National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

Incidents/Adverse Events Reporting Policy

8 January, 2018

Version 2.0

1. INTRODUCTION

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 investigate the cause of the problem, share lessons within and across organizations, elevate and boost patient safety culture. This is usually done through a quality assurance review and analysis of the incident report, which aims to:

1. Identify and document trends within service(s) and those that cross over services.
2. Recognize and develop policies and procedures to deal with the identified problems and prevent future errors.
3. Assess conformance to required standards of practice and care.

Law no. (21) of 2015 regarding private health care 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. In order to implement the above article, the Supreme Council of Health issued decision no. (7) Of 2016 specifying the required NHRA standards. It is clearly stated in items 4.5 and 4.6 of Element number 4 of the Licensing and regulations standards for hospital and ambulatory health care facilities which is concerned with Quality Management and Patient Safety that health facilities should have an incident reporting system and a policy and process to handle them. This adds to NHRA the responsibility of studying and monitoring of incidents occurring within health care facilities and affecting patient safety. Incident reporting will be used for monitoring, analysis and trending.

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 misjudgment and preventable adverse events.

NHRA 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 incident directly associated with the care or services provided to the patient. The adverse event is an adverse outcome, injury and not 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 • Requires in-patient hospitalization or prolongs an existing hospitalization • Results in persistent or significant disability or incapacity • Is any medically significant event that may put the patient at risk or may require medical or surgical intervention to prevent one of the outcomes listed above.

3. Policy Purpose

1.1. To have a positive impact in improving patient care, treatment, and services and preventing incidents/adverse events.

1.2. To focus the attention of an organization that has experienced an incident/adverse event on understanding the causes that underlie the event, and on changing the organization's systems and processes to reduce the probability of such an event in the future.

1.3. To increase the general knowledge about incidents/adverse events, their causes, and strategies for prevention.

1.4. To maintain the confidence of the public and accredited organizations in the accreditation process.

4. Policy Statement

a. It is mandatory of all health care facilities (governmental and private) to develop an incidents/adverse events management and reporting system in accordance with the NHRA licensing and regulation standards for hospitals and ambulatory heath care facilities

b. It is mandatory of all healthcare facilities (governmental and private) to report sentinel events to National Health Regulatory Authority (NHRA) based on circular (1/2018) issued by NHRA.

c. This policy and procedure guidelines define the process for identification, reporting for sentinel events to the National Health Regulatory Authority in Kingdom of Bahrain.

5. Sentinel events include:

a. Care management events:

i. 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)

ii. Patient death/ serious harm due to a hemolytic reaction / incompatible blood or blood products.

iii. Maternal deaths.

iv. Unanticipated death of a full-term infant.

v. Patient death/ serious harm due to spinal manipulation therapy or spinal tap.

vi. Deaths occurring within 48 to 72 hours of admission of patient.

vii. Performing diagnostic or therapeutic procedure on the wrong patient

viii. Infant discharge to wrong family.

ix. Deaths related to delay in treatment.

x. An unexpected or unexplained death or loss of a limb or major permanent loss of function.

b. Patient protection:

i. Patient death / serious harm associated with patient disappearance for more than 4 hours

ii. Suicide of a patient receiving care, treatment, or services in a staffed around-the- clock care setting or within 72 hours of discharge

c. Criminal events:

i. Any instance of care ordered or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provided.
ii. Sexual assault within or on the grounds of facility.
iii. Death or significant injury resulting from physical assault that occurred within or on the grounds of facility.
iv. Infant abduction.

d. Environmental Events in a health care facility:

i. Patient death / serious harm due to an electric shock while being cared for in a facility.
ii. 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.
iii. Patient death / serious harm due to burn incurred from any source.
iv. Patient death / serious harm due to a fall.
v. Patient death / serious harm due to the use of bed rails / restraint

e. Product or Device Event in a health care facility:

i. Patient death / harm disability due to the contaminated drugs / devices / biologics.
ii. Patient death / serious harm due to the use of a device which it was not intended (device includes but not limited to a catheter, drain, or other specialized tube, infusion pump or ventilator).
iii. 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.

f. Surgery Related Events in a health care facility:

i. Surgery performed on the wrong patient.
ii. Surgery performed on the wrong body part inconsistent with the documented informed consent.
iii. Wrong surgical procedure performed on a patient.
iv. Retention of foreign object in a patient after surgery or other procedure
v. Intraoperative or immediately post-operative coma or death.
vi. Death occurring during or up to 24 hours after induction of anesthesia in a normal healthy patient
vii. Deaths occurring within 24 hours postoperatively

g. Requirements of the Healthcare Facilities

All healthcare facilities (governmental and private) should:

1. Have an incident/adverse event reporting system (policy, process and form) in accordance with NHRA standards and all staff are aware of it.
2. Identify staff members responsible of managing incidents/adverse events reporting system.
3. Have a policy and a process for handling incidents/adverse events/ sentinel events.
4. Use monitoring and trending reports of incidents/adverse events for improvement.
5. Report all sentinel events to NHRA as per the procedure as delineated below.
6. Submit to NHRA an annual summary report on all incidents/adverse events reported within the facility, the summary should include but not limited to sex and age of patient involved, inpatient/outpatient, , the type of event (adverse, sentinel, near miss), category (medical/surgical clinical care management , falls, medication errors, devices related, …etc.), department involved, category of profession involved (doctor, nurse, pharmacist, allied, administrative), effect of adverse event (no harm, low harm, moderate harm,), actions taken and recommendations
7. The facility should be ready to provide NHRA with all documents related to incidents/adverse events reporting and handling system (policies, processes, forms) and any information of the identified and reported adverse events 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.
8. 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 health care staff from the affected facility.

h. Procedures for reporting sentinel events:

A. All sentinel events should be reported to NHRA.

B. 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).

C. The notification should be supported by a copy of the medical record including all tests and radiological images performed and statements from the concerned professionals' involved /in charge of the patient, they can be sent with the notification form via email or if not possible sent as a hard copy within the same specified period of time.

D. 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.

i. Role of NHRA :

a. Define the type of incidents/adverse events to be reported and the requirements for reporting.

b. Revise the list of incidents/adverse events to be reported in accordance with available evidence as needed.

c. NHRA will keep a record of all sentinel events received, investigation reports, and any other documents related to the reported incidents.

d. Revise the yearly report received on incidents/adverse events and the investigations reports of sentinel events submitted by the health care facilities and may ask for additional information, undertake its own further investigation or seek opinion from external parties, and give recommendations to address any identified issues.

e. 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.

f. Share learning from reported events when applicable while maintaining confidentiality.

g. NHRA reserves the right to take actions against a facility or health care provider in cases such as if the facility fails to take corrective actions, the incident results in police investigation or prosecution, a patient or his representative raised a complaint, if the incident indicates a gross misconduct, or it shows a repeated pattern of occurrences without taking any actions from the health facility or failure of the violator to abide with the measures taken.