

Name of Policy: <u>Adverse drug reaction reporting</u> Policy Number: 3364-100-70-02 Department: Hospital Administration Approving Officer: Chief Executive Officer Responsible Agent: Chief Medical Officer Scope: The University of Toledo Medical Center and its Medical Staff	 Effective Date: 10/1/2023 Initial Effective Date: March 8, 2000
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy

(A) Policy Statement

All adverse drug reactions (“ADR”) shall be reported in Patient Safety Net (PSN) or directly to pharmacy. An ADR is defined as any unexpected unintended, undesired, or excessive response to a that:

- 1.requires discontinuation of the drug
- 2.requires changing drug therapy
- 3.requires modifying the dose (except for minor dosage adjustments
- 4.necessitates admission to a hospital
- 5.prolongs stay in a health care facility
- 6.necessitates supportive treatment
- 7.negatively affects prognosis
- 8.results in temporary or permanent harm, disability or death. Uncommon reactions are those which occur in less than 5% of patients taking the drug. Unexpected reactions are those which have not been well described in the medical literature, and which are not obviously extensions of the therapeutic actions of the drug.

Definitions:

For reporting purposes: FDA categorizes a serious adverse event as one in which “the patient outcome is death, life-threatening, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage

Non-ADR

- 1.Side effect: well-known reaction resulting in little or no change in patient management (e.g. drowsiness for opioids or nausea from chemotherapy). Side effects are predictable in frequency and an effect whose intensity and occurrence are related to the size and dose.
- 2.Drug withdrawal, drug-abuse syndromes, accidental poisonings, and drug-over-dose complications are not ADRs

(B) Purpose of Policy

To monitor adverse drug reactions at the University of Toledo Medical Center. The data collected will aid the Pharmacy and Therapeutics Committee in its assessment of drug use, individual patient incidents related to drug use, and drug interactions, and will provide the basis for medical and nursing staff education that may minimize the occurrence of adverse reactions.

(C) Procedure

Appropriate documentation of the adverse reaction and treatment received must be made in the Medical Record. In addition, the reaction will be reported to the Pharmacy according to the following procedure:

A. Monitoring

- a. Ongoing and concurrent by pharmacists, nurses, physicians, and patients
- b. Prospective for high risk drugs and patients
- c. Monitoring alerting orders such as reversal agents
- d. Prescribers, caregivers, and patients should be notified

B.

Reporting Mechanism

1. Any member of the medical, nursing, pharmacy, or utilization review staff may initiate the report. The report should be initiated within 24 hours after the reaction is recognized. The report may be entered into Patient Safety Net or called into the "ADR Hotline", Ext. 8359. Suspected ADRs will also be identified through the AcuDose medication dispensing system.
2. The information on the report form will include:
 - ◆ Date of Report
 - ◆ Date of Reaction
 - ◆ Patient Location/Nursing Unit
 - ◆ Patient Name
 - ◆ Diagnosis (if known)
 - ◆ Known allergies/hypersensitivities
 - ◆ Drug suspected of causing reaction
 - ◆ Dose given and date/time dose given
 - ◆ Other concurrent drugs used within 24 hours (i.e., prescription, OTC, herbal, etc.)
 - ◆ Description of reaction
 - ◆ Treatment of reaction and response
 - ◆ Reporter name (optional)

C Pharmacy Review and Data Collection

1. The pharmacy will rate the ADR using predefined criteria as to probability, severity, and type of ADR.
2. Records will be kept of the number of reactions to each drug.
3. The pharmacy will provide the physician or nurse with any information that might prevent the recurrence of the adverse reaction, or which might allow treatment to shorten the duration of the reaction.
4. The pharmacy will assign a probability score in Patient Safety Net utilizing subjective questions and tools

D. Review by Pharmacy and Therapeutics Committee.

The Pharmacy and Therapeutics Committee will review adverse drug reactions that have been reported to the Pharmacy. One or more of the following actions may be taken:

1. The information may be provided to the manufacturer if the adverse reaction is not well known, or if the drug was only recently released for use
2. Medical or Nursing Staff may be informed of the reaction as a part of the educational function of the Pharmacy, and of the Pharmacy and Therapeutics Committee. Related information (recommended treatment of the reaction, ways to avoid the reaction, etc.) will also be provided. This will be done by memo, the Drug Information bulletin, Medical Staff Bulletin, or other means.
3. Depending on the nature of the reaction and its frequency, a drug utilization review may be initiated, and the committee may re-evaluate the inclusion of the drug in the Hospital Formulary.
4. Depending on the severity and type of reaction, a report should be filed with the FDA through the standard reporting mechanism.
5. Any other actions that may reduce the risk of recurrence of the adverse reaction, or serve to educate the nursing and medical staff.

<p>Approved by:</p> <p><u>/s/</u> <u>09/29/2023</u> Michael Ellis MD Chief Medical Officer Date</p> <p><u>/s/</u> <u>10/03/2023</u> Richard Swaine Chief Executive Officer Date</p> <p><i>Review/Revision Completed By:</i> HAS Chairman, Pharmacy & Therapeutics Committee Director, Pharmacy</p>	<p>Review/Revision Date:</p> <p>7/30/84 11/15/2010 4/15/86 11/01/2013 6/26/87 11/01/2016 12/14/88 11/18/2019 2/17/89 11/15/2022 5/9/90 8/1/2023 9/11/91 4/14/93 9/11/96 9/14/98 9/12/01 9/8/04 9/12/07</p> <hr/> <p>Next Review Date: 8/1/2026</p>
<p>Policies Superseded by This Policy: 7-70-02</p>	

References: ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting