HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Quality Managemnet and Patient Safety		
Document:	Administrative Policy and Procedure		
Title:	Management of Sentinel Events		
Applies To:	Hospital wide		
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1. PURPOSE:

1.1 To establish a framework, for sentinel event identification, reporting, investigation and action plan.
- 1.1.1 To ensure a comprehensive and thoughtful investigation and analysis of an incident, going beyond the more usual identification of fault and blame.

1.2 To have a positive impact in improving patient care, treatment, and services and preventing sentinel events.

1.3 To focus the attention of an organization that has experienced a sentinel 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.

1.4 To increase the general knowledge about sentinel events, their causes, and strategies for prevention.

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

2. DEFINITIONS:

2.1 **Action Plan** – is the product of the Root Case Analysis (RCA) because analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

2.2 **Adverse Event** – is an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

2.3 **Care Delivery Problems (CDPs)** – are problems that arise in the process of care, usually actions or omissions by members of staff.

2.4 **Root Cause Analysis (RCA)** – is an approach for identifying the underlying causes of an incident so that the most effective solutions can be identified and implemented. A Root Cause Analysis focuses primarily on systems/processes, and human factors.

2.5 **Sentinel Events** – is any event leading to serious patient harm or death and is caused by healthcare (human error/behaviour and/or system failure) rather than the patient's underlying illness. The following events are considered Sentinel Events even if the outcome is not death or major permanent loss of function:
- 2.5.1 Child/ Infant abduction
- 2.5.2 Discharge or handing of a newborn or an infant to the wrong family
- 2.5.3 Discharge of a Minor or Incapacitated Patient to an unauthorized person
- 2.5.4 Suicide, attempted suicide, or self-harm (Para suicide)
- 2.5.5 Staff Suicide, attempted suicide, or self-harm
- 2.5.6 Invasive diagnostic or therapeutic procedure or surgery, on the wrong patient, wrong site or side, wrong implant
- 2.5.7 Administration of incompatible ABO, Non-ABO of blood/ blood products, or transplantation of incompatible organs
- 2.5.8 Unintended retention of a foreign object
- 2.5.9 Unexpected Death of a full-term Newborn
- 2.5.10 Rape
- 2.5.11 Assault or homicide

2.5.12 Assault or homicide of Visitor or Watcher
2.5.13 Physical and Psychological violence, or homicide of a staff member
2.5.14 Fire, flame, unanticipated smoke, or flashes
2.5.15 Unauthorised departure of the patient (absconded)
2.5.16 Medication error
2.5.17 Patient severe temporary harm, permanent harm, or death associated with intravascular air embolism
2.5.18 Patient severe temporary harm, permanent harm, or death as a result of medical device breakdown or failure when in use
2.5.19 Unexpected building collapse, or malfunctioning structure or overturning of any healthcare facility load bearing part of any lift or lifting equipment when in use or during installation
2.5.20 Transfusing/ transplantation of contaminated blood, blood products, organ or tissue or transmission of disease as a result of using contaminated instruments or equipment provided by the healthcare facility
2.5.21 Death or serious disability associated with failure to manage/identify neonatal hyperbilirubinemia
2.5.22 Delivery of radiotherapy to the wrong body region or dose exceeds more than 25% of the total planned radiotherapy dose
2.5.23 Patient severe temporary harm, permanent harm, or death as a result of patient fall
2.5.24 Patient severe temporary harm, permanent harm, or death associated with administration/ connection of the wrong medical gas
2.5.25 System failure leading to service interruption and total evacuation outside healthcare facility
2.5.26 Unexpected death
2.5.27 Unexpected Loss of a limb or a function
2.5.28 Maternal death, permanent harm, or severe temporary harm
2.5.29 MR damage or Patient or staff severe temporary harm, permanent harm, or death associated with introduction of a metallic object
2.5.30 Loss or damage to specimen sample or tissue biopsy after invasive procedure

2.6 Task Force is the subcommittee appointed by the Committee to:
2.6.1 Investigate an occurrence or process variation.
2.6.2 Determine whether such occurrence or process variation meets the definition of a Sentinel Event.
2.6.3 Complete a comprehensive and credible RCA and resulting Action Plan describing the hospital's risk reduction strategies when a Sentinel Event occurs.

3. POLICY:

3.1 It is the policy of Maternity and Children Hospital (MCH), Hafer Al Batin to identify Sentinel Events, enhance individuals' awareness within the institution about Sentinel Events, take immediate action, investigate and understand the causes that underlie Sentinel Events. Moreover, introduce changes in the hospital systems and processes to reduce the probability of such Sentinel Events in the future.

3.2 It is the policy of MCH that all identified sentinel events must be reported with 48 hours from discovery to the MOH sentinel event reporting website. https://hsp.moh.gov.sa/Login.aspx. As well, the identified event should be reported to CBAHI within five working days after accreditation.

3.3 The appropriate response to sentinel event must include conducting a thorough RCA and developing an action plan made up of recommendations with responsibilities and timeline within 14 working days, upon becoming aware of the event. RCA focuses primarily on systems and processes, not on individual performance.

3.4 Any intentional unsafe act must be handled through administrative lines of authority, for appropriate disciplinary action.

3.5 MOH mandates to maintain a system for the disclosure of patient safety events to the patients and their families. Therefore, in case of sentinel event occurred at MCH, an appropriate disclosure must be carried out as per the approved disclosure policy.

3.6 MCH should provide appropriate support to the staff involved in sentinel event. If staff members feel that they need to discuss the incident and the circumstances involved with a counsellor/ professional who can provide support and understanding. Therefore, MCH should provide every opportunity to do so and take the appropriate measures to see that the staff member's needs are addressed.

3.7 The medical director or his/her designee will report sentinel events activities to the board.

3.8 The Quality committee upon review of the case shall determine if the professional conduct requires professional peer review.

3.9 Each facility must maintain a database of all sentinel events that will help the organization to monitor action plans, and conduct necessary analysis for the data.

3.9.1 Database must contain but not limited to the following data fields:

- 3.9.1.1 Medical Record Number
- 3.9.1.2 Patient age
- 3.9.1.3 Gender
- 3.9.1.4 Primary diagnosis
- 3.9.1.5 Comorbidities
- 3.9.1.6 Event Type
- 3.9.1.7 Event outcome
- 3.9.1.8 Event location – Time – date – day of the week
- 3.9.1.9 Root cause/s
- 3.9.1.10 Action plan
- 3.9.1.11 Action plan follow up

3.10 The Quality Management and Patient Safety (QM&PS) Department at MCH must ensures dissemination of lessons learned from RCA using multiple ways:

- 3.10.1 Newsletter
- 3.10.2 Ground round
- 3.10.3 Posters
- 3.10.4 Meetings

3.11 All files and written materials generated because of an Adverse Event shall be maintained and reported by the QM & PS Department with complete precautions to ensure confidentiality and security at MCH.

3.12 Monitoring:

The Quality Management and Patient Safety (QM&PS) Director/Risk Manager will ensure that all incidents are acknowledge and correctly referenced, graded, collated, reported and archived in order to provide a permanent record of reported incidents for legal and informative and education purposes.

- 3.12.1 The Quality Management Director and/or Risk Manager shall request further clarification, investigation or action as a result of the incident and will advise relevant unit/service/department manager/supervisor accordingly.
- 3.12.2 The Learning from experience group will review all complaints and incidents to identify trends and refer them to appropriate operational group. So, that investigation can take place, action taken and lessons learned for the future.

3.13 Goals of the Sentinel Event Policy

- 3.13.1 To have a positive impact in improving patient care, treatment, services and preventing sentinels events.
- 3.13.2 To focus the attention of an organization that has experienced a sentinel event on understanding the causes that lie beneath the event, and on changing the organization's systems and process to reduce the probability of such event in the future.

4. PROCEDURE:

4.1 Reporting of Sentinel Event:

4.1.1 Staff discovered the event should report and submit an OVR form to person in-charge/ direct manager **immediately**.

4.1.2 Send the report to the QM&PS Director by the person in charge/ supervisor **immediately**.

4.1.3 Conduct initial review to determine if it meets the sentinel event criteria by the Risk Manager or QM&PS Director **within 48 hours**.

4.1.4 If a sentinel event is confirmed, **immediately** secure the medical record and a copy of the medical record will be made for investigation.

4.1.5 Then, incident must be reported **immediately** to the MOH sentinel event reporting website. https://hsp.moh.gov.sa/Login.aspx. By the Risk Manager or QM&PS Director. Also, the identified event should be reported to CBAHI within five working days.

4.1.6 **Immediately** QM&PS Director or the Risk Manager should notify MCH Medical Director, the Hospital Director, Nursing Director, the regional Directorate Director, and the regional directorate QPS director using email and/or short message SMS.

4.2 Investigation of Sentinel Event:

4.2.1 Activation of core investigation team (3 - 5) Individuals by Medical Director, QM&PS Director and Risk Manager should be straightway.

4.2.1.1 Team composition: Incident investigation team and analysis experts.

4.2.1.2 External expert(s) view (this can be a non-executive board member with no specific medical knowledge).

4.2.1.3 Senior management expertise (e.g. Medical Director, Director Of Nursing).

4.2.1.4 Senior clinical expertise (medical director or senior consultant).

4.2.1.5 It is also valuable to have someone who knows the relevant unit or department well, though they should not have been directly involved in the incident.

4.2.1.6 When appropriate, the core investigation team members will be released from their regular duty to conduct the investigation for a certain amount of days, as determined by the investigation team leader and the QM&PS Director.

4.3 Information Gathering conducted by Investigation Team (risk manager to coordinate and facilitate) within 5 working days:

4.3.1 All facts, knowledge and physical items related to the incident should be collected as soon as possible. This may include:

4.3.1.1 The medical records.

4.3.1.2 Documentation and forms related to the incident (e.g. protocols and procedures).

4.3.1.3 Immediate statements and observations.

4.3.1.4 Interviews with those involved in the incident.

4.3.1.5 Physical evidence (e.g. ward layout schematics, etc.).

4.3.1.6 Secure equipment involved in incident (e.g. CTG machine).

4.3.1.7 Information about relevant conditions affecting the event (e.g. staff Rota, availability of trained staff, etc.).

4.4 **Analysis (identify care delivery problems (CDPs) and contributory factors)** conducted by Investigation Team (risk manager to coordinate and facilitate) **within 3 working days:**

4.4.1 Gathered information will be organized in a chronological order using one of the following tools:

4.4.1.1 Narrative chronology

4.4.1.2 Time Person Grid

4.4.1.3 Flow chart

4.4.2 Variation from appropriate practice will be determined by comparing actual events sequence with what should have occurred (according to the relevant policy and procedures).

4.4.3 The investigation team will identify active failures - unsafe acts or omissions committed by those at the `sharp end' of the system (anaesthetists, surgeons, nurses, etc.) whose actions can have immediate adverse consequences.

4.4.4 The investigation team should now identify the care delivery problems (CDPs).

4.4.4.1 All CDPs are specific actions or omissions on the part of the staff, rather than more general observations on the quality of care.

4.4.5 The investigation team then considers the conditions in which errors occur and the wider organizational context, which are known as contributory factors (Appendix 7.2).

With many CDPs, it is best to select a small number of these regarded as most important.

Nominal group technique and multi-voting can be used to agree on the top CDPs, contributory factors and causes.

4.4.6 The team can use fishbone diagram to organize the information and analyse the causes.

4.4.7 To add credibility to the analysis the team should review relevant literature where applicable.

4.4.8 The analysis identifies changes that could be made in systems and processes (either through redesign or development of new systems or processes) which would reduce the risk of such events occurring in the future.

4.5 Making Recommendations and Developing an Action Plan conducted by Investigation Team (risk manager to coordinate and facilitate) within 2 working days:

4.5.1 The action plan should include the following information:

4.5.1.1 Prioritize the contributory factors in terms of their importance for the safety of future healthcare delivery.

4.5.1.2 List of actions needed to address these contributory factors as determined by the investigation team

4.5.2 Identify:

4.5.2.1 Responsible individuals for implementing the actions.

4.5.2.2 The timeframe for implementation.

4.5.2.3 Any resource requirements.

4.5.2.4 Evidence of completion (such as training record, approved forms/policy).

4.5.2.5 Formal sign-off of actions as they are completed.

4.5.2.6 The date to evaluate the effectiveness of the Action Plan.

4.6 After accreditation by CBAHI, the root cause analysis and risk reduction plan are sent to CBAHI within 30 working days from the date of the internal notification of the event.

4.7 QM&PS Director or/ and Risk Manger submit the Investigation Report to Medical director, Regional Directorate and MOH Headquarters (QM&PS Directorate and Clinical System e – health) within 1 working day.

4.8 QM&PS Director presents the recommendations and action plan to the quality committee for approval.

4.9 **Monitoring of Action Plan**

4.9.1 Review of all RCAs action plans monthly by the Risk Manager.

4.9.2 Review measures of success monthly by the Risk Manager.

4.9.2.1 The organization will use measures of success (MOS) to follow up of the RCA action plan.

4.9.3 The planned action element of performance (EP) compliance will be determined according to the following:

4.9.3.1 If the action EP is associated with a standard or Essential Safety Requirement (ESR) the level of the compliance will be level "A" which is equivalent to 100%.

4.9.3.2 If the action is not associated with ESR equivalent to an EP that is identified as a "B" EP, the minimum required level of compliance for the sentinel events MOS for that action will be 90%.

4.9.3.3 The compliance will be determined by conducted an audit of appropriate sample.

4.9.3.4 Data must be collected for a period of 4 months or until level of compliance has been achieved

4.9.3.5 Aggregate all MOS results and Action Plans status by the Risk Manager every 3 months.

4.9.3.6 Write Action Plans Status Report quarterly by the Risk Manager.

4.9.3.7 Review and Approve the Status Report by the QM&PS Director.

4.9.3.8 Share the report with Hospital Director and the QM&PS committee members.
4.9.3.9 Hospital Director reviews and approves the report every 3 months.
4.9.3.10 QM&PS Director submits the report to the QPS director of the regional directorate.

5. MATERIALS AND EQUIPMENT:

5.1 Action Plan Form
5.2 Contributory Factors Table
5.3 Occurrence Variance Incident Report (OVR) Form
5.4 Root Cause Analysis (RCA) Form

6. RESPONSIBILITIES:

6.1 Staff discovered the event
6.2 Person in – charge/ Direct manager/ Head of Department
6.3 Quality Management and Patient Safety Director
6.4 Risk Manager
6.5 Medical Record Director
6.6 Medical Director
6.7 Hospital Director

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Saudi Patient Safety Taxonomy
8.2 RMT manual

9. APPROVALS:

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