CGP 149
Clinical Incident Reporting and Investigation Policy

LINK TO POLICY

LINK TO PROCEDURES & FORMS

1. POLICY INTRODUCTION

National Ambulance (NA) strives to deliver safe and quality services in accordance with international evidence based best practices adopted or adapted for use with other clinical policies, procedures and guidelines approved and/or published by NA and to comply with all relevant Laws and Regulations. National Ambulance is committed to fostering a culture of excellence and continuous improvement and has therefore developed capacity and capability to provide best standards for all stakeholders.

NA clinical staff must act in the best interests of the patient, any relatives or guardians accompanying the patients and within their specified scope of practice and must use relevant qualifications, training, skills and experience to provide optimal clinical care.

Clinical Incident reporting and investigation can contribute to clinical improvements and help to prevent recurrence of adverse incidents

CGP 149 Policy identifies the minimum elements required to achieve Clinical Investigation success under Policy NA CGP 150 Clinical Governance. Other Policies related to this Policy are NA QHP 401 Customer and Patient Feedback, Enquiries and Complaints Policy and Procedure and NA QHP 203 Near Miss and Incident Policy and Procedure.

2. SCOPE

This policy covers all clinical incident reporting and investigation activities that are necessary to ensure consistent, safe and appropriate patient care response under the principles of good clinical governance. It applies to all NA clinicians to which this policy refers. This policy only applies to clinical issues, Non-clinical issues are addressed in National Ambulance Policy QHP 203 Near Miss and Incident Policy and procedure however a QHSE report form should be completed for all clinical incidents.

3. DEFINITIONS

TERM	DEFINITION
Clinician	An EMT, Paramedic, Extended scope of practice paramedic, Physician, or Pharmacist employed by National Ambulance with certain privileges as permitted by the MD / Medical Delegate to provide patient care under defined patient care protocols
Scope of practice	A framework to give authority to healthcare professionals to carry out certain duties. Scope of practice is limited by the individual's professional license, experience and competence as well as facility support, and resources including other staff and equipment
DCI	Designated Clinical Investigator; a licensed clinician with experience in investigation of clinical incidents and trained in use of Root cause analysis and other evidence based investigative tools

4. ROLES AND RESPONSIBILITIES

Medical Director (MD)

The Medical Director for National Ambulance is the primary authority for clinical governance related to clinical care and shall receive notification of a clinical incident and may initiate a clinical incident investigation including appointing the DCI. The MD shall provide clinical oversight of the investigation and documentation. The MD can evaluate the DCI report, complete and sign the Report of the clinical incident investigation and have oversight of completion of all relevant clinical items from action plans that result from the investigation and make recommendation to COO.

Chief Operations Officer

The Chief Operations Officer (COO) will receive notification of a clinical incident and can initiate clinical incident investigation including delegation of DCI with support of clinically qualified senior management. The COO is responsible for ensuring that operational input that relates to clinical incident reporting and investigation is efficient and effective. The COO should have oversight of completion of all relevant items from action plans that result from the investigation.

Clinical Governance & Audit Officer

Provides oversight of the process, ensuring compliance to regulation, policies, fitness to practice and professional standards.

Designee Clinical Investigator (DCI)

A designee of the Medical Director or Chief Operations Officer delegated, in writing specifically for the purpose of clinical investigations. The DCI should be an NA licensed clinician with suitable qualifications as a physician, paramedic or pharmacist with training and experience to meet the scope of practice and competency requirements of NA. The DCI is responsible for giving regular updates to Senior Management throughout the investigation and submitting the final report in accordance with an agreed time frame.

Managers

Managers are responsible for following this policy and raising any issues to the designated senior management. They may act as DCI or investigation team members if designated by senior management and must understand the roles and responsibilities.
They also provide guidance and support for the staff they are responsible for when needed.

All Clinical Employees

All clinical employees are required to notify and report any clinical incident; and if requested participate in any investigations, and implement any recommendations arising from investigations.
All staff involved in the process of clinical investigation are required to maintain high levels of confidentiality both internally and externally. Documents redacted with clinician and patient's details will be used where possible. If staff wish to self-report clinical issues or highlight clinical concerns this can be done so directly to the MD. Any identified breach of confidentially can lead to disciplinary actions.

4. POLICY

Reporting, Investigation, and Actions

Procedures and processes for reporting, investigation, remediation and/or referral for Regulation, Certification, and licensure actions outlined in Appendix 1 must be followed.
Internal reporting may also include the following policies but is not limited to:

CGP 128 Remediation and Independent Training Plan (ITP)
CGP 150 Clinical Governance Policy
QHP 203 Near Miss and Incident Policy and Procedure
QHF 201 QHSE Report Register
QHF 202 QHSE Reporting Form
QHF 225 Root Cause Analysis Template

Scope of Practice Actions:

Depending on the outcome of the clinical investigation; restriction, suspension or revocation of privileges may be applied by the MD as well as an Individual Training Plan. The outcome should be immediately communicated with senior operational staff and administration staff, this maybe in the form of an adhoc Case Management Team (comprising of the MD, COO, CAO and HR representatives)

Failure to complete all prescribed actions in an ITP may result in revocation of all privileges, a report to the licensure authorities, removal from patient care duties and/or other sanctions in accordance with the NA Disciplinary Policy.

Regulatory /Licensure/Certification Actions

The UAE Ministry of Health (MOH) and/or the Department of Health (DOH) have sole responsibility for regulatory, licensure and certification actions, including sanctions of remediation, revocation, or suspension of an individual clinician's license or a Facility license.

The regulator may also undertake Disciplinary actions on the receipt of a clinical complaint. National Ambulance is required by law to report specific events and actions to these agencies including, but are not limited to: Sentinel events, practice outside agreed protocol, and practice outside scope of practice or approved competencies, medication errors, narcotics and controlled drug incidents, procedural errors, and patient injury from clinician care.

Determine Levels and Reporting Incidents:

All clinical incidents are to be reported immediately to the MD /COO. The MD /COO (with assistance from any suitably qualified delegated senior manager) will classify incidents into Level I-III using the table at Appendix 1.
Re classification can be made by MD at any time when further information is considered as well as based on the investigation performed by the Designee Clinical Investigator.
In addition, incidents reported directly to the regulatory agency will be offered full investigative support by National Ambulance.

5. PROCEDURE

Appendix 1 – Flow chart

Step 1. Notification

1. Identify source of clinical incident (QHSE, Operations, Audit, Medication Management, receiving facilities, witnesses, patients, etc…)
2. Notification may occur through, but not limited to:
   2.1. Duty Manager
   2.2. QHP401 Customer, Patient Feedback, Enquiries and Complaint's Policy and Procedure
3. QHF202 QHSE Reporting Form must be completed by the individual making the notification (an initial Risk Rating score will be generated and recorded)
4. Undertake a Clinical Severity Level Assessment as per **Appendix 2** ensuring the Clinical Incident Register is reviewed to determine if repetitive incidents have occurred of the same nature or with the same person.
   4.1. Severity Levels I and II may/may not progress to a full investigation
   4.2. Severity Levels II and III – COO or Operation Manager are notified especially if requirement for escalation is identified
   4.3. Severity Level III requires notification within 2 hours to Duty Manager and will in most cases progress to a full investigation.
      4.3.1. For Sentinel event DOH will require notification within 48 hours, with Provisional Clinical Incident Assessment Form completed and sent to them within 7 days of occurrence and final report with action plan to prevent re-occurrence to them within 45 working days.
5. A member of the Clinical Services team will complete the CGF185 - Provisional Clinical Incident Assessment Form for MD to review and sign within 5 working days
   5.1. If decision to close, follow appropriate arm on the flow chart (Appendix 1)
   5.2. If decision to progress to full investigation, then the MD to appoint Lead Investigator (DCI) and investigation team members within 1 working day.
      5.2.1. All documents provided to the DCI must be redacted with patient and staff identifiers (Appendix 1) the DCI report must be completed in 5 working days.
   5.3. Document at this stage if it is necessary to remove clinician from active operation duty and notify appropriate Operation Director of such requirement once approved by MD
6. Secure the original PCR if possible. It is permissible to request an independent clinical audit of the redacted chart by NA Clinical Auditor

Step 2. Investigation - Initial Response (Level II/III):

As soon as notification of a Level II or III incident occurs, the initial response should be as follows:

1. Get treatment for individuals that may be injured;
2. Notify as per above process;
3. Secure the clinicians involved in separate areas for interview;
4. Secure the site and equipment, ensure duty manager and line manager are notified.
5. Duty Manager or Line manager to request police assistance if required;
6. DCI to allocate investigation tasks to investigation support team to be completed within the 5 days as per 5.2.1

Step 3 Investigation– Information Gathering:

1. Inspect the incident site if appropriate;
2. Secure and segregate the involved Clinicians for interview;

3. Identify, secure/quarantine or photograph the following:
   3.1. Equipment and materials used,
   3.2. Safety devices in use,
   3.3. Positions of controls of devices,
   3.4. Damage to equipment,
   3.5. Weather conditions,
   3.6. Lighting levels.
4. Data Collection
   4.1. Obtain original PCR and hospital Emergency Department report where possible
   4.2. Removed PCR from normal audit process and request independent clinical audit of chart by member of Clinical Audit team based at HQ, with feedback given to the DCI
   4.3. Confirm and evidence timelines on equipment
   4.4. Service and calibration history obtained
   4.5. Competent individuals are required to download the necessary data
   4.6. Where possible obtain initial original reports and compare to new reports from equipment

5. Interview and obtain statements (template in CGF186 - Clinical Investigation Statement Template) if viable
   5.1. Patient, if possible;
   5.2. Clinician (explain Appendix 1 Clinical Incident Process Flowchart to the staff member)
   5.3. Witnesses;
   5.4. Line Manager;
   5.5. Personnel involved in incident.
   Note: It is important the interviewer establish an understanding and obtain the interviewee's own words as to what happened.

6. Interview Technique
   6.1. Ask Who? What? Where? When? How?
   6.2. Use a questioning matrix as per CGF187 - Questioning Approach for Critical Examination;
   6.3. Conduct interviews separately and have subjects separated immediately after incident;
   6.4. Make it clear to all personnel being interviewed that they are in an investigative process;
   6.5. Make it clear that the investigation process is primarily used to gather information, avoid recurrence, and not to assign blame put reveal the causation.
7. Interview Process:
   7.1. Explain the reason for the investigation
   7.2. Complete the interview with minimal interruption of the interviewee
   7.3. Interviewee to sign the notes of the interview to verify the notes taken are what was said.
   7.4. Ask open ended questions at a minimum of 90% during the interview period;
   7.5. Use a question matrix as per CGF187 - Questioning Approach for Critical Examination if possible.
   7.6. Inform the interviewee that the following is not permitted to:
      7.6.1. Allow video or audio recording in the interview;
      7.6.2. Allow phones in the interview room;

Step 4 Investigation - Analysis and Conclusions:

1. Isolate contributory factors (process, person, equipment, etc.);
   1.1. If an investigator is concerned as to a clinician's competencies, the investigator may require the clinician to undergo an assessment of competencies with a Clinical Educator;
   1.2. Would the incident have occurred if this particular factor was not present?
2. Determine

2.1. Why the incident occurred;
2.2. A likely sequence of events and probably causes.
3. Use an Incident Decision Tree Reference to assist you if appropriate
4. Complete a Root Cause Analysis (QHF225) utilising the Risk Management Clinical Risk Categories (Appendix 3)
5. Draw conclusions and make recommendations based on key contributing factors and causes. Seek consult from experienced professionals or subject matter experts as required
6. Provide complete timetable of recommendations with responsible person suggested after consultation with relevant staff e.g. Clinical Educator, Operations Coordinator
7. Contact Warehouse Coordinator to report a defective/damaged device if we suspect or identify it to be at fault; this in turn maybe cascaded to DOH (Circular HRD/22/16 of 08 August 2016)
8. Inform Human Resources team if it is possible that disciplinary action may be required (in accordance with the NA Disciplinary Policy).

Step 5 Clinical Investigation - Designated Clinical Investigators Report (CGF188 Clinical Investigators Final Report):

1. The initial Investigates report has to be completed in 5 working days. Statement and interview of employee(s) concerning the incident;
2. The Full Investigation Folder will contain - but it's not limited to (See Appendix 6 for Templates);
   2.1. Summary of Conclusion of Incident (Including CGF185 Provisional Clinical Incident Assessment and CGF188 Clinical Investigators Final Report);
   2.2. CGF184 - File and Document Log;
   2.3. The Incident Notification;
   2.4. Email communications;
   2.5. Employee information regarding training history and policy compliance;
   2.6. Equipment involved;
   2.7. Witness statements;
   2.8. Interview notes;
   2.9. Root Cause Analysis;
   2.10. Other factors or contributing causes;
   2.11. Policies used (with highlighted section if used/quoted in any reports);
   2.12. Additional documents use;
   2.13. Findings and Recommendations;
   2.14. Any other documents as needed
3. Recommendation for the Corporate Risk Register;
4. Recommended corrective action or disciplinary plan;
5. Conclusions can only be drawn with concrete evidence
6. Updates given to Senior Managers and MD /COO in accordance with agreed timeframes
7. For confidentiality:
   7.1. Ensure all printing is done in a confidential manner to protect all parties involved, use secure PIN coded printing.
   7.2. All necessary hard copies must be stored in the Investigation file and kept in locked storage at all times.
   7.3. Any excess documentation must be immediately shredded
   7.4. The final Full Investigation Folder must be scanned as soft copy and be given to the Clinical Governance & Audit Officer with the hard copy. This includes all emails and any other document pertaining to the investigation
   7.5. Deletion of emails and soft copies from the DCI computer account will be witnessed by the Clinical Governance & Audit Officer

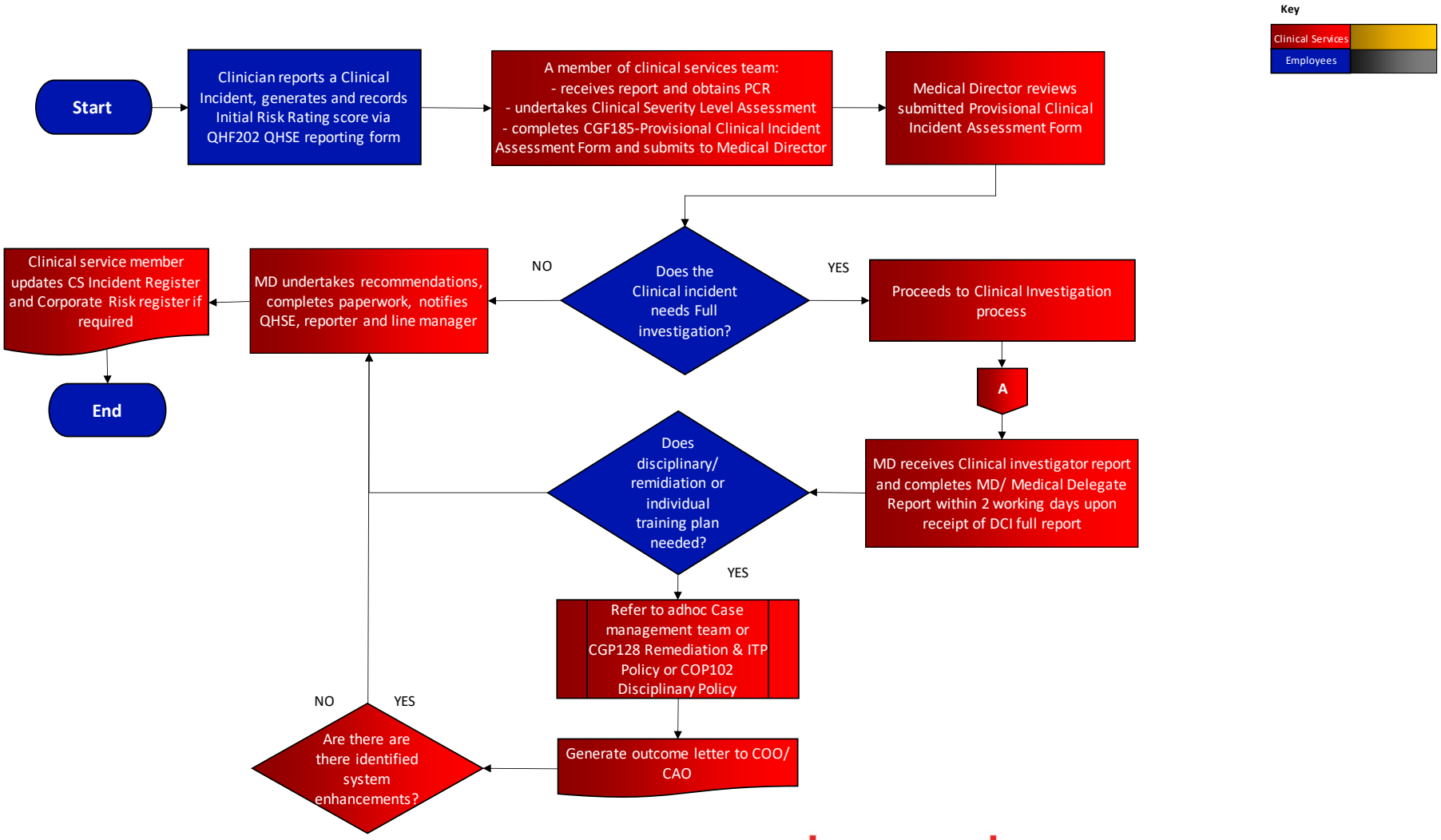
7.6. All soft copies will be stored on the restricted access folder pertaining to Clinical Investigations in the Clinical Governance Directory
7.7. Information pertaining to the individuals and investigation will be on a needs to know basis

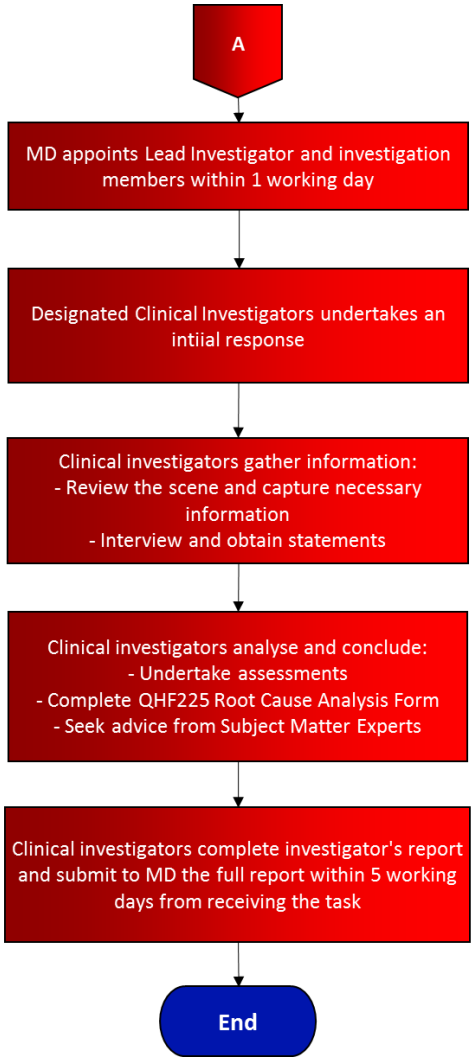
Step 6 Clinical Investigation - Medical Director Report (see CGF189 Clinical Investigation - Medical Director Report):

1. The Medical Director / Medical Delegate Report is required to be complied within 2 working days after the receipt of the DCI Final Report.
2. Any additional tasks undertaken to supplement the DCI report is required to be documented.
3. List recommendations
4. Corporate Risk Register is updated.
5. MD to notify COO and CAO to the outcome of the investigation using the template in Appendix 4
6. Notify the individual to the outcome of the investigation using the template in Appendix 5
7. Notify patient / family if required

Appendix	Title
1	Clinical Incident Process Flowchart
2	Clinical Severity Level Assessment
3	National Ambulance Risk Management Clinical Risk Categories
4	Sample Template internal email / letter to COO and COA
5	Sample Template Letter to HR and employee
6	Template Front Cover for Clinical Investigation Template Full Investigation Folder Document Index File and Document Log for Investigation Sheet

Appendix 1 - Clinical Incident Process Flowchart




A
MD appoints Lead Investigator and investigation members within 1 working day
Designated Clinical Investigators undertakes an intiial response
Clinical investigators gather information:
- Review the scene and capture necessary information
- Interview and obtain statements
Clinical investigators analyse and conclude:
- Undertake assessments
- Complete QHF225 Root Cause Analysis Form
- Seek advice from Subject Matter Experts
Clinical investigators complete investigator's report and submit to MD the full report within 5 working days from receiving the task
End

Appendix 2 - Clinical Severity Level Assessment

Incident Level	Description
Level I	• Minor deviation from established clinical policy or patient care protocol in which the action or inaction would be unlikely to result in harm to patient. • Conduct unbecoming a patient care clinician (COP 202 Code of conduct, COP102 Disciplinary Policy).
Level II	• Deviation from established clinical standards in which such action or inaction may result in harm to a patient • Multiple minor errors in a single incident, or, • Repeated minor errors within a twelve-month time period.
Level III	• Patient death secondary to alleged actions of clinician • Sentinel event possibly related to clinical care • Deviation from established clinical standards in which such action or inaction did, produce harm to a patient • Multiple moderate errors in a single incident, or, • Repeated moderate errors within a twelve-month time period.

Definition of Sentinel Event

Sentinel Event is an event related to actions or inactions of our personnel leading to unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition.

For example: As a result of a medication error, a result of wrong treatment or a result of a fall, in addition:

- Abduction of any patient receiving care, treatment or services
- Rape, assault, (leading to death or permanent loss of function), or homicide of any patient receiving care, treatment or services
- Rape, assault, (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor or vendor while on site at the healthcare facility.
- Unanticipated death during transport
- Suicide during transport
- Staff or citizen death as the result of vehicle accident

Appendix 3 – National Ambulance Risk Management Clinical Risk Categories

Risk Type	Causes	Consequences	Controls
Patient Experience	Clinical error Adverse drug reaction NA staff working outside scope of practice	Minor injury or illness to death or permanent disability	Clinical Education and training. Maintenance of CME. Clinical Audit. Policy Review Committee. Development of policies in line with international best practice. Integrate clinical governance in the theoretical and clinical assessment processes.
Complaint / Claim Potential	Communication error	Spectrum varies from adverse experience to formal complaints and litigation	Introduce clinical governance early in the education program with focus on good verbal and non-verbal communication.
Service / Business Interruption	Failure of electronic dispatch system	Failure of staffed ambulance to arrive to a patient in need	System redundancy. Initial system design around a paper based dispatch system rather than electronic.
Human Resources / Organizational Development	Reduced staffing levels diminishes capacity to respond in a timely manner and to deliver quality services. Critical error due to staff with inappropriate qualifications, experience or skills or insufficient education and training.	Failure of appropriately staffed ambulance to arrive to a patient in need	Anticipate and future proof staff and equipment redundancy.
Inspection / Audit	Breech of a regulatory or national standard	Varies from warning to formal service suspension	Use the principles for good clinical governance as a guide in problem and work based learning. Work within the limits of standards and work with regulatory bodies to change standards where these are insufficient.
Adverse Publicity / Reputation	Failure to keep the focus on the patient	This ranges from rumors and innuendo to continuous and sustained adverse media focus	Use the principles for good clinical governance. Maintain focus on a patient centered service – 'put the patient first'.
Patient Experience	Communication error Poor clinical care e.g. inadequate pain control	Unhappy patient Patient suffers	Ensure that clinical governance is not seen as a separate stand-alone topic but is integrated across all domains / modules.
Complaint / Claim Potential	Clinical error Failure to keep the focus on the patient	Adverse patient outcome or experience	Use the principles for good clinical governance. Maintain focus on a patient centered service – 'put the patient first'.

*Taken from NA Risk Management Department: Operating Procedure Manual Feb 2014

Appendix 4 Sample Email / Template Letter to COO and CAO

Dear Chief of Operations and Chief of Administration,

Re: Clinical Investigation on CAD YYYYMMDD-XXXX

Staff Name:

Designation:

Clinical Category:

Employee Number:

Following a recent Clinical Investigation, it has been determined that the above staff member is required to have:

- ☐ No further action taken
- ☐ Remediation Action
- ☐ Supervision until *(Date)* or until completion of supervision plan if this is longer
- ☐ Clinical Privileges revoked until *(Date),* to be reinstated only with the successful completion of ITP
- ☐ Clinical Privileges permanently revoked immediately and deployment sought elsewhere in NA
- ☐ Clinical Privileges permanently revoked immediately and to proceed with HR Disciplinary Policy
- ☐ Other, please Specify……

This decision is effective from: *(Date)*

Information pertaining to the incident is available for your review.

Yours sincerely

Dr ……
Medical Director

Appendix 5 Sample Template Letter to Employee and HR

Dear *Name of Staff,* Employee Number …….

Re: Clinical Investigation on CAD *YYYYMMDD-XXXX*

As the Medical Director, I am required to oversee Clinical Competency and make a decision on whether an employee is suitable in a clinical role.

As a result of the clinical investigation and assessment of your standard of practice in the field, I have determined that *(please choose one or provide alternative and delete remaining)*
you are required to have remediation
you are required to work under supervision until the successful completion of a supervision plan
you are required to work under supervision until the successful completion of an ITP
your clinical privileges to practice as an EMT-B/I/A, / Pharmacist / Physician will be revoked until successful completion of your ITP
your clinical privileges to practice as an EMT-B/I/A, / Pharmacist / Physician will be permanently revoked and your file will now be forwarded to HR for further consideration

You will be advised in due course by HR / Clinical Education.

Yours sincerely

Dr ……
Medical Director

Appendix 6

Template Front Cover for Clinical Investigation

CONFIDENTIAL

CLINICAL INCIDENT: 201YMMDD-****

QHSE Number: RNXXXX

Subject: From Standard List

Template Full Investigation Folder Document Index

1. Summary of Conclusion of Incident (Including Appendix 3 and 7)
2. File and Document Log
3. The Incident Notification
4. Email communications
5. Employee information regarding training history and policy compliance
6. Equipment involved
7. Witness statements
8. Interview notes
9. Root Cause Analysis
10. Other factors or contributing causes
11. Policies used (with highlighted section if used/quoted in any reports)
12. Additional documents use
13. Findings and Recommendations
14. Any other documentation as needed

DOCUMENT CONFIGURATIONS CONTROL DATE

A review and update of this document will take place as necessary, when changes occur that identify the need to revise this Policy such as changes in roles and responsibilities, release of new legislative or technical guidance, or identification of a new policy area.

This document ownership for editing is identified as: **Medical Director**

Change Brief

Version No.	Date	Changes
1	26 November 2014	New document
2	March 2016	Major restructure Clinical Incident Review Flowchart created Provisional Clinical Assessment Form developed Statement Template created Questioning Approach for Critical Examination created NA Risk Management Clinical Risk Categories included End of page signatures included Updated Clinical Investigation Forms for DCI Updated Chief Medical Advisor Report Sample Template Letter to Staff Member created
3	September 2016	Confidentiality clauses Data security detail Data collation requirements Page numbers in initial signature boxes Template Full Investigation Folder Document Index, front cover created and File and Document Log For delegation of responsibility, Deputy included for CMA Reporting of known/suspected medical devices to be reported to Supply chain as per HAAD Circular HRD/22/16
4	January 2017	Medical Delegate Terminology Include sentinel event definition Notification to patient or family member if required.
5	July 2017	Senior Medical Officer Terminology in place of Medical Delegate Clarity on who will complete Provisional Clinical Incident Assessment Form Timelines for reporting HAAD for Sentinel Events Method to self-report or highlight clinical concerns Inclusion of redacting of necessary documents Remove reference to CGF125 Remediation and ITP Forms
6	March 2018	HR enhancements with confidentiality and notifications
7	December 2019	Medical Director Terminology DOH Terminology Clinical Governance & Audit Officer Terminology Delete Directors and Managers from the roles and responsibilities

		Add “Adverse drug reaction” to Appendix 6 under “Patient Experience” Replace “Clinical Policy Review Group” with “Policy Review Committee” Appendix 3, 4, 5, 7, & 8 as a separate controlled form Rename Appendix 6, 9, 10 & 11 to become 3, 4, 5 & 6 Update “Appendix 1 - Clinical Incident Process Flowchart” Removal of the CAO roles and responsibilities Additional word in Medical Director Roles and Responsibilities “make recommendation to COO”
8	February 2021	Update definition of “Sentinel Event” • Unanticipated death during transport • Suicide during transport • Staff or citizen death as the result of vehicle accident

Review & Approval:

_____ Date
Medical Director Name

_____ Stamp:
Medical Director Signature