



National Ambulance Service (NAS)

Policy

Management of Adverse Clinical Events

Document reference number	NASCG003	Document developed by	Prof. Cathal O Donnell
Revision number	1	Document approved by	Director of NAS
Approval date	10 th May 2011	Responsibility for implementation	Education and Competency Assurance & Medical Directorate
Revision date	31 st December 2020	Responsibility for review and audit	NAS Medical Directorate

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1.0 POLICY STATEMENT

- 1.1 The National Ambulance Service (NAS) is committed to excellence in the clinical care of patients.
- 1.2 NAS acknowledges that the occurrence of occasional adverse clinical events is inherent in delivering clinical care to patients.
- 1.3 NAS wishes to create a safety culture in which NAS clinical staff can self-report clinical error without fear of punishment or disciplinary measures.
- 1.4 Such a safety culture allows NAS to learn from episodes of clinical adverse events and put measures in place to prevent these adverse events being repeated throughout the organisation.
- 1.5 NAS ultimately aspires to an organisational safety culture whereby no patient comes to harm from the actions of NAS and it's staff.
- 1.6 NAS commits that if a staff member is responsible for an adverse clinical event and reports the error in a timely manner, the staff member will be dealt with in a sympathetic manner and will not undergo any disciplinary process or punitive measures. Excluded from this principle are the following:
 - A. criminal or deliberately malicious acts
 - B. where an incident is deliberately concealed
 - C. gross negligence or professional misconduct
- 1.7 If a staff member knowingly fails to report an adverse clinical event or attempts to conceal an adverse clinical event, commits a criminal or deliberately malicious act, or displays gross negligence or professional misconduct, the staff member will face disciplinary proceedings, to include Stage 4 of the Disciplinary Procedure of Dismissal or Action Short of Dismissal, and/or referral to the PHECC Registrar for consideration of Fitness to Practice proceedings. Excluded from this is the situation whereby a staff member causes an adverse clinical event but is genuinely unaware that he/she has done so.

2.0 PURPOSE

2.1 To provide a structure for NAS staff to report and manage clinical error and clinical adverse events, and to allow NAS to learn from these events and put in place measures to prevent such events recurring.

3.0 SCOPE

3.1 This policy applies to all NAS staff or HSE staff tasked by NAS who are involved with clinical patient care either directly or indirectly -Emergency Medical Technicians, Paramedics, Advanced Paramedics, EMS Call Takers and Dispatchers, Managers/Ambulance Officers, Nurses and Doctors.

4.0 LEGISLATION/OTHER RELATED POLICIES

- A. Policy NASCG001 Clinical Effectiveness
- B. PHECC Clinical Practice Guidelines
- C. PHECC Code of Professional Conduct and Ethics
- D. HSE Policy OQR006 Serious Incident Management Procedure
- E. HSE Policy QCCD001 HSE Risk and Incident Escalation Procedure,
- F. HSE Disciplinary Procedure

5.0 GLOSSARY OF TERMS AND DEFINITIONS

- 5.1 **Safety:** freedom from accidental injuries.
- 5.2 **Error:** The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). Errors may be errors of commission or omission, and usually reflect deficiencies in systems of care.
- 5.3 **Adverse Event:** An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.
- 5.4 **Near Miss:** Serious error or mishap that has the potential to cause an adverse event, but fails to do so because of chance or because it is intercepted.
- 5.5 **Adverse Drug Event:** a medication related adverse event.
- 5.6 **Adverse Device Event:** an adverse event related to a medical device or equipment.
- 5.7 **Significant/Serious Adverse Event:** an event that results in death or serious injury/illness to a patient, or with the potential to cause serious injury or illness to a patient.

- 5.8 **Serious Incident:** means an incident which involved or is likely to cause extreme harm or is likely to become a matter of significant concern to service users, employees or the public (HSE, 2008).
- 5.9 **ECAO:** Education and Competency Assurance Officer.
- 5.10 **AMA:** Area Medical Advisor.

6.0 ROLES AND RESPONSIBILITIES

6.1 All Staff

- 6.1.1 To report adverse events, near misses or patient safety concerns as soon as these occur to the relevant Education and Competency Assurance Officer, or in his/her absence, the Operations Performance Manager or other Manager.
- 6.1.2 To ensure that no further harm comes to the affected patient, and that clinical staff to whose care the patient is being transferred are aware of the error.
- 6.1.3 To co-operate with any review of clinical adverse events.
- 6.1.4 To report safety concerns, where a clinical adverse event has not occurred but where circumstances exist whereby one might occur (e.g. faulty equipment).
- 6.1.5 To support and promote a culture of patient safety within NAS that encourages reporting of and learning from adverse clinical events.

6.2 Education and Competency Assurance Officers

- 6.2.1 To receive reports on clinical adverse events, near misses or patient safety concerns.
- 6.2.2 To review all clinical adverse incidents, near misses or patient safety concerns reported.
- 6.2.3 To ensure that any immediate actions to prevent further harm to the patient involved in the incident are enacted.
- 6.2.4 To ensure that the staff member concerned is afforded any necessary emotional or professional support.
- 6.2.5 To liaise with Area Medical Advisor on all incidents reviewed.
- 6.2.6 In conjunction with the AMA, to immediately advise the Medical Director/Deputy Medical Director of moderate, major or extreme adverse clinical events (see 7.2.3).
- 6.2.7 In conjunction with AMA, to provide the Medical Director with quarterly clinical adverse event reports.
- 6.2.8 To support and promote a culture of patient safety within NAS that encourages reporting of and learning from clinical adverse events.

6.3 Operations Performance Manager

- 6.3.1 In the absence of the ECAO, to take the place of the ECAO in the initial management of adverse clinical events-in particular the actions outlined in sections 6.2.1 through to 6.2.6
- 6.3.2 To support and promote a culture of patient safety within NAS that encourages reporting of and learning from clinical adverse events.

6.4 Area Medical Advisor

- 6.4.1 To assist ECAOs with the review and resolution of adverse clinical events.
- 6.4.2 In conjunction with an ECAO, to immediately advise the Medical Director/Deputy Medical Director of moderate, major or extreme adverse clinical events.
- 6.4.3 In conjunction with an ECAO, provide the Medical Director with quarterly adverse clinical event reports.
- 6.4.4 In conjunction with the Medical Director/Deputy Medical Director, devise responses to adverse events that can be implemented across the organisation to prevent such events re-occurring.
- 6.4.5 To support and promote a culture of patient safety within NAS that encourages reporting of and learning from clinical adverse events.

6.5 Medical Director/Deputy Medical Director

- 6.5.1 To respond in a timely manner to reports of adverse clinical events communicated by an ECAO and/or AMA.
- 6.5.2 To ensure that serious adverse events and near misses are responded to promptly, and that measures to mitigate further actual or potential patient harm are enacted promptly.
- 6.5.3 To provide quarterly reports on clinical adverse events to the Director and Leadership Team.
- 6.5.4 To ensure that measures identified to minimise clinical risk are enacted throughout the organisation in a timely manner.
- 6.5.5 To support and promote a culture of patient safety within NAS that encourages reporting of and learning from clinical adverse events.
- 6.5.6 To comply with the HSE Policy OQR006 Serious Incident Management Procedure.

6.6 NAS Director and Leadership Team

- 6.6.1 To consider and implement clinical risk mitigation advice received from the Medical Directorate.
- 6.6.2 To support the ECA Team and Medical Directorate in monitoring and managing adverse clinical events.
- 6.6.3 To support and promote a culture of patient safety within NAS that encourages reporting of and learning from clinical adverse events.
- 6.6.4 To comply with the HSE Policy OQR006 Serious Incident Management Procedure.

7.0 PROCEDURE

7.1 All Staff

- 7.1.1 On recognition of a clinical adverse event, staff must report this to the relevant Education and Competency Assurance Officer, or in his/her absence, to the relevant Operations Performance Manager or other Manager.
- 7.1.2 This should be done as soon as is practicable, without distracting from ongoing patient care-ideally when the call is complete and the patient has been handed over to receiving clinical staff.
- 7.1.3 The staff member must ensure that no further immediate risk to the patient resulting from the adverse clinical event exists, and all measures to prevent further patient harm must be put in place-this takes priority over all other actions. In most cases, this will include informing receiving clinical staff of the error, and documenting the events on the Patient Care Report
- 7.1.4 The adverse clinical event should be reported in person or by telephone in the first instance, with a subsequent written notification using Form ACE 1 (see Appendix II), to include the PCR for the call.
- 7.1.5 The staff member will participate fully in any review of the incident. This includes:
 - A. Providing a written report of the incident

B. Identifying other potential sources of information e.g. other NAS Paramedic/Advanced Paramedic staff involved in the call, clinical staff at the sending or receiving facility, General Practitioner, etc.
C. Making him/herself available for reviews with the ECAO, AMA or Medical Director/Deputy Medical Director to discuss the case.

- D. Co-operating with any measures required to progress or conclude the review.
- E. If an issue with the staff member's clinical practice is identified, cooperating with a personal improvement plan advised by an ECAO, AMA or Medical Director/Deputy Medical Director e.g. refresher training or a period of supervised practice.
- F. If a potentially significant on-going risk to patients resulting from the staff member's clinical practice is identified, the staff member may have their clinical privileges restricted by the Medical Director or Deputy Medical Director pending formal conclusion of the incident. This will be done without prejudice, only in the interest of patient safety, and will not influence the outcome of any review.
- 7.1.6 Staff members must report any near misses to the ECAO.
- 7.1.7 Staff members must report any patient safety concerns to the ECAOthis is where a potential for patient harm exists, but no patient harm has yet ensued.

7.2 Education and Competency Assurance Officer and Area Medical Advisor

- 7.2.1 On being made aware of an adverse clinical event, the ECAO will immediately ensure that no further potential for harm to the patient exists, and if so, will make every effort to ensure any potential for ongoing harm is minimised.
- 7.2.2 The ECAO will gather all necessary information regarding the incident, including, but not limited to:
 - A. The Patient Care Report
 - B. A report from the staff member involved
 - C. A report from any other NAS staff involved
 - D. Video from the vehicle
 - E. Control Centre logs and recordings
 - F. Emergency Department/receiving facility clinical information
- 7.2.3 The ECAO will then come to a preliminary conclusion and grade the event as one of the following:
 - A. Negligible: minor injury not requiring first aid
 - B. Minor: minor injury/illness-first aid treatment required
 - C. Moderate: significant injury requiring medical treatment
 - D. Major: major injury, long term incapacity or disability
 - E. Extreme: Death or major permanent incapacity

- 7.2.4 Any incident deemed to be of major or extreme significance must be communicated immediately to the Medical Director or Deputy Medical Director, as well as to the Area Medical Advisor.
- 7.2.5 For incidents of negligible, minor and moderate severity, the ECAO will discuss the incident with the Area Medical Advisor, and the ECAO and AMA will determine the following:
 - A. Cause of the incident
 - B. Any adverse patient outcome

C. If a Personal Improvement Plan of the staff member involved is required e.g. training, or a period of supervised practice

D. If such an event could occur again and what is required to mitigate the risk

- 7.2.6 If a Personal Improvement Plan is recommended for the staff member, and the staff member feels this is not warranted, he/she has the right to appeal this decision to the Medical Director. The Medical Director's decision will be final.
- 7.2.7 The ECAO and AMA will complete Form ACE 2 (see Appendix III) and submit this to the Medical Director with any recommendations for risk mitigation in the wider organisation.
- 7.2.8 The ECAO and AMA will submit quarterly adverse clinical event reports to the Medical Director.

7.3Medical Director/Deputy Medical Director

- 7.3.1 On notification of an adverse clinical event, the Medical Director, in conjunction with the Deputy Medical Director, will determine if any aspects of the incident require measures to be put in place throughout NAS to prevent a further similar occurrence.
- 7.3.2 Such measures will be advised to the NAS Director and Leadership Team for consideration and implementation
- 7.3.3 On notification of an incident that indicates serious concerns about a staff member's clinical competence, the Medical Director/Deputy Medical Director will take any protective measures to ensure ongoing patient safety. These may include, but are not limited to:
 - A. Withdrawal or modification of the staff member's clinical privileges
 - B. Reassignment of the staff member to non clinical duties
 - C. Putting the staff member off duty with pay

- 7.3.4 On notification of an incident that indicates gross negligence or deliberate malfeasance of the staff member, the Medical Director/Deputy Medical Director may choose to refer the staff member for HSE disciplinary measures or consideration of PHECC Fitness to Practice proceedings.
- 7.3.5 Any staff member being dealt with under sections 7.3.3 or 7.3.4 has the right to appeal the Medical Director/Deputy Medical Director's decision to the NAS Director. The NAS Director's decision will be final.
- 7.3.6 Where any clinical adverse event is categorised as a **"Serious Incident"** as defined in the HSE Policies - OQR006 – Serious Incident Management Procedure and - QCCD001 - HSE Risk and Incident Escalation Procedure, the Medical Director/Deputy Medical Director will ensure that the appropriate reporting procedures are adhered to.
- 7.3.7 The Medical Director will submit quarterly adverse clinical events to the NAS Director and Leadership Team.

7.4 Notification of affected patients

- 7.4.1 NAS has a policy of open disclosure to patients affected by adverse clinical events.
- 7.4.2 The person affected by an adverse clinical event (and/or their next of kin) will be kept informed of the event and its outcome.

7.5 Adverse clinical events - causes other than practitioner Error

- 7.5.1 NAS recognises that adverse clinical events may occur for reasons other than practitioner error, e.g. equipment failure, unavailability of a medication, non-deployment of a particular resource etc.
- 7.5.2 Any staff member becoming aware of such an instance should report the incident in the same manner as a practitioner related adverse clinical event (see Section 7.1).

7.6 Patient safety concerns/near misses

7.6.1 Staff members may become aware of the potential for an adverse clinical event, which does not actually occur - prevented by good fortune, a staff member's foresight, or some other reason. These potential events should also be reported as per Section 7.1.

8.0 IMPLEMENTATION PLAN

- 8.1 This Policy will be circulated electronically to all Managers, Supervisors and Staff.
- 8.2 This Policy will be available electronically in each Ambulance Station for ease of retrieval and reference.
- 8.3 Each Operational Support and Resilience Manager will ensure that the Manager/Supervisor responsible for updating Policies and Procedures will return the Confirmation Form to NAS Headquarters to confirm document circulation to all staff.

9.0 REVISION AND AUDIT

- 9.1 This policy will be reviewed on an ongoing basis or when necessary following changes in clinical, legislation or governance arrangements.
- 9.2 The Medical Directorate has the responsibility for ensuring the maintenance, regular review and updating of this policy.
- 9.3 Revisions, amendments or alterations to the policy can only be implemented following consideration and approval by the Medical Director following consultation with key stakeholders.
- 9.4 The application of this policy may be subject to audit to establish compliance and any procedural deficits.
- 9.5 The NAS Education and Competency Assurance Team is responsible for carrying out an internal audit of this Policy and it's Procedures.

10.0 REFERENCES

None

11.0 APPENDICES

- 11.1 Appendix 1 Procedure Acknowledgement Form
- 11.2 Appendix 2 Procedure Approval Group
- 11.3 Appendix 3 Document Control

Name:	Title:

APPENDIX 1 – Procedure Acknowledgement Form

APPENDIX 3 – Procedure Approval Group

Name:	Title:
Martin Dunne	National Director - NAS
Dr. Cathal O'Donnell	Medical Director – NAS
Macartan Hughes	Education & Competency Assurance Manager
Pat McCreanor	Control Manager
Sean Brady	Control & Performance Manager
William Merriman	Area Operations Manager – NL
Paudie O'Riordan	Area Operations Manager – West
Paul Gallen	Area Operations Manager - South

APPENDIX 4

Document Control No. 1 (to be attached to Master Copy)

Policy Governing Adherence to all SOP's, Policies and Procedures

Reviewer: The purpose of this statement is to ensure that a Policy, Procedure, Protocol or Guideline (PPPG) proposed for implementation in the HSE is circulated to a peer reviewer (internal or external), in advance of approval of the PPPG. You are asked to sign this form to confirm to the committee developing this Policy or Procedure or Protocol or Guideline that you have reviewed and agreed the content and recommend the approval of the following Policy, Procedure, Protocol or Guideline:

Title of Policy, Procedure, Protocol or Guideline:

Policy Governing Adherence to all SOP's, Policies and Procedures

I acknowledge the following:

- I have been provided with a copy of the Policy, Procedure, Protocol or Guideline described above.
- I have read Policy, Procedure, Protocol or Guideline document.
- I agree with the Policy, Procedure, Protocol or Guideline and recommend its approval by the committee developing the PPPG.

Name	Signature (Block Capitals)	Date
Please return this completed f	orm to:	

Name: Niamh Murphy

Contact Details: National Ambulance Service, Rivers Building, Tallaght Cross, Dublin 24 or email <u>niamhf.murphy1@hse.ie</u>

Document Control No. 2 (to be attached to Master Copy)

Key Stakeholders Review of Policy, Procedure, Protocol or Guidance Reviewer Statement

Reviewer: The purpose of this statement is to ensure that a Policy, Procedure, Protocol or Guideline (PPPG) proposed for implementation in the HSE is circulated to Managers of Employees who have a stake in the PPPG, in advance of approval of the PPPG. You are asked to sign this form to confirm to the committee developing this Policy or Procedure or Protocol or Guideline that you have seen and agree to the following Policy, Procedure, Protocol or Guideline:

Title of Policy, Procedure, Protocol or Guideline:

Policy Governing Adherence to all SOP's, Policies and Procedures

I acknowledge the following:

- I have been provided with a copy of the Policy, Procedure, Protocol or Guideline described above.
- I have read Policy, Procedure, Protocol or Guideline document.
- I agree with the Policy, Procedure, Protocol or Guideline and recommend its approval by the committee developing the PPPG.

Name	Signature (Block Capitals)	Date	
Please return this	completed form to:		
Name:	Niamh Murphy		
Contact Details:	National Ambulance Service, Rivers Building, Tallaght Cross, Dublin 24 or email <u>niamhf.murphy1@hse.ie</u>		

Document Control No. 3 Signature Sheet:

(to be attached to Master Copy)

Policy, Procedure, Protocol or Guideline:

Policy Governing Adherence to all SOP's, Policies and Procedures

I have read, understand and agree to adhere to the attached Policy, Procedure, Protocol or Guideline:

Print Name	Signature	Area of Work	Date