

SUBJECT: ADVERSE DRUG EVENT

APPROVED BY:

EFFECTIVE

Executive Director

DATE: 03-22-11 (replaces 07-31-09)

Medical Director

Reviewed (no changes): \_\_\_\_\_  
\_\_\_\_\_

Pharmacist

POLICY

It is the policy of McIntosh Trail CSB that clinicians will identify and respond appropriately to adverse drug events.

PURPOSE

To identify medication reactions, to improve education for staff and consumers aimed at preventing or minimizing adverse effects, and to monitor whether appropriate action has been taken in response to adverse drug reactions.

DEFINITIONS

An adverse drug reaction is a consumer's clinical reaction to a medication that results in any unintended, undesirable, or unexpected event that requires discontinuing a drug or modifying the dose, requires or prolongs hospitalization, results in disability, requires treatment with a prescription drug or results in death. It does NOT refer to expected or anticipated side effects (e.g.-dry mouth, constipation, EPS, etc. secondary to antidepressants, antipsychotics or other such medications).

There are two categories of adverse drug reactions:

- A. The first is hypersensitivity, allergic reactions, or idiosyncratic reactions. These reactions are largely unpredictable and unavoidable. These reactions are generally not dose-related.
- B. The second category of adverse drug reactions are characterized as responses to overdosage or extension of pharmacology effects, side effects, toxic reactions, and drug interactions which are known to occur but which are not anticipated. These reactions may be dose-related and may respond to dosage adjustment.

PROCEDURE

- A. In the event a suspected adverse drug reaction as defined above should occur, all staff have a responsibility to:
  - 1. Institute CPR if indicated and/or obtain prompt medical attention in a potential emergency situation.
  - 2. Notify physician immediately of nature and severity of reaction for further instructions.
  - 3. Report suspected drug reactions on approved form and forward to Medical Director or Pharmacist.
  - 4. If an ADR resulted in an emergency situation, a Critical Incident Report should be filed per policy for evaluation as a possible sentinel event.
  - 5. Document in consumer's chart.

SUBJECT: ADVERSE DRUG EVENT

APPROVED BY:

EFFECTIVE

Executive Director

DATE: 03-22-11 (replaces 07-31-09)

Medical Director

Reviewed (no changes): \_\_\_\_\_  
\_\_\_\_\_

Pharmacist

---

PROCEDURE (CONTINUED)

- B. The pharmacist will assess for significant reactions. All reactions found to fulfill adverse drug reaction definition are brought to Pharmacy and Therapeutics Committee for conclusions, recommendations, action, and follow-up.
- C. The Pharmacy and Therapeutics Committee
  - 1. Will discuss finding and act to improve reporting and prevent future adverse drug reactions.
  - 2. Will track results and effectiveness of action taken in response to adverse drug reactions.
  - 3. Will identify strengths and weaknesses of consumer and staff education and overall reporting.
  - 4. Will report any unexpected or significant adverse drug reactions to Food & Drug Administration.
- D. All ADRs are reviewed quarterly by medical staff.

Attachment: Adverse Drug Reaction Assessment Form

**McIntosh Trail CSB  
Adverse Drug Reaction (ADR) Assessment Form**

**DEFINITION:**

An Adverse Drug Reaction (ADR) is any unintended, undesirable, or unexpected response to a drug. It includes any reaction that results in the discontinuation of a drug, necessitates additional drug therapy, or causes a hospital admission, prolongation of hospital stay, permanent injury, or death.

**EVENT REPORT:**

Consumer: \_\_\_\_\_ CID No. \_\_\_\_\_ Age: \_\_\_\_\_ Sex \_\_\_\_\_

Diagnosis: \_\_\_\_\_ Site: \_\_\_\_\_

Date of Reaction: \_\_\_\_\_ Number of Doses Admin: \_\_\_\_\_

Known Drug Allergies: \_\_\_\_\_

Current Medications: \_\_\_\_\_

Medication Suspected (generic and trade name, route, dose, frequency):  
\_\_\_\_\_  
\_\_\_\_\_

Reaction Description: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

TREATMENT: \_\_\_\_\_

Additional comments: \_\_\_\_\_

Signature of staff completing report: \_\_\_\_\_ Date \_\_\_\_\_

**PHARMACY AND THERAPEUTICS COMMITTEE REVIEWS:**

*Consumer outcome:*

- \_\_\_\_\_ Slight morbidity – may/may not require change in drug therapy.
- \_\_\_\_\_ Moderate morbidity – drug therapy must be discontinued.
- \_\_\_\_\_ Severe morbidity – potential for life-threatening or irreversible reaction.
- \_\_\_\_\_ Death.

*Classification:*

- \_\_\_\_\_ Definite – reaction appears after rechallenge.
- \_\_\_\_\_ Probable – reaction disappears after drug DC'd, but without rechallenge.
- \_\_\_\_\_ Possible – reaction fits known response pattern, but may also be caused by other elements of the consumer's disease.
- \_\_\_\_\_ Unrelated – reaction is unrelated to drug therapy (does not meet ADR definition).
- \_\_\_\_\_ Unclear.

RECOMMENDATIONS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Prescribing MD notified: \_\_\_\_\_ Noted in chart: \_\_\_\_\_

\_\_\_\_\_  
Pharmacist Date Medical Director Date