1.0 PURPOSE

1.1 To establish a mechanism to ensure that adverse drug reactions are systematically reported, monitored, evaluated, and documented in order to prevent future recurrences.

2.0 DEFINITION

2.1 **Adverse Drug Reaction (ADR)** – is any noxious, unintended, undesirable, or unexpected response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease, or for modification of psychological function. This definition excludes predictable, dose-related side effects due to drugs which result in little or no change in patient management, and in particular, mild extrapyramidal side effects due to neuroleptic drug therapy.

2.2 **Criteria for an ADR** – include anaphylaxis, arrhythmia, convulsions, hallucinations, shortness of breath, rashes, itching, hypotension, dystonia, leucopenia, urinary retention, symptoms associated with neuroleptic malignant syndrome, initial report of tardive dyskinesia, EPS related to non-antipsychotic drugs and also includes true allergic (hypersensitivity) reactions and idiosyncratic reactions.

2.3 **A significant Adverse Drug Reaction is one that:**

   2.3.1 Requires discontinuing the drug.
   2.3.2 Requires large, (greater than 50%) dosage decrease.
   2.3.3 Necessitates admission to an acute care hospital.
   2.3.4 Delays anticipated discharge from the hospital.
   2.3.5 Necessitates supportive treatment.
   2.3.6 Significantly complicates diagnosis.
   2.3.7 Negatively affects prognosis.
   2.3.8 Results in temporary or permanent harm, disability, or death.
3.0 RESPONSIBILITY

3.1 The nurse: is responsible for:
   3.1.1 Notifying the treating physician of any suspicion of an Adverse Drug Reaction.
   3.1.2 Monitoring the patient while contacting the treating physician to report the Adverse Drug Reaction.

3.2 The physician: responsible for filling up the ADR Alert Form and send it to the inpatient pharmacy.

3.3 Medication Safety Officer: is responsible for:
   3.3.1 Reviewing the ADR Alert Form.
   3.3.2 Analyzing and evaluating the ADR Alert Form to determine whether the ADR is significant or serious.
   3.3.3 Reporting to the director of medical services about any trends or significant occurrences.
   3.3.4 Providing educational feedback to the patient.

4.0 CROSS REFERENCES POLICY
   4.1 Poison / Overdose Anti-Dotes Medications List

5.0 POLICY

5.1 All adverse drug reactions shall be documented, investigated, and resolved in a consistent and timely manner.
5.2 Any unexpected and serious ADR is reported to MOH.
5.3 The Pharmacy Department must ensure that the patient must receive appropriate care for ADR and to implement the process for reporting ADR.

6.0 PROCEDURE

6.1 Reporting ADR:
   6.1.1 All ADE’s will be documented by the person identifying the ADR on a form located in patient care areas.
   6.1.2 The form is to be filled out completely with specific, factual, and objective information, so that the true magnitude and nature of circumstances can be studied.
   6.1.3 As a private and confidential document, the ADR Reporting Form must not be:
       6.1.3.1 Left in a patient’s room or shared with personnel other than those specified by the procedure below.
       6.1.3.2 Referenced or placed in a patient’s chart or an employee’s file; or
6.1.3.3 Copied.
6.1.3.4 All ADR’s will be communicated to the Attending Physician.

6.1.4 The nurse should notify the treating physician *immediately* of any suspicion of an Adverse Drug Reaction.

6.1.5 The physician documents the presence of an ADR on the top of the physician order sheet.

6.1.6 The medical record will be flagged for known allergies.

6.1.7 The physician shall complete the top portion of ADR Form, or submit the information into the computerized order entry system.

6.1.8 If submitted via the computer order entry system, a confirmation will be printed in the appropriate pharmacy area.

6.1.9 The ADR Alert Form is reviewed by the pharmacist on duty.

6.1.10 Medication Safety Officer will report to the director of medical services about any trends or significant ADR occurrences which will be reported to the Saudi FDA & MOH medical supply.

6.1.11 The pharmacy department will use a **Trigger System** to detect any ADR that’s not reported.

6.1.12 The trigger system will include a list of medications that are used as antidotes or abnormal lab values that the pharmacist will assess to determine whether there is a probable ADR and follow the regular procedure for reporting.

6.2 **Report Routing:**

6.2.1 Forms that are received in the Pharmacy Department are routed to the appropriate person (Medication Safety Officer) for investigation and narrative information within 24 hours to determine whether the ADR is significant or serious.

6.2.2 The information gathered is then written into the ADR Form for documentation purposes.

6.2.3 Forms are then routed for required signatures per routing slip.

6.2.4 When all signatures have been retrieved, the form is returned to the Department of Pharmacy for analysis purposes.

6.3 **Analysis:**

6.3.1 Reports are presented to the Medication Safety Committee by the Medication Safety Officer at their monthly meeting for assessment, outcome, and compilation of data.

6.3.2 Medication Safety Officer will enter the case into the ADR database.

6.3.3 A report is submitted quarterly to the P&T Committee for review and/or necessary action.
6.3.4 The P&T Committee will analyze the data for trends and make recommendations.

All serious and unexpected ADRs are reported to the Saudi Food & Drug Authority.

6.4 Monitoring ADR:

6.4.1 The nurse will monitor the patient while contacting the treating physician to report the Adverse Drug Reaction.

6.4.2 The physician will examine the patient, order necessary intervention, if needed, and complete the medical section of the Adverse Drug Reaction Report.

6.4.3 The nurse will monitor the patient signs and symptoms which prompted the ADR reporting procedure.

6.4.4 The nurse will document the date and time the physician and head nurse were notified of the suspected ADR.

6.5 Documenting ADR:

6.5.1 The physician / nurse will complete the Adverse Drug Reaction Alert Form.

6.5.2 The nurse will document in the patient's Medical Record, all events associated with reporting the suspected ADR.

6.5.3 The physician will fill the ADR Form and document in the patient's medical record, the Adverse Drug Reaction along with the interventions, if any were necessary.

6.5.4 The pharmacy will maintain all ADR reports and communicate pertinent data to the Quality Management, P&T committee, and Director of Medical services.

6.6 Process For Improving ADR Management:

6.6.1 Proper documentation of ADRs.

6.6.2 Analysis of each reported ADR.

6.6.3 Flagging the patient medical record for known allergies.

6.6.4 Feedback to appropriate healthcare staff.

6.6.5 Educational efforts for prevention of ADRs and improve patient safety.

6.6.6 Evaluation of prescribing patterns, patient monitoring practice, patient outcomes and the impact of ADR program on overall or individual patient outcome.
### 6.7 The following table depicts the procedure for reporting and recording ADR’s:

<table>
<thead>
<tr>
<th>SEVERITY</th>
<th>IF THE LEVEL OCCURRENCE IS</th>
<th>THEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0</td>
<td>No actual occurrence (potential errors would be classified here).</td>
<td>Complete the ADR Reporting Form: Obtain necessary signatures; and forward to the QM department within seven days.</td>
</tr>
<tr>
<td>Level 1</td>
<td>Occurrence did not result in patient harm.</td>
<td>1. Report immediately to physician (if discovered by non-physician). 2. Complete the ADR Form: Obtain necessary signatures and forward to the QM department within 7 days of the occurrence.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Occurrence resulted in the need for increased patient monitoring but no change in vital signs and no patient harm.</td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>Occurrence resulted in the need for increased patient monitoring with a change in vital signs but no ultimate patient harm, or any occurrence that resulted in the need for increased laboratory monitoring.</td>
<td></td>
</tr>
<tr>
<td>Level 4</td>
<td>Occurrence resulted in the need for treatment with another drug or an increased length of stay of that affected patient participation in an investigational drug study.</td>
<td>1. Report immediately to the - Physician - Nursing Director - Pharmacy Department - Risk Management Department Complete the ADR Reporting Form immediately; obtain necessary signatures; and forward to the QM department.</td>
</tr>
<tr>
<td>Level 5*</td>
<td>Occurrence resulted in permanent patient harm.</td>
<td></td>
</tr>
<tr>
<td>Level 6*</td>
<td>Occurrence resulted in Patient harm.</td>
<td></td>
</tr>
</tbody>
</table>

*Denotes those levels classified as a possible sentinel event.

### 6.8 TRACER DRUGS:

(Trigger drugs commonly used to treat ADR’s):
<table>
<thead>
<tr>
<th>TRACER DRUG</th>
<th>RATIONAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsants IV STAT dose</td>
<td>Drug induced seizures</td>
</tr>
<tr>
<td>Antihistamine IV (e.g. Diphenhydramine) STAT dose or single dose</td>
<td>Allergic drug reaction</td>
</tr>
<tr>
<td>Corticosteroids IV (esp. of combined with an antihistamine) STAT dose or single dose.</td>
<td>Allergic drug reaction</td>
</tr>
<tr>
<td>Dextrose 50% IV</td>
<td>Insulin overdose</td>
</tr>
<tr>
<td>Digbind</td>
<td>Digoxin toxicity</td>
</tr>
<tr>
<td>Epinephrine IV/SC STAT dose</td>
<td>Allergic drug reaction</td>
</tr>
<tr>
<td>Flumazenil</td>
<td>Benzodiazepine overdose</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Antibiotic–induced pseudomembranous colitis</td>
</tr>
<tr>
<td>Naloxone</td>
<td>Opiate overdose</td>
</tr>
<tr>
<td>Phytomenadione (Vitamin-K)</td>
<td>Warfarin (INR &gt; 6)</td>
</tr>
<tr>
<td>Protamine Sulfate</td>
<td>Heparin (PTT &gt; 100 sec.)</td>
</tr>
<tr>
<td>Vancomycin PO</td>
<td>Antibiotic–induced pseudomembranous colitis</td>
</tr>
</tbody>
</table>

7.0 FORMS

7.1 ADR Alert Form.
7.2 ADR Report Form.
7.3 Physician’s Order Sheet.

8.0 EQUIPMENT

8.1 N/A.

9.0 REFERENCES

9.1 CBAHI Resource manual.
9.2 ASHP guidelines on ADR monitoring and reporting.