KINGDOM OF SAUDI ARABIA

Ministry Of Health

General directorate of Health Affairs AL-Baha

Mayyara General Medical Complex

المملكة العربية السعودية
وزارة الصحة
المديرية العامة للشئون الصحية بمنطقة الباحة
مجمع ميارا الطبي العام

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

TITLE		POLICY NUMBER/V#
Incident Reporting Policy		MMC – ADM – 04 (01)
INITIATED DATE	**EFFECTIVE DATE**	**REVISED DATE**
02/08/2025	01/09/2025	01/08/2028
REPLACES NUMBER		**NO. OF PAGES**
N/A		05

APPLIES TO	RESPONSIBILITY
All Admin workers	Quality and patient safety

1. PURPOSE:

1.1 To provide a systematic, standardized problem identification mechanism for early detection and prevention of problems which have/may have a direct or indirect adverse effect on patient outcomes; and which represent a potential hazard to patients, visitors, or Employees.

1.2 To outline the types of incidents to be reported internally and to relevant regulatory authorities and the time frame and mechanism for reporting.

2. DEFINITION:

2.1 Incident: Events that are unusual, are unexpected, may have an element of risk or may have a negative effect on patients, staff or the clinic.

2.2 An Occurrence: is any event that happens in the center which is not consistent with routine patient care or the routine operation of the facility and that adversely affects or threatens to affect the health or life of patient, visitor, employee, or which involves loss or damage to personal or center's property. An occurrence also includes any event that might otherwise result in any other adverse situation or a claim against the organization.

2.3 Occurrence Variance Report (OVR): an automated internal system used to document the details of the occurrence/event and the investigation of that occurrence with the corrective action/s taken.

2.4 Adverse Event: a patient safety event that results in harm to the patient.

2.5 Near Miss: An event or situation that could have resulted in an adverse event that caused patient harm but that did not, either by chance or through timely intervention.

2.6 Risk: The combination of the assessment of the magnitude of an injury or potential injury, with the probability that certain actions/events will occur.

2.7 Root Cause: The ultimate reason for an event/condition.

2.8 Root Cause Analysis: A collective term used to describe a wide range of approaches, tools and techniques used to uncover causes of problems

2.9 Sentinel Event: An event that, when noted, requires intensive assessment and prompt response. An unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof, and any event that might cause embarrassment or risk to the healthcare organization, with potential legal ramifications and/or media inquiries or coverage. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “Sentinel “because they signal the need for immediate investigation and response.

2.10 Medication Error: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

2.11 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.

2.12 Harm: An unexpected or normally avoidable outcome that negatively affects a patient’s health and/or quality of life and that occurs or has occurred during the course of receiving healthcare or services.

2.13 Harm Levels:

2.13.1 Level 0 (No harm).

2.13.2 Level 1 (Insignificant)
2.13.3 Level 2 (Minor)
2.13.4 Level 3 (Moderate)
2.13.5 Level 4 (Major)
2.13.6 Level 5 (Catastrophic)

3. POLICY:

3.1 It is the responsibility of all employees to report the details of any occurrence variance including near misses which may or already has negatively impacted the care or safety of a patient, visitor, staff or facility.
3.2 The OVR shall be used to identify the facts surrounding the occurrence/near miss and guide quality improvement actions by the concerned staff and will not be used to criticize or speculate on actions of the staff involved and shall not in staff file.
3.3 The reporting shall be anonymous and OVRs reports shall be used for professional quality review.
3.4 Incidences, including near misses, involving patients shall be documented in the medical record and patient and family are informed by the physician of any investigation results.
3.5 The clinic manager shall compile a report on incidences according to type and severity, and an action plan to prevent its recurrence is distributed to staff and governance at least quarterly.
3.6 An annual evaluation of the OVR system shall be conducted and reported to the center's executive committee as part of the annual evaluation of the Risk Management plan.

4. PROCEDURE:

4.1 The first person encountering the occurrence/near miss (witnessing/involved) will assess the situation and take the necessary measures.
4.2 The witnessing/involved person will immediately notify the clinic manager.
4.3 In case the occurrence needs medical intervention, the witnessing/involved person will inform the available physician.
4.4 The witnessing/involved person will have submitted the OVR form on the system within the same shift of the occurrence/near miss.
4.5 The form will be sent automatically to the clinic manager.

4.6 The clinic manager will review the details of the reported incident and most importantly will categorize the incidents by type and severity.
4.7 The clinic manager will use the risk scoring matrix to identify the severity (harm)of the incidence.
4.8 If the Harm level was ≥ 3 ex: Sentinel Event/ Near Misses/ Adverse Drug Reaction or Significant Medication Error, the clinic manager will initiate an RCA, attended by the medical director and the clinic director and staff involved.
4.9 In case of sentinel event, nel everefer to sentient policy.
4.10 misses for occurrences/near with harm levels of ≤ 2, the clinic manager will investigate within 1 working day.

4.11 Upon completion of investigation, the clinic manager will put his/her recommendations to prevent reoccurrence.
4.12 For the trended occurrences/near misses and near sentinel event, the clinic manager will initiate RCA and include it with the quarterly report.
4.13 The clinic manager will close the OVR based on the following recommendations:
- 4.13.1 Review/Initiate Policy & Procedure
- 4.13.2 Education/Training.
- 4.13.3 Resources related.
- 4.13.4 Refer to committee
- 4.13.5 RCA.
- 4.13.6 Initiation of PI. Project.
- 4.13.7 No further action.

4.14 After the closure of the OVR, the reporter (who initiate the OVR on the system) and other relevant staff will receive an email notification state the recommendations for non-recurrence.
4.15 The clinic manager will prepare a quarterly OVR analysis report to be included in the quality report sent to the clinic director and discussed in the center's executive committee and shared with all staff and with the governing body.

5. RESOURCES:

5.1 N/A

6. CROSS REFERENCE:

6.1 Sentinel event policy

7. REFERENCES:

7.1 CBAHI National Standards for Ambulatory Care Centers, Effective Jan,2020.
7.2 The Joint Commission International (JCI), 7th Edition, Effective Jan 2021.

8. FORMS & ATTACHMENT:

8.1 OVR Form
8.2 Risk Matrix
8.3 List of reportable events.

9. Approved:

APPROVALS & REVIEWS::			
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