Department of Pharmacy

Monitoring and Evaluation – Adverse Drug Reaction Reporting Program (N 11-03)

Intent:
Adverse consequences to medication therapy can result in morbidity, mortality and increased cost of care. Some adverse drug reactions are predictable and sometimes preventable. It is the goal of the Adverse Drug Reaction Reporting Program to identify, analyze, trend, and reduce the number of adverse reactions to medications that occur in this institution, thereby improving patient outcomes.

Policy:
1. **Adverse Drug Reaction** – The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as any unexpected, unintended, undesired, or excessive response to a drug that:
   a. Requires discontinuing the drug (therapeutic or diagnostic)
   b. Requires changing the drug therapy
   c. Requires modifying the dose (except for minor dose adjustments)
   d. Necessitates admission to a hospital
   e. Prolongs stay in a health care facility
   f. Necessitates supportive treatment
   g. Significantly complicates diagnosis
   h. Negatively affects prognosis, or
   i. Results in temporary or permanent harm, disability, or death.

   Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADR.

2. **Categorizing Adverse Reaction** – Categories for severity should be approved by the Pharmacy and Therapeutics (P&T) Committee, and used for reporting of trends. The severity of the adverse drug reaction is defined by the following categories:
   a. **Lethal**: An adverse drug reaction that results in death.
   b. **Serious**: An adverse drug reaction that results in hospitalization or extended stay, a life threatening circumstance that requires medical intervention to prevent further impairment or damage, results in disability, birth defect of a newborn.
      **EXAMPLE**: Digoxin toxicity that requires administration of Digibind®.
   c. **Moderate**: An adverse drug reaction that is not life threatening, but is serious enough to require non-emergent intervention.
      **EXAMPLE**: Rash from epidural and administering Benadryl®.
   d. **Minor**: An adverse drug reaction that is insignificant or secondary to another coexisting reaction.
      **EXAMPLE**: Stomach pain associated with the administration of ibuprofen to a patient with a history of GI discomfort.
Procedure:

1. All Adverse Drug Reactions (ADR) that have harmed, have the potential to harm the patient, or the outcome is unknown must be brought to the immediate attention of the attending or covering physician and documented in the medical record. ADR that result in no or insignificant harm to the patient must also be documented in the medical record but do not require immediate reporting to the physician. Attempts to contact the physician must be noted in the permanent medical record. Reports of ADR may be initiated by any person identifying the reaction, including nurses, pharmacists, physicians, laboratory assistants, other hospital personnel, patients and family members. To maximize the effectiveness of the program, Utilization Review and Medical Records Personnel are responsible for reporting ADR that they detect may have been previously unreported. The reporting of ADR will occur via electronic entry into Rx Medi-TrendSM or paper forms (only when Rx Medi-TrendSM is unavailable). Access to either must be available on each nursing unit and in the pharmacy (the paper form is provided in Appendix A). All reports are sent to the Director of Pharmacy or designee for follow-up and reporting to the P&T Committee at least quarterly. The patient and/or family member must be notified of an ADR.

2. Although any person may experience an ADR, some patient-specific indicators associated with a higher potential for ADR are outlined below. These indicators may be useful in identifying patients to be selectively screened for ADR.

   a. Infants and children, due to their immature body systems and metabolic pathways, are particularly sensitive to the effects of medications. Small dosage changes may result in substantial changes in the child’s reaction to the medication.

   b. Geriatric patients, due to age-related organ dysfunction, altered metabolic pathways, and complex medication regimens.

   c. Patients of any age with significant organ dysfunction such as renal or hepatic impairment.

   d. Patients receiving five (5) or more medications.

   e. Patients with three (3) or more concurrent disease states.

   f. Patients receiving drugs that require therapeutic monitoring.

   g. Patients with medication orders that are frequently changed, dose adjusted, or abruptly discontinued.

3. The following are signs of potential ADR:

   a. Any significant change in the patient’s symptomatology or mental status that is not explained by the diagnosis or other factor; hearing loss, change in renal or hepatic function, GI bleed.

   b. Symptoms suggesting an allergic reaction (pruritus, skin rash, angioneurotic edema, anaphylaxis, arthralgia or arthritis, wheezing, laryngospasm).
c. Hematologic changes that are unexplained by the working diagnosis (leukopenia, thrombocytopenia, eosinophilia, purpura, acute lymphadenopathy).

d. Instability of gait or level of consciousness resulting in a fall (especially in elderly patients receiving sedative/hypnotic agents).

e. Changes in laboratory values (hyperkalemia, hypokalemia, elevated hepatic or cardiac enzyme in the absence of a related working diagnosis, etc.).

f. Toxic or severely subtherapeutic serum drug levels in a patient receiving a “normal” dose of a medication, often a result of a drug interaction (e.g., ciprofloxacin/ theophylline).

4. Each ADR reported is investigated to assess whether the noted patient reaction was actually due to a drug. The following questions may be asked as part of the analysis:

a. Did the ADR follow in a reasonable sequence after drug administration?
   - When was the drug given?
   - When did the reaction begin in relation to drug administration?
   - Are the dates of drug administration recorded?

b. Did the reaction cease or change when the drug was discontinued?

c. Did the reaction cease or change despite continued drug treatment?

d. Did rechallenge occur with the same resulting ADR?

e. Could the disease be causing the reaction observed as an ADR?

f. Could any concurrent drugs cause the same problem, and is the time sequence reasonable?

g. Were concurrent drug levels performed showing results above the therapeutic range?

h. Did a reduction in dose eliminate the ADR, and was this verified with a decrease in drug level?

5. Significant ADR categorized with a severity of serious or lethal, require an intense analysis. Appendix B may be used to document this analysis. Significant ADR that cause any patient death, paralysis, coma, or other major permanent loss of function, are to have a root cause analysis completed may be used to document this analysis.

6. Regardless of the method of reporting, all adverse drug events should be entered into Rx Medi-Trend SM for uniformity and historical comparison.
7. A summary report is presented to the P&T Committee for its review. Root cause analysis reports will also be presented to the committee. The ADR are analyzed to determine whether trends or patterns exist. The committee will then determine whether action may be taken to reduce the incidence of reactions. Examples of actions that may be helpful are:

   a. Education about drug/drug or food/drug interactions.

   b. Modification of standing orders to reduce the dose of sedative/hypnotic agents when falls have been reported.

   c. Changes in the formulary status of a medication that has proven to be problematic.

   d. Intensive evaluation of a medication that has been problem prone within the institution.

8. Federal drug problem reporting (MedWatch) is a voluntary process for monitoring and evaluating products after distribution and marketing approval is granted by the Food and Drug Administration (FDA). All reports are confidential and used for product monitoring purposes only. Whenever an ADR is deemed “serious” or “lethal,” it should be reported to the FDA via MedWatch. Options for reporting include manual completion of form 3500 submitted via mail. Appendix C, a consumer-friendly version of this form is available at: [http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf) or electronic submission at: [https://www.accessdata.fda.gov/scripts/medwatch/](https://www.accessdata.fda.gov/scripts/medwatch/)

   Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at: [https://vaers.hhs.gov/esub/step1.](https://vaers.hhs.gov/esub/step1)

References:
1. CMS 42 CFR 482.25 (b)(6)) Appendix A State Operations Manual
ADVERSE DRUG REACTION REPORTING FORM

ADVERSE DRUG REACTION: An adverse drug reaction is defined as any unexpected, unintended, undesired, or excessive response to a drug that requires discontinuation of the drug, requires changing the drug therapy, requires modifying the dose, necessitates admission to a hospital, prolongs stay in a healthcare facility, necessitates supportive treatment, significantly complicates diagnosis, negatively affects prognosis, or results in temporary or permanent harm, disability, or death.

Directions: Complete the following six (6) questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>1. Suspected medication(s) causing adverse effect:</td>
<td>___________________________</td>
</tr>
<tr>
<td>2. Is the patient pregnant? Yes No</td>
<td>Yes No</td>
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<tr>
<td>3. Time and date reaction observed:</td>
<td>___________________________</td>
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<td>4. Physician notified? Yes No</td>
<td>Yes No</td>
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<tr>
<td>5. Check Adverse Drug Clinical Indicators that best represents suspected adverse reaction</td>
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<tr>
<td>6. Severity category:</td>
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Completed by: ___________________________  
Date: ___________________________

Please forward to Pharmacy Department for Processing  
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**ADVERSE DRUG REACTION CLINICAL INDICATORS**

<table>
<thead>
<tr>
<th>Group</th>
<th>Indications</th>
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| Antianxiety agents | persistent drowsiness  
increased excitement, irritability, insomnia |
| Antibiotics | persistent itching, redness, or rash  
N/V which prevents drug administration  
persistent diarrhea lasting > 3 days  
evidence of hearing loss  
evidence of renal compromise |
| Anticoagulants | evidence of unusual bleeding, tarry stools  
discoloration of toes, painful/tender to touch |
| Anticonvulsants | muscle incoordination, numbness  
inability to focus eyes, eye pain  
inflammation or swelling of gums  
itching or redness of skin  
development of unexplained fever |
| Antidepressants | blurred vision  
orthostatic  
sweating  
hypotension |
| Antihypertensives | persistent throbbing headaches  
recurring episodes of dizziness or fainting  
persistent nasal congestion  
rapid heart rate |
| Anti-inflammatories | occurrence of fever or chills  
ringing in ears  
ulceration of mouth or sore throat  
headaches, especially in morning  
GI bleed, ulcers |
| Antiparkinson Agents | confusion  
involuntary jerking  
agitation  
lack of movement |
| Antipsychotics | “pill rolling”  
blurred vision  
drowsiness  
facial muscle spasm |
| Sedatives/Hypnotics | excessive daytime sedation  
daytime disorientation  
unstable gait, falls  
hallucinations  
headache  
respiratory depression |
| Respiratory Agents | anxiety, apprehension  
nausea and vomiting  
proteinuria  
tachycardia |
| Miscellaneous | shortness of breath  
anaphylaxis  
change in mental status  
abnormal blood values  
phlebitis  
angioedema  
jaundice  
rash/redness at site of needle insertion  
unexpected high or low drug level  
change in system function (renal, hepatic, cardiovascular)  
low potassium level outside normal limits |
| Other (describe): | |
Appendix B

Adverse Drug Reaction Intense Review

Patient Name: _____________________________________________
M.R.#: ____________________

Age: _____ Sex: _____ Race: _____ Known Allergies:______________________________________________

Diagnosis (or reason for admission): _______________________________________________________________

Physician Name and Number: ____________________________________________ Admit Date: _____________

Reaction Date: ____________________ Suspected Medication (s): ______________________________

Note: If the suspected medication is an out-of-range drug level, do not complete this form, unless the patient is symptomatic, e.g., wheezing and theophylline level is 3.

Suspected medication(s) were noted in patient’s allergy data before administered? Yes: _____ No: _____

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Reaction

(Physical symptoms and/or patient complaints) Circle all that apply

- Constipation
- Drowsiness
- Photosensitivity
- Pain
- Renal Failure
- Diarrhea
- Excitability
- Inflammation
- Numbness
- Nasal Congestion
- El. Blood Pressure
- Fainting
- Swelling
- Headache
- Mouth Ulcers
- Dry Mouth
- Dizziness
- Unexplained Fever
- Rash
- Insomnia
- Drooling
- Vomiting
- Chills
- Loss of Appetite
- Rigidity
- Mouth Movement
- Nausea
- Shock
- Rapid Heart Rate
- Paralysis
- Sweating
- Blurred Vision
- Dark Tarry Stools
- Itching
- Tremors
- Fatigue
- Severe Eye Pain
- Tingling
- Hearing Loss
- Confusion
- Ringing in Ears
- Additional Description: ________________________________________________________________

Onset was: _____ Slow (> 3 hours) _____ Moderate (1/2 - 3 hours) _____ Fast (< 1/2 hour)

Type of Reaction: (Check appropriate box)

_____ Definite: An adverse reaction commonly known to occur; rechallenge or laboratory confirmation.

_____ Probable: An adverse reaction commonly known to occur, improvement on withdrawal of medication.

_____ Possible: An adverse reaction known to occur; other etiologies possible.

_____ Doubtful: Another cause of an adverse reaction judged more likely.

Lethal: An adverse drug reaction that results in death.

Serious: An adverse drug reaction that results in hospitalization or extended stay, a life threatening circumstance requires a medical intervention to prevent further impairment or damage, results in disability, birth defect of a newborn.

Moderate: An adverse drug reaction that is not life threatening, but is serious enough to require non-emergent intervention.

Minor: An adverse drug reaction that is insignificant or secondary to another coexisting reaction.
**Pertinent Medication Information**

Please list medications that may have interacted with the suspected medication(s):

<table>
<thead>
<tr>
<th>Date</th>
<th>Medication</th>
<th>Dose/Route</th>
<th>Frequency</th>
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List relevant laboratory values:

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Briefly describe what happened:

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____________________________________________________________________________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________________________________________________________________________

Intervention:

____________________________________________________________________________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________________________________________________________________________

Outcome:

____________________________________________________________________________________________________________________________________________________________________________________

____________________________________________________________________________________________________________________________________________________________________________________

Do you think this may have been a preventable reaction? _____ Yes _____ No

Pharmacist Reviewing: __________________________ Review Date: _________