HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Pharmaceutical Care Department		
Document:	Multidisciplinary Policy And Procedure		
Title:	Handling Adverse Drug Reaction (ADR) Reports		
Applies To:	Pharmacists, Physicians & Nurses		
Preparation Date:	December 22, 2024	**Index No:**	MM-MMP-026
Approval Date:	January 05, 2025	**Version:**	2
Effective Date:	February 05, 2025	**Replacement No.:**	MM-MMP-026 (1)
Review Date:	February 05, 2028	**No. of Pages:**	03

1. PURPOSE:

1.1 To outline the process of detecting, reporting, and evaluating adverse drug reactions (ADR).

2. DEFINITONS:

2.1 Adverse drug reaction: Response to a drug which is noxious and unintended which occurs at doses normally used in human prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.

2.2 Serious Adverse Event: An adverse drug event that results in:
- 2.2.1 Patient death
- 2.2.2 A life threatening condition
- 2.2.3 Hospitalization or prolongation of hospitalization
- 2.2.4 Significant, persistent, or permanent disability
- 2.2.5 Congenital anomaly, or
- 2.2.6 Requirement for medical or surgical intervention to prevent permanent damage or impairment

2.3 Saudi Food and Drug Authority (SFDA) ADR Reporting Program: A voluntary reporting program of the SFDA in Saudi Arabia for reporting serious adverse events and product manufacturing problems.

2.4 ADR Classification: based on the type of reaction:
- 2.4.1 Type A (Exaggeration): Predicted from the known pharmacology of the drug, associated with high morbidity and low mortality, usually dose-dependent and alleviated by dose reduction.
- 2.4.2 Type B (Idiosyncratic):
  Not predicted from basic pharmacology, associated with low morbidity and high mortality, rarely dose dependant.

2.5 ADR Classification based on level of severity:
- 2.5.1 Minor: Bothersome but requires no change in therapy or reduction in dosage
- 2.5.2 Moderate: Requires changes in drug therapy, treatment with another drug or additional treatment
- 2.5.3 Severe: Refer to previous definition of Serious Adverse Event

2.6 ADR Probability (Naranjo Scale): a series of questions that are answered by pharmacists to determine if the suspected drug was the cause of the adverse drug reaction.

3. POLICY:

3.1 An adverse drug reaction may or may not be a medication error, and does not necessarily reflect poor patient care, i.e. "NO ONE IS AT FAULT".

3.2 All encountered ADRs shall be documented by healthcare providers who encounter the event in the patient MR.

3.3 The ADR may be reported by any member of the healthcare team.

3.4 When reporting an ADR, the following information is required: patient medical record number (MRN), patient name, the name of the suspected drug(s), a brief description of the reaction, the name of the person reporting the reaction, the date of the reaction, and any other pertinent information.

3.5 A suspected ADR may be reported to the Drug Information Center (DIC) in the Pharmacy department by at least one of the following means; phone, fax, interdepartmental hospital mail, electronic e-mail, ADR Alert form.

3.6 The filled form of ADR will be forwarded to Medication Safety or responsible pharmacist within 24 hours and the treating physician should be notified immediately to proceed with the appropriate action.

3.7 The Medication Safety Officer/ Drug Information Pharmacist will coordinate the completion of the ADR Form, evaluation of a suspected ADR, and data for regular P&T committee. Only documented ADRs in patient MR will be evaluated and discussed.

3.8 If deemed necessary physicians responsible for patients with serious ADRs will be requested to provide input about the nature, outcome and possible prevention strategies for the reaction.

3.9 Drug Information Pharmacist shall collect a report of reported ADRs every 3 months and submit it to the Medication Safety Officer and P&T committee for review and recommendations.

4. PROCEDURE:

4.1 Monitor patient for any ADR (Healthcare provider); i.e., assess patient for any suspected ADR and identify suspected medications including vaccines and contrast media.

4.2 The physician must be notified so that he/she can decide what course of action is required. Notification may take precedence over all else depending on the patient's condition.

4.3 Documentation in the patient MR is mandatory by Healthcare provider. For details refer to the assessment, documentation, review and evaluation of patient allergies.

4.4 Identify sources of ADR reports as the following: Spontaneous ADR received through phone, fax, email, mail, ADR Form. Only incidents involving medications resulted in ADRs should be forwarded to the Drug Information Centre.

4.5 The assigned pharmacist will ensure that the ADR has been documented in the patient's chart.

4.6 Serious ADRs are further reported to the SFDA through the reporting program.

4.7 The ADRs Report will include, at the minimum, a list of reactions and suspected drugs, the probability of the drug(s) being the cause of the reaction(s), classification of the ADR as to type and seriousness.

4.8 The P&T committee will evaluate the report for all ADRs for trends, for situations that can be targeted for prevention strategies, etc., and will decide if any action needs to be initiated based on the information in the report (e.g. referred to Quality Management Department, education initiatives, etc.)

5. MATERIAL AND EQUIPMENT:

5.1 Pharmacist note.

5.2 ADR Report Form.

5.3 Medication-Errors Report Form.

5.4 Medical record notes.

6. RESPONSIBILITIES:

6.1 The responsibility of implementing and ensuring compliance with this Policy and Procedure lies with Medical and Nursing staff. Responsibility for updating and archiving this policy rests with Pharmacy Services department.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 General Pharmaceutical Care Administration, MOH policy and procedures manual.

8.2 Saudi Food and Drug Administration

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Ph. Mohammad Al Mutairi	Pharmacy QI Facilitator		December 22, 2024
Reviewed by:	Ph. Reem Al Dhafeeri	Medication Safety Officer		December 24, 2024
Reviewed by:	Ph. Mutlaq Al Dhafeeri	Pharmaceutical Care Director		December 24, 2024
Reviewed by:	Mr. Sabah Turayhib Al Harbi	Nursing Director		December 25, 2024
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		December 26, 2024
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM & PS Director		December 29 2024
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 5, 2025