HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Quality Management and Patient Safety		
Document:	Administrative Policy and Procedure		
Title:	Electronic Occurrence Variance Incidents Reporting (OVR)		
Applies To:	Hospital Wide		
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1. PURPOSE:

1.1 To ensure Maternity and Children Hospital, Hafer Al Batin has a clearly defined responsibility and accountability framework in place to appropriately manage incidents.

1.2 To have a positive impact in improving patient care, treatment, and services and preventing incidents that may affect patient safety.

1.3 To ensure that there is immediate management of an incident when required and that every incident is appropriately documented, prioritized, investigated and managed.

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

1.5 To provide a means of analysing trends in incidents and identification of factors contributing to incidents, to assist in implementation of service improvement and risk reduction strategies, thereby minimizing risk to staff, patients, clients and visitors, and the organization.

2. DEFINITIONS:

2.1 **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.

2.2 **Incident** – is an event or circumstance that harmed or has the potential to harm a person or a property in relation, resulting from human behaviour and/or system failure.

2.3 **Near Miss** – an error that has the potential to cause an adverse event (patient harm) but fails to do so because of chance or because it is intercepted

3. POLICY:

3.1 It is the policy of Maternity and Children Hospital, Hafer Al Batin that centralized system for identification and investigation of occurrences by provide Occurrence Variance Incidents Reporting (OVR), available from the Quality Management and Patient Safety (QM&PS) Department. The reported incidents should be entire actual, objective and are not intended for use in discipline or counselling. The occurrences discussed in this document are limited to those that may lead to injury or loss of the patient and result in claim against Maternity and Children Hospital, Hafer Al Batin employee. In the other hand, brief description about **Significant and Potentially Significant Medication Error** and **Adverse Drug Reactions** should be submitted by an OVR then detailed information and description of the incident should be completed according to Medication Error and Adverse Drug Events Policies and Procedures.

3.2 Occurrence reports will be utilized as sources of data for tracking and managing risks at Maternity and Children Hospital, Hafer Al Batin environment, Quality Management (QM) /Peer Review Processes, identifying and resolving potential claims against Maternity and Children Hospital, Hafer Al Batin.

3.3 Occurrence reports intend to be reviewed by QM & PS Committee.

3.4 Confidentiality: Electronic OVR must never be presented at patient's area or file. As well, only persons involved in OVR process can see and document OVR information or feedback. OVR process should ensure the following:

3.4.1 No reference should be made to the OVR on a patient's chart.

3.4.2 Necessary information should be extracted and shared with other departments only as warranted.

3.4.3 The Ministry of Health emphasizes that incident reporting will not result in disciplinary proceedings, except in the most exceptional circumstances, for example, where there has been a breach of law, gross negligence or professional misconduct. Therefore, the Maternity and Children Hospital, Hafer Al Batin policy as well encourages the detection of adverse events in a safe and blameless environment in situations other than those mentioned above, which contributes to improving the quality and safety of maternal and child health services.

3.5 All adverse occurrences at Maternity and Children Hospital, Hafer Al Batin areas should be reported via Electronic OVR without any omissions for any unit or department included at Maternity and Children Hospital, Hafer Al Batin. In addition, serious incidents involving staff, patients and visitors are required to be reported.

3.6 Training:

3.6.1 The policy states that all new members of the staff will be oriented about the principles of Quality and Risk Management, including incident reporting procedures, during their initial training period.

3.6.2 All staff will receive mandatory update training annually on incident reporting as part of Risk Managements Training.

3.6.3 Each department or unit leader will undergo training in incident reporting, root cause analysis and workplace violence as part of Maternity and Children Hospital, Hafer Al Batin Training Program.

3.7 Facilities:

3.7.1 All auxiliary equipment used in the patient's care settings such as beds, hoist, wheelchairs, etc. should be monitored regularly to ensure quality of work.

3.7.2 Any equipment involved in an incident should be retained in a safe place for future examination. Configuration and settings on equipment must not be altered before the primary examination has been completed. If possible, do not turn off or reset any medical device until the biomedical engineers approve the clinical setup.

3.7.3 Such equipment should not be re – used without the approval of either the Hospital Director or Facility and Management Safety (FMS) - Engineering and Maintenance Department.

3.8 For any reportable event, the Electronic OVR must be completed and forwarded to the quality department within 24 hours from its occurrence.

4. PROCEDURE:

4.1 **Identification and Reporting of an Incident:**

4.1.1 Incidents include, but are not limited to:

4.1.1.1 Injuries to employee, patient, family, members and/or visitors resulting from accidents or error such as: falls, equipment failures, medication errors, adverse drug reactions, injuries caused by violence.

4.1.1.2 Near Miss Incidents.

4.1.1.3 Security violations

4.2 **Upon discovery of an incident, the following process will be initiated immediately before completion and submission of OVR report.**

4.2.1 Mitigate the harm, by treating the patient (affected person whether patient, staff or visitor).

4.2.2 Maintain safe environment (protect the scene).

4.2.3 In the case of adverse event, document the event in the patient medical record that it was initiated.

4.2.4 In the case of Narcotics, or controlled drug related incidents, specifically broken ampoules, pharmacy and internal audit must be immediately notified.

4.2.5 Once sentinel event has been identified, the Reporting and Investigation of Sentinel Event Policy and Procedure must be followed.

4.2.6 A complete OVR report must be filled.

4.2.7 All communication (verbal and written) associated with the investigation of OVR will be documented in the Electronic OVR.

4.2.8 All persons involved in the incident must be clearly identified on the incident report (i.e. individual client/patient/staff/student member(s) adversely affected, staff involved in the incident itself, and witnesses to the incident).

4.2.9 Incident report should provide a clear and factual description of the circumstances of the incident. Opinion should not be provided. Abbreviations may be used, but only if they are explained in the first instance. So, that assistance can be provided, and the incident documented accordingly.

4.2.10 Separate statements may be provided where there is insufficient space to record information on the Electronic OVR. Depending on the circumstances, statements should also be sought from staff/students involved in the incident or who witnessed events, as appropriate. Statements must be signed and dated.

4.2.11 If staff is concerned about the appropriateness of completion of an incident, he/she should contact a member of the Risk Management Team/OVR manager for advice.

4.2.12 If a staff is unable to complete the Electronic OVR, for example, due to disability, he/she should contact a member of the Risk Management Team.

4.2.13 Incident Reports should be forwarded to the direct Manager/Person in charge at time and place of incident within 24 hours of the incident occurring for sign-off. The manager reviewing the incident report should ensure that all relevant information has been accurately recorded.

4.2.14 Notify the Senior Manager of all extreme (red) rated incidents and high (amber) rated incidents which are deemed to be serious enough to require immediate attention.

4.2.15 Contact the on-call if, the incident occurs out of normal working hours, e.g. on call senior manager/out of hours' social worker as appropriate.

4.2.16 In case of potential sentinel event, report the OVR to the QM&PS Director for further evaluation with the Risk Manager.

4.2.17 In case of medication related OVR, call the attention of the medication safety officer.

4.2.18 **In case of patient fall, fill the patient fall investigation form.**

4.2.19 Any material amendments (e.g. description of incident) must be discussed and agreed with the member of staff who reported the incident.

4.3 **Grading of the Incident:**

4.3.1 All incidents must be graded once reported, at the time of reporting the incident using the Impact Assessment Table and Risk Evaluation Matrix

4.3.2 Determine the **potential likelihood** of recurrence.

4.3.3 Grade according to the actual impact/severity on the individual and/or organization.

4.3.4 If two or more areas have been affected by the incident, consider which has been affected the most, to assist in your judgement of the impact/severity of the incident.

4.3.5 Calculate overall risk level (i.e. Red, Amber, Yellow or Green).

4.3.6 Once OVR is received in the risk unit, the OVR will be tracked, entered in excel data base, reviewed and prioritized according to the severity level.

4.3.7 Review and amend/edit incident reports if there are errors or inadequacies in the report provided, for example:

4.3.7.1 The description of the incident is factually incorrect.

4.3.7.2 The description of the incident does not provide adequate information.

4.3.7.3 There are grammatical/ typographic errors, Names of staff have been included in free text fields.

4.3.7.4 Any material amendments (e.g. description of incident) must be discussed and agreed with the member of staff who reported the incident.

4.3.8 Review and determine the actual impact/severity based on information provided on the report and input this in the risk assessment section in the OVR form

4.3.9 Once OVR is received by the responding department, the OVR will be tracked, entered in excel database, reviewed and prioritized according to the severity level.

4.4 **Incident investigation and closure:**

4.4.1 All OVRs rated within the green risk zone must be closed within 5 working days of discovery date, except those in the amber (high) and red (extreme) risk zones.

4.4.2 All OVRs rated within the amber (high) risk zone must be closed within 10 working days.

4.4.3 All OVRs rated within the red (extreme) risk zone must be closed within 14 working days.

4.4.4 Responsibility for investigation of incidents lies with the manager of the service that was responsible for one or more of the following:

4.4.4.1 The circumstances which led to the incident occurring.

4.4.4.2 The staff involved in the incident.

4.4.4.3 The equipment or other asset/facility involved in the incident.

4.4.4.4 The investigation of incidents and 'near misses' must be thorough and comprehensive to ensure causes are identified and remedial action taken.

4.4.4.5 Regardless of the grading of the incident, 'action taken to prevent recurrence' and lessons learned must be formally recorded in the OVR.

4.4.5 Take the action and send back the OVR to the Risk Management Unit.

4.4.6 Track the OVR, entered in excel data base, review the feedback and send back to the initiator for review and acknowledgment.

4.4.7 Review the feedback from the responding department, share it with the initiating staff (the reporter) and sign it off. The initiator head/the initiator can contact the risk management unit if they have any concern about the feedback received.

4.4.8 Send back the OVR to the risk management unit.

5. MATERIAL AND EQUIPMENT:

5.1 OVR site/ link

6. RESPONSIBILITIES:

6.1 All MCH Employees

7. APPENDICES:

7.1 OVR Process Flow Chart
7.2 Sentinel Events List
7.3 Mandatory Reportable Events List

8. REFERENCES:

8.1 Patient Safety Taxonomy
8.2 Risk Management Policies and Procedures Manual, 2018

9. APPROVALS:

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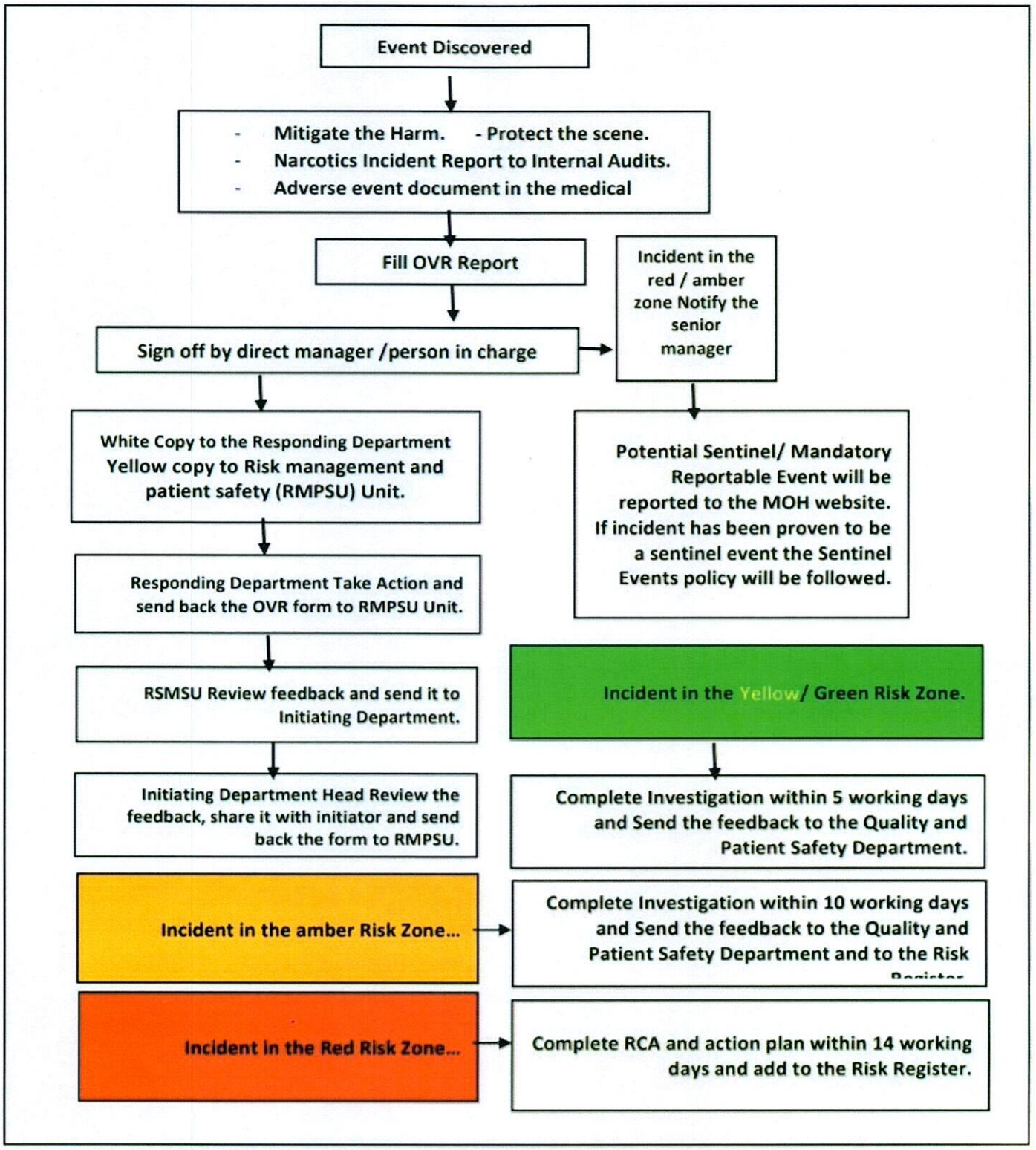
APPENDIX 7.1: OVR Process Flow Chart



APPENDIX 7.2: Sentinel Events List

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

Sentinel Events List

1	Child/ Infant abduction
2	Discharge or handing of a newborn or an infant to the wrong family
3	Discharge of a Minor or Incapacitated Patient to an unauthorized person
4	Suicide, attempted suicide, or self-harm (Para suicide)
5	Staff Suicide, attempted suicide, or self-harm
6	Invasive diagnostic or therapeutic procedure or surgery, on the wrong patient, wrong site or side, wrong implant
7	Administration of incompatible ABO, Non-ABO of blood/ blood products, or transplantation of incompatible organs
8	Unintended retention of a foreign object
9	Unexpected Death of a full-term Newborn
10	Rape
11	Assault or homicide
12	Assault or homicide of Visitor or Watcher
13	Physical and Psychological violence, or homicide of a staff member
14	Fire, flame, unanticipated smoke, or flashes
15	Unauthorised departure of the patient (absconded)
16	Medication error
17	Patient severe temporary harm, permanent harm, or death associated with intravascular air embolism
18	Patient severe temporary harm, permanent harm, or death as a result of medical device breakdown or failure when in use
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
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
21	Death or serious disability associated with failure to manage/identify neonatal hyperbilirubinemia
22	Delivery of radiotherapy to the wrong body region or dose exceeds more than 25% of the total plannedradiotherapy dose
23	Patient severe temporary harm, permanent harm, or death as a result of patient fall
24	Patient severe temporary harm, permanent harm, or death associated with administration/ connection of the wrong medical gas
25	System failure leading to service interruption and total evacuation outside healthcare facility
26	Unexpected death
27	Unexpected Loss of a limb or a function
28	Maternal death, permanent harm, or severe temporary harm
29	MR damage or Patient or staff severe temporary harm, permanent harm, or death associated with introduction of a metallic object
30	Loss or damage to specimen sample or tissue biopsy after invasive procedure

APPENDIX 7.3: Mandatory Reportable Events List

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

Mandatory Reportable Events List

1	Third or fourth perienal tear post delivery
2	Erb's palsy
3	Eclampsia in a booked patient
4	APGAR score 5 in 10 minutes
5	Unexpected unplanned return to operation room
6	Unplanned blood transfusion
7	Unscheduled return to emergency room after discharge from the ward(within 72H)
8	Injury or unplanned repair of an organ
9	Complication post ERCP
10	Complication of angiogram
11	Patient harm resulting from medical device/equipement error/malfumction(if the harm resulting in permanent of function/organ or has led to death the event must be reported as a sentinel event)
12	ROP needing laser or cryotherapy
13	IHV grade III/IV
14	Maternal ICU admission
15	Injury to commom Bile Duct during laparoscopic Cholecystectomy
16	Still birth
17	Therapeutic Abortion
18	Septic abortion
19	Venous thromboembolism
20	Uterine rupture
21	Febrile non-heamolytic transfusion reaction(Acute Transfusion Reactions)
22	Urticarial (Allergic) Reaction(Acue Transfusion Reactions)
23	Anaphylactic Reaction (acute Transfuion Reactions)
24	Transfusion-realted acute lung injury (TRALI) (Acute Transfusion Reactions)
25	Transfusion-associated circulatory overload (TACO) (Acute Transfusion Reactions)
26	Immunologica haemolysis due to alloimmunization (Delayed transfusion Reactions)
27	Delayed haemolytic transfusion reaction(Delayed Transfuion Reactions)