursing and pharmacy departments. They will explore issues such as IV drip standardization, STAT and NOW orders, revision of the MAR, and many other projects to improve workflow.

### Where is the Department's policy located for reporting adverse drug reactions?

The policies for the Department of Pharmacy Services are located on PharmWeb. Click on Policies and Procedures and then Pharmacy Administration. The policy for reporting adverse drug reactions is #324, portions of which are reprinted below

### 1. What is considered an adverse drug reaction in our policy?

- a) Adverse Drug Reaction (ADR): Any response to a drug that is noxious and unintended and that occurs in man at doses for prophylaxis, diagnosis, or therapy, including:
- b) New, rare, or previously poorly documented reactions.
- c) ADRs associated with newly marketed medications
- d) Serious, life-threatening, or fatal reactions.
- e) According to the Food and Drug Administration, a serious adverse event is one in which the patient outcome is death, life-threatening), disability, hospitalization (initial or prolonged), a congenital anomaly, or necessitates medical or surgical intervention to prevent permanent impairment or damage.
- f) Unusual increases in numbers or severity of reactions.
- g) Allergic reactions and idiosyncratic reactions are also considered ADRs, if they are deemed to be serious, life threatening, or fatal, as described above.

### 2. For the purposes of this policy, the definition of ADR shall not include:

- a) Adverse effects of the drug which are expected, well-known reactions which do not result in changing the care of the patient. These adverse effects are those effects occurring predictably and effects whose intensity and occurrence are related to the size of the dose.
- b) Drug withdrawal, drug-abuse syndromes, accidental poisoning, and drug-overdose complications also should not be defined as ADRs (e.g., drowsiness from diphenhydramine).
- c) Reactions which are extensions of the pharmacologic effect for which the drug is given (e.g., bone marrow suppression with antineoplastic agents).
- d) Disturbances totally dependent on the pathological state (e.g., diarrhea from cancer and not from a laxative).

### 3. How is the information reported on the MedWatch Form and how does it get reported to the FDA?

- a) Adverse drug reactions meeting at least one of the criteria stated in definition III A shall be reported.
- b) The individual who suspects or identifies the adverse drug reaction shall report the incident by calling the pharmacy or the Drug Information Service (936-8200).
- c) The Drug Information Service and all pharmacies shall have the Food and Drug Administration (FDA) Voluntary MEDWATCH Form ([FDA Form 3500, Exhibit A](#)) available for use at all times, and shall immediately record the required information on the form and contact the patient's primary physician when an ADR has been identified.
- d) Pharmacy staff members who detect a potential adverse drug reaction are responsible for investigating the suspected ADR. If the suspected ADR fits the ADR definition given above (section III A), the pharmacist shall obtain and complete the FDA Voluntary MEDWATCH Form and contact the patient's primary physician.
- e) The patient's primary physician shall note the potential ADR in the patient's medical record.

- f) The pharmacist shall forward the completed MEDWATCH Form to the Drug Information Service.
- g) The Drug Information Service shall record and file all ADRs.
- h) Medical Information Service shall provide the Drug Information Service with weekly reports of Event ("E") codes for ADRs that contain the patient name, registration number, and admission dates.
- i) The Drug Information Service shall check their files to see if a MEDWATCH Form has been previously filed for the patients identified using the "E" codes. If no report has been filed, the Drug Information Service shall review the patient's computerized medical information and determine if the "E" code may be considered an ADR necessary to report to the FDA. If the pharmacist considers the ADR necessary to report to the FDA, the patient's chart will be reviewed and a MEDWATCH form will be completed. All "E" codes will be reviewed by the Drug Information Service. A record will be kept of ADRs identified from "E" codes in order to provide a comprehensive ADR-monitoring and reporting program for the health-system.
- j) For those suspected adverse drug reactions that indeed are associated with the administration of the suspected agent and fit the definition of an ADR as provided in section III A, the Drug Information Service shall file copies of the Voluntary MEDWATCH Forms and shall forward the original form to the FDA.
- k) A copy of a form that is sent to the FDA shall also be sent to the manufacturer of the drug, if deemed necessary.
- l) The Drug Information Service shall report ADRs to the Pharmacy and Therapeutics Committee monthly, and the Continuous Quality Improvement Program office on a quarterly basis.

### **What is a Sentinel Event and what events fall into that category?**

1. A Sentinel Event is an unexpected occurrence involving death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. The following are also considered Sentinel Events:
  - a) Infant abductions
  - b) Infants discharged to wrong family
  - c) Rape by either another patient or staff
  - d) Hemolytic transfusion reaction
  - e) Surgery on the wrong patient or body part
  - f) Suicide of a hospitalized patient

### **How does this differ from a root cause analysis (RCA)? Who determines which events classify as a Sentinel Event? What steps should staff members take if they feel an event may be sentinel in nature?**

1. A Root Cause Analysis (RCA) is a systematic process to determine the underlying reasons for a sentinel event. The analysis focuses on systems and processes rather than individuals. The analysis repeatedly digs deeper by asking "Why?"; then, when answered, "Why?" again. The RCA assists in the identification of changes that should be made in systems and processes through redesign or new development, and that reduce the risk of reoccurrence

of the event. Root cause analyses will be completed within 45 calendar days for all sentinel events.

2. The Chief of Staff shall determine if the event meets the criteria for a sentinel event review. If so, Medical Center Risk Management (MCRM) shall conduct an initial investigation of the facts of the event and identify discipline(s) to participate in the review. Specific staff participants will be recommended based on the facts known.
  - a) The staff involved shall complete the following
  - b) Immediate stabilization of situation by clinical staff.
  - c) Responsible attending or resident physician should examine the patient and document the findings in the medical record for all sentinel events.
  - d) Immediate notification of attending physician, nurse manager/charge nurse, and/or department manager about the event. This is the responsibility of the staff discovering the event. (see Exhibit B)
    - The attending physician will notify the Service Chief(s), Departmental Chair(s)/designee. In the event of death, the attending will follow the reporting process for the Medical Examiner. See Death Certificate and UMHHC Post Mortem Care Policy # 02-03-002.
    - On weekends and after-hours, notify the Administrator-on-Call who will then determine the need for notifying MCRM
  - e) If the event is recognized as it is occurring or just after it has occurred, in addition to doing whatever is necessary for safety (including stopping any causative medications or treatments), leave everything else intact - i.e. leave pumps on but running into a receptacle, leave equipment in the room, etc.:
    - Leave all monitors/pumps ON. Save ALL syringes/vials/ IV bags/ tubing or other equipment and packaging in a plastic bag labeled with the patient's name.
    - Documentation by staff with knowledge of the event must be:
      - In the medical record: factual, descriptive, accurate and legible.
      - Incident Report Form: in accordance with UMHHC Policy # 03-07-001. (Staff should not write/keep any additional notes of the event).
  - f) For sentinel events involving patients enrolled in research, or research related equipment, the attending physician must inform the Internal Review Board (IRB) within seven working days of determining that a sentinel event has occurred.

### **What is the role of Risk Management and when should they be contacted?**

1. Risk Management strives to minimize the adverse effects of loss due to unforeseen events or situations, which could result in harm to patients, staff or visitors. Medical Center Risk Management strives to provide support services to all departments, faculty and staff, patients and visitors. This requires close coordination with, and cooperation from, the entire UMHS community for identification of potential risks and prompt notification of all situations that may result in harm to patients, staff or visitors.
2. Medical Center Risk Management should be contacted whenever a patient incident occurs. A patient incident is defined as whenever anything happens involving a patient that is not consistent with the routine operation of the hospital or the routine medical care of that

particular individual. It may be an accident or a situation, which might result in an accident; it may cause injury or have the potential for injury. There are many ways to contact Risk Management in the event of an incident:

**No injury:**

Fill out and send Incident Report form to Risk Management, L5003 Women's, Box 0275.

If medical equipment or devices are used, save the device and the packaging.

**Injury:**

Call Medical Center Risk Management ASAP - **734-763-5456**.

After regular business hours, call the Administrator on Call (AOC) if this is an event resulting in injury. This is done by calling **734-936-6267** and asking to speak to the AOC.

When in doubt, call Medical Center Risk Management. We will be happy to speak with you about any questions you might have.

**I have heard a lot about the ISMP. What does this organization do?**

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about adverse drug events and their prevention. The Institute provides an independent review of medication errors that have been voluntarily submitted by practitioners to a national Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in the USA. Information from the reports may be used by USP to impact on drug standards. All information derived from the MERP is shared with the U.S. Food and Drug Administration (FDA) and pharmaceutical companies whose products are mentioned in reports.

The Institute is an FDA MEDWATCH partner and regularly communicates with the FDA to help to prevent medication errors. The Institute encourages the appropriate reporting of medication errors to the MEDWATCH Program.

ISMP is dedicated to the safe use of medications through improvements in drug distribution, naming, packaging, labeling, and delivery system design. The organization has established a national advisory board of practitioners to assist in problem solving.

Their web site is <http://www.ismp.org/>

## What are some useful tips for preventing medication errors

<p><b>Abbreviations</b></p>	<ul style="list-style-type: none"> <li>• If any doubt exists, clarify rather than assume.             <ul style="list-style-type: none"> <li>• Is MSO4 morphine sulfate or magnesium sulfate?</li> <li>• Is CPZ chlorpromazine or Compazine</li> <li>• Is it Q.D or QID</li> </ul> </li> </ul>																		
<p><b>Watch for common types of errors</b></p>	<ul style="list-style-type: none"> <li>• “U” that looks like an extra zero for insulin and heparin orders</li> <li>• Decimal points written without a leading zero (eg, .5 versus 0.5)</li> <li>• Extra zeros that are written after a decimal point (eg, 20.0 on an order can look like 200)</li> </ul>																		
<p><b>Drug selection and the computer</b></p>	<ul style="list-style-type: none"> <li>• <u>Always</u> use the drug code to select the drug. The drug code carries with it important information from the drug files. Typing in the drug name bypasses patient safety check points and other important data such as information to print on the MAR, drug interaction alerts, etc</li> <li>• Make sure you select the correct drug after doing a search. Carefully read the full description before selection</li> </ul>																		
<p><b>Beware of look alike / sound alike drugs</b></p>	<ul style="list-style-type: none"> <li>• This type of error represent 1/3 of errors reported to ISMP</li> <li>• Example include (only a small sample of many):             <ul style="list-style-type: none"> <li>Lente versus Lantus insulin</li> <li>Cerebyx versus Celebrex</li> <li>Oxycontin versus oxycodone</li> </ul> </li> </ul>																		
<p><b>All drugs require your careful attention; however, some “high-alert” drugs have the highest potential of patient harm</b></p>	<ul style="list-style-type: none"> <li>• High alert drugs include drugs that have a low margin of safety or a high risk of patient injury if given incorrectly. Some examples include:             <table border="0" style="margin-left: 20px;"> <tr> <td>chemotherapy</td> <td>heparin</td> <td>digoxin</td> </tr> <tr> <td>theophylline</td> <td>IV calcium</td> <td>hypertonic saline</td> </tr> <tr> <td>insulin</td> <td>lidocaine</td> <td>IV magnesium</td> </tr> <tr> <td>narcotics</td> <td>warfarin</td> <td>IV potassium</td> </tr> <tr> <td colspan="3">neuromuscular blocking agents</td> </tr> <tr> <td colspan="3">oral hypoglycemic agents</td> </tr> </table> </li> </ul>	chemotherapy	heparin	digoxin	theophylline	IV calcium	hypertonic saline	insulin	lidocaine	IV magnesium	narcotics	warfarin	IV potassium	neuromuscular blocking agents			oral hypoglycemic agents		
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<p><b>Trust your instincts</b></p>	<ul style="list-style-type: none"> <li>• If you sense that the order is wrong, investigate before dispensing.</li> <li>• If you are unsure, consult with a colleague. It’s impossible to remember everything. Ask someone else even if you have a little doubt.</li> </ul>																		

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