(A) Policy Statement

All adverse drug reactions ("ADR") shall be reported to the Pharmacy. An ADR is defined as any serious, unexpected or uncommon response to a drug that may involve one or more of the following: requires discontinuation of the drug, requires changing drug therapy, necessitates admission to a hospital, prolongs stay in a health care facility, necessitates supportive treatment, negatively affects prognosis, and/or 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.

(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. 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 called into the "ADR Hotline", Ext. 8359 or may be submitted to the pharmacy via the "Adverse Drug Reaction Report" form, which may be obtained from the Pharmacy. Suspected ADRs will also be identified through the AcuDose medication dispensing system and the ICD 9 E-code report. An ADR report will be generated by pharmacy for each over-ride used for an adverse drug reaction.

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
3. If report is made by utilizing the written form, the form will be forwarded to the Pharmacy.

B. Pharmacy Review and Data Collection

1. The pharmacist or the medication safety officer will rate the ADR using predefined criteria as to probability, severity, type of ADR, and patient type.

2. Records will be kept of the number of reactions to each drug.

3. The pharmacist 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.

C. 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, The UTMC Pharm Report, 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.

Approved by:

Daniel Barbee, RN, BSN, MBA
Chief Executive Officer - UTMC

Date

Thomas Schwann
Chief of Staff

Date

Linda Speer, MD
Interim Chief Medical Officer

Date

Monecca Smith
Chief Nursing Officer

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