PURPOSE

The purpose of this policy is to outline a mechanism for reporting adverse drug reactions in accordance with Title 22, California Code of Regulations, Section 70263, and The Joint Commission standards.

STATEMENT OF POLICY

San Francisco General Hospital Medical Center (SFGH) inpatient, Ambulatory Care, and Emergency Service health care providers participate in a program to detect and concurrently report adverse drug reactions. Reports of adverse drug reactions are submitted to the Medication Error Reduction Plan (MERP) Subcommittee of the SFGH Pharmacy and Therapeutics (P&T) Committee for review and investigation with appropriate action to be taken.

It is the policy of SFGH to responsibly disclose adverse drug reactions to the patient, and when appropriate, to a family member or surrogate. (Refer to Administrative Policy 21.5 Unusual Occurrences: Adverse Events, Reporting to Patients and Families, Significant Others or Legally Authorized Representatives.)

DEFINITION

Adverse Drug Reaction: An adverse drug reaction (ADR) is a serious noxious, unintended, or undesirable clinical event (symptom, sign, or lab finding) caused by a drug administered for prophylactic, therapeutic, or diagnostic purpose. Therapeutic failures and adverse effects of intentional poisoning or drug abuse are excluded. Adverse effects which occur routinely as part of the pharmacological spectrum of drug activity should not be reported unless categorized as severe, or necessitating an emergency visit, admission, or increase in hospital stay.

PROCEDURE

I. Voluntary Reporting Mechanism

A. If an ADR occurs or is suspected:

1. Notify the provider

2. Provider will treat reaction, if appropriate

3. Report the ADR by one of four mechanisms:
i. Calling the ADR hotline at 206-4282 or

ii. Filling out the ADR reporting form found on the SFGH Intranet site or Pharmacy

iii. Generating an Unusual Occurrence Report on the SFGH Intranet site, in the Electronic Medical Record (EMR) or Pharmacy

iv. Filling out the Patient Notification and Chart Documentation Form. This is a triplicate form, one copy of which is sent to Pharmacy.

B. The Medication Error Reduction Plan (MERP) Subcommittee of the Pharmacy and Therapeutics committee monitors adverse drug reactions. All notifications to the ADR hotline, ADR form submissions, or unusual occurrence report submissions will be compiled and reported to MERP. The hospital care provider must report actual or suspected adverse drug reactions that occur via one of the mechanisms mentioned above; providers are also encouraged to report all potential ADRs. The ADR Report does not become part of the patient's medical record.

1. Questions regarding the reporting of an ADR may be directed to a member of the MERP Subcommittee via the Department of Pharmaceutical Services at 415-206-4282.

C. When reporting an ADR by phone the Caller should report the patient’s name and medical record number, the date the ADR occurred, the drug involved, and a brief description of the reaction.

D. If the ADR that is potentially life-threatening requires intensive medical care, causes complications or death, it must be reported to the SFGH Risk Management Staff (ext. 6-6600) and an Unusual Occurrence Report form completed.

1. The Pharmacy Director is notified of the Unusual Occurrence by the SFGH Risk Management Staff, and these cases are reviewed as in section II. below.
E. The ADR Reporting form is maintained in all inpatient and outpatient care areas and is accessible on the SFGH Intranet site and in the Electronic Medical Record (EMR).

1. As a guide for reporting, the definition of an ADR is printed on the ADR reporting form. Each section on the right hand side of the ADR form must be completed. A brief statement is sufficient regarding the suspected adverse drug reaction.

2. The ADR Reporting form may be submitted in two ways:
   i. Fax the form to MERP Subcommittee (Medication Error Reduction Plan) at 206-3504, or
   ii. Fold and seal the form, and mail it to the Department of Pharmaceutical Services, Room 1P2, through the interdepartmental mailing service

3. It is the responsibility of the Nurse Manager or the clinic managers to ensure that the form is available to providers.

II. Trigger Drug Program

A. Trigger drugs for identifying suspected ADR are defined as drugs used to reverse, mitigate or treat symptoms secondary to administration of another drug.

B. Drugs shall be approved for the Trigger Drug Program by the MERP Subcommittee and approved by the Pharmacy and Therapeutics Committee.

C. Reports of suspected ADR detected through the Trigger Drug Program will be provided at least quarterly to the MERP Subcommittee.

   1. Reports from the Pharmacy computer systems will be generated and reviewed by a pharmacist.

   2. For all trigger drugs dispensed, the pharmacist will investigate to determine if the drug was administered by review of the patient’s Medication Administration Record (MAR) and determine if an ADR occurred.
3. A Trigger Drug Report summarizing all trigger drug use for both ADRs and non-ADRs will be compiled monthly. All ADRs will be reported to the MERP Subcommittee. Each reported ADR is entered in the hospital’s ADR database for further monitoring and analysis.

   i. The total number of each trigger drug dispensed will be reported to the Pharmacy and Therapeutics Committee quarterly. The Department of Pharmaceutical Services will be responsible for executing the procedures of the Trigger Drug Program.

III. Health Information Systems Record Review

   A. A report of all patient records that contain an ICD code for ADR will be available from Health Information Services.

   B. A pharmacist will review the report and enter the information into the hospital’s ADR database for investigation, monitoring, and analysis.

   C. Reports of ADR reported through Health Information Systems records will be reported to the MERP Subcommittee.

IV. Monitoring of ADR Reports from All Sources

   A. The reported ADR is investigated in a timely manner by reviewing the patient's medical record.

      1. Priority for investigation and follow-up is given to those preventable ADRs rated as severe or lethal and probable or definite.

      2. When, in the judgment of the Subcommittee, an ADR necessitates follow-up with the treating provider or Chief of Service, a more detailed account of the ADR's investigation is prepared by the MERP Subcommittee and forwarded to the provider and service identified on the ADR report.

   B. The Chair of the MERP Subcommittee submits a summary of evaluated drug reactions identified through voluntary reporting, Trigger Drug Program, Unusual Occurrence, and Health Information System records to the Pharmacy and Therapeutics Committee.
C. Unusual or severe ADRs may also be reported to the drug manufacturer or the Food and Drug Administration, when appropriate, by the provider reporting the adverse drug reaction or the MERP Subcommittee.

APPENDICES

Appendix__A: ZSFG Adverse Drug Reaction Reporting Form

CROSS REFERENCES

SFGHMC Administrative Policy and Procedures

| 16.25 | Pharmaceutical Services: Medication Errors |
| 21.01 | Unusual Occurrence: Reporting and Investigation |
| 21 05 | Unusual Occurrences: Adverse Events Reporting to Patients and/or Families, Significant Others or Legal Representatives |

SFGHMC Nursing Department Policy and Procedures:

11.2 Documentation of the Nursing Process

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