DEPARTMENT OF OPERATIONAL SUPPORT

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Standard Operating Procedure

CLINICAL ADVERSE EVENT REPORTING

APPROVAL SIGNATURE: _____ DATE: 2 June 2025

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STANDARD OPERATING PROCEDURE FOR CLINICAL ADVERSE EVENT REPORTING

A. PURPOSE

1. This Standard Operating Procedure (SOP), issued by the Division of Healthcare Management and Occupational Safety and Health (DHMOSH) in the Office of Support Operations (OSO), Department of Operational Support (DOS), provides instruction on the submission and management of clinical adverse event reports. The purpose of this SOP is to ensure that clinical adverse events are recorded promptly and accurately through the electronic Clinical Adverse Event Report (CAER) system. The frequency, magnitude and impact of clinical adverse events can only improve care if data are collected, analysed and acted upon.

    1.1. This SOP supports the objectives set forth in the "Quality and Patient Safety" chapter of both publications:

    - United Nations Manual for Healthcare Quality and Patient Safety – Level 1 Clinics (2020) [1];
    - United Nations Manual for Healthcare Quality and Patient Safety - Level 1+, 2 and 3 Medical Facilities (2019) [2];

    1.2. This SOP supports the strategic objective 6 of the Global Patient Safety Action Plan 2021–2030 [3], set forth by the World Health Organization, to ensure a constant flow of information and knowledge to drive mitigation of risk, a reduction in levels of avoidable harm and improvements in the safety of care.

2. Reporting is fundamental to detecting patient safety problems and driving meaningful process improvement activities. Having a process to submit a clinical adverse event report includes the following benefits:

    2.1. Allows for the collection and analysis of adverse events or incidents.

    2.2. Enables a systemic approach to improvement through data collection, analysis and process improvement.

    2.3. Enables the identification of potential safety concerns with both the active process issues (at the point of interface between human and complex systems) and latent process issues (hidden problems within complex systems) which require solutions.

    2.4. Provides an opportunity to respond to the event in a manner consistent with the science of safety and just culture principles. This promotes a positive culture of safety and encourages bedside healthcare workers to speak up regarding patient care concerns.

    2.5. Provides an opportunity to identify events which may benefit from a Root Cause Analysis.

    2.6. Provides a method of comparing patient safety data across disciplines, between levels of health facility, and over time.

    2.7. Helps identify trends in patient safety issues.

    2.8. Helps develop priorities and safety solutions.

[1] Please refer to Section F, Document C
[2] Please refer to Section F, Document D
[3] Please refer to Section F, Document B

B. SCOPE AND APPLICABILITY

3. This SOP shall apply to all United Nations Level 1, Clinic, Level 1+, 2, 2+ and 3 medical facilities and their personnel in field missions administered by the Department of Operational Support, Department of Peace Operations (DPO) and Department of Political and Peace-building Affairs (DPPA).

4. This SOP should be read in conjunction with the most current editions of the United Nations Manuals for Healthcare Quality and Patient Safety, the Medical Support Manual for United Nations Field Missions, the Casualty Evacuation in the Field Policy ("CASEVAC Policy"), the Manual on Policies and Procedures concerning the Reimbursement and Control of Contingent-Owned Equipment of Troop/Police Contributors Participating in Peacekeeping Missions ("COE Manual")[4] and all other relevant documents pertaining to medical care in field missions.

C. REPORTING PROCEDURE

5. The personnel of medical facilities described in paragraph 3 of this SOP shall report and document all Clinical Adverse Events (which include near misses) within 48 hours of the occurrence.

6. Regardless of the level of harm to the patient, clinical adverse events should be reported in the following circumstances:

    6.1. Patient care management related adverse preventable events
    6.2. Surgery or other invasive procedure performed on the wrong site or wrong patient
    6.3. Wrong surgical or other invasive procedure performed on a patient
    6.4. Unexpected intraoperative or immediate post-operative death
    6.5. Unintended retained instrument/foreign object after surgery/procedure
    6.6. Adverse events associated with surgical/procedural sedation, regardless of administration site
    6.7. Patient suicide, attempted suicide, or self-harm that is preventable and results in death or injury
    6.8. Patient death or serious injury resulting from failure to follow up or to communicate laboratory, pathology, or radiology results
    6.9. Patient death during medical evacuation
    6.10. Patient death within 24 hours of medical evacuation
    6.11. Patient sudden/unexpected death while receiving hospital care in any facility mentioned above (Section B.3)
    6.12. All medication errors
    6.13. All serious adverse drug events
    6.14. All confirmed transfusion reactions or blood product association adverse events (if applicable to the healthcare setting)
    6.15. Maternal death or serious morbidity in a low-risk pregnancy associated with labour and delivery
    6.16. Other adverse events: for example, healthcare associated infections, infectious disease outbreaks, documentation deficiencies, etc.
    6.17. A major permanent loss of function unrelated to the patient's natural course of illness or underlying condition
    6.18. Near misses

[4] Please refer to Section F, Documents C through G

7. Staff shall report the clinical adverse event using the online Clinical Adverse Event Reporting System (CAER). See Annex A
8. In the event of system downtime or outage, staff shall report the clinical adverse event using the paper downtime form (see Annex B) and shall email it to the Clinical Governance Section (CGS) within the DHMOSH.
9. The online form, once completed, shall be electronically submitted through the system to CGS for review. See Annex C
10. CGS shall review the online incident report and, if necessary, follow-up with the reporter if additional information, or any changes, are necessary. Reporter information is for the use of DHMOSH only and will not be disclosed to the facility or any other entity.
    10.1. If the report is anonymous, CGS shall follow up with leadership in the field medical facility.
11. CGS shall collect, collate and analyse patient safety incident data from all reported incidents and report findings to CGS senior management.
12. The CGS shall provide all United Nations Level 1, Clinic, Level 1+, 2, 2+ and 3 medical facilities with report data on CAER and patient safety statistics and other mission-specific operational relevant safety data derived from analysis of submitted incident reports.

D. ROLES AND RESPONSIBILITIES

13. All medical and non-medical personnel working in a United Nations Level 1, Clinic, Level 1+, 2, 2+ and 3 medical facilities involved in or witnessing a patient safety incident are obligated to submit an incident report.
14. CGS shall review, support and assist staff in completion of the online CAER form.

E. ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviations	Definitions
CAE	Clinical Adverse Event
CAER	Clinical Adverse Event Report
CGS	Clinical Governance Section
CMO	Chief Medical Officer
COE	Contingent-Owned Equipment
DHMOSH	Division of Healthcare Management and Occupational Safety and Health
DPO	Department of Peace Operations
DPPA	Department of Political and Peace-Building Affairs
FMO	Force Medical Officer
PCC	Police-Contributing Country
SOP	Standard Operating Procedure
TCC	Troop-Contributing Country

UN HQPS	United Nations Healthcare Quality & Patient Safety
UNHQ	United Nations Headquarters
UNOE	United Nations-Owned Equipment

Terms	Definitions
Adverse event	An incident that results in preventable harm to a patient
Adverse reaction	Unexpected and non-preventable harm resulting from a justified action where the correct process was followed for the context in which the event occurred
Ameliorating action	An action taken or circumstances altered to make better or compensate any harm after an incident
At Risk Behavior	A behavioural choice that increases risk where risk is not recognized, or is mistakenly believed to be justified
Coaching	A values-supportive discussion with the employee on the need to engage in better behavioural choices
Contributing factor	A circumstance, action or influence that is thought to have played a part in the origin or development of an incident or to increase the risk of an incident
Counseling	A first step in disciplinary action; putting the employee on notice that performance is unacceptable
Detection	An action or circumstance that results in the discovery of an incident
Disciplinary Action	Actions beyond remedial, up to and including punitive action or termination
Error	Failure to carry out a planned action as intended or application of an incorrect plan
Event	Something that happens to or involves a patient
Hazard	A circumstance, agent or action with the potential to cause harm
Human Error	Unintentionally doing something other than what was intended
Impossibility (Just Culture)	Condition outside of employee's control that prevents duty from being fulfilled
Incident	Any deviation from usual medical care that either causes an injury to the patient or poses a risk of harm, including errors, preventable adverse events and hazards
Incident characteristics	Selected attributes of an incident

Incident type	A descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features
Knowingly Cause Harm (Just Culture)	Having knowledge that harm is practically certain to occur
Mitigating Factor	An action or circumstance that prevents or moderates the progression of an incident towards harming a patient
Near miss	An incident that did not reach the patient
Never event	A patient safety incident that results in serious patient harm or death (this refers to particularly shocking medical errors - such as wrong-site surgery, which should never occur)
Patient characteristics	Selected attributes of a patient
Patient outcome	The impact upon a patient that is wholly or partially attributable to an Incident
Patient safety	A framework of organized activities that creates cultures, processes and procedures, behaviours, technologies and environments in healthcare that consistently and sustainably: lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur
Performance Shaping Factors (Just Culture)	Attributes that impact the likelihood of human errors or behavioural drift
Punitive Action	Punitive deterrent to encourage an individual or group to refrain from undesired behavioural choices
Purpose to Cause Harm (Just Culture)	Conscious objective to cause harm
Reckless Behavior	Behavioural choice to consciously disregard a substantial and unjustifiable risk
Remedial Action	Actions taken to aid employee including education, training, and/or reassignment to a task appropriate to knowledge and skill
Risk	Likelihood or chance that harm will occur if exposed to a hazard
Root cause analysis	A systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking “why” until the underlying root causes have been elucidated
Sentinel event	An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome

Substantial and Unjustifiable Risk	A behavioural choice where the risk of harm outweighs the social benefit attached to the behaviour

F. REFERENCES

A. DOS/2025.05 Policy on United Nations Standards for Healthcare Quality and Patient Safety.

B. Global Patient Safety Action Plan 2021–2030: Towards Eliminating Avoidable Harm in Health care. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

C. United Nations Manual for Healthcare Quality and Patient Safety – Level 1 Clinics (2020);

D. United Nations Manual for Healthcare Quality and Patient Safety - Level 1+, 2 and 3 Medical Facilities (2019);

E. Manual on Policies and Procedures concerning the Reimbursement and Control of Contingent-Owned Equipment of Troop/Police Contributors Participating in Field Missions (COE Manual) (A/78/87)

F. Medical Support Manual for United Nations Field Missions

G. Casualty Evacuation in the Field Policy (CASEVAC Policy)

G. MONITORING AND COMPLIANCE

15. DHMOSH has the overall authority for oversight, monitoring and assessment of the compliance with this Policy.

H. CONTACT

16. The contact for this SOP is the Senior Medical Officer, Clinical Governance Section, DHMOSH at clinicalgovernance@un.org.

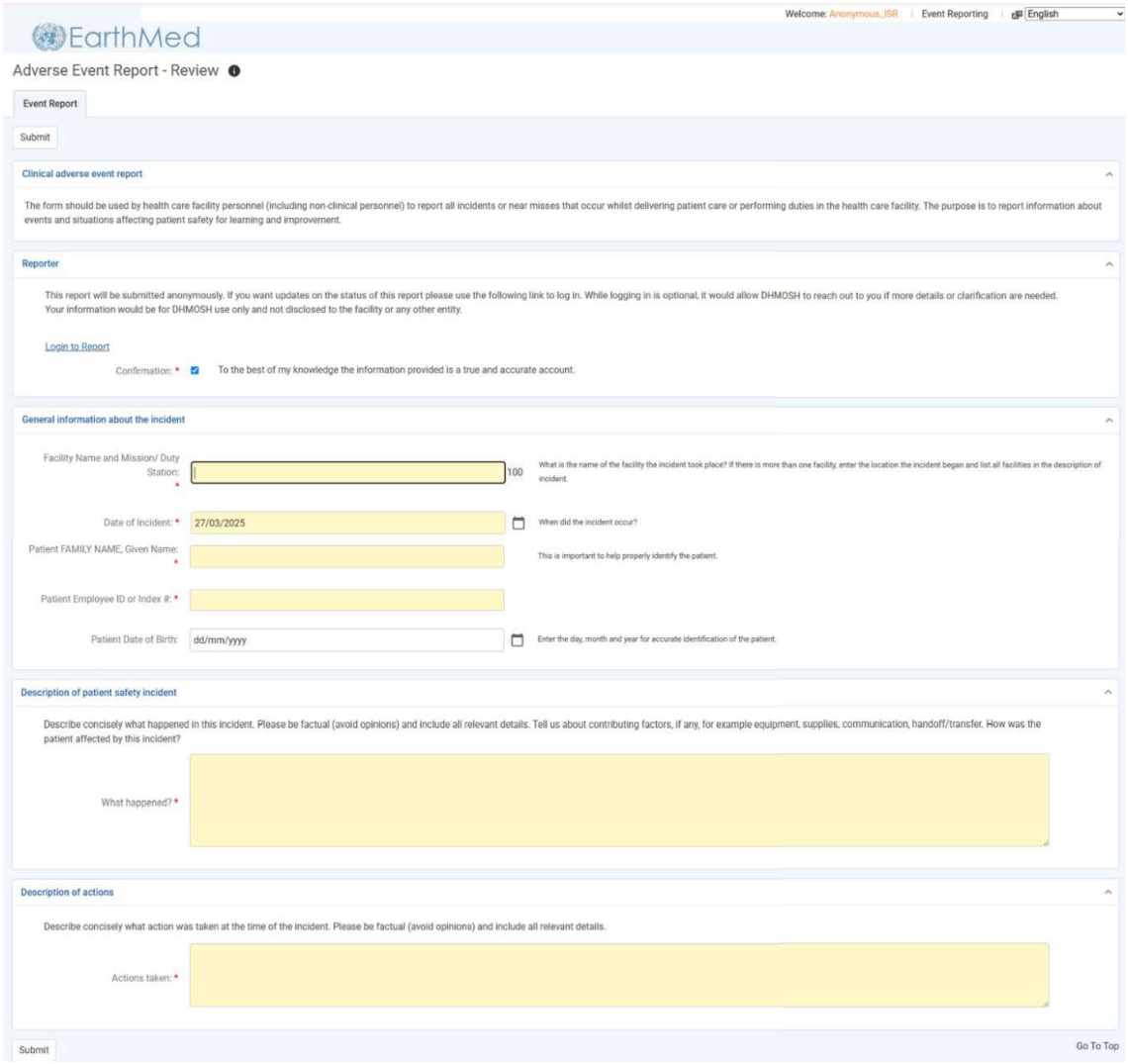
I. HISTORY

17. This is the first SOP on this issue.

Annex A: Clinical Adverse Event Reporting Form

The online incident reporting form is available on the EarthMed Platform. It can be accessed at the following URL or QR code:

https://emed.un.org/medgategx2/safetyincidentselfreportselection/displaystandalone.rails



Annex B: Clinical Adverse Event Reporting Form – Paper Copy

Adverse Event Report

Clinical Adverse Event Report

The form should be used by healthcare facility personnel (including non-clinical personnel) to report all incidents or near misses that occur while delivering patient care or performing duties in the healthcare facility. The purpose is to report information about events and situations affecting patient safety for learning and improvement.

Reporter

This report can be submitted anonymously. If you want updates on the status of this report, please fill in your name and email address below. This will also allow DHMOSH to reach out to you if more details or clarification are needed. Your information is for the use of DHMOSH only and will not be disclosed to the facility or any other entity.

Name:	
Email address:	

General information about the incident:

Facility name and Mission/ Duty Station*:		What is the name of the facility the incident took place? If there is more than one facility, enter the location the incident began and list all facilities in the description of incident.
Date of incident*:		When did the incident occur? Enter in DD/MM/YYY format
Patient FAMILY NAME, Given Name*:		This is important to help properly identify the patient.
Patient Employee ID or Index #*:		
Patient Date of Birth:		Enter the day, month and year for accurate identification of the patient in DD/MM/YYYY format

Description of patient safety incident:

Describe concisely what happened in this incident. Please be factual (avoid opinions) and include all relevant details. Tell us about contributing factors, if any, for example, equipment, supplies, communication, handoff/transfer. How was the patient affected by this incident?

What happened?*	

Description of patient safety incident:

Describe concisely what action was taken at the time of the incident. Please be factual (avoid opinions) and include all relevant details.

Actions taken*	

Submit this form to ClinicalGovernance@un.org

* Mandatory fields. Please make sure these fields are complete before you submit this report.

Annex C: Clinical Adverse Events Review