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Adverse Event Management Procedure

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Contents

1. PURPOSE

This document is complementary to, and should be read in conjunction with, the NSS Adverse Event Management Policy. This procedure is designed to ensure a consistency of approach in the management of, and learning from adverse events and near misses, including consideration of duty of candour.

Should members of staff have questions about any aspect of this procedure or its application, they should discuss this with their Line Manager and if necessary seek further advice from a Strategic or Support Business Unit (SBU) adverse event lead or organisational information governance lead or clinical lead specific to the relevant clinical area.

2. SCOPE

This procedure covers the management of all adverse events and near misses. In NSS, these are categorised as information governance[1] and/or clinical[2] adverse events or near misses.

3. DEFINITIONS

1.1 Adverse Event

An **adverse event** is defined as **an event that could have caused (a near miss), or did result in, harm to people or groups of people or the organisation**. **Harm** is defined as **an outcome with a negative effect**. Harm to a person or groups of people may result from unexpected worsening of a medical condition, escalation of treatment, the mishandling of person identifiable information, system failure, service performance issues, service disruption, financial loss or adverse publicity. These are examples and not an exhaustive list.

Not all harm is avoidable, for example the worsening of a medical condition as a natural progression of disease or the inherent risk of treatment. It is not always possible to determine whether harm was avoidable until a review is carried out. Areas for improvement and learning should always be identified if possible.

People are defined as:

- service users
- patients
- donors
- members of staff
- carers
- family members
- visitors

Groups of people include any functional grouping of individuals such as an organisation. This means that adverse events that result in, for example, reputational harm or financial harm are included within the scope of this policy. Also included are populations of users of a particular service, for example screening service users.

1.2 Near Miss

A near miss is defined as when an error or omission has occurred which could have caused harm but there was no adverse outcome or where the error was about to take place but was prevented from happening, either by chance or intervention.

1.3 NSS and External Adverse Events

As a national board supporting and commissioning services across NHSScotland the reporting, reviewing and managing of adverse events and near misses is complex. It is vital that we keep a comprehensive record of events where NSS has had direct responsibility, or where NSS services are partially responsible for the management of an event that has occurred in another NHS health board or other third party. For example, national IT contracts or national screening programmes.

1.3.1 NSS adverse events

These are:

- an event occurred within NSS and for which NSS has direct responsibility
- an event occurred within systems or processes where NSS has joint responsibility and for which NSS has accepted full or partial responsibility

1.3.2 External adverse events:

An adverse event can occur within another organisation and staff must still report these external events to NSS and take action to 1. make the originating organisation or individual aware of the error and 2. minimise the impact of the error. External adverse events can occur:

- in a localised or board environment external to NSS, however, whilst these events have taken place externally to NSS, they may be considered programmatic adverse events within a service for which NSS has overall responsibility or oversight
- externally where NSS does not deliver the service, for example business confidential, person identifiable or clinical information sent in error by another health board, external organisation or member of the public
- externally within systems or processes, for which NSS has joint responsibility in delivering the service, for example a third party service contractor experiences a malware breach which affects their service to NSS or missed/lost samples within a health board such as in the newborn screening programme

Where more than one SBU is involved in the response to an adverse event, whether internal or external, senior managers must identify the lead SBU and jointly agree a co-ordinated response.

It is worth noting that there may be an occasion whereby NSS, through its third party involvement, becomes the agent of discovery for a possible adverse event. NSS would be expected to inform the relevant NHS Board or practitioner that in its view an adverse event should be raised and/or that the duty of candour procedure should be activated. For example, where:

- NSS does not directly deliver a service but does have a duty of governance, for example in dental governance oversight through the National Dental Governance Committee
- NSS administer for, or on behalf of another agency, for example, in dental tribunals on behalf of territorial boards in conjunction with the Scottish

Government and the General Dental Council which are hosted by NSS which then holds information related to the tribunal or investigation

1.4 **Significant Adverse Event**

A significant adverse event is an event that caused death or major harm to people, or serious harm to the organisation, such as a penalty or fine (£>1,000k), or severe impact on reputation and stakeholder relations. These are national category 1 adverse events in NSS. The adverse event national category can help decide the level of review required and all national category 1 adverse events must be considered for a Level 1 significant adverse event review.

4. SUPPORTING DONORS, PATIENTS AND FAMILIES

Although NSS is not primarily a patient facing organisation there is a possibility that a person may be harmed by an error made by NSS. The first consideration is that the person affected must be cared for and further harm prevented. The person's family or carers must be similarly cared for and involved where a patient or donor has been harmed. Compassion and understanding should be demonstrated at all times and arrangements made for regular contact to keep people involved and informed.

NSS will provide information and support to donors, patients or families if they are affected by an adverse event. This will include:

- acknowledgement of the possible distress that the adverse event has caused
- a factual explanation of what has happened (as much as is known at the time)
- a clear statement of what is going to happen next as part of the adverse event review
- any action which can be taken in the interim to resolve the adverse event
- a named contact

The Institute for Healthcare Improvement (IHI) publication *Respectful Management of Serious Clinical Adverse Events (Second Edition)*[3] suggests that an adverse event does not necessarily break down the trust between people involved. The way in which the organisation responds can often be the key factor in the erosion of trust. The IHI publication provides a number of ways in which organisations should keep

people at the centre of the process when responding to an event. Communicating effectively with people is a vital part of dealing with errors or problems in the delivery of care. Saying sorry, providing an explanation and keeping them informed will help people to cope when things have gone wrong.

A reference document[4] has been published for Scotland that builds on the principles within the National Patient Safety Agency's (NPSA) *Being Open Framework* (2009) to support care providers develop their approach to communicating and engaging with people who have suffered harm following an adverse event. These tools are available on the Community of Practice website.[5]

5. DUTY OF CANDOUR

This approach aligns with the Scottish Government's introduction of the statutory organisational Duty of Candour in April 2018.[6] The duty of candour also sits alongside and complements the principles of candour that exist within many professional codes of conduct and staff in a health setting are expected to follow.

An event, which triggers the duty of candour, will most likely be categorised as a National Category 1 or National Category 2. The procedure for duty of candour should be used in conjunction with the Level 1 review procedure. Please refer to appendices 3 and 4.

An event is defined as an individual who has received a health service has been the subject of an **unintended or unexpected incident**, and in the reasonable opinion of a registered health professional, has resulted in or could result in one or more of the following happening:

- The death of the person.
- Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions.
- Harm which is not severe harm but which results in one or more of the following criterion:
    - An increase in the person's treatment.
    - Changes to the structure of the body.

    - The shortening of the life expectancy of the person.
    - An impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days.
    - The person experiencing pain or psychological harm which has been, or is likely to be, experienced by the person for a continuous period of at least 28 days.
- The person requiring treatment by a registered health professional in order to prevent:
    - the death of the person
    - any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned above

The key stages of the procedure include:

- to notify the person affected of the event (and/or family/relative if appropriate)
- to provide an apology
- to carry out a review into the circumstances leading to the event
- to offer and arrange a meeting with the person (and/or family/relative if appropriate)
- to provide the person affected with an account of the incident
- to provide information about further steps taken
- to make available, or provide information about, support for persons affected by the event
- to prepare and publish an annual report on the duty of candour setting out:
    - the number of times duty of candour processes have been used
    - how NSS has complied with the duty of candour legislation
    - what learning and improvement have been put in place as a result

The duty of candour **is not** activated in relation to a near miss.

The organisational duty of candour procedure can be activated through a report made by the whistleblowing process[7], [8] or the NHS complaints handling procedure and vice versa.

Whether a service is delivered directly, whether it is delivered in a shared capacity or whether NSS is in a support role, all duty of candour events should be reported through the adverse event management process and any learning documented.

See appendix 4 for further guidance on the duty of candour process in NSS.

6. SUPPORTING STAFF

NSS has a commitment to all staff who are involved in an adverse event or near miss to ensure that they are offered support at a time and in a way, which meets their needs. Staff involved in an adverse event or near miss may be physically and / or psychologically affected by what has happened. Line managers have a responsibility to check in with their staff and help to identify appropriate support for individuals and teams. This may include:

- protected time for an individual in order to prepare information as part of an adverse event review
- referral to occupational health or advice around counselling services (HR connect)
- contact with their staff side representative

7. TRAINING AND EDUCATION

ServiceNow is the electronic system used by NSS to report and record information relating to adverse events and near misses. ServiceNow must be used throughout all stages in the management of an adverse event or near miss to record all information, communications, outcomes and improvement plans, so that an audit trail is evident.

A system guide is accessible from the NSS staff intranet adverse event management pages.

The Clinical Governance and Quality Improvement group and Corporate IG Leads are responsible for the development of processes to support the management of clinical and information governance adverse events or near misses respectively.

NSS must ensure that all users are provided with ServiceNow system guidance.

All staff are mandated to complete the information governance in action e-learning module, which includes details on how to report an adverse event or near miss. The information governance session at corporate induction includes adverse events.

Guidance on adverse events, near misses and duty of candour is available on the staff intranet under adverse event management. Guidance to support information governance related adverse events is available on the information governance pages on the staff intranet.

8. MANAGING ADVERSE EVENTS

The circumstances surrounding each adverse event or near miss will vary in terms of:

- levels of harm
- numbers of people involved
- risk exposure
- financial loss
- media interest, and
- the need to involve other stakeholders

Therefore, the response to each adverse event or near miss must be proportionate to its scale, scope, complexity and opportunity for learning. The five stages involved in managing events are summarised in this section and illustrated in the flowcharts at appendices 1, 2 and 3.

Five stages of adverse event management

1. Identification and immediate actions following an adverse event or near miss, including consideration of duty of candour
2. Initial reporting and notification
3. Assessment and categorisation, including consideration of duty of candour
4. Adverse Event Review
5. Improvement planning and monitoring

1.5 Risk assessment and prevention

Adverse event management is one part of effective risk management. Avoidance, prevention and mitigation of risk is part of the NSS approach to all its activities and should be the primary defence to prevent adverse events or near misses occurring.

Risk assessment and prevention is a continuous process and should take place regularly. Where there is potential risk, mitigating actions must be put in place that are proportionate to the risk to prevent it occurring, or if this is not possible, minimise the likelihood and impact. These should be recorded and managed via the NSS Risk Register.

Managing and learning from when things go wrong is an integral component of risk management processes and supports risk prevention. These data can act as an early indicator that a system is not functioning effectively, and analysing trends can provide valuable insight into where improvements may be required.

Risk in NSS is managed in line with the NSS Integrated Risk Management Approach.

1.6 Stage 1: Identification and immediate actions following an adverse event, including consideration of duty of candour

The first priority following an adverse event or near miss is to ensure that the needs of individuals affected are attended to, including any urgent clinical care, which may reduce the harmful impact. This includes patients, donors, relatives, carers, visitors and staff. A safe environment should be re-established, all equipment or materials retained, and relevant documentation copied and secured to preserve evidence and facilitate review and learning.

Your line manager should also be notified at the first opportunity that an adverse event or near miss has occurred and that you will submit an electronic reporting form (if you have not already done so).

Immediate action must be taken to notify a Senior Clinician / Senior Manager/Subject Matter Expert where:

- a significant clinical adverse event, including duty of candour, has occurred or is suspected (see appendices 3 and 4 for further guidance)
- a serious data breach involving personal information has occurred or is suspected
- a serious information or cyber security event has occurred or is suspected

Once aware of the event, the relevant manager(s) is responsible for ensuring that all appropriate actions outlined above have been taken.

1.7 Stage 2: Initial reporting and notification

1.7.1 How to report

When an adverse event or near miss occurs, this must be reported using the NSS electronic reporting form. This should happen as soon as possible after the adverse event or near miss has been identified and preferably within one working day, unless there are exceptional reasons for delay, for example the event was identified retrospectively following a complaint. All adverse events or near misses should be reported whenever they have been identified, even if some time has passed since the event occurred.

The electronic form can be accessed from the staff intranet landing page or the adverse event management pages.

If the electronic reporting form is unavailable or the system is temporarily down a template form is accessible from the adverse event management pages on the staff intranet. This should be completed and submitted by you, your Line Manager or SBU adverse event lead as soon as practicably possible.

The adverse event or near miss should be reported to the SBU where the event occurred or where it is most appropriate for the event to be managed, for example, screening services related events are managed within Procurement, Commissioning and Facilities or events relating to payroll are managed by Finance. The event details

are automatically routed to assigned individuals (assessors) within that SBU. The electronic form will capture the following as a minimum data set:

- The location where the adverse event or near miss occurred.
- The date and time of the adverse event or near miss.
- The name and contact details of the reporter.
- A brief description of the adverse event or near miss.
- Any immediate actions taken including any remedial action taken to minimise risk of recurrence of the adverse event or near miss.

It is essential that the information recorded on the electronic reporting form contains only factual information, and avoid making assumptions or stating opinions. It is important that details are accurate, up to date and factual for any future review. Supporting information can be attached to the form, such as an email or scanned letter, if it will assist with the review. No person identifiable, confidential or sensitive business information should be included or attached to the form. Always avoid the use of abbreviations or jargon.

The system is set up to notify the appropriate SBU contact however it does not replace personal and timely communication and escalation procedures must be followed appropriate to the severity of the adverse event or near miss as set out in the flowcharts at appendices 1 and 2, and the SAE flowchart at appendix 3.

There are also events where there are statutory reporting requirements that dictate escalation and external reporting within strict timescales. For example, a serious breach of personal information or serious cyber security event must be reported to their respective bodies within 72 hours of becoming aware of the event. See 8.3.3.

1.7.2 What to report

The type of adverse event or near miss will be varied therefore it would not be possible to provide an exhaustive list. Some examples of what to report are listed below:

- Missing clinical notes on national IT systems, for example Emergency Care Summary.

- Missing / lost patient records during transfer between NSS sites.
- Sending person identifiable information (PII) to the wrong person.
- Finding papers containing PII or confidential business information in unattended areas.
- Failure to recall participants on screening programmes, for example breast screening or bowel screening.
- Losing a mobile device, such as a laptop, USB or mobile phone.
- Overhearing a confidential conversation.
- Failure to redact person identifiable, confidential or sensitive business information before it is shared, such as via email, web page or presentation.
- Missed or wrong information on donor session record resulting in incorrect donor acceptance.
- Complication with cannulation not recognised at donor session leading to additional medical treatment for the donor.
- Failure to comply with legislative timelines, for example in data protection or Freedom of Information.
- Mis-association of Community Health Index number.
- Incorrect labelling of blood and subsequent transfusion.

1.7.3 Reporting to external agencies

Specific events must be reported to external regulators / competent authorities at a national or UK level. Specific roles within NSS will be responsible for reporting externally. This includes:

- all significant adverse event reviews commissioned for a national category 1 adverse event reported to **Healthcare Improvement Scotland.** See supplementary guidance on national notification data.[9]
- personal data breaches likely to result in a risk to individuals' rights and freedoms to the **Information Commissioners Office (ICO)**[10]
- events where there is an impact on the provision of an essential service reported to the competent authority, i.e. **Scottish Government**, in line with the Network and Information Systems (NIS) Regulations 2018

- events relating to blood to the **MHRA** as required by the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive[11]
- adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme to the **MHRA**[12]
- events involving the loss of NSS devices, such as laptops and mobile phones, to **Police Scotland**[13]
- events involving health, social care, estates and facilities equipment to the **Incident Reporting and Investigation Centre (IRIC)** within Health Facilities Scotland as set out in CEL 43 (2009)[14]
- ionising radiation adverse events to Healthcare Improvement Scotland

Staff working within specific specialities or areas, such as those detailed in the list above, should be aware of the arrangements for reporting an adverse event or near miss in NSS and onward reporting to external organisations.

1.8 Stage 3: Assessment and categorisation, including consideration of duty of candour

Following initial reporting of an adverse event or near miss, the electronic reporting form is automatically routed to assessors within the SBU or Directorate. The purpose of the assessment is to help determine NSS's response to the event. The assessor will usually follow-up with the reporter of the event and, in some cases, subject matter experts, such as the NSS Information Security Officer or NSS Data Protection Lead. The assessor must establish whether it is an NSS or external adverse event or near miss, as described in Section 3.1. They must then assign a risk scoring, national adverse event category and manager to oversee the event record within **72 hours of the event being reported on the system (excluding weekend hours and public holidays).**

As part of the initial assessment, an assessor may transfer responsibility of an event to another SBU or Directorate. For example, where the reporter has chosen the wrong SBU or Directorate or if it is deemed more appropriate for the event to be managed in another SBU or Directorate. It will become the responsibility of an

assessor in this SBU or Directorate to ensure that the risk scoring, national category and manager is assigned to the event record.

The corporate IG Leads and clinical governance and quality improvement group will quality assure the categorisation of information governance and clinical events respectively and appropriate action taken should the original categorisation be inappropriate.

1.8.1 National categories

The following categories are nationally agreed for NHSScotland and must be used to group adverse events and near misses in NSS.

Category 1 – Events that may have contributed to or resulted in permanent harm, for example death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as catastrophic impact on the NSS IRMA).

Category 2 – Events that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded as major or moderate impact on the NSS IRMA).

Category 3 – **Events that had the potential to cause harm but no harm occurred,** for example near miss events (by either chance or intervention) or low impact events where an error occurred, but no harm resulted (likely to be graded as minor or negligible impact on the NSS IRMA). Category 3 is separated into three groupings:

- **3(i)** - an error did not result
- **3(ii)** - an error occurred but did not reach the person
- **3(iii)** - an error reached the person but did not result in harm.

1.8.2 Links with Duty of Candour

In most cases, an event falling under duty of candour requirements will be identified before an adverse event review takes place and appropriate procedures will have been followed. However, if the initial assessment identifies an instance where the organisation has not yet met the requirements of duty of candour, this should be undertaken as soon as possible.

1.9 Stage 4: Adverse Event Review

All events are subject to review. The purpose of the review is to determine what happened, how it happened, why it happened, and whether there are learning points for the service, the wider organisation or nationally. It should follow the principles of a just culture and take a systems approach, meaning that it should not focus on individuals. If the review team consider that there are any issues around the performance of an individual member of staff, this should be referred to the appropriate line manager and should not be part of the review. The review process may also identify good practice that should be shared, or learning points that could lead to further service improvements.

1.9.1 Multi SBU or Directorate Review

Where an event involves more than one SBU or Directorate there should be a discussion between managers as to who is best placed to lead the review and the decision recorded within the event record. The manager in the lead SBU or Directorate will have overall responsibility for completion of the event record. Other SBUs/directorate should still contribute to the adverse event review and any improvement plan. Multi SBU or Directorate involvement should be electronically documented.

1.9.2 Multi-agency Review

There will be occasions where an adverse event review has the potential to involve more than one organisation or sector. At the outset of the review process, consideration should be given to whether a collaborative approach is needed. The lead organisation (where the adverse event or near miss was reported) should contact the other organisation and agree the scale of the involvement (from providing

information or documentation to being part of the review team). A single point of contact for the patient, service user, family or carer should be clearly defined at the outset and should ensure that all organisational duty of candour responsibilities are met. A multidisciplinary review team with experience relevant to the different components of the care system being reviewed should also be agreed at the outset. Guidance[15] has been developed to support a consistent approach to collaborative reviews and is available on the Community of Practice website.

1.9.3 Level of review

The designated manager is responsible for confirming that the event has been allocated the appropriate national category. They also have responsibility for assigning an appropriate level of review. As previously mentioned, the national category will help determine the level of review but will also take into consideration other factors such as the risk impact score and potential for learning. The review level will determine the timescales by which the event should be concluded. The manager is responsible for monitoring the event and providing an explanation as part of the event record if the target date is breached.

Considering the potential for learning from the event aims to ensure that responses are not overly focused on the impact or outcome. This aims to gain an insight on underlying weaknesses of the systems or areas where the system could be improved. The following decision making prompts may help to determine the potential for learning:

- Is the outcome a known complication of the disease, treatment or process?
- Has there been any known breach or deviation in policy or procedure?
- Are there unknowns surrounding the event?
- Does the event activate duty of candour procedures?
- Is there learning to be gained/would you do anything differently next time?
- Is the donor, service user, family or management concerned about the event?
- Is there any risk to the rights and freedoms of the individual(s) affected?

The table below provides a guide on the levels of review for each category based on the national adverse events framework. Where a decision is made to apply a different

level of review to that suggested below the rationale should be clearly documented within the event record.

Table 1 Guide to levels of review

Adverse event category	Suggested minimum level of review	Review team	Reporting of findings and learning	Guidance timescale
Category 1	**Level 1** Significant adverse event analysis and review. Use of validated analysis tools or evidence of screening and clear rationale for any not progressing to analysis.	Director or Associate Director in the lead SBU or Directorate to agree Review Lead and Terms of Reference (the review team should be sufficiently removed from the event, and have no conflict of interest, to be able to provide and objective review).	Final report through governance structures with evidence of finding and recommendations as required. The development of the improvement plan should sit within the team/department where the adverse event took place.	Commence review within 10 working days of adverse event being reported on the adverse event management system. Commence and close review (report submitted for approval) within 90 working days on the adverse event management system. Final approval should take place as soon as possible and no later than 30 working days from report submission. Develop improvement plan within 10 working days from report being approved.
Category 2	**Level 2** Local management team review.	Service manager in lead SBU or Directorate with multidisciplinary team input.	Reported through local governance structures with evidence of findings and recommendations as required.	Commence and close review (report submitted for approval) within 30 working days of adverse event being reported on

Adverse event category	Suggested minimum level of review	Review team	Reporting of findings and learning	Guidance timescale
			The development of the improvement plan should sit within the team/department where the adverse event took place.	the adverse event management system. Final approval should take place as soon as possible and no later than 30 working days from report submission. Develop improvement plan within 10 working days from report being approved.
Category 3	**Level 3** Local review by manager assigned to the event in discussion with staff.	Managers and staff in SBU or Directorate. Specialist advice should be sought where appropriate	Aggregated reports and learning points reported through local service management and governance structures	Adverse event or near miss approved and closed within 30 working days of adverse event or near miss being reported on the adverse event management system.

1.9.4 Review Documentation

ServiceNow and QPulse (SNBTS only) are the electronic systems used by NSS to maintain an accessible record of review documentation. The record should include (but is not limited to):

- Report, including the notification process (and documentation of decision to proceed to review).
- Risk assessment.
- Any written recollections of events submitted as part of the review.
- All contact and communication with third parties.
- Any reports and documented information provided to support the review.
- Details of any equipment (including location) or IT systems involved in the adverse event or near miss.
- Improvement plan and / or learning summary.

Documentation, which includes any person identifiable or confidential or sensitive business information, should not be added to the electronic system. It should be filed in a secure area on the NSS network in line with the NSS business classification scheme (BCS). It is recommended that it is stored in a folder using the reference number of the event record and the secure area filepath is recorded within the event record. Staff should ensure that the folder permissions and information is kept up to date. The written and electronic record must be retained in line with the NSS Document Storage, Retention and Disposal Policy.

1.9.5 Review Process

The basic process of adverse event review and analysis is essentially the same for all levels as summarised in Table 1 above. However, some events due to the complexity or the potential for learning require a more formal, extensive review making full use of associated tools and techniques to examine the chronology, the care or service delivery provided, contributory factors and any lessons that could inform service improvement or reduce the risk of recurrence. A variety of tools, such as cause and effect charts, fishbone diagrams and contributory factor frameworks, can be used.

1.9.6 Levels of Review

A **Level 1** review or **significant adverse event review** should be considered for all National Category 1 adverse events and events that trigger the statutory duty of candour. The national category of the event can help decide the level of review, however, it must be stressed that a severe or tragic outcome is not the only indicator for a Level 1 review. Near miss events with no adverse outcome and complex Category 2 or 3 events may also warrant a Level 1 review due to the potential for learning that has been uncovered. A final anonymised report must be approved by the Medical Director (clinical) or Senior Information Risk Owner (IG) and shared across services, the wider organisation and nationally as appropriate. It should be shared with all people involved in or affected by the adverse event.

Guidance on how to conduct a Level 1 review at appendix 3.

Refer to the significant adverse event flowchart at appendix 3

A **Level 2** local management review is conducted by a manager ensuring that there is engagement with all staff and third parties, such as contractors or suppliers, involved in the adverse event. If the event is IG related, the review should have input from a relevant IG lead. Where the event is clinical, the review should include clinical input. Communication requirements should be clarified where the event involves patients, donors, service users or their representatives. A final report or SBAR report must be approved by a relevant senior manager and shared with the appropriate SBU or Directorate governance group or equivalent. It should be shared with all people involved in or affected by the adverse event. Refer to flowchart at appendix 2.

A **Level 3** local review will involve engagement with the reporter, other staff involved and any third parties, such as contractors or suppliers, to establish what happened and why. If the event is IG related, the review should have input from a relevant IG lead. Where the event is clinical, the review should include clinical input. Details of action taken and any improvement plan should be recorded and closed by the manager with approval responsibility in the event record. These events will be reported to SBU or Directorate level governance groups to support the identification of trends. Refer to flowchart at appendix 2.

National guidance[16] has been developed to support a standard approach to writing adverse event review reports to enable appropriate learning to be shared, whilst safeguarding patient, service user, family, carer, donor and staff confidentiality. This includes writing review reports in a format that minimises the need to redact PII so that information can be more freely shared. NSS guidance is available on criteria to consider for redaction before external release.

1.9.7 Links with Resilience Management

Where there is a significant loss of services, for example due to a major cyber security event or systems failure resulting in an inability to distribute blood, consideration must be given to whether the NSS Resilience Management Plan needs to be invoked. Where it is agreed that an adverse event will be managed via the NSS Resilience Management Plan, this should be documented within the event record along with the resilience incident reference number. Reports and / or improvement plans produced as part of the resilience incident are used as part of the adverse event record and removes the need for duplication.

1.9.8 Links with the NSS Integrated Risk Management Approach (IRMA)

Where risks to NSS are identified during the adverse events review these should be discussed with a relevant senior manager and, where agreed, added to the Corporate NSS Risk Register in line with the IRMA. Risks may be added to the risk register at any stage during the adverse event review or may be recommended as part of a Level 1 or Level 2 final report and associated improvement plan or Level 3 improvement action.

1.9.9 Links with conduct process

In the unlikely event that a review uncovers evidence of a criminal act, the appropriate enforcement agencies will be informed. Where there is evidence of misconduct, including malicious or reckless behaviour, Human Resources processes will be invoked where appropriate. This is not part of the adverse event review although both processes can run in parallel provided the rights of the individual are not compromised.

1.10 Stage 5: Improvement planning and monitoring

Level 1 and 2 adverse event reviews must have an improvement plan developed in response to the findings and recommendations. The outputs from the review should focus on service improvements and ideally each review should have an improvement aim established at the end of the review (an overarching 'how much by when' in terms of service improvement).

Those with the responsibility for making the agreed changes should develop improvement plans and who therefore have control and responsibility for implementation. This may be the team or department where the adverse event or near miss took place or it may be a corporate management team if a consistent corporate response is required. All actions should identify owners and timescales for completion. Final plans should be shared with those who reported and were involved in the original adverse event or near miss.

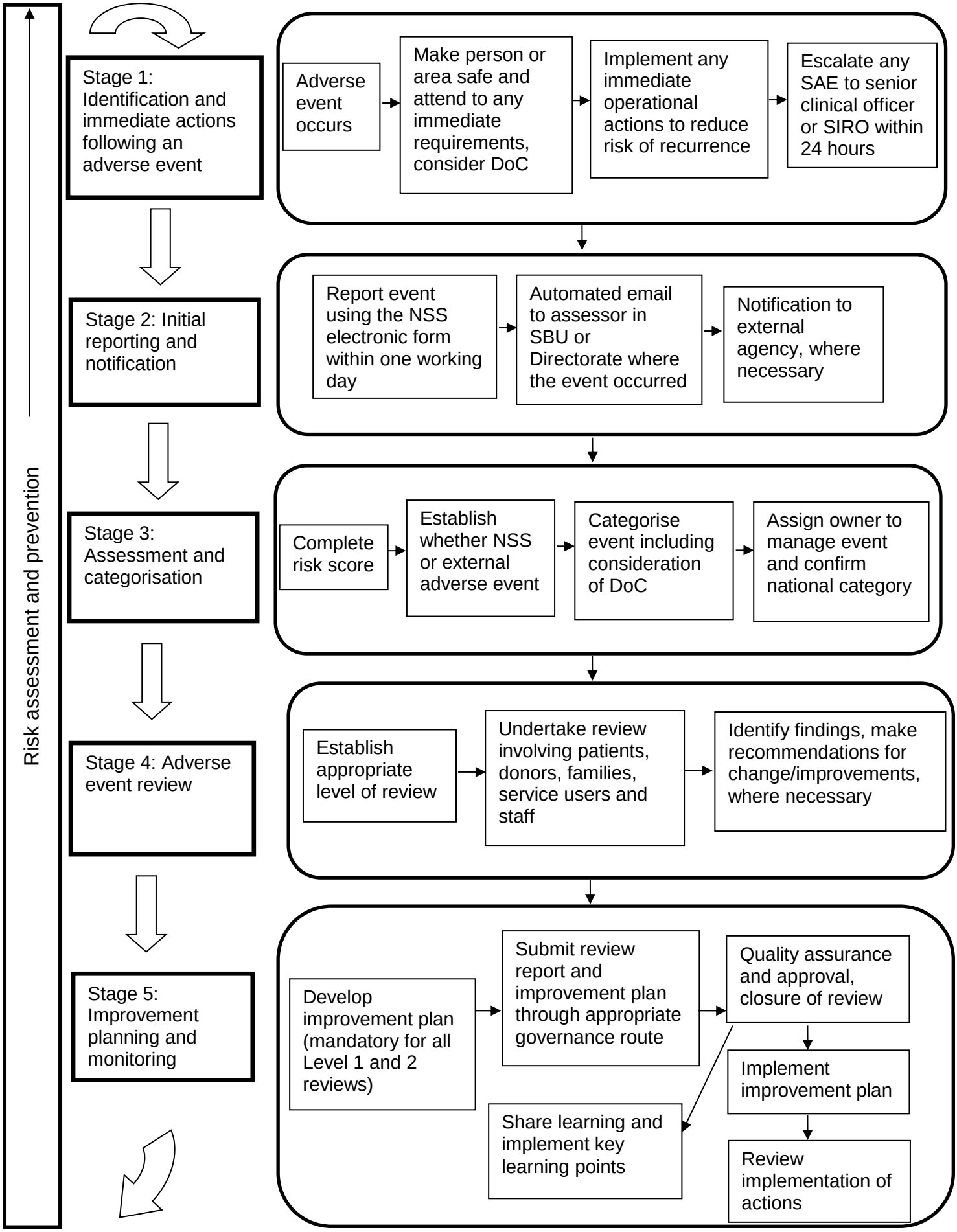
Improvement plans should be owned locally, reviewed and updated regularly. This includes escalating outstanding issues to senior management within the SBU or Directorate area or department where an action/recommendation is not being progressed. The reason for this should be recorded within the event record. The SBU Senior Management Teams will have this responsibility for monitoring implementation of improvement plans for Level 1 and Level 2 adverse event reviews respectively.

NSS will share learning and improvements from adverse event reviews across services, the wider organisation and nationally as appropriate. A brief learning summary is likely to be a better way to share key learning points. A one-page template has been developed as part of the event record to summarise what happened, what went well, what if anything could be improved and what learning has been identified.

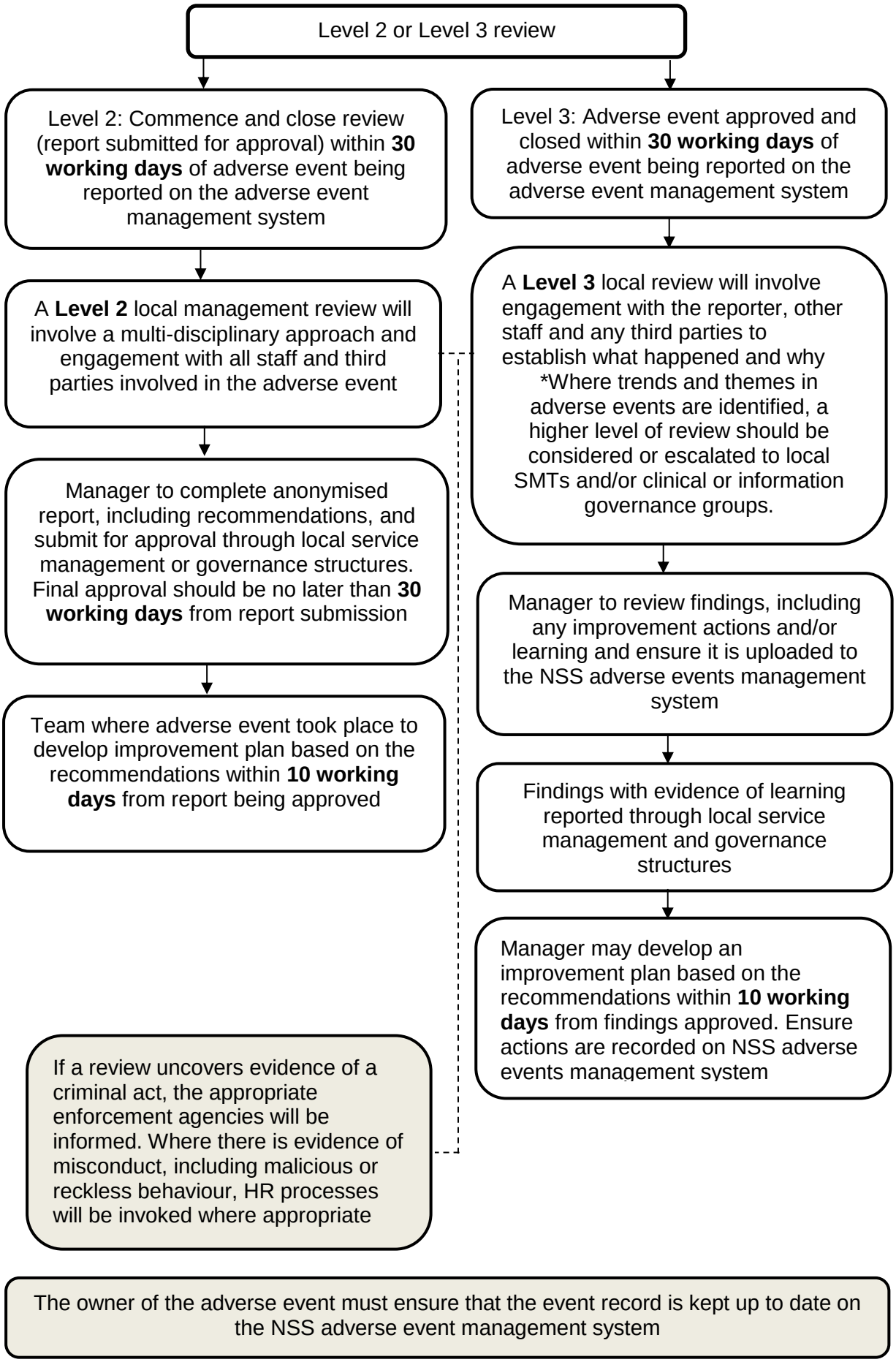
9. MONITORING AND REVIEW

The Clinical Governance and Quality Improvement group and Corporate IG Leads will continuously review this procedure. Changes may also be made by exception and through formal review every three years by any of the groups with oversight responsibility.

10. APPENDIX 1: ADVERSE EVENT/NEAR MISS FLOWCHART



11. APPENDIX 2: LEVEL 2 AND 3 REPORTING FLOWCHART



12. APPENDIX 3: SIGNIFICANT ADVERSE EVENT REVIEW

All National Category 1 adverse events and events that trigger the organisational statutory duty of candour should be considered for a Level 1 review significant adverse event review. In some cases, near miss events can also warrant a Level 1 review due to the potential for learning that has been uncovered.

Notification and communications for significant adverse events should be immediately escalated to the senior clinical officer (clinical) or Senior Information Risk Owner (IG). The Director or Associate Director, Senior Clinical Lead or Senior IG Lead of the SBU or Directorate where the event took place should be notified within **24 hours** of the event. Consideration should be given as to whether wider communication about the event is necessary.

If a significant adverse event occurs outside of business hours (9 to 5) then the senior clinician on call (clinical) or SIRO should be contacted. Consideration should be given as to whether wider communication about the event is necessary outside of business hours depending on the severity of the event.

The reporting form should be completed as soon as possible. The assessor(s) for the SBU where the event occurred should complete the initial assessment of the adverse event within **72 hours** and assign to an appropriate manager. The manager will confirm the national category and consider, in consultation with senior management and any specialist advisors, whether a Level 1 Review is required. If it does not progress to a Level 1 review the rationale and decision making should be clearly documented in the event record.

Level 1 adverse event reviews must be completed within 90 working days (excluding weekends and public holidays). Where the event has triggered the organisational duty of candour, this process will run in parallel. If not a duty of candour, the Being Open principles still apply.

Where a Level 1 adverse event review has been confirmed, the following should be established:

- A lead director or senior manager (Band 7 and above) assigned to ensure a through and appropriate review is undertaken.
- The scale, scope and timescale for the review should be included with a Terms of Reference.
- A review team (members with knowledge of the specialty) with a lead reviewer appointed and roles within the team clearly defined (the review team should be sufficiently removed from the event, have no conflict of interest to be able to provide an objective view).
- At least one member of the review team trained in review methodologies and their application or where this not possible support from IG lead and/or senior clinician.
- The lead responsibility for establishing and meeting the communication requirements of patients, donors, service users or their representatives should be clarified by the lead reviewer, taking into account the duty of candour.
- Staff and managers involved should be informed of the review and invited to contribute to the review process. Staff should be kept informed of progress throughout the review.
- A comprehensive, access controlled file of review documentation maintained in a secure area of the NSS network.

A report presenting the findings, conclusions and recommendations of the review should be produced and shared with everyone involved in the event. The report should:

- be anonymised so that no staff members, service users, patients or donors can be identified
- be agreed by the review team
- include recommendations that clearly state its aim to support changes in practice and quality improvement and the timescale for making a decision about whether the recommendations will be accepted and for developing the improvement plan
- be shared with the review team and all staff involved in the event
- be shared with patients, donors, service users or their representatives involved in the event
- be approved by the Medical Director (clinical) or Senior Information Risk Owner (IG) through the appropriate governance approval process

- The final report stored on the NSS adverse event management system

Level 1 adverse event reviews must have an improvement plan developed in response to the findings and recommendations within ten days of the report being approved. The outputs from the review should focus on service improvements and ideally each review should have an improvement aim established at the end of the review (an overarching ‘how much by when’ in terms of service improvement).

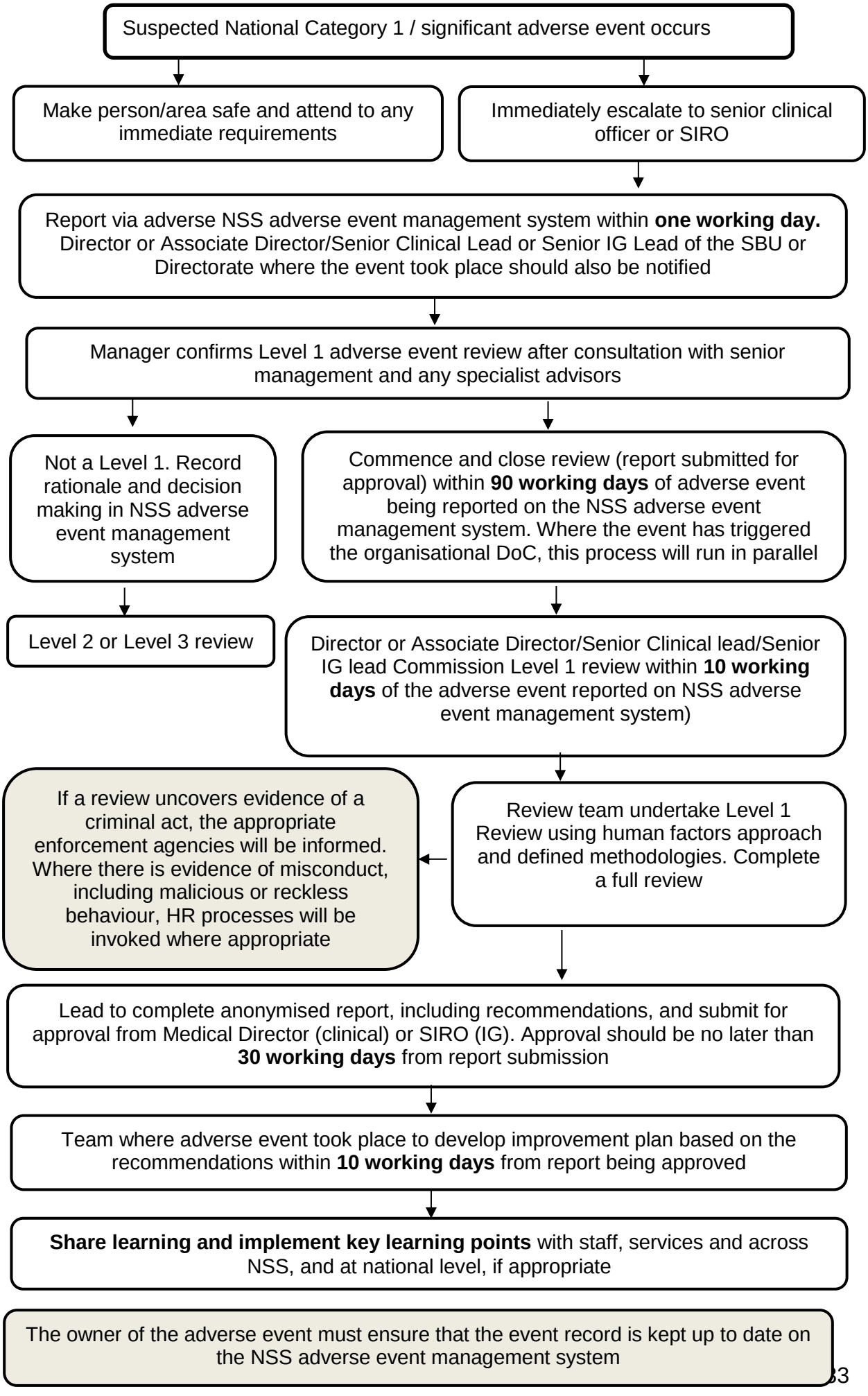
Those with the responsibility for making the agreed changes should develop improvement plans and who therefore have control and responsibility for implementation. This may be the team or department where the adverse event took place or it may be a corporate management team if a consistent corporate response is required. All actions should identify owners and timescales for completion. Final plans should be shared with those who reported and were involved in the original adverse event.

Improvement plans should be owned locally, reviewed and updated regularly. This includes escalating outstanding issues to senior management within the SBU or Directorate area or department where an action/recommendation is not being progressed. The reason for this should be recorded within the event record.

The SBU Senior Management Team will have this responsibility for monitoring implementation of improvement plans for Level 1 reviews.

NSS will share learning and improvements from adverse event reviews across services, the wider organisation and nationally as appropriate. A brief learning summary is likely to be a better way to share key learning points. A one-page template has been developed as part of the event record to summarise what happened, what went well, what if anything could be improved and what learning has been identified.

SAE Flowchart



13. APPENDIX 4: DUTY OF CANDOUR PROCEDURE

Summary

The Health (Tobacco, Nicotine etc. And Care) (Scotland) Act 2016 introduced a new organisational Duty of Candour on health, care and social work services from 1 April 2018.

The overall purpose of the duty of candour is to ensure that organisations are open, honest and supportive when there is an unexpected or unintended incident resulting in death or harm, as defined in the Act.

Professional Duty of Candour

The duty of candour also sits alongside and complements the principles of candour that exist within many professional codes of conduct and staff in a health setting are expected to follow.

Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care, which causes, or has the potential to cause, harm or distress.

The Responsible Person

The duty of candour applies to organisations and not individuals. The “responsible person” is defined here as a health board. NSS, therefore, has responsibility to:

- carry out the procedure
- undertake any training required by regulations
- provide training, supervision and support to any person carrying out any part of the procedure as required by regulations
- report annually on the duty of candour

Events That Trigger the Organisational Duty of Candour

The responsible person must trigger the duty of candour procedure as soon as reasonably practicable after becoming aware that an individual who has received health, social care or social work services that has been the subject of an unintended or unexpected incident, and in the reasonable opinion of a registered health professional has resulted in, or could result in:

A. the death of a person
B. permanent lessening of bodily sensory motor physiological or intellectual functions
C. Harm which is not severe harm but which results in:

- an increase in the person's treatment
- changes to the structure of the person's body
- the shortening of the life expectancy of the person
- an impairment of the sensory, motor or intellectual functions of the person which has lasted or is likely to last for a continuous period of at least 28 days
- the person experiencing pain or psychological harm which has been or is likely to be experienced by the person for a continuous period of at least 28 days

D. The person requiring treatment by a registered health professional in order to prevent:

- the death of the person
- any injury to the person which if left untreated would lead to one or more of the outcomes mentioned above

The view of the registered health professional

A registered health professional must give their view on the event and its relationship to the occurrence of death or harm and pre-existing illnesses or underlying conditions. The registered health professional who gives the opinion mentioned above, following an unintended or unexpected incident, is not someone who was involved in the incident.

The following core information should be provided to the health professional in the first instance:

- What was the event?
- What was the outcome?
- What is/was the person's illness or underlying condition?

If the registered health professional is of the opinion that the event is unlikely to cause harm, then the duty of candour procedure need not be activated.

The Procedure

The key stages of the procedure include:

- to notify the person affected (and/or family/relative where appropriate)
- to provide an apology
- to carry out a review into the circumstances leading to the incident
- to offer and arrange a meeting with the person affected and/or their family, where appropriate
- to provide the person affected with an account of the incident
- to provide information about further steps taken
- to make available, or provide information about, support to persons affected by the incident
- to prepare and publish an annual report on the duty of candour

NSS process

In most cases, adverse events, which would trigger the duty of candour, will be identified as part of the adverse events management procedure either at the time of the event or during the adverse event review. There may also be events that are identified through other processes such as complaints or whistleblowing. These must also be reported using the adverse events management procedure.

The Clinical Directorate Clinical Governance and Quality Improvement Group will provide oversight to the duty of candour procedure to ensure it is being appropriately triggered and reporting requirements on Q-Pulse (SNBTS only) and ServiceNow are met.

SBU duty of candour leads must notify the Clinical Directorate clinical governance mailbox within **72 hours** of all suspected or confirmed duty of candour events at nss.clingov@nhs.scot.

Direct and indirect roles in NSS

This procedure relates to events that trigger the duty of candour procedure and NSS is the responsible person.

However, NSS may also have a shared role in supplying the health service with another NHS board or have a supporting role in providing that health service. Although NSS are not the responsible person we may be asked to contribute to a duty of candour procedure being carried out in another health board. It is still

important that we keep a comprehensive record of the event, timelines and NSS involvement via Q-Pulse (SNBTS only) or ServiceNow. NSS are expected to share any learning and necessary actions identified by the procedure with the other health boards. A table documenting NSS's direct, shared and support roles is accessible from the duty of candour page on the staff intranet.

Procedure to be followed, once agreed that duty of candour is triggered

The procedure for duty of candour will be used in conjunction with the Level 1 review procedure. Please see appendix 3.

1. Identify and contact the relevant person

The **relevant person** means the person who has received the health service, or where that person has died, or is, in the opinion of the responsible person, lacking capacity, or otherwise able to make decisions about the service provided, a person acting on behalf of that person.

The relevant person must firstly be identified. Reasonable steps should then be taken to find out their preferred method of communication. Establishing contact by phone in the first instance might be necessary in order to establish the preferred method of communication going forward in the duty of candour procedure.

If NSS is unable to contact the relevant person or the relevant person does not wish to speak to the representative of the organisation, this should be recorded as part of the event record in line with the duty of candour procedure.

NSS must also consider the support needs of the relevant person at the earliest opportunity and throughout the duty of candour procedure.

2. Notification

The relevant person should be contacted as soon as reasonably practicable and within **10 working days** of the procedure start date (the date the registered health professional confirms duty of candour). Notification can be by various methods, for example by telephone, face to face or by letter. Each SBU can decide on a case-by-case basis who is the most appropriate person to make this notification such as in SNBTS where this is likely to be a SNBTS Consultant.

Before this notification, it is helpful to consider what discussions or information exchanges may have already taken place between colleagues and/or the relevant person or other family members.

The notification must include:

- a factual account of the event at time of writing
- an explanation of the actions taken/to be taken by NSS
- if more than a month has passed since the event occurred, an explanation of why the procedure has been delayed

Consideration should also be given to what support the relevant person may need as early as possible following the duty of candour procedure.

3. Apology

In addition to any apology given at the time of the event, as part of the duty of candour procedure, NSS must offer the relevant person a written apology (this can be an electronic communication if this is the person's preferred means of communication) in respect of the event. An offer of a written apology can be discussed as part of the meeting (see step 4).

An apology is important as it acknowledges that harm has been caused and can be the first step in repairing relationships and restoring dignity and trust. It is an acknowledgment of the emotions felt by the patient/donor or their family. It should be sincere, individual and timely, and written in clear, plain and direct language.

In this instance, an apology means an expression of sorrow or regret in respect of the unintended or unexpected event that has happened, and for the distress caused to the patient/donor and their family. The Act sets out that an apology given in accordance with the duty of candour procedure **does not** of itself amount to an admission of negligence or a breach of a statutory duty.

In giving an apology, the following should be considered:

- **Reflect:** stop and think about the situation

- **Regret:** give a sincere and meaningful apology, including acknowledging what has happened, what went wrong and the impact the event has had on the individual or their family. Responsibility for the harm caused should also be claimed.
- **Reason:** if you know and can, explain why something has happened or not happened and if you don't know, say you will find out.
- **Remedy:** outline what actions you are going to take to ensure that this won't happen again and that the organisation learns from the event.

Further guidance on making an apology as part of the duty of candour procedure can be found on the Little Things Make a Big Difference web site.[17]

4. Meeting

Once it is clinically appropriate to do so, the relevant person should be invited to attend a meeting. It is always recommended that a meeting be held in person with the relevant person. This meeting should be held **no later than one month** of the duty of candour start date.

The relevant person should be given the opportunity to ask questions or express their concerns in advance of the meeting. Where it is possible to address any concerns immediately this should be done.

NSS must take reasonable steps to ensure that the meeting is accessible to the relevant person, having regard for their needs. For example, the relevant person may need an interpreter if English is not their first language or making reasonable adjustments if they have a disability.

This conversation should be held in a private room. Every effort must be made to maintain the privacy of the conversation.

A medical consultant should must chair the personal meeting.

The following should be covered at the meeting:

- A verbal account of the event.

- An explanation of the SAE/duty of candour process should be offered including expected timescales for completion. Give the relevant person an information leaflet on the duty of candour to take home.
- An explanation of any further steps that will be taken by NSS to review the circumstances it considers led or contributed to the event.
- An opportunity for the relevant person to ask questions about the event.
- An opportunity for the relevant person to express their views about the event.
- The provision of information to the relevant person about any legal, regulatory or review procedures that are being followed with respect to the event in addition to the procedure. There may be several review processes operating in parallel, for example a complaint or disciplinary procedure. This meeting with the relevant person must include details of these other procedures including their scope and focus.

After the meeting, the relevant person must be provided with:

- a written note of the meeting. Agree with the relevant person what the meeting notes should include such as:
    - location
    - who was present
    - record of an apology
    - actions taken
    - timescales
    - communications going forward
- contact details of a member of staff from within the appropriate SBU acting on behalf of NSS who the responsible person can contact with any queries in respect of the procedure

If the relevant person does not wish to, or is unable to attend a meeting the above information or details should still be offered to them.

5. The Review

NSS will carry out a review of the circumstances that led to the adverse event. In most cases, this will be in line with the NSS significant adverse event review process. This review must include:

- the scale, scope and timescales

- a multidisciplinary approach to ensure all relevant subject matter expertise is drawn upon to ensure the review is as comprehensive as possible
- the use of review methodology
- established communication between the relevant person and NSS
- the views of the relevant person are included as part of the review
- staff and managers involved in the event are invited to contribute to the review process
- an agreed improvement plan and list of actions including expected timescales for completion.
- any learning identified as part of the review process should be considered for sharing across the organisation and more widely where relevant

The review should be completed **within 3 months** of the procedure start date. If not, the relevant person should be provided with an explanation for the reasons for the delay.

6. The Report

NSS must complete a written report of the review, which must include:

- a description of the manner in which the review was undertaken
- a statement of any actions to be taken by NSS for the purpose of improving the quality of service it provides and sharing learning within the NSS and more widely where relevant
- a list of the actions taken for the purpose of the procedure in respect of the event and the date each action took place

The report should be written in clear, plain language and avoid using jargon, abbreviations, acronyms. The report should also be written in a manner that minimises the need for extensive redaction.

The SBU duty of candour lead must submit the report to their SBU clinical governance group or equivalent for local approval. Final sign off should be sought from the Medical Director as NSS duty of candour lead.

NSS will offer to send the relevant person a written copy of the final report with an offer of a follow up meeting discuss in person. Details of any services, which may

provide assistance or support to the relevant person, should be offered along with the report.

7. Records

All events to which the duty of candour procedure is applied must be recorded and documented using Q-Pulse (SNBTS only) or ServiceNow. The event record must be kept up to date throughout the adverse events management process by the staff member assigned to the event record. Every document or piece of correspondence relating to the event can be added to the event record in a redacted form (link to be added). Documentation, which includes any person identifiable or confidential or sensitive business information, should not be added to the electronic system. It should be filed in a secure area on the NSS network in line with the NSS business classification scheme. It is recommended that it is stored in a folder using the reference number of the event record and the secure area filepath is recorded within the event record. Staff should ensure that the folder permissions and information is kept up to date. The written and electronic record must be retained in line with the NSS Document Storage, Retention and Disposal Policy.

8. Reporting and Monitoring

The decision to implement the duty of candour is taken locally. These events will be reported and monitored via their local clinical governance groups.

Those with the responsibility for making the agreed changes should develop improvement plans and who therefore have control and responsibility for implementation. This may be the team or department where the event took place.

The SBU Clinical Governance Group are responsible for ensuring improvement plans are implemented and follow-up actions are completed. The SBU duty of candour Lead will submit a report to the NSS Clinical Governance and Quality Improvement Committee by exception.

9. Annual report

NSS must prepare an annual report, as soon as reasonably practicable after the end of that financial year. A sample report template is available.

The report must include:

- information about the number and nature of events to which the duty of candour procedure has applied in NSS
- an assessment of the extent to which the responsible person carried out the duty of candour
- information about NSS's policies and procedures in relation to the duty of candour, including information about procedures for identifying and reporting adverse events, and support available to staff and to persons affected by these events
- information about any changes to NSS's policies and procedures as a result of events to which the duty of candour has applied
- any other information NSS feels is relevant to the report

The report must not mention the name of any individual, or contain any information that could identify any individual. This is important to note in NSS due to the limited amount of patient/donor services and it is anticipated that the number of events, which may trigger the duty of candour, will usually be low.

The Clinical Directorate Clinical Governance and Quality Improvement group will produce the annual report with engagement from all SBUs where the duty of candour procedure has been triggered. The Clinical Governance and Quality Improvement Committee will approve the report before final sign off at the NSS Board.

The report must be published in a manner that is publicly accessible. The annual report is accessible on the NSS website.

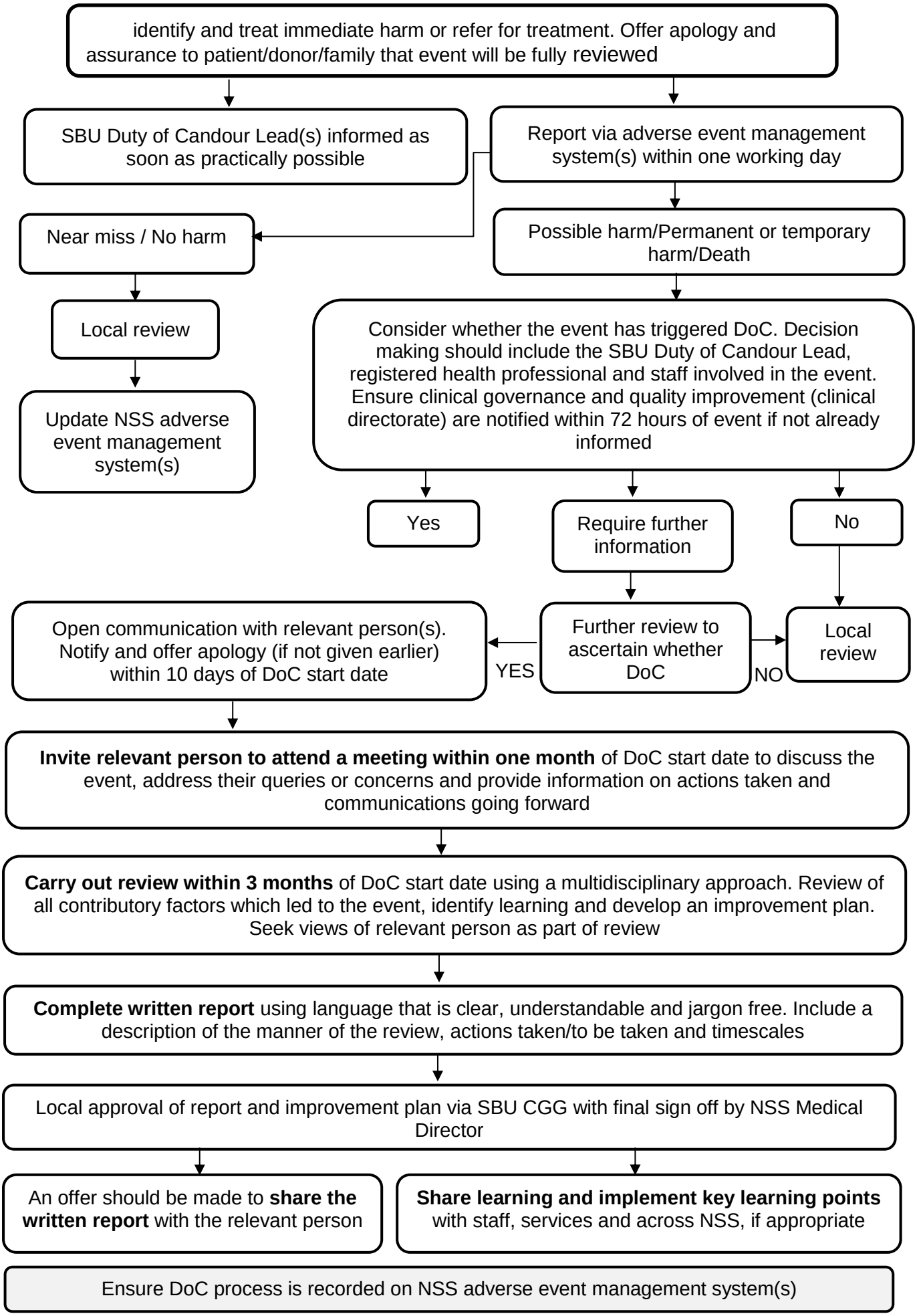
The Clinical Directorate Clinical Governance and Quality Improvement group are responsible for notifying Scottish Government when it is published. The notification is sent to: dutyofcandour@gov.scot

10. Training

The Clinical Directorate Clinical Governance and Quality Improvement Group will support education and awareness of the duty of candour responsibilities in collaboration with the SBUs.

NHS Education for Scotland, The Scottish Social Services Council, The Care Inspectorate and Healthcare Improvement Scotland has produced an e-learning module. Any NSS staff who carry out the procedure must complete the module available on TURAS.

Duty of Candour Flowchart



[1] **Information governance** is “a framework for handling information in a confidential and secure manner to appropriate ethical, legal and quality standards.”

[2] **Clinical governance** is “a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.” (Scally and Donaldson, 1998, p.61)

[3] Respectful Management of Serious Clinical Adverse Events (Second Edition). Conway J, Federico F, Stewart K, Campbell MJ. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011 www.ihi.org/knowledge/Pages/IHIWhitePapers/RespectfulManagementSeriousClinicalAEsWhitePaper.aspx (accessed 13/05/2021)

[4] Being Open guidance, http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/being_open_guidance.aspx (accessed 13/05/2021)

[5] Community of Practice website, www.knowledge.scot.nhs.uk/adverse-events.aspx (accessed 13/05/2021)

[6] Duty of Candour (Scotland) Regulations 2018 www.legislation.gov.uk/ssi/2018/57 (accessed 13/05/2021)

[7] NHSScotland Workforce Policy for Whistleblowing, April 2021 https://workforce.nhs.scot/policies/whistleblowing-policy/ (accessed 13/05/2021)

[8] Raising Whistleblowing Concerns – A Guide for NSS www.nhsnational-hr.scot.nhs.uk/2.NATIONAL%20BOARDS/NSS/POLICY%20PROCESS%20AND%20Ts%20AND%20Cs/People%20Advice%20and%20Support/Whistleblowing/Whistleblowing%20Process%20NSS.docx (accessed 13/05/2021)

[9] Adverse Events: Guidance on national notification data www.healthcareimprovementscotland.org/his/idoc.ashx?docid=105f7c3e-fcbd-4887-8eb9-f7e37c16a0b3&version=-1

[10] ico.org.uk/ (accessed 13/05/2021)

[11] www.gov.uk/blood-authorisations-and-safety-reporting#report-a-serious-adverse-event-or-reaction-related-to-blood (accessed 13/05/2021)

[12] yellowcard.mhra.gov.uk/the-yellow-card-scheme/ (Note: the yellow Card scheme collects information on events involving medical devices, however, this information should be reported in the first instance to IRIC who collect the information for Scotland and are responsible for onward transmission to MHRA) (accessed 13/05/2021)

[13] www.scotland.police.uk/ (accessed 13/05/2021)

[14] www.nss.nhs.scot/browse/health-facilities/incidents-and-alerts (accessed 13/05/2021)

[15] Multi-board approach to significant adverse event reviews, www.knowledge.scot.nhs.uk/adverse-events/adverse-events-toolkit.aspx (accessed 13/05/2021)

[16] Data Redaction Standardised Reports 2.0 (scot.nhs.uk) www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4099486/a9c89d8e-c8df-4261-9f0b-2d8de341a93c.pdf (accessed 13/05/2021)

[17] Little Things Make a Big Difference www.knowledge.scot.nhs.uk/making-a-difference/resources