AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

FACT SHEET
for health services

National Clinical Trials Governance Framework (NCTGF)

Incident Management

Purpose

To provide guidance on how an incident arising from a clinical trial is identified, reported, and managed in Health Service Organisations (HSOs).

Definitions

Incident Management in an HSO is the process through which incidents are effectively identified, recorded, analysed, managed, and resolved with the aim of improving safety and quality of care. Incident Management involves the workforce, consumers, patients, and their families.

An **incident** is an event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer, or a complaint, loss or damage. An incident may also be a near miss. Incidents may also be associated with omissions where patients are not provided with a medical intervention from which they would have likely benefited.[1]

Key Messages

- ***The intent of Action 1.11 of the NCTGF is to integrate the reporting of safety and quality incidents arising from clinical trials within existing clinical and corporate systems (i.e. processes, policies and procedures) and not to create separate systems.***
- ***Incident Management and Incident Management Systems rely on strong governance arrangements that comply with legislative requirements, state or territory incident management policies and best-practice principles.***
- ***The HSO is responsible for establishing an organisation-wide Incident Management Information System with accompanying policies and processes. Examples of Incident Management Systems include RiskMan, ims+, CIMS.***
- ***The HSO is responsible for determining, via local policies, which clinical trial-related incidents should be reported.***
- ***Incidents emerging from the conduct of clinical trials should be reported through the same Incident Management System, and process, as established by the HSO for general patient care.***

[1] Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022; Australian Commission on Safety and Quality in Health Care. *Incident Management Guide*. Sydney: ACSQHC; 2021,

- ***Reporting and evaluation of Incidents must add value, be actionable and inform training and prevention strategies, and inform continuously quality improve within the HSO.***
- ***Safety events, Adverse Events[2] and other events arising from a clinical trial that results (or may result) in unintended or unnecessary harm, a complaint or loss or damage should only be reported as incidents if they arise from an error[3][4] OR fulfill the definition of an Incident and aligns to local incident management policies.***
- ***For guidance on Safety monitoring[5] and Serious Breach Reporting[6] in clinical trials refer to guidance by National Health and Medical Research Council (NHMRC).***
- ***Information on clinical trial related incidents and their management should be communicated to the clinical trial workforce and incorporated into the HSO's risk management and quality improvement plan.***
- ***A comprehensive description of best practice principles can be found in the ACSQHC Incident Management Guide.***

Examples of Clinical Trial Incidents to be reported to the HSO

(Note: Below examples are provided as general guidance only. Reporting should be as per local HSO policies.)

EVENT/ INCIDENT	REPORT in HSO Incident Management System	REPORT via clinical trial requirements
Patient reported fever and headache after administration of a new clinical trial medication.	NO Not due to an error, no safety learning, or improvement to HSO operations to be made.	YES Adverse event (AE), specific to clinical trial reporting, affects trial participant only, not HSO.
Research Staff accidentally dropped tubes containing trial biomarker bloods causing breakage and spillage.	YES Hazard reporting, safety issue due to error, part of HSO operations, immediate remediation/control by HSO required, impact on safety and quality, learning involved.	NO If can be redone. YES If not redone - report as missed assessment.
During a clinical trial monitoring visit the ECG machine (hospital equipment) found to have missed annual calibration.	YES Unless contrary to HSO requirements.	YES Requirement for research equipment maintenance.

[2] AE is any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and that does not necessarily have a causal relationship with this treatment. AEs include side effects to medicines and vaccines, and problems or incidents involving medical devices. *Adverse Event Reporting, TGA, DHDA*
[3] Any act of commission (doing something wrong) or omission (failing to do the right thing) that exposes people to a potentially hazardous situation. ARCS 2024 Incident Management White Paper
[4] ARCS Australia, Identifying Incident Relating to Clinical Trials Service Provision, Position Paper May 2024
[5] National Health and Medical Research Council (2016). Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods. Canberra: National Health and Medical Research Council.
[6] National Health and Medical Research Council (2018), Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods

EVENT/ INCIDENT	REPORT in HSO Incident Management System	REPORT via clinical trial requirements
Trial participant reported dizziness after a routine blood draw for safety check prior to receiving treatment.	NO Not due to an error, no safety learning, or improvement to HSO operations to be made.	NO Does not meet AE reporting criteria.
A clinical trial participant complained about a broken step that nearly caused a fall.	YES Patient safety issue due to error, part of HSO operations, impact on safety and quality, learning involved, 'near miss' event.	NO Unrelated to trial conduct.
Patient had injection site reaction due to a trial drug being given as a subcutaneous injection.	NO Not due to error, or improvement to HSO operations to be made, no learning implication.	YES Meets AE reporting criteria.
Medication error resulting in serious harm to a trial patient.	YES HSO staff error, learning involved, affects HSO operations, increased risk to HSO.	YES Meets AE and Safety reporting criteria.
Research staff inadvertently emailed trial participant name and treatment dates to study sponsor.	YES Privacy & Confidentiality breach, Trial Staff error, needs immediate escalation and reporting. Quality & safety implication.	YES Privacy & Confidentiality breach, Quality & safety implication.

Key reference documents

- *Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022*
- *Australian Commission on Safety and Quality in Health Care. Incident Management Guide. Sydney: ACSQHC; 2021*

Find Out More

For more information, please visit the Commission's website.

You can also email the Advice Centre or Health and Medical Research team or call 1800 304 056.

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