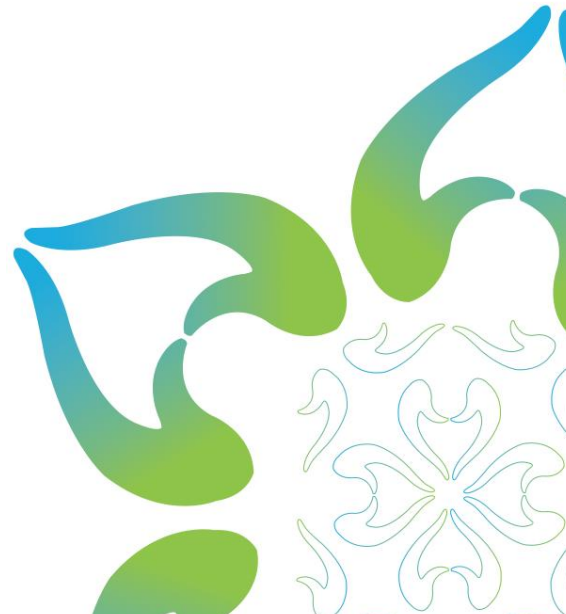




الهيئة الوطنية لتنظيم المهن والخدمات الصحية NATIONAL HEALTH REGULATORY AUTHORITY

DPP	Department Policy and Procedure		
TITLE	INCIDENT REPORTING POLICY		
DEPARTMENT	MCIS	POLICY NO.	MCIS-P-003-03
No. of PAGES	17	REPLACES NUMBER	MCU-P-003-02
EFFECTIVE DATE	August 2021	REVISION DUE	August 2023
APPROVED BY	Dr.Mariam Al-Jalahma		23/8/21



INCIDENT REPORTING POLICY

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1. Introduction

Effective incident reporting is considered a cornerstone for improving patient safety and identifying systems hazards. The objective of reporting an incident is not to punish a health professional but to identify errors, root causes and trends which leads to reduced risk, organizational learning and ultimately an elevated patient safety culture. It is important to note that reporting in itself does not improve safety. It is the response to reports that leads to change.

Law No. (38) for the year 2009 has laid the foundation for the establishment of the National Health Regulatory Authority (NHRA) in Bahrain. Article (3) addresses the role of the NHRA in monitoring the implementation and proposing the development of health professions and health services systems in both the public and private sectors. This is to ensure the high efficiency, safety, speed and effectiveness in providing these services in accordance with the best scientific principles and standards of health practice approved in the Kingdom of Bahrain in accordance with this law.

Moreover, Law no. (21) of 2015 regarding private healthcare facilities, indicates in article (19) NHRA's responsibility for evaluating health services provided in all facilities in order to ensure quality and high performance of those services, and ensure compliance with regulations and standards related to patient safety, clinical performance, infection control, medication management, continuity of care, risk management and other technical standards.

Subsequently, The Supreme Council of Health issued decision no. (7) of 2016 to further detail the required NHRA standards. Items 4.5 and 4.6 of Element no. (4) of the Licensing and Regulations standards for hospital and ambulatory healthcare facilities state that health facilities should have an incident reporting system, policy and process to handle

the incidents. This adds to NHRA the responsibility of studying and monitoring of incidents occurring within healthcare facilities and affecting patient safety.

Facilities have a duty to establish a practical and feasible reporting system as the first step in discovering the contours and root causes of the medical misjudgement and preventable incidents.

NHRA's objective is to encourage accurate and reliable incident reporting as an opportunity for improving quality and patient safety and not for penalizing healthcare professionals and organizations. However, NHRA shall take the necessary legal steps in case of failure of adherence to the attached policy.

2. Definitions

Term	Definition
Adverse Event	An unexpected and undesirable event directly associated with the care or services provided to the patient and not considered to be a complication of a disease.
Near Miss	Circumstances or events that had the capacity to cause an adverse event, but which did not reach the patient either by chance or through timely intervention.
Sentinel events	Any unanticipated adverse event or 'Near Miss' event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not arising from the natural course of the patient's illness, including events that: • Are life threatening • Require in-patient hospitalization or prolong an existing hospitalization • Result in persistent or significant disability or incapacity • Are medically significant events which may put the patient at risk or may require medical or surgical intervention to prevent one of the outcomes listed above

Term	Definition
Root cause analysis	A systematic process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events until the underlying root causes have been elucidated. A root cause analysis focuses primarily on systems and processes, not on individual performance.

3. Purpose

- 3.1 To describe the process by which healthcare facilities report an incident (Appendix 1).
- 3.2 To increase the general knowledge about incidents, their causes, and prevention.
- 3.3 To focus the attention of an organization that has experienced an incident on understanding the causes that underlie the event, and on changing the organization's systems and processes (policies, procedures, etc) to reduce the probability of such an event in the future.
- 3.4 To ensure conformance to required standards of practice and care.
- 3.5 To have a positive impact in improving patient care, treatment, and services and preventing incidents.
- 3.6 To maintain the confidence of the public and accredited organisations in the accreditation process.

4. Policy Statement

- 4.1 It is mandatory of all healthcare facilities (governmental and private) to develop an incidents management and reporting system in accordance with the NHRA licensing and regulation standards for hospitals and ambulatory healthcare facilities
- 4.2 It is mandatory of all healthcare facilities (governmental and private) to report sentinel events to the National Health Regulatory Authority (NHRA) based on circular (1/2018) issued by the NHRA.
- 4.3 This policy and procedure guideline defines the process for the identification and reporting of sentinel events to the National Health Regulatory Authority in the Kingdom of Bahrain.

5. Healthcare Facilities Requirements

- 5.1 Have an incident reporting system (policy, process and form) in accordance with NHRA standards and all staff are aware of it.
- 5.2 Identify staff members responsible of managing incidents reporting systems.
- 5.3 Use monitoring and trending reports of incidents for improvement.
- 5.4 Report all sentinel events to NHRA as per the procedure delineated below.
- 5.5 The facility should be ready to provide NHRA with all documents related to incidents reporting and handling system (policies, processes, forms) and any information of the identified and reported incidents including their causes or suspected causes, trends, actions and improvements planned or implemented to prevent recurrence, as well as training activities undertaken or planned, or any other information seen necessary when requested.
- 5.6 Facilities should also be prepared for unannounced visits from the NHRA Licensure inspectors, which can be triggered not only by the sentinel events reported but also by calls from concerned healthcare staff from the affected facility.

6. Sentinel Events

Sentinel events include but not limited to:

6.1 Care management events:

- 6.1.1 Patient death/serious harm due to medication error (including and not limited to error involving wrong dose, wrong patient, wrong rate, wrong preparation, or route of administration).
- 6.1.2 Patient death/ serious harm due to a haemolytic reaction/incompatible blood or blood products.
- 6.1.3 Maternal deaths.
- 6.1.4 Unanticipated death of a full-term infant.
- 6.1.5 Patient death/serious harm due to spinal manipulation therapy or spinal tap.
- 6.1.6 Death occurring within 48 to 72 hours of admission of patient.
- 6.1.7 Performing diagnostic or therapeutic procedure on the wrong patient.
- 6.1.8 Infant discharge to the wrong family.
- 6.1.9 Death related to delay in treatment.
- 6.1.10 An unexpected or unexplained death or loss of a limb or major permanent loss of function.

6.2 Patient protection:

- 6.2.1 Patient death/serious harm associated with patient disappearance for more than 4 hours.
- 6.2.2 Suicide of a patient receiving care, treatment, or services in a staffed around- the- clock care setting or within 72 hours of discharge.

6.3 Criminal events:

- 6.3.1 Any instance of care ordered or provided by someone impersonating a physician, nurse, pharmacist or other licensed healthcare professional.
- 6.3.2 Sexual assault within or on the grounds of facility.
- 6.3.3 Death or significant injury resulting from physical assault that occurred within or on the grounds of facility.
- 6.3.4 Infant abduction.

6.4 Environmental events in a healthcare facility:

- 6.4.1 Patient death/serious harm due to an electric shock while being cared for in a facility.
- 6.4.2 Any incident in which a line designated for O2 or other gas to be delivered to a patient contains wrong gas or is contaminated by a toxic substance.
- 6.4.3 Patient death/serious harm due to burn incurred from any source.

6.4.4 Patient death/serious harm due to a fall.

6.4.5 Patient death/serious harm due to the use of bed rails/restraint.

6.5 Product or Device event in a healthcare facility:

6.5.1 Patient death/harm/disability due to the contaminated drugs/devices/biologics.

6.5.2 Patient death/serious harm due to the use of a device which was not intended (device includes but not limited to a catheter, drain, or other specialized tube, infusion pump or ventilator).

6.5.3 Patient death/serious harm due to intravascular air embolism excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

6.6 Surgery related events in a healthcare facility:

6.6.1 Surgery performed on the wrong patient.

6.6.2 Surgery performed on the wrong body part inconsistent with the documented informed consent.

6.6.3 Wrong surgical procedure performed on a patient.

6.6.4 Retention of foreign object in a patient after surgery or other procedure.

6.6.5 Intraoperative or immediately post-operative coma or death.

6.6.6 Death occurring during or up to 24 hours after induction of anaesthesia in a normal healthy patient.

6.6.7 Deaths occurring within 24 hours postoperatively.

7. Procedure for reporting Sentinel Events

- 7.1 All sentinel events should be reported to NHRA.
- 7.2 The director of the facility or designee should notify NHRA within a maximum of 5 working days from the date of the event using the Sentinel Event reporting Form through (incidents@nhra.bh).
- 7.3 The notification should be supported by the following via e-mail or if not possible through a hard copy during the same period of time:
 - 7.3.1 A copy of the medical record including all tests and radiological images performed.
 - 7.3.2 Statements from the concerned professionals involved/in charge of the patient.
- 7.4 A copy of the full internal investigation report conducted in the facility including the root cause analysis, related policies, action plans for improvement/prevention of recurrence, training conducted, and any actions taken against involved staff should be sent to NHRA within 45 days of the event.

8. Role of NHRA

- 8.1 Define the type of incidents to be reported and the requirements for reporting.
- 8.2 Revise the list of incidents to be reported in accordance with available evidence as needed.
- 8.3 NHRA will keep a record of all sentinel events received, investigation reports, and any other documents related to the reported incidents.
- 8.4 Revise the investigations reports of sentinel events submitted by the healthcare facilities
- 8.5 NHRA may ask for additional information on incidents, undertake its own further investigation or seek opinion from external parties, and give recommendations to address any identified issues.
- 8.6 If an investigation is run by NHRA, the facility will be notified of the result of the investigation and any comments or recommendations for improvement accordingly.
- 8.7 Share learning from reported events when applicable while maintaining confidentiality.
- 8.8 NHRA reserves the right to take actions against a facility or healthcare provider in cases such as:
 - 8.8.1 The facility fails to take corrective actions.
 - 8.8.2 The incident results in police investigation or prosecution.
 - 8.8.3 A patient or his representative raised a complaint.
 - 8.8.4 The incident indicates a gross misconduct.

8.8.5 A repeated pattern of occurrences without actions taken by the facility OR failure of the violator to abide with the measures taken.

9. Closing the loop

The NHRA is committed to supporting an open and fair culture in which healthcare professionals are confident about reporting incidents. Evidence suggests that by creating a “reporting culture”, organisations increase their ability to learn when things go wrong. As a result, reporting systems should yield learning to improve safety and not simply be a vehicle to communicate failure.

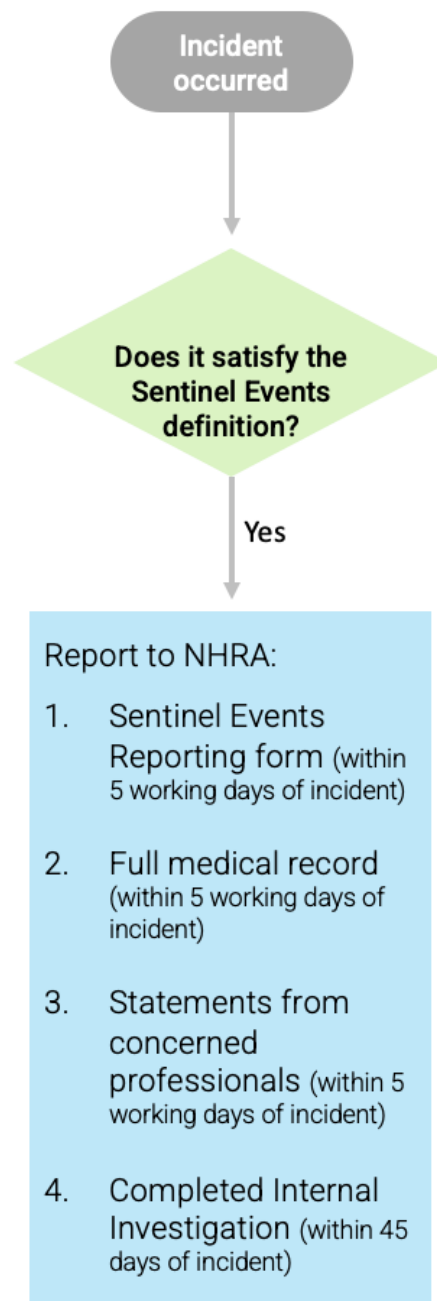
Therefore, it is expected that healthcare facilities communicate with their staff when incidents occur and upon completion of the internal investigation. This is to promote a positive response to the investigation recommendations, to positively influence the culture and practice and minimise the possibility of a similar incident occurring in the future.

10. Dissemination

This policy will be disseminated through NHRA’s webpage: www.nhra.bh

11. Appendix

Appendix 1: Incident reporting flow chart.



Approval	Name	Position	Signature	Date
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