National Health Regulatory Authority
Kingdom of Bahrain

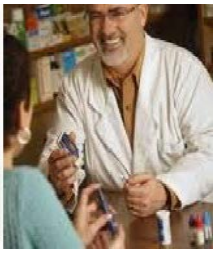
THE NHRA GUIDANCE ON SERIOUS ADVERSE EVENT MANAGEMENT AND REPORTING

THE PURPOSE OF THIS DOCUMENT IS TO OUTLINE SERIOUS ADVERSE EVENTS THAT SHOULD BE REPORTED AND THE REPORTING AND MONITORING PROCESSES INVOLVED.

VERSION 2.0 - EFFECTIVE: May 2017

THIS GUIDANCE WAS LAST UPDATED IN May 2017





1 INTRODUCTION

2 PURPOSE

The NHRA guidance for Serious Adverse Events Management and Reporting sets out the definitions, requirements and approach to be applied to improve patient safety and quality of care by:

- Advocating the requirement to develop and implement a management and reporting system in all healthcare facilities for all nonstandard incidents and adverse events; and
- Identifying the criteria for and means by which to collect, notify and report on serious adverse/ sentinel events defined in the guideline.

3 Scope

3.1 The process is identified for all NHRA licensed healthcare facilities.

3.2 All healthcare facilities are encouraged to follow the guideline and implement processes for the management and reporting of serious adverse / sentinel events to the NHRA.

3.3 All healthcare facilities are encouraged to record and monitor all adverse events, near misses and incidents internally, including those related to all aspects of direct patient care, occupational health and safety, equipment and medications.

4 Definitions

4.1 **Safety**: Freedom from accidental injuries.

4.2 **Error:** The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning) Errors may be errors of commission or omission, and usually reflect deficiencies in the systems and processes of care.

4.3 **Hazard:** Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names.

4.4 **System:** A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

4.5 **Adverse Event** – an event that causes harm, or has potential to cause harm to a patient.

4.6 **Serious Adverse/ Sentinel Event**

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, includes events that:

4.6.1 Are life threatening

4.6.2 Requires in-patient hospitalization or prolongs an existing hospitalization

4.6.3 Results in persistent or significant disability or incapacity

4.6.4 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

4.7 **Near Miss:** circumstances or events that had the capacity to cause an adverse event, but which did not reach the patient.

4.8 Adverse Event Severity

4.8.1 Mild: discomfort noticed but no disruption of normal activity

4.8.2 Moderate: discomfort sufficient to reduce or affect normal daily activity

4.8.3 Severe: interferes significantly with the subject's normal activity or course of illness. All Serious Adverse Events should be classified as severe.

4.9 Pattern of Events

4.9.1 Single event: The event occurred just once, and has ended by the time of reporting.

4.9.2 Continuous: The event began just once, and is still ongoing at the time of reporting.

4.9.3 Intermittent: The event has gone through at least one cycle of starting, stopping, and starting again.

5 Requirements of the Healthcare Facilities

5.1 To develop an adverse events management system in accordance with the NHRA guidance based on the following principles:

- quality and safety
- continuous improvement,
- Transparency
- Accountability

5.2 A system and process should be identified within the healthcare facility and should:

5.2.1 Set out in writing the details of the system in a policy and supporting standard operating procedures and documentation;

5.2.2 Establish a governance mechanism to oversee, manage, monitor and report on the effectiveness of this system and any corrective actions;

5.2.3 Use the definitions identified by the NHRA in the guidance for the purposes of categorization of all events and actions including corrective actions; and

5.2.4 Include delineated roles, responsibilities and accountabilities for staff, and as well as provide appropriate training and orientation plans and materials for all staff.

5.2.5 Each licensed healthcare facility should be able to demonstrate that an adverse events management system is implemented and managed in the facility in accordance with NHRA guidance. To do so, a facility should make available to the NHRA, if and when directed to:

5.2.5.1 The adverse events management policy and supporting documents that set out in detail the process and operating procedures and the governance system in place;

5.2.5.2 Documentary evidence of identified and reported adverse events, their causes or suspected causes, trends, actions and improvements planned or implemented to prevent recurrence, as well as training activities undertaken or planned within specified timelines.

5.2.6 To comply with NHRA directions:

5.2.6.1 The NHRA reserves the right within its role as regulator to investigate any and/or all events and apply sanctions in accordance with its remit under the regulatory legislation that is in force in Bahrain.

5.2.7 All healthcare facilities and employees should:

5.2.7.1 Comply with all applicable NHRA policies and licensing standards; and

5.2.7.2 Comply with NHRA inspection requirements, and cooperate with the NHRA licensure inspectors.

5.2.7.3 Assist the NHRA with its requests for information and/or documentation, and submit requested information within the identified timeframes.

6 Requirements of the NHRA

6.1 The NHRA will set out the definitions and types of serious adverse events/sentinel events to be reported externally and the requirements for reporting.

6.2 Reviews and from time to time revises the list of events that should be reported and investigated in accordance with evidence and reported information to ensure the safety and quality of care for patients is continuously assured and improved.

6.3 The NHRA should share learning from serious adverse events reported, patient safety and quality issues, whilst maintaining confidentiality at all times.

6.4 The NHRA should investigate and may commission its own investigations, by independent third party, of certain cases if necessary.

6.5 The NHRA can receive information on serious adverse events via the complaints system and, where necessary, will investigate any complaint in accordance with the NHRA Policies and Standard for Complaints management .(this can be found on the NHRA website)

6.6 Where it finds evidence of noncompliance with the legislation, standards and regulations, NHRA may impose sanctions consistent with its remit and the NHRA Policy on Noncompliance and Sanctions.

6.7 The NHRA will analyze investigations and any reports submitted by health care facilities and may direct them to:

6.7.1 Provide additional information;

6.7.2 Undertake further investigations into cases;

6.7.3 Develop/revise action plans to address issues identified.

6.8 Facilities should also be prepared for unannounced visits from the NHRA Licensure inspectors, which can be triggered not only by the serious adverse event reports but also by reports in the media, calls from the patient or family, or calls from concerned health care staff from the affected organization.

7 The Sentinel Event Reporting Process

7.1 For the Sentinel Event Reporting process, refer to Sentinel Event Reporting Policy, Click here.

7.2 To access the Sentinel Event Reporting Form, Click here.

7.3 A list of examples of Serious Adverse Events that should be reported to the NHRA. See Appendix (1).

APPENDIX ONE

A List of Examples of Serious Adverse events that should be reported to the NHRA

Care Management Events in a health care facility

- Patient death / harm due to medication error
- Patient death / harm due to a haemolytic reaction / incompatible blood or blood products
- Maternal death / harm due to labour / delivery in a low risk pregnancy
- Patient death / harm due to hypoglycaemia
- Stage 3 or 4 pressure ulcer acquired after admission
- Patient death / harm due to spinal manipulation therapy or spinal tap.
- Suicide of an in patient
- Other event causing patient death / harm.

Environmental Events in a health care facility

- Patient death / harm due to an electric shock
- Patient death / harm due to oxygen / gas delivery – wrong gas delivery / contaminated gasdelivery.
- Patient death / harm due to burn incurred from any source
- Patient death /harm due to a fall
- Patient death / harm due to the use of bed / restraint rails
- Other event causing patient death / harm

Product or Device Event in a health care facility

- Patient death / harm due to the use of contaminated drugs/devices/biologics
- Patient death / harm due to the use of a device which it was not intended
- Patient death / harm due to intravascular air embolism
- Patient death / harm due the use of a single use device in which the device is used other than is intended
    - New single use device
    - Reprocessed single use device
- Other event causing patient death / harm

Surgery Related Events in a health care facility

- Surgery performed on the wrong patient
- Surgery performed on the wrong body part
- Wrong surgical procedure performed on a patient
- Retention of foreign object in a patient after surgery or other procedure
- Intraoperative or immediately post-operative coma or death.
- Other event causing patient death / harm