Standards For Sentinel Events Notification And Management In Health Facilities

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Clinical Audit and Control Department

Health Regulation Sector (2025)

ACKNOWLEDGMENT

The Clinical Audit and Control Department (CACD) developed this Standard in collaboration with Subject Matter Experts and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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INTRODUCTION

Health Regulation Sector (HRS) plays a key role in regulating the health sector. HRS is mandated by the Dubai Health Authority (DHA) Law No. (6) of the year (2018) with its amendments pertaining to DHA, to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector;
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice;
- Managing patient complaints and assuring patient and physician rights are upheld;
- Governing the use of narcotics, controlled and semi-controlled medications;
- Strengthening health tourism and assuring ongoing growth; and
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for Sentinel Events Notification and Management in Health Facilities aims to fulfil the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Leading global efforts to combat epidemics and infectious diseases and prepare for disasters.

EXECUTIVE SUMMARY

The Health Regulation Sector faces an ongoing challenge with DHA licensed health facilities in defining 'Sentinel Event' for its own purposes in establishing mechanisms to identify, report and manage these events. At a minimum, a health facility definition must include those events that are subject to review under the Sentinel Event Standards.

All DHA licensed health facilities are expect to conduct a timely, thorough and credible root cause analysis; develop at action plan designed to implement improvements to reduce risk, minimize reoccurrence of sentinel events implement the improvements; and monitor the effectiveness of those improvements. Encouraging an effective communication between health facilities and the public will ensure that such an event will not happen again, strengthened by its acknowledged collaboration with regulatory and accredited bodies.

The purpose of this document is to assure the provision of the highest levels of safety and quality by to defining the process for identifying and reporting a sentinel event and to minimize reoccurrence when sentinel events occur in any Healthcare facility within DHA.

The standards cover the followings:

- Health Facility Responsibilities,
- Sentinel Events Reporting's,
- Sentinel Event Members Responsibilities,
- And Inclusion and Exclusion Criteria.

DEFINITIONS

Corrective Action Plan (CAP): Steps to prevent recurrence of the event.

Clinical Governance Committee: is a committee within the health facility that is responsible for applying clinical governance and continuous improvement for the services provided to patients and clinical results.

Hospital Executive Team: it includes the hospital CEO and Hospital leadership (Medical Director, Nursing Director, Clinical Support Services Director, Finance and Administration Director and Head of Quality).

Health Facility: is a facility licensed by DHA to provide medical services to individuals, including areas of prevention, treatment, and convalescence owned and managed by natural or corporate body.

Hospital leadership: A group of individuals who typically report to the chief executive of the hospital and most frequently include Medical Director representing the medical staff, a Nursing Director representing all levels of nursing in the hospital, Clinical Support Services Director, Finance and Administration Director and Head of Quality any other individuals the hospital selects.

Hospital Leaders: The individuals who manage and direct the "subgroups" of the hospital, commonly referred to as departments, services, units, and/or wards. And these are the Head of Departments and service directorates and managers.

Invasive procedure: a procedure in which skin or mucous membranes and/or connective tissue are incised or punctured, an instrument is introduced through a natural body orifice, or foreign material is inserted into the body for diagnostic or treatment-related purposes.

Medical Director: A medical professional licensed from DHA and is responsible for the clinical procedures at the licensed health facility.

Medication Errors: These occur when there is a mistake in administering medication to a patient, such as giving the incorrect drug, administering the wrong dosage, or using an incorrect method of delivery.

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

Notification: is a notice or written notification for the purpose of confirming the sentinel event within 48 hours.

Open disclosure: An open discussion with a patient about an incident(s) that resulted in harm to that patient while they were receiving health care. The elements of open disclosure are an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence. Open disclosure is a discussion and an exchange of information that may take place over several meetings.

Quality Office: is an office within the health facility, responsible for administrating the operations and the quality indicators of the health facility.

Reporting: is to deliver the statement components to confirm sentinel events within 72 hours and by using the primary report of SE.

Root Cause Analysis (RCA): systematic and comprehensive reactive methodology for identifying the gaps in hospital systems and processes of care that may not be immediately apparent and which may have contributed to a sentinel event or near miss of a serious incident.

Sentinel Event (SE): is a type of serious incident that is wholly preventable and has caused serious harm to, or death of a patient, and not primarily related to the natural course of the patient's illness or underlying condition. A patient safety event can be, but is not limited to, the result of a defective system or process design, a system breakdown, equipment failure, or human error.

Serious harm: is indicated where, as a result of the incident, the patient: Requires life-saving surgical or medical intervention, or has shortened life expectancy, or has experienced permanent or long-term physical harm, or has experienced permanent or long-term loss of function.

Second victim: A health care practitioner involved in an unanticipated adverse patient event, medical error, and/or a patient-related injury who becomes victimized in the sense that the practitioner is traumatized by the event.

ABBREVIATIONS:

CACD	:	Clinical Audit and Control Department
CAP	:	Corrective Action Plan
CEO	:	Chief Executive Officer
DHA	:	Dubai Health Authority
DAMA	:	Discharge against medical advice
HRS	:	Health Regulation Sector
HMMC	:	Hospital Morbidity and Mortality committee
MOM	:	Minutes of Meeting
RCA	:	Root Cause Analysis
SE	:	Sentinel Event

1. BACKGROUND

In alignment with our Health Sector Strategy for 2026, our core objective is to foster a human-centered approach to healthcare, underpinned by transparency, accountability, resilience, and innovation. This philosophy not only resonates with our broader vision to make our region a beacon of pioneering healthcare, well-being, and prosperity but also serves as the cornerstone for this Sentinel Events Notification and Management Standards within facilities overseen by the Dubai Health Authority.

This Standards is not designed to assign blame, but rather to proactively identify and resolve errors, ensuring that they are not repeated. Human error is unavoidable, but it is also preventable, particularly when it comes to Sentinel Events (SE) defined as preventable errors. This Standards aims to establish a structured framework for identifying, analysing, reporting, and learning from preventable errors.

We see this Standards as an essential step toward creating safer healthcare environments for our patients and offering protective measures for our medical staff. We believe that this Standards will serve as a foundational element in realizing our strategic objectives for 2026.

2. SCOPE

2.1. Cases related to sentinel events that may result in death or serious harm in DHA licensed health facilities.

3. PURPOSE

3.1. Initiate a transparent process for identifying and reporting, disclosure, investigating, analysing and managing a sentinel events occurs in any health facility licensed by DHA.

3.2. Understanding the causes and contributing factors of sentinel event and the underlying factors that led to a sentinel event.

3.3. To establish a robust evidence-based practice across DHA-licensed health facilities to reduce sentinel events.

3.4. Minimize the likelihood of similar events happening again in the future.

4. APPLICABILITY

4.1. All Health Facilities licensed under the jurisdiction of DHA.

5. STANDARD ONE: HEALTH FACILITY RESPONSIBILITIES

5.1. Health facilities shall adhere to the applicable federal laws, local legislations and regulations approved by DHA, including this standard and in particular those related to Care of Patients, Risk Management, Patient and Family Rights, Prevention and Control of Infection and Facility Management and Safety to minimize risk in the care environment.

5.2. Health facilities shall consider the provisions of applicable legislation regarding on any accident, error or harm that may be caused to the patient during his stay in the health facility, and this is what should be considered the differentiation between the provisions of medical errors and the provisions of any errors or other incidents that fall outside the concept of medical error.

5.3. All health facilities must conduct staff development sessions and ensure access to continuing education programmes to educate and encourage participation of all staff in patient safety programmes. Educational programmes must be consistent with Quality

Improvement/ Assessment Plan of the facility and conducted annually for clinical and non-clinical staff.

5.4. Health facilities should implement an internal policies and procedures, to identify SE based on definition, terms and process of this policy, and to be guided by the events that is notified in this standard.

5.5. Health facilities shall notify and report SE to the Clinical Audit and Control Department (CACD)–in Health Regulation Sector-DHA; through the Hospital Quality representative or Risk Manager; as per the below process:

5.5.1. Notify within 48 hours from the date of confirmation of SE through e-mail address: MC_HRS@dha.gov.ae.

5.5.2. Initiating the Root Cause Analysis (RCA) within 48 hours of SE identification and confirmation.

5.5.3. Provide Preliminary Report within 72 hours from the date of notification of SE, using the SE Preliminary Report **(Appendix 1)**.

5.5.4. Conduct a comprehensive investigation using RCA method and issue the final report within 45 calendar days of the date of SE Notification **(Appendix 2).**

a. The final report should be comprehensive, including all completed RCA as well as any investigation materials that have been gathered. This may include, but is not limited to, peer review reports, additional testimonies, supplementary patient file documents, and other relevant materials.

5.5.5. Based on the results of the RCA, develop an improvement plan with a clear timeline for implementation.

a. This plan should enhance the current systems or procedures at the facility to minimize or prevent the recurrence of similar risks in the future.

5.5.6. If the proposed action plan is deemed inadequate or unrelated to the severity of the case, it will be rejected. The facility will then have 10 calendar days to revise and resubmit the action plan. **(Appendix 3)**.

5.5.7. Facilities are encouraged to provide strong evidence of completed Action plans and initiatives, when submitting their reports.

5.5.8. The facilities are encouraged to design new or modify services or processes to incorporates information gained through sentinel event investigations as part of lesson learned initiatives.

5.5.9. Lessons learned from root cause analysis, system or process failures and the results of proactive risk assessments are communicated to all staff that provide services specific to the event or situation.

5.5.10. The health facility Quality or Risk Department Representative should monitor the effectiveness of the improvement plan with raising the report of performance progress to the clinical governance Committee at the facility. For more information, refer to the DHA Manual for Clinical Governance Framework.

5.6. The CACD shall put recommendations whenever necessary and takes any other suitable actions concerning this issue, and may have field visits to the concerned health facility related to the event to confirm the application of the working plan.

5.7. All suspected SE that has been transferred to another health facility, the concerned health facility must report the case in writing and notify the CACD department through the email address: MC_HRS@dha.gov.ae.

5.8. If a patient is referred from one facility to another and experiences a patient safety event upon arrival at the new facility or within 24 hours of admission, both the new facility and the previous facility must be involved in the sentinel event report until further instructions are provided by the HRS team.

5.9. The health facility should report all SE in its reporting system and inform its quality office.

5.10. The health facility reporting on an SE must take all precautions to ensure confidentiality and security.

5.11. All medical records and related evidences of SE shall be kept safe and secure until all related investigations completed.

5.12. Health facilities should strongly involve patients and their families in any sentinel event cases. Documenting this engagement is crucial to ensuring that the affected parties are well-informed and that the case is openly disclosed and investigated.

5.13. Health facilities should develop an internal process that supports the communication with the affected patients and activates the action of open discussion.

5.14. In the event of receiving false information in the medical complaint system, the hospital management will be subjected for an investigation.

5.15. All sentinel event cases reported to DHA – HRS are treated with utmost confidentiality.

6. **STANDARD TWO:** SENTINEL EVENT MEMBERS RESPONSIBILITIES

6.1. Medical director shall;

6.1.1. Supervise the submission of the ongoing Annual Quality Reports to CACD, overseeing the follow up and the execution of the working plan at the facility including; the number, type of SE and analyse the root causes for it to happen, and actions taken to improve safety in response to events.

6.1.2. Confirm the sustainability of following the improvement process to avoid repeating the events at the future.

6.1.3. Participate in all investigations of sentinel events, collaborating closely with the facility's risk manager.

6.1.4. Develop internal process regarding the delegation and empowerment of staff to implement priorities for proactive reduction in patient risk.

6.1.5. Enable the allocation of all essential resources for thorough investigation of sentinel events within the facility. Also, endorse the team designated for the investigation of such events and authorize the implementation of the action plan.

6.1.6. Approve all reports generated by the risk manager and ensure they are updated according to the DHA standard.

6.1.7. Assist in securing the required resources for executing the action and educational/awareness plans related to sentinel event cases.

6.1.8. If the Medical Director is unavailable, representative shall be appointed to oversee and participate in the investigation on their behalf. This appointee

should be delegated with all necessary privileges to ensure the facilitation of a thorough and proper investigation.

6.2. Quality or Risk Department Representative shall;

6.2.1. Assigned Quality representative or facility risk manager are often the first to be notified of a sentinel event. They are responsible for ensuring that the event is properly reported to health regulation sector.

6.2.2. Secure all medical records and evidences immediately after the event at the time of the event.

6.2.3. Conduct a preliminary investigation to determine the severity and implications of the event, including immediate risk to patients and staff.

6.2.4. Report the preliminary investigation to HRS using the unified format.

6.2.5. Coordinate with relevant departments to form a multi-disciplinary team tasked with investigating the sentinel event.

6.2.6. Lead or oversee a thorough RCA to identify underlying issues that contributed to the event.

6.2.7. Compile a comprehensive report detailing the event, the findings of the RCA, and recommendations for preventing future occurrences.

6.2.8. Keep key stakeholders, including senior management, medical staff, and relevant committees, informed about the status of the investigation and recommended action steps.

6.2.9. Work with various departments to implement corrective and preventive measures.

6.2.10. After corrective measures have been implemented, continuously monitor their effectiveness and adjust as needed.

6.2.11. Provide/facilitate training sessions for staff members on new protocols or systems that are put in place as a result of the sentinel event investigation.

6.2.12. Ensure all actions and documentation comply with local and federal regulations, as well as with accreditation standards.

6.2.13. Facilitate transparent communication with patients and families affected by the sentinel event, in accordance with legal and ethical guidelines.

6.2.14. Ensures that the referrals for the appropriate health professional is sent to obtain counselling/support services for family members of the client involved in the incident.

6.2.15. Periodically review past sentinel events to identify trends and areas for ongoing improvement, either annually or biannual statistical data review.

6.2.16. Coordinate with leadership and offer essential assistance to staff affected by the incident, as a part of secondary victim support framework, to ensure their well-being.

6.3. Hospital Morbidity and Mortality committee (HMMC);

6.3.1. Involvement is not required but preferred during the investigation of the cases with other facility leadership.

6.3.2. Involvement is preferred if the SE is a Mortality or Morbidity.

6.3.3. All Grade 5 morbidity cases should be treated as sentinel event and reported as a sentinel event. Refer to DHA Guidelines for the Management of Mortality and

Morbidity in Health Facilities for better scoring criteria and identification of the incident grade.

6.3.4. An overlap or similarity may be observed between the criteria for mortality reporting and those for sentinel events. However, this does not mean that only one report is required. In such cases, two separate reports are necessary. Refer DHA Guidelines for the Management of Mortality and Morbidity in Health Facilities for more information regarding submitting the mortality report.

6.3.5. The HMMC team members should be informed of the final report of the event occurring in the health facility during the monthly meetings as required.

6.3.6. Shall sign and endorse the Minutes of Meeting (MOM).

6.4. Hospital Executive Committee;

6.4.1. Should receive reports at least quarterly and act on reports submitted by the hospital leaders (Head of Departments and service directorates and managers) of patient safety programs including reports on significant adverse events, sentinel events, data on infection prevention and control process and facility management and safety programs.

6.4.2. If a new committee is formed to investigate a sentinel event; member of this new committee should have no relationship to the case management under review.

6.4.3. If a hospital is unable to form a separate committee, the facility's risk manager or any appointed quality representative may enlist the assistance of the MMC committee to investigate, report, and develop an action plan for the case.

6.4.4. RCA team must be appointed by the Executive Committee for hospitals. RCA team members must:

a. Have the appropriate skills, knowledge and experience to conduct an RCA of the event, having regard to the nature of the event.

b. Not be directly involved in providing the health service for the patient during the time at which the event happened.

7. **STANDARD THREE:** LIST OF THE EVENTS THAT REPORTED AS SENTINEL EVENT

7.1. Health facilities may encounter incidents that could be classified as sentinel events but are not explicitly listed below. As long as the incident aligns with the definition of a sentinel event, reporting and investigation are mandatory.

7.2. List of events that are reported as sentinel events are as follow:

7.2.1. Unexpected Death which occurs in the course of treatment and is not part of the patient's prognosis. This includes and not limited to death from a postoperative infection or a procedure related pulmonary embolism.

7.2.2. Procedures involving the wrong patient or wrong procedure or wrong site, this includes but not limited to the following:

a. Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death.

b. Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death.

c. Wrong surgical procedure or other invasive procedure performed on a patient resulting in serious harm or death.

7.2.3. Medication errors under Categories of Medication Error Classification G, H and I which result in permanent harm or death are reported. Refer to **(Appendix 4)**.

7.2.4. Unintended Retention of a Foreign Object; where medical equipment's or surgical tools are unintentionally left inside a patient after surgery, especially if it results in identified patient harm or requiring another operation / invasive procedure for removal.

7.2.5. Haemolytic blood transfusion reactions resulting from ABO incompatibility.

7.2.6. Transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues.

7.2.7. Sexual Assault and /or workplace violence.

7.2.8. Patient suicide at the health facility while receiving healthcare or within 72 hours of discharge.

7.2.9. Maternal death associated with pregnancy, birth and the puerperium.

7.2.10. Severe maternal morbidity leading to serious harm.

7.2.11. Infant Abduction or discharged with the wrong family.

7.2.12. Use of physical or mechanical restraint resulting in serious harm or death.

7.2.13. Unanticipated death of a full-term infant or infant born weighting more than 2500g.

7.2.14. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter).

7.2.15. Major service failure events at the health facility, this includes fire, unanticipated smoke, heat, or flashes.

7.2.16. Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or >25% above the planned radiotherapy dose.

7.2.17. Fall which may result in:

a. Fracture of any type,

b. Surgery, casting, or traction,

c. Requiring a neurological assessment as a result of skull fracture, subdural or intracranial haemorrhage or internal injury such as rib fracture and small liver laceration,

d. Requiring a blood Transfusion (Patient with coagulopathy who receives blood products as a result of the fall),

e. Death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall).

8. **STANDARD FOUR:** EXCLUSION CRITERIA FOR SENTINEL EVENT REPORTING

8.1. Health facilities are highly encouraged to investigate internally any sentinel events within the exclusion criteria and treat the matter as lesson learned cases.

8.2. Exclusion criteria for sentinel event reporting includes the following:

8.2.1. Close Call or Near Miss Event.

8.2.2. A death or loss of function following a discharge against medical advice (DAMA).

8.2.3. Refusal of treatment with a signed refusal form.

8.2.4. Unsuccessful suicide attempts unless resulting in major permanent loss of function.

8.2.5. Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequelae.

8.2.6. Foreign object, such as a needle tip, microneedles or screw, is left inside a patient due to a clinical judgment deeming the risks of locating and extracting the object surpass the benefits of its removal.

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APPENDIX

APPENDIX 1: SENTINEL EVENT PRELIMINARY REPORT

Health Facility Details	
Health Facility	☐ Hospitals ☐ Primary Healthcare Centres ☐ Specialized Centres ☐ Others (Please Specify):
Health Facility Name	
Reporting Details	
Location of event	
Event Date & Time	
Event Discovery Date & Time	
Date of Confirmation of Sentinel Event:	
Date of Notification to HRS	
Type of the event:	
How was the event reported? What is the adverse outcome which the patient had?	*(describe down the specific end result of what happened to the patient)*
Basic Information	
Person affected' s Initials	
Person affected' s ID/Passport	
Age	
Gender	
Medical Record Number if applicable	
Person affected' s Encounter	☐ Outpatient ☐ Inpatient ☐ Employee ☐Visitor ☐Vender ☐Licensed independent practitioner
Working Diagnosis/ Final Diagnosis if applicable	
Concerned Dept. & Specialty if applicable	
Event Description	
Event Summary: the event from the time of patient arrival or date of admission to the hospital till the time the event happened as appropriate. Describe the event: (what happened, when, where and how it happened. Do not include the name(s) of staff, patient(s), or other individual(s) involved in the event):	
Immediate action taken?	☐ Yes ☐ No **Mention the immediate actions taken:**
Reporters Details	
Reporter name	
Reporter title	
Facility name	
Contact details/Email & & Phone number	
Signature	
Date	
CEO/Medical Director Details	
CEO Name	
Contact details/Email & Phone number	
Signature: Date:	
Medical Director Name	
Contact details/Email & Phone number	
Signature Date:	
For Official Use only –by DHA - HRS team	
Signature Date:	Ref No. (For HRS use)

APPENDIX 2: ROOT CAUSE ANALYSIS AND ACTION PLAN FRAMEWORK TEMPLATE

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
1.	What was the intended process flow?	List the relevant process steps as defined by the policy, procedure, protocol, or guidelines in effect at the time of the event. You may need to include multiple processes. ***Note:*** The process steps *as they occurred in the event* will be entered in the next question. Examples of defined process steps may include, but are not limited to: • Site verification protocol • Instrument, sponge, sharps count procedures • Patient identification protocol				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
		• Assessment (pain, suicide risk, physical, and psychological) procedures • Fall risk/fall prevention guidelines				
2.	Were there any steps in the process that did not occur as intended?	Explain in detail any deviation from the intended processes listed in Analysis Item #1 above.				
3.	What **Human Factors** were relevant to the outcome?	Discuss staff-related human performance factors that contributed to the event. Examples may include, but are not limited to: • Failure to follow established policies/procedures • Fatigue and Inability to focus on task • Intentional blindness/ confirmation bias • Lack of complex critical thinking skills • Rushing to complete task				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
		• the unintended deviation from an appropriate plan i.e. a slip or lapse in concentration, • the incorrect solution to a known problem • lack of knowledge to deal with the problem results in the decision being made based on experience • shortcutting the process, • reasoned deviation from required process, • malicious deviation from the required process				
4.	How did the Equipment Performance affect the outcome?	Consider all medical equipment and devices used in the course of patient care, including AED devices, crash carts, suction, oxygen, instruments, monitors, infusion equipment, etc. In your discussion, provide information on the following, as applicable: • Descriptions of biomedical checks • Availability and condition of equipment				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
		• Descriptions of equipment with multiple or removable pieces • Location of equipment and its accessibility to staff and patients • Staff knowledge of or education on equipment, including applicable competencies • Correct calibration, setting, operation of alarms, displays, and controls				
5.	What controllable **Environmental Factors** directly affected this outcome?	What environmental factors within the organization's control affected the outcome? Examples may include, but are not limited to: • Overhead paging that cannot be heard • Safety or security risks • Risks involving activities of visitors • Lighting or space issues The response to this question may be addressed more globally in Question #17. This response should be specific to this event.				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
		Was the physical environment fit for purpose? Was there environmental damage				
6.	What **Uncontrollable External Factors** influenced this outcome?	Identify any factors the organization cannot change that contributed to a breakdown in the internal process, for example natural disasters.				
7.	Were there any **other factors** that directly influenced this outcome?	List any other factors not yet discussed.				
8.	What are the other areas in the	List all other areas in which the potential exists for similar circumstances. For example:				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
	organization where this could happen?	• Inpatient surgery/outpatient surgery • Inpatient psychiatric care/outpatient psychiatric care Identification of other areas within the organization that have the potential to impact patient safety in a similar manner. *This information will help drive the scope of your action plan.*				
9.	**Human Resource Issues**- Was the staff properly qualified and currently competent for their responsibilities at	Include information on the following for all staff and providers involved in the event. Comment on the processes in place to ensure staff is competent and qualified. Examples may include but are not limited to: • Orientation/training • Competency assessment (What competencies do the staff have and how do you evaluate them?) • Provider and/or staff scope of practice concerns • Whether the provider was credentialed and privileged for the care and services he or she rendered				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
	the time of the event?	• The credentialing and privileging policy and procedures • Provider and/or staff performance issues				
10.	How did actual staffing compare with ideal levels?	Include ideal staffing ratios and actual staffing ratios along with unit census at the time of the event. Note any unusual circumstance that occurred at this time. What process is used to determine the care area's staffing ratio, experience level and skill mix? • To what degree is staff properly qualified and currently competent for their responsibilities? • How did actual staffing compare with ideal levels?				
11.	What is the plan for dealing with **staffing contingencies**?	Include information on what the organization does during a staffing crisis, such as call-ins, bad weather or increased patient acuity. Describe the organization's use of alternative staffing. Examples may include, but are not limited to: • Agency nurses				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
		• Cross training • Float pool • Mandatory overtime • PRN pool				
12.	Were such contingencies a factor in this event?	If alternative staff were used, describe their orientation to the area, verification of competency and environmental familiarity.				
13.	Did **staff performance** during the event meet expectations?	Describe whether staff performed as expected within or outside of the processes. To what extent was leadership aware of any performance deviations at the time? What proactive surveillance processes are in place for leadership to identify deviations from expected processes? Include omissions in critical thinking and/or performance variance(s) from defined policy, procedure, protocol and guidelines in effect at the time.				

Formal Root Cause Analysis			
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Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
14.	**Communication Issues**- To what degree was all the necessary information available when needed? Accurate? Complete? Unambiguous?	Discuss whether patient assessments were completed, shared and accessed by members of the treatment team, to include providers, according to the organizational processes. Identify the information systems used during patient care. Discuss to what extent the available patient information (e.g. radiology studies, lab results or medical record) was clear and sufficient to provide an adequate summary of the patient's condition, treatment and response to treatment. Describe staff utilization and adequacy of policy, procedure, protocol and guidelines specific to the patient care provided.				
15.	To what degree was the communication among participants	Analysis of factors related to communication should include evaluation of verbal, written, electronic communication or the lack thereof. Consider the following in your response, as appropriate: • The timing of communication of key information				

Formal Root Cause Analysis			
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#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
	adequate for this situation?	• Misunderstandings related to language/cultural barriers, abbreviations, terminology, etc. • Proper completion of internal and external hand-off communication • Involvement of patient, family and/or significant other				
16.	What are the **barriers to communication of potential risk factors**?	Describe specific barriers to effective communication among caregivers that have been identified by the organization. For example, residual intimidation or reluctance to report co- worker activity. Identify the measures being taken to break down barriers (e.g. use of SBAR). If there are no barriers to communication discuss how this is known.				
17.	What systems are in place to identify **environmental risks**?	Identify environmental risk assessments. • Does the current environment meet codes, specifications, regulations? • Does staff know how to report environmental risks? • Was there an environmental risk involved in the event that was not previously identified?				

Formal Root Cause Analysis			
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#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
18.	What **emergency and failure- mode responses** have been planned and tested?	Describe variances in expected process due to an actual emergency or failure mode response in connection to the event. Related to this event, what safety evaluations and drills have been conducted and at what frequency (e.g. mock code blue, rapid response, Behavioural emergencies, patient abduction or patient elopement)? Emergency responses may include, but are not limited to: • Fire • External disaster • Mass casualty • Medical emergency Failure mode responses may include, but are not limited to: • Computer down time • Diversion planning • Facility construction				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
		• Power loss • Utility issues				
19.	**System Factors**	Are the policies, procedures, guidelines relating to the system appropriate? Does the design of the system meet the organizational requirements?				
20.	**Equipment Factors**	1. Has all equipment relating to the event been tested according to policy? 2. Is the testing up to date? 3. Is the equipment obsolete? 4. Have all staff been trained to use the equipment? 5. Is the equipment appropriate for use?				
21.	Was available **technology** used as intended?	Examples may include, but are not limited to: • CT scanning equipment • Electronic charting • Medication delivery system				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
22.	How might technology be introduced or redesigned to reduce risk in the future?	Describe any future plans for implementation or redesign. Describe the ideal technology system that can help mitigate potential adverse events in the future.				
23.	How can **orientation and in-service training** be revised to reduce the risk of such events in the future?	Describe how orientation and ongoing education needs of the staff are evaluated and discuss its relevance to event. (e.g. competencies, critical thinking skills, use of simulation labs, evidence-based practice, etc.)				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
24.	**Leadership issues:** How does the **organization's culture** support risk reduction?	How does the overall culture encourage change, suggestions and warnings from staff regarding risky situations or problematic areas? • How does leadership demonstrate the organization's culture and safety values? • How does the organization measure culture and safety? • How does leadership establish methods to identify areas of risk or access employee suggestions for change? • How are changes implemented?				

Formal Root Cause Analysis			
Date Analysis Initiated:		**Date Completed:**	
Principal Investigator name:			
Team Member Name	**Signature**	**Team Member Name**	**Signature**

#	Analysis Question	Prompts	Analysis Findings	Root cause	Contributing factor	Plan of Action
25.	**Encouragement of communication and Clear communication of priorities**- How is the prevention of adverse outcomes communicated as a high priority?	To what degree is the culture conducive to risk identification and reduction? Describe the organization's adverse outcome procedures and how leadership plays a role within those procedures.				
For Official Use only –by DHA - HRS team						
Approved by:		Date:			Signature:	
Head of Unit Approval:		Date:			Signature:	

APPENDIX 3: ACTION PLAN & RECOMMENDATIONS TEMPLATE

Action Plan & Recommendations: Required	Responsible Person	Action Plan Due Date	Source of evidence to support action (e.g. policy, Staff Meetings, training. announcements).	Monitoring & Evaluation Arrangements
Prepared by:		**Date:**		**Signature:**
Approved by Medical Director:		**Date:**		**Signature:**
For Official Use only –by DHA - HRS team				
Approved by:		**Date:**		**Signature**
Head of Unit Approval:		**Date:**		**Signature:**

APPENDIX 4: CATEGORIES OF MEDICATION ERROR CLASSIFICATION