**Institution Name:** Directorate General of Quality Assurance Centre, MoH  

**Document Title:** Policy & Procedure of Occurrence Variance Reporting  

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Acknowledgement

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## Acronyms:

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<td>DCDQD</td>
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OCCURRENCE VARIANCE REPORT SYSTEM

1. Introduction
Rapid development which has taken place over the past few years as a result of combination factors, including heightened expectation of the community in getting safe and good quality of care, great complexity of health system, technological, market changes, and necessary saving measures, government regulation changes, and the need for standardization and variance control. Such driving forces made many healthcare systems globally to take active role to ensure safe delivery of healthcare services. Reporting of adverse events is encouraged throughout the Ministry of Healthcare institutions and is considered as an essential component of Risk Management program. This policy is designed to allow for the identification of and appropriate response of all sentinel events, adverse events including near misses.

2. Scope
This document is applicable to all healthcare institutes in MOH.

3. Purpose
3.1 Improve the quality of patient care.
3.2 Provide a systematic, standardized mechanism to identify occurrence and/or to develop prevention /improvement programs, which have direct or indirect adverse effect on patient care; and which represent a potential hazard to patients, visitors, staff or the facility.
3.3 Occurrence Variance Report (OVR) is used as a mechanism for monitoring and quality Improvement in a non-punitive approach.
3.4 To have a positive impact in improving patient care, treatment and services and preventing sentinel events.
3.5 To focus the attention of the organization that has experienced a sentinel event, on understanding the causes that triggered the event and on changing the organization’s systems and processes to reduce the probability of such an event reoccurring in the future.

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

3.7 To make changes in the hospital systems and processes to reduce the probability of Sentinel Events in the future

4. Definitions

5.1 An Occurrence : Any occurrence that is not consistent with routine patient care or hospital procedure which either did or could have resulted or loss to patient or visitor or which may give rise to claim against the hospital, an employee of the hospital, or a member of the hospital medical staff.

5.2 Occurrence Variance Report (OVR): A form used to document the details of the occurrence/event and the investigation of an occurrence and the corrective actions taken.

5.3 Adverse Drug Event: Any occurrence in which the use of medication at any dose, improper administration of medications or a special nutritional product (for example dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient.

5.4 Adverse Events: Unexpected incidents, therapeutic misadventures, iatrogenic injuries or other adverse occurrences directly associated with care or services provided. Adverse events can be categorized as either a sentinel event or near miss that results from acts of commission or omission (e.g. administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.).
5.5 Sentinel Event (SE): A “Sentinel Event” is an unexpected occurrence involving death or serious physical or psychological injury, not related to the natural course of a patient’s illness or underlying condition (Please refer to Appendix1: Examples of Sentinel Event).

5.6 Near Miss: Is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.

An example of a Near Miss would be:

5.6.1 Surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification but caught at the last minute by chance.

5.6.2 Near misses will receive the same level of analysis as Adverse Events that result in actual injury, and for learning purposes.

5.7 Malpractice: Improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position, often applied to physicians, dentists, nursing to denote negligent or unskillful performance of duties when professional skills are obligatory.

5.8 Variation: The differences in results obtained in measuring the same event more than once. The sources of variations can be grouped into two major classes: common causes and special causes. Too much variation often leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services.

5. Policy

It is the policy of the Directorate General of Quality Assurance Centre (DGQAC) through implementation of a comprehensive national Occurrence Variance reporting system to minimize risk to patient’s visitors, staff, contractors, or the facility.

This policy involves the following steps:

5.1 The person who has the best knowledge of the occurrence must complete the OVR form/online.
5.2 Minimize negative consequences to the injured individual when Adverse Events occur.

5.3 Ensure appropriate and timely communication with patients and their families regarding adverse events.

5.4 Trend and analyze all reported occurrence in a monthly or quarterly basis.

5.5 Submit to the leadership recommendations based on trending data to rectify identified system failures or exposures.

6. **Procedure**

The procedure of reporting and feedback can be carried out through the following:

6.1 The person who has the best knowledge of the occurrence must complete the Risk/Quality Occurrence Report form/online. *Please refer to Appendix 2 &3: OVR “Occurrence Variance Report flow chart.*

6.2 Adverse event reporting is the responsibility of the directly involved/affected individuals.

6.3 When incident entered at *adverse event reporting & Learning System (RLS)*, according to the reporting system electronic cascade, it will go to the institution director/governorate, concerned director and Quality Management Director/event manager by default.

6.4 The report must be completed as soon as the occurrence has happened.

6.5 Name of all witnesses to the occurrence must be documented on the safety/risk occurrence report, including all pertinent information, i.e. status (visitor, staff, etc.).

6.6 The person completing the report should answer the “who, what, where, why and how” of the occurrence. Only the facts must be documented.

6.7 The event manager is the *only* authorized person to directly forward the reported incident to the concerned departments and/or according to the involvement parties (single or multiple involvements) and as per investigation requirements.

6.8 If an adverse event is a nursing related issue, it will be forwarded to the director of nursing department and/or unit nurse for information or needful action. A further forwarding can be requested by nursing management to investigate and incident progression follow up.
6.9 If an adverse event is computer related, information technology (IT) department should be notified first to rectify the problem immediately, an IT request to be entered and then an adverse report to be initiated.

6.10 If the adverse event is equipment related directly affecting patient safety, a work order to be entered first and then an adverse event to be initiated.

6.11 When reporting an event involving Equipment/Supply or a Medical Device, the following information, as applicable, must be included with the report:

- Equipment Name
- Manufacturer
- Model Number
- Serial Number
- Lot Number
- Removed from service: Yes / No / Unknown
- Biomedical Engineering Number: If known
- Biomedical Assess Number: If known

6.12 If the adverse event is related to other departments or sections, it will be forwarded to the head of the department or section, which will investigate the event, follow up and feedback the risk manager either online or in writing if required.

6.13 Event Manager/appointed QA staff will follow up investigation / feedback and send reminders if needed.

6.14 Sentinel events will require a Root Cause Analysis in which RCA team to be formed as per involvement in order to investigate the incident.

6.15 Time frame for forwarding and feedback as per adverse event severity classification scale. Major type adverse event shall be reported immediately and feedback within a month of occurrence. Moderate and minor adverse events feedback expected within two weeks of adverse event occurrence.

6.16 Reporter must follow up reported incident online for any further details, comments or feedback. Risk manager will close the adverse event on completion of investigation, analysis, action and as per policy identified time frame.

7. Investigation feedback and summary report will be sent to the concerned department...
with areas for improvement and recommendations by the end of each month or when investigation and analysis finalized.

**Sentinel Events**

**7.1 Sentinel Events Committee**

**7.1.1 Creation of Committee**

The hospital shall form a committee called the Sentinel Event Committee.

**7.1.2 Composition of Committee**

The Sentinel Event Committee shall be composed of the following:

A. Event Manager/appointed QA for incident management (Chairman).
B. Medical Director/administrator.
C. Patient safety focal point.
D. Ad-hoc members.

**7.1.3 Duties of the Committee**

The Committee shall:

A. Review an occurrence or process variation.
B. Determine whether such occurrence or process variation meets the definition of a Sentinel Event.
C. Ensure completion of a Root Cause Analysis and resulting Action Plan describing the hospital’s risk reduction strategies when a Sentinel Event occurs.
D. The Sentinel Event Committee may appoint a Task Force to perform some or all of these functions or may serve as the Task Force performing these functions.

**7.2 Procedure**
7.2.1 A significant variation in patient care (suspected Sentinel Event) can be identified by any of the following:

A. Department Heads, Nurse Managers, Unit Managers.
B. Any Hospital Committee.
C. Risk/Quality rounds.
D. Any Staff Member

7.2.2 Whenever a significant variation in patient care is suspected, it is the responsibility of the individual(s) identifying the variance to report the event via the hospital chain of command process (Please refer to Appendix 4: Sentinel Events Flowchart). (i.e., staff to immediate supervisor to charge nurse, nurse in charge to Director of Nursing).

7.2.3 Whenever the variation in patient care is an obvious sentinel event, Clinical Risk Manager will be immediately notified by forwarding through the QA reporting system and verbally too. The Clinical Risk manager shall notify Director of Quality and patient safety officer. A Root Cause Analysis will then be scheduled.

7.2.4 Identification of a Sentinel event: If any individual in the hospital discovers, witnesses, has knowledge of or otherwise becomes aware of any unexpected occurrence that is a possible Sentinel event must verbally report as follows:

A. Sunday - Thursday, 8:00 AM – 3:00 PM immediately report to the Hospital Director.
B. All other hours, immediately reports the event to the administrator in-duty.
C. If any of the above is unavailable, verbally report to the Medical Director.
D. If any of the above is unavailable, report to risk manager.
E. After the verbal report, a completed OVR should be submitted.

7.2.5 Whenever the variation in patient care is a questionable sentinel event, the Sentinel Event Committee will meet within 24 hours of discovery of the
event to determine if variation falls within definition of a sentinel event and the level of investigation to be conducted (Root Cause Analysis).

7.2.6 A follow-up report from the Root Cause Analysis (RCA) will be submitted to the Sentinel Event Committee. An aggregate report will be submitted to Hospital/Directorate Quality Committee.

7.2.7 Confidentiality: All documentation related to the investigation of a Sentinel Event will be protected against disclosure per peer review process.

7.2.8 For further information on conducting a Root Cause Analysis (Refer to Appendix 5: Root Cause Analysis form).

7.2.9 The Committee Chairman shall call a meeting of the Sentinel Event Committee after he is notified of an occurrence not later than forty-eight (48) hours after the occurrence or process variation is reported to him, to investigate the occurrence or process variation and to determine whether such occurrence or process variation meets the definition of a Sentinel Event.

7.2.10 Completion of Root Cause Analysis and Action Plan
The Sentinel Event Committee shall investigate and understand the causes that underlie the event within seventy-two (72) hours, and complete a thorough and credible Root analysis and resulting Action Plan describing the hospital’s risk reduction strategies within forty-five (45) days of the known occurrence of the Sentinel Event.

7.2.11 The Sentinel Event Committee shall subsequently direct the Root Cause Analysis and Action Plan to be reported to and thoroughly reviewed by the hospital’s relevant clinical committees (e.g. if the Sentinel Event involves a medication error, the Root Cause Analysis and Action Plan shall be reported to and reviewed by the Pharmacy and Therapeutic Committee)
8. Root Cause Analysis

8.1 Purpose of Root Cause Analysis
The purpose of the Root Cause Analysis is to understand how and why a Sentinel Event occurred and to prevent the same or similar event from occurring in the future.

8.2 Focus on Systems and Processes
The Root cause Analysis must:

8.2.1 Focus primarily on systems and processes, not individual performance.
8.2.2 Progress from identifying special causes in clinical processes to common causes in organizational processes.
8.2.3 Repeatedly “dig deeper” by asking “Why?” and then, when answered, “Why?” again.
8.2.4 Identify changes and improvements that could be made in system and processes, through correction of existing systems or processes or development of new systems or processes that would reduce the risk of such events occurring in the future.

8.3 Documentation of Root Cause Analysis
The Sentinel Event Committee shall produce full documentation of its Root Cause Analysis within forty-five (30) days of the known occurrence of the event. The Root Cause Analysis shall be maintained confidentiality by the Chairman of the Committee.

8.4 Action Plan And Measurement Strategy
8.4.1 The Purpose of the Action Plan: is to identify strategies that the hospital intends to implement to reduce the risk of similar Events occurring in the future.
8.4.2 Implementation: The hospital leaders shall implement the systems and processes identified in the Action Plan (after initial testing, if appropriate).
9. **Confidentiality**

9.1 All OVR shall be handled and maintained in a confidential manner, with access to such documentation restricted to authorized individuals. OVR shall not be duplicated, with exception of the event manager/appointed QM&PS staff, when deemed necessary.

9.2 The information contained in the OVR form cannot be used against any individual for disciplinary action.

9.3 Hospital staff is not at liberty to discuss the contents of an OVR or the events and circumstances relative to the occurrence either with patient, visitor or other members of the staff, unless clarifying facts under investigation with the proper authorities.

9.4 Discussion of general issues on OVR for instructional or educational purposes with view to improving patient care is, however, strongly encouraged.

9.5 Names of involved/concerned person should not be used, however to use only job title.

9.6 Use of OVR template.

9.7 Write objective view and comments. Avoid personal opinions.

9.8 The OVR form consists of the following sections:

9.8.1 Upper: Patient Information
9.8.2 Event Details: (by the person witnessed/affected by the occurrence)
9.8.3 Type of occurrence
9.8.4 Persons affected
9.8.5 Occurrence brief description
9.8.6 Decision of sentinel event
9.8.7 Physician Follow Up Notification including severity of Injury:

A. Slight/minor injury: the incident resulted in abrasion, reddening of the skin, a bruise or other apparently minor damage to tissue. The treatment required was non-invasive for e.g. topical ointment, dressing or ice packs.
B. Moderate injury: the incident resulted in hemorrhage, tissue impairment and required clinical intervention. For e.g. suturing, first and second degree burn

C. Serious injury: the incident resulted in fracture, hemorrhage, aspiration, third degree burns, serious drug reaction or the incident resulted in admission to hospital if (outpatient), transfer to critical care area, or increase in length of stay (inpatient).

D. Death.

E. Immediate action taken.

F. Recommendations to prevent recurrence.

9.9 Event Manager/appointed QA staff comments.

10. Responsibilities

10.1 The staff who witness or discover an occurrence has the professional obligations and responsibility for:

10.1.1 Immediately notifying the in charge or supervisor on call

10.1.2 Initiating the OVR form before the end of the shift.

10.2 System Administrator:

Responsible for adding department/location into the system, defaults incident as agreed by the QM&PS department, adding & deleting users and trouble shooting.

10.3 Event Manager/Appointed QA staff for occurrence management:

Responsible for reviewing all event reports, classifying events assigning follow up, review, updating reports, tracking follow ups, monitoring the entire database and closing completed reports.

10.4 The Supervisor is responsible for:

10.4.1 Ensuring that all employees are aware of OVR system and how to report and process of OVR form.
10.4.2 Conducting immediate follow-up of the occurrence by initiating and documenting on the OVR the actions taken at the time of the occurrence and any corrective measures taken to prevent a recurrences of the events.

10.4.3 Ensuring thorough and accurate completion of the OVR form.

10.4.4 Forwarding the completed OVR form to Risk management office within 72 hours of the occurrence.

10.4.5 Conducting any further investigation and documenting investigative findings of the reported occurrence upon request of the hospital administration, quality management department or the risk manager.

10.5 All staff shall:

10.5.1 Be familiar and adhere with this document.

10.5.2 Comply with the written policy & procedure of OVR.

11. Document History and Version Control

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Written by: OVR Group  
Reviewed by: DGQAC  
Approved by: DGQAC
12. Related Documents:

12.1 OVR flowchart (PHC).
12.2 OVR flowchart (Hospital).
12.3 Sentinel Events Flowchart
13. Reference

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<td>National Patient Safety Agency</td>
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<td>Runciman WB.</td>
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<td>World Health Organization</td>
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<td>Volunteer State Health Plan</td>
<td>2012</td>
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Appendix 1: Sentinel Event Examples:

1. Unanticipated death unrelated to the natural course of the patient’s illness or underlying condition (for example, suicide, homicide)
2. Major permanent loss of function unrelated to the patient’s natural course illness or underlying condition.
3. Hemolytic Blood Transfusion.
4. Wrong-site, wrong-procedure, wrong-patient surgery
5. Infant abduction or infant who was sent home with the wrong parents.
6. Any patient death, paralysis, coma, or other major permanent loss of function associated with a medication error.
7. Any event(s) resulting in unanticipated death or major permanent loss of function not related to the natural course of the patient’s illness or underlying condition.
8. Any elopement, (i.e., unauthorized departure of a patient from an around-the-clock care setting) resulting in death (suicide or homicide) or major permanent loss of function.
9. Any procedure on a wrong patient, or wrong side of the body or wrong body part.
11. A patient fall that results in death or major permanent loss of function such as a direct result of the injuries sustained in the fall.
12. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.
13. Infant abduction or discharge to wrong family.
14. Unintended retention of a foreign body, such as a sponge or forceps, in a patient following surgery or other procedure.
Appendix 2: Occurrence Variance Reporting Flowchart (PHC)

**Incident occur**

- Ensure person/ Situation safe
- Notify in-charge on duty
- Fill OVR Form
- Notify Head HC for Investigation & Comments

**Obvious SE**

- Yes: RCA Schedule & Report → Implement action plan
- No: Head HC takes corrective action plan → Monitor occurrence & forward quarterly report → DGHS-QM&PS

DGHS-QM&PS
Appendix 3: Occurrence Variance Reporting Flowchart (Hospital)

1. Incident occur
2. Ensure person/ Situation safe
3. Notify in-charge/ supervisor on duty
4. Report QA Module
5. Quality Staff review & forward incident to concern dept
6. Obvious SE
   - Yes: RCA Schedule & Report
     - Implement action plan
   - No: Supervisor takes corrective action plan and enters feedback in QA Module
     - Monitor occurrence & forward quarterly report
     - Patient Safety Committee
Appendix 4: Sentinel Events Flowchart

Sentinel Event Identified

Verbally reported to Hospital Director

Sentinel events committee

Occurrence is a sentinel event

No

Refer to QM&PS

OVR flowchart

Yes

Root Cause Analysis

Completed within 30 days

Action plan & Risk reduction strategies

E.g. if sentinel event involves medication error, RCA and action plan is reviewed by pharmacy and therapeutic committee

Relevant Committee

Implementation

Family approach starts

If unavailable: Administrator on duty Medical Director Risk Manager

Not later than 48Hrs
Appendix 5: Root Cause Analysis form