☐ ADMINISTRATE POLICY & PROCEDURE (APP)	✓ INSTITUTIONAL POLICY & PROCEDURE (IPP) ✓ INTERDEPARTMENTAL ☐ INTERNAL

TITLE		POLICY NUMBER/V#
Monitoring Therapeutic Effects and Adverse Drug Reactions (ADRs)		MMC – MED – 12 (01)
INITIATED DATE	**EFFECTIVE DATE**	**REVISED DATE**
02/08/2025	**01/09/2025**	**01/08/2028**
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N/A		**03**

APPLIES TO	RESPONSIBILITY
Physicians, Nurses & other Clinical Staff	<Insert text>

1. PURPOSE:

1.1 To ensure the reporting of medication allergies.

1.2 Adverse Drug Reaction (ADR) reporting at the medical center aim to encourage monitoring, detecting, evaluating, documenting, and reporting ADRs as well as intervening and providing educational feedback to prescriber.

1.3 To ensure that drug therapy is appropriate and adverse events are minimized.

2. DEFINITION:

2.1 **Adverse Drug Reaction**: A response to a medicinal product that is noxious and unintended and that occurs at doses normally used in a human for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction, or modification of a physiological function.

2.2 **Serious Adverse Drug Reaction:** An adverse drug reaction that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent or significant disability or incapacity.

3. POLICY:

3.1 All prescriptions shall clearly highlight the patient's allergy status. As part of the prescription review process, relevant staff shall discuss allergy status with the prescriber to stop or change prescribed medication.

3.2 Allergies and/or adverse reactions shall be documented in the patient medication profile.

3.3 Medications shall be administered to patients by qualified nurses to verify correctness of medications, dosage, and route of administration according to the physician order.

3.4 Medication effects on patient are monitored by Physicians, Nurses, Pharmacists, respiratory therapists, and other Clinical Staff each in his/her area of practice.

3.5 Medication dosage, frequency and/ or entire therapeutic plan shall be reviewed and updated by the most responsible physician (MRP) according to the patient's clinical response and reaction to a given drug.

3.6 An intensive analysis shall be performed for all significant ADRs and the MRP will be notified about the results.

3.7 The medical record is flagged for significant ADRs and the patient receives the appropriate medical care for the reaction.

3.8 Serious Adverse Drug Reactions are reported to the Saudi Food and Drug Authority.

3.9 Any health care worker discovering any undesirable outcome suspected to have been caused by one or more medications shall notify the attending physician immediately, and then can fill out the ADR Alert Form within the same shift in which undesirable outcome developed.

3.10 A collective ADR report shall be compiled every 6 months and presented to the Pharmacy and Therapeutics Committee for review and determination of further actions.

3.11 In case if the ADR meet the criteria of Sentinel Event definition as per Policy (Refer to: Sentinel Event Policy) the ADR form will be completed then all the steps and consequences explained in the policy will be followed.

4. PROCEDURE:

4.1 Patient response to any medication should be documented by healthcare providers after each dose in the multidisciplinary progress note.

4.2 After prescribing, physicians must inform patients of the need for follow -up care to monitor whether any changes to the treatment plan (e.g., prescription) are required.

4.3 The effects of all medications will be assessed and evaluated, whether the first dose or last dose.

4.4 Monitor will be applied on medication effects and adverse reaction, paying special attention to observation of patient's response to the first dose(s) of a medication new to the patient, as a higher likelihood of an adverse reaction to a medication that's new to a patient than to a medication the patient has successfully taken in the past.

4.5 Effects of newly introduced formulary medications are monitored by the prescribing physicians over a period of three months after formulary introduction. The final report is then submitted to the head of pharmacy and medical director for final evaluation of the medication.

4.6 Nurses will immediately report any inadequate, exaggerated, or lack of patient response to a given treatment to the prescriber to review and revise therapeutic plan.

4.7 Report any unexpected reaction using ADR Alert Form.

4.8 The ADR Alert Form hardcopies will be available in all nursing units to be used when the system is down.

4.9 Physician/nurse must update the allergy field on the HIS. If no known drug allergies, the prescriber should enter No Known Allergy "NKA". This entry is mandatory for any orders to be processed.

4.10 Once a suspected ADR is encountered, attending physician should be notified immediately so that he/she decides what sort of appropriate care is required, and then the ADR Alert Form should be filled out by the person who first identifies it within the same shift.

4.11 ADR shall be investigated and fully evaluated by a qualified Pharmacist and the data will be added to the electronic ADR database.

4.12 The assigned pharmacist will ensure that the ADR Alert Form is completed and placed in the patient's medical record.

4.13 The MRP should sign the ADR Alert Form within 24 hours of its receipt and update the patient medical record with necessary flagging as required.

4.14 4 The assigned pharmacist is responsible to confirm that the medical record of suspected patient has been flagged accordingly to the ADR score

4.15 A summary of ADR Reports will be submitted to the Medical Committee every quarter. The ADR report will include, at the minimum, a list of reactions and suspected drugs, and the probability of the drug(s) being the cause of the reaction(s) based on the Naranjo ADR Probability Scale.

4.16 The Medical Committee will evaluate the report 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.

5. RESOURCES:

5.1 Naranjo Algorithm.

6. CROSS REFERENCE:

6.1 Sentinel Event Policy
6.2 Incident management Policy
6.3 Management of High Alert & LASA Medications Policy
6.4 Medication preparation Policy

7. REFERENCES:

7.1 ASHP guidelines on adverse drug reaction monitoring and reporting. Am J Health -Syst Pharm. 1995; 52:417 – 9
7.2 CBAHI National Standards for Ambulatory Care Centers, Effective Jan,2020.
7.3 The Joint Commission International (JCI), 7th Edition, Effective Jan 2021.

8. FORMS & ATTACHMENT:

8.1 ADR Alert Form

9. Approved

APPROVALS & REVIEWS:			
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