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NHS Western Isles

Clinical Governance

Title: Framework for Adverse Event Reporting, Management and Learning Version 4

Table of Contents

1 Introduction 4
2 Definitions 7
3 Managing an adverse event 7
3.1 Stage 1 – Risk Assessment and Prevention 8
3.2 Stage 2 - Identification and immediate actions following an adverse event 10
3.3 Stage 3 - Initial reporting and notification 11
3.4 Stage 4 - Assessment and categorisation, including consideration of duty of candour . 13
3.5 Stage 5 - Review and analysis 15
3.6 Stage 6: Improvement planning and monitoring 17
4 Roles and responsibilities for reporting, managing and learning from adverse events 19
5 Reference and Bibliography 22
6 Appendices/Related Documents 24
6.1 Appendix 1 – Guide to Levels of Review 24
6.2 Appendix 2 Flowchart of actions to be taken to effectively manage Adverse Events 25
6.3 Appendix 3 – Briefing Note 26
6.4 Appendix 4 – Significant Adverse Event and Report Review Pathway 30
6.5 Appendix 5 – National Notification Data 33
6.6 Appendix 6 – Duty of Candour flowchart 38
6.7 Appendix 7 - RCA Tool – Tabular Timeline 39
6.8 Appendix 8- RCA Tool – Five Why's 40
6.9 Appendix 9 - RCA Tool – Fishbone Template 41
6.10 Appendix 10 – Risk Matrix 42
6.11 Appendix 11 – Duty of Candour Screenshots from Datix 44
6.12 Appendix 12 – Personal Data Breach Screening Questions: 45
6.13 Appendix 13 – Cyber Security Breaches 49

1 Introduction

Introduction

Health services in Scotland aim to provide high quality care that is safe, effective and person-centred. This is a complex system and adverse events occur that do, or could have, a major effect on the people involved. Each of these events should be regarded as an opportunity to learn and to improve in order to increase the safety of our care system for everyone. Disclosure of adverse events (including near misses) is a professional duty of all NHS Western Isles staff members.

The Health Improvement Scotland document, 'Learning from adverse events through reporting and review, a national framework for Scotland, 4th edition, December 2019, reviewed 2021 is intended to provide an overarching approach developed from best practice to enable care providers to effectively manage adverse events.

NHS boards are responsible and accountable for effectively managing adverse events. CEL (2013)203 sets out the expectation that NHS Boards adopt this framework to improve their local approaches to handling adverse events. This framework and associated documents have been developed in line with the national framework. They describe the management system within NHS Western Isles for reporting, reviewing and learning from all types of adverse events utilising an integrated adverse event reporting system. This includes clinical events involving patients, families, staff and carers (including health and safety, accidents or incidents) and non-clinical events (including information governance and finance). The organisation fully supports an open and fair culture and is committed to implementing the improvements identified to support a greater level of safety.

The scope of the framework can be summarised as follows:

The draft framework is based on the 6 steps of the national framework and covers all adverse events that are reported in NHS Western Isles.
Including:

- Acute care and managed community services
- Primary care (GP practices, dental practices, community pharmacies and optometrists)
- Employees, visitors and independent contractors,

And relates to

- Any clinical and non-clinical events (including information governance, health and safety at work, adverse publicity and finance)

The scope includes any event that could have contributed or did result in, harm to people or groups of people. This includes harm to patients and service users, as well as harm to staff.
All adverse events have a local review undertaken to establish the level of harm. A briefing note is completed which will advise risk management if the record requires to be escalated to an executive director to consider if a Significant Adverse Event is required.

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The findings of the Significant Adverse Event Review will determine if the Duty Of Candour process has been triggered (see page 38 for flowchart).
The Duty of Candour may apply to specific adverse events or incidents that have resulted in death or harm. The Scottish Government has published guidance which has been locally adopted into a local procedure with flowcharts to help and support staff.

- It is the responsibility of all staff to report all adverse events and near-misses, and to be involved in the review and learning from adverse events as appropriate and relevant to their role. All staff are accountable for ensuring that the principles of the Framework for Adverse Event Reporting, Management and Learning are followed.
- All adverse events require to be actively managed in a timely way, at different levels of the organisation. Reports are routinely sent to the Learning Review Group Clinical and Care Governance and Healthcare Governance and Audit Committees to give assurance that lessons have been learned and that this learning has been routinely shared with all relevant groups;
- Feedback will be given to staff and will inform decision-making;

This framework is in support of and should be read in conjunction with the operational procedures. They complement the framework and inform the implementation by providing further detail of the standard methodology for the management of adverse events and specific processes for certain types of adverse event.

The Framework for Adverse Events covers all accidents, adverse events and system failures which either caused, or could have caused harm or death to people or groups of people or damage or loss to property. This includes clinical events involving people receiving services, families, staff and carers (including health and safety, accidents or adverse events) and non-clinical events (including information governance, adverse publicity and finance)

Aims

- To learn locally and share nationally where appropriate to make service improvements that enhances the safety of the care system for everyone.
- Support adverse event management in a timely and effective manner.
- Support a consistent approach to the identification, reporting and review of adverse events, and allow best practice to be actively promoted across NHS Western Isles.
- Present an approach that allows reflective review of events which can be adapted to different settings, and provide resources to develop the skills, culture and systems required to effectively learn from adverse events to improve health and care services across NHS Western Isles.
- For all staff to be accountable to ensure the requirements of the national and local framework are adhered to.

- Organisations are open, honest and supportive towards the affected person, apologising for any harm that occurred.
- Any staff involved are supported in a consistent manner.
- Events are reviewed in a consistent way, and
- Learning is shared and implemented across the organisation and more widely to improve the quality of services.
- The principles of the Framework for Adverse Event Reporting, Management and Learning will be followed for all adverse reviews being undertaken including Child Death Reviews, Whistleblowing, Drug and Alcohol related reviews, Suicide Reviews and Maternity and Neonatal Reviews.

Datix is the Risk Management Information System that is used by NHS Western Isles for web based reporting of Adverse Events.

2 Definitions

What is an adverse event?

The term **adverse event** refers to an unexpected occurrence or event arising that did result in harm, loss or damage to persons, property or organisational reputation. It can include any event that may give rise to physical, emotional, psychological harm or death.

A **near miss** is any situation that could have resulted in an adverse event but did not due to either chance or intervention. This should be considered as an opportunity to review and learn from the circumstances of what happened before those circumstances result in an adverse event at some point in the future.

Harm is defined as **an outcome with a negative effect.** Harm to a person (service users, patients, members of staff, carers, family members, volunteers and visitors) or groups of people (including organisations) may result from unexpected worsening of a medical condition, the inherent risk of an investigation or treatment, violence and aggression, system failure, provider performance issues, service disruption, financial loss or adverse publicity. (NHS, HIS 2015)

All harm is not avoidable, for example the worsening of a medical condition or the inherent risk or complication of treatment. However, it is often not possible to determine if the harm caused was avoidable until a full and systematic review is carried out and often areas for improvement are identified even when harm is not avoidable.

3 Managing an adverse event

The circumstances surrounding each adverse event 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 should be proportionate to its scale, scope, complexity and opportunity for learning. This section outlines steps to manage adverse events.

This Framework follows the 6 stages of adverse event management as set out in the Health Improvement Scotland National Framework for Adverse Events (December 2019):

1. Risk assessment and prevention.

2. Identification and immediate actions following an adverse event including consideration of the Duty of Candour
3. Initial reporting and notification
4. Assessment and categorisation including consideration of the Duty of Candour.
5. Review and Analysis
6. Improvement planning and monitoring

3.1 Stage 1 – Risk Assessment and Prevention

NHS Western Isles strives to embed a positive safety culture, and creating an environment that is open, just and informed, in which speaking up, reporting and learning is the norm.
The organisation promotes and supports the elements of a safety culture and this is incorporated into risk management training.

Elements of a Safety Culture

Open Culture – Staff are encouraged through risk management awareness sessions to feel comfortable speaking up and discussing adverse events and raising safety issues with both colleagues and senior managers.

Just Culture - Staff, patients, service users and carers are treated fairly, with empathy and consideration when they have been involved in an adverse event or have raised a safety issue. Staff are expected to have practised in a reasonable and accountable manner.

Reporting Culture – Staff will have confidence in the local adverse event reporting system and use it to notify managers of adverse events that are occurring, including near misses.
As part of the reporting culture the following are being actioned:-

- Barriers to adverse event reporting have been identified and will be actioned.
- Our aim is that staff will receive constructive timely communication and feedback after submitting an adverse event report, and be directly involved in reviews.
- Staff will be involved in changes being made to Datix the Risk Management Reporting System to make the system and processes for Adverse Management easier.

Learning Culture - The organisation is committed to learning safety lessons and will communicate learning outcomes to colleagues, keep them updated on progress with improvement plans through Learning Review Group and the Themes and trends will be identified from Adverse Events and the key learning points from learning summaries will be shared with staff.

Informed Culture – NHS Western Isles has learned from past experience and aims to identify and mitigate future adverse events by:

- Learning from events that have already happened (for example, adverse event reviews, morbidity and mortality reviews and the complaints process).
- Sharing key learning points.
- Undertaking trend analysis and developing appropriate improvement plans.
- Using learning from adverse events to promote a positive safety culture.

Adverse event management is one part of an effective risk management strategy. Anticipation, avoidance, prevention and reduction of risks are a proactive measures to prevent adverse events occurring. Care will never be risk free, but we can minimise these risks in order to provide high quality care for the people of NHS Western Isles.

Risk assessments will assist in the identification of the hazards present in our care system; evaluate the likelihood of potential harm, the potential severity of that harm and the number of people that might be affected. Mitigating actions should then 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.

Acting on key learning points from adverse event reviews and other safety lessons, such as safety alerts is an essential part of risk prevention. Safety alerts are a mechanism that can be used to rapidly alert the care system to risks and provide guidance on preventing potential events that may lead to harm.

Acting on key learning points from adverse event reviews and other safety lessons from safety alerts, is an essential part of our risk prevention and a monthly report on adverse events, safety alerts and risk registers is provided for the Operational Service Delivery Team.

As part of an integrated risk management approach, the governance principles for the management of adverse events will be integrated with the organisation's risk management strategy and governance processes, including complaints, claims and Duty of Candour procedures.

A clear link with structured departmental Mortality and Morbidity Meetings/ Team Based Quality reviews and feedback from complaints facilitates a positive reporting and learning culture across all levels in the organisation. This also ensures a more effective governance of the process by providing the necessary support and oversight.

3.2 Stage 2 - Identification and immediate actions following an adverse event

In all instances, the first and immediate priority is to ensure the needs of individuals (includes patients, visitors, contactors and members of staff impacted or potentially harmed by work activities) affected by the adverse event are attended to, including any urgent clinical care which may reduce the harmful impact. A safe environment should be re-established, all equipment or medication retained and isolated, and relevant documentation copied and secured to preserve evidence and facilitate review and learning.

The person must be cared for, theirs and other people's health and welfare secured and further risk mitigated. The person's family or carers must be similarly cared for and involved where a person has been harmed. Compassion and understanding should be shown at all times even if simply making regular contact to keep people involved and informed. No electro medical equipment should be removed from the scene and under no circumstances returned to the manufacturer.

The organisation will give early consideration to the provision of information and support to patients, service users, families, carers and staff involved in the adverse event, including details on available support systems. Information leaflets are available for staff, patients, relatives and carers relating to adverse events.

This approach aligns with the Scottish Government's introduction of a statutory organisational Duty of Candour for Health and Social Care Services.

Since 1 April 2018, the Duty of Candour legislation has required all organisations providing care in Scotland to be open, honest and supportive towards anyone affected by an unexpected or unintended event which results in death or harm.

Organisations must notify the person affected, apologise and offer a meeting to explain what happened. They must also review the event, and publish an annual report outlining the learning and improvements put in place as a result of these procedures.

This statutory organisational duty has been developed to be in close alignment with the requirements of the professional duties of candour, such as those required by the Nursing and Midwifery Council, the General Medical Council, the General Dental Council, and the General Optical Council.

3.3 Stage 3 - Initial reporting and notification

It is essential that the person or people reporting the adverse event provide a comprehensive factual overview. There is no place for any opinion or assumptions. It is important that details are accurate and factual for any future review. When an adverse event (including near misses) occurs, Datix which is the organisation's electronic adverse event reporting system must be used.

The types of information to be reported in the first instance include:

- The location of where the adverse event occurred.
- The date and time of the adverse event.
- Personal details relating to the person or people involved in the adverse event description of the adverse event.
- The outcome of the person/people involved (if known at this stage).
- The immediate treatment given to the person or people involved.
- Any immediate action taken.
- Any remedial action taken to minimise risk of recurrence of the event, and
- Others who were involved in observing or reporting the adverse

The adverse event reporting form (DIF1) available on the intranet should be completed as soon as possible after the event, within 12 hours, unless there are exceptional reasons for delay, for example the event was identified retrospectively following a complaint or claim, case note review or following a review for mortality and morbidity cases.

All adverse events must be reported whenever they have been identified, even if some time has passed since the event occurred. The electronic adverse event reporting system (Datix) is set up to automatically notify the reporter's manager and staff that are included in the relevant security group on the system.

Reporting to external agencies
Specific events must be reported to external organisations. This includes:

- From 01 January 2020, all significant adverse event reviews commissioned by the NHS boards for a category 1 adverse event will be reported to **Healthcare Improvement Scotland (HIS)** in alignment with the new national notification system. This reporting is to be completed by the 6th of each month.
- Deaths and injuries due to a work related accident to the **Health and Safety Executive** as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).

- 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).
- Events relating to blood to the **Medicines and Healthcare Products Regulatory Agency (MHRA)** as required by the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive.
- Adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme to the **MHRA**.
- Suicides of individuals in contact with mental health services to **Healthcare Improvement Scotland**.
- Sudden deaths associated with medical or dental care to the **Procurator Fiscal**.
- Relevant information to UK-wide national audits and enquiries managed by the **Healthcare Quality Improvement Partnership (HQIP).**
- Information governance events to the e Health Division within **Scottish Government** and the **Information Commissioners Office.**
- Ionising Radiation adverse events to **Healthcare Improvement Scotland** via hcis.irmer@nhs.net.
- All deaths of patients subject to mental health detention or a community based order under the Mental Health (Care and Treatment)(Scotland) Act 2003 or the Criminal Procedure (Scotland) Act 1995; all homicides committed by people with recent contact with mental health services; and serious crimes (serious assault, serious sexual assault) by an individual who is receiving care from mental health or learning disability services are notified to the **Mental Welfare Commission for Scotland**.

3.4 Stage 4 - Assessment and categorisation, including consideration of duty of candour

Following initial reporting of an adverse event or near miss, the handler for the record will assess the reporting form to consider the organisation's response to the event. The initial handler will be the line manager of the reporter and in cases where another handler would be more appropriate the initial handler can assign this role once the record has been considered. The risk matrix must be applied to the record as soon as it is possible after the record has been submitted on to Datix. A briefing note for a potential Significant Adverse Event Review must be completed for all Major and Extreme risk rated adverse events but must be considered for all events depending on the individual circumstances. All adverse events are subject to review. The level of the review will be dependent on the event in terms of its complexity and potential for learning.

Adverse events will be categorised to support decision-making processes to determine the level of review required. However, the level of review will not only be mandated by the categorisation of the event as other factors also impact this decision such as the characteristics of the event, the patient or service user, the service, the outcome and the potential for learning.

Information, communications and outcomes should be centrally recorded and stored on the Datix reporting system, so that an audit trail is evident. The decision to proceed, or not, to a significant adverse event review must be clearly documented.

Categorisation of adverse events

Every event should be reviewed, but the level of review will be determined from the category of the event and other factors such as the potential for learning. The following categories will be used to group adverse events.

- **Category I – events that may have contributed to or resulted in permanent harm**, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHS Scotland risk assessment matrix.
- **Category II – 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 minor or moderate impact on NHSScotland risk assessment matrix.
- **Category III** – **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 on NHSScotland risk matrix).

When an adverse event is reported on to Datix the reporter is asked to add the name of their line manager to the record. The line manager then becomes the handler of the record and will receive an e mail notification from the system advising them of this.
If the line manager thinks that it is not appropriate to be the handler of the record the risk manager can be contacted for advice. The line manager can also change the handler on the system and reassign to the appropriate person.
The handler will apply the risk matrix to the adverse event and also make the decision who should be assigned as the investigator. Depending on the risk scoring following the application of the risk matrix a briefing note will be required to be completed for forwarding to the risk manager. There is a prompt on the Datix system to alert staff to complete this form.

There are prompts on the datix system to alert staff to complete different sections of the record including the Duty of Candour.

Levels of review
All events are subject to review. The basic process of adverse event review and analysis will be essentially the same as per procedure.

The category of the event will support the decision-making process for the level of review required, however it must be stressed that a severe or tragic outcome is not the only determining factor. Near miss events with no adverse outcome and complex lower severity adverse events (Category III) can also warrant high level review if there is potential for learning.

. 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?
- Is there learning to be gained/would you do anything differently next time?
- Is the patient, service user, family or management concerned about the event?
- Does the event activate duty of candour procedures

Time frames
The following time frames must be followed for reviewing adverse events:

Category 1 – All Category 1 events should be notified to the on call Executive Manager at the earliest opportunity. The Executive Manager will assess the need for any immediate action and or review which may be necessary in the first 24 hours after a Category 1 adverse event. A formal note should be completed of any immediate actions/decisions. Complete the briefing note and commission a Significant Adverse Event.
Review within 10 working days of the adverse event review being reported on to datix.

Commence and close review (report submitted for approval) within 90 working days of the commissioning date.
Report to be agreed by the commissioning director, the CEO and the Central Legal Office.
Final approval will take place as soon as possible and no later than 30 working days from the report submission.
Develop improvement plan within 10 working days from the report being approved.

Category 2 – Commence and close review (report submitted for approval) within 30 working days of the adverse event being reported on to Datix. Develop improvement plan within 10 working days from report being approved.

Category 3 – Adverse event approved and closed within 10 working days of adverse event reported on to Datix.

Links with Duty of Candour
In most adverse events, 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 an adverse event review identifies an instance where the organisation has not yet met the requirements of the Duty of Candour, this will be undertaken as soon as possible.

3.5 Stage 5 - Review and analysis

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, wider organisation, or nationally. It will follow the principles of a just culture and take a systems approach. The review will examine the processes of care delivery and identify if any system failures occurred which contributed to the adverse event and the outcome. The review will also identify good practice which will be shared, or learning points that are not directly related to the adverse event, but can have an impact on improving the system.
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Multi-agency review
There may be occasions where an adverse event review has the potential to involve more than one organisation. At the outset of the review process, consideration will be given as to whether a collaborative approach is needed.
The lead organisation (where the adverse event was reported) will contact the other organisation(s) 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 will be clearly defined at the outset.

Methodology for a Level 1 Significant Adverse Event Review:

- A lead Director will be assigned to commission the SAER and ensure a thorough and appropriate review is undertaken.
- A review team will be identified with a lead reviewer appointed and roles within the team clearly defined (the review team will be sufficiently removed from the event, and have no conflict of interest, to be able to provide an objective view).
- Terms of Reference for the Significant Adverse Event Review will be defined.
- The responsibility for establishing and meeting the communication requirements of patients, service users or their representatives will be clarified by the lead reviewer.
- Staff and managers involved will be informed of the review and invited to contribute to the review process. Staff will be kept informed of progress throughout the review process.
  The support needs of staff involved in the adverse event will be considered and information leaflets provided.
- An electronic information management system will be established to ensure a secure file of review documentation is maintained and accessible to members of the review team.
- The SAER will ensure a structured and consistent approach by using NHS Western Isles approved Root Cause Analysis investigation tools and techniques to identify the contributory factors, details of the care provided and any lessons that could inform service improvement or reduce the risk of recurrence.

A human factors approach using contributory factors will form part of the review. This will support the review team to:-

- understand if there are systems and process factors in place in the organisation which threaten safety.
- improve the safety culture of teams and organisations.
- enhance teamwork and improve communication between care staff.
- improve the design of care systems and equipment.
- identify ‘what went wrong’ and predict ‘what could go wrong’, and
- appreciate how certain tools can help to lessen the likelihood of harm.

Review outcomes.

An outcome code will be applied to Significant Adverse Event Reviews to indicate the findings of the review in relation to the link between care and outcome which will allow identification of those events where improvements are required. The following codes will be used:

1. Appropriate care - The adverse event review concluded that the care and/or service was well planned and appropriately delivered; no care or service delivery problems were identified; and the adverse event outcome was ultimately unavoidable. However, it is likely there are still learning points (especially good practice points).

2. Indirect system of care issues - The adverse event review identified indirect or incidental sub-optimal care or service issues and lessons that could be learned (and good practice

points). However, these were unlikely to have affected the final outcome. For example, a protocol was not strictly followed or there was a delay in accessing the case notes, but these were unlikely to have affected the final outcome.

3. Minor system of care issues - The adverse event review identified minor or sub-optimal care or service provision and that a different plan or delivery of care/service may have resulted in a different outcome. For example, system or management factors were identified (such as incomplete records or a delay in transferring the patient or service user), but there was uncertainty regarding their impact on the final outcome. Learning points have been identified and improvement plans developed.

4. Major system of care issues - The adverse event review identified that a different plan and/or delivery of care or service would, on the balance of probability, have been expected to result in a more favourable outcome. Factors were identified which negatively influenced or contributed to the adverse event outcome. For example, how the case was managed had a significant impact on the level of harm. Learning points have been identified and improvement plans developed.

3.6 Stage 6: Improvement planning and monitoring

All Level 1, Level 2 and Level 3 adverse event reviews will have an improvement plan developed in response to the recommendations included in the approved report following the review.
Improvement plans will be developed by those with the responsibility for making the agreed changes and who therefore have control and responsibility for implementation. All actions on the improvement plan will identify owners and timescales for completion. Final plans will be shared with those who reported and were involved in the original adverse event.

Learning summaries will be used to share key learning points with staff involved in the review and the wider organisation to inform them of the learning and improvement plan arising from the review.

Updates with evidence on the risk management improvement plan tracker will be requested by Risk Management monthly and then reported to the Learning Review Group. The Learning Review Group will also be kept informed of any slippage occurring with the timescales agreed.

The Clinical and Care Governance Committee will be kept informed of the updates received for the improvement plan risk management tracker.

Reports relating to thematic learning will be collated over specific timeframes to assist and inform wider service and organisation improvement programmes. NHS Western Isles will also identify and share nationally any learning that could inform improvements to the process of managing adverse events.

The established modules on datix will support safety within NHS Western Isles and link managing adverse events, risk registers and complaints so that learning and improvement activity are integrated and co-ordinated.

4 Roles and responsibilities for reporting, managing and learning from adverse events.

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The Board

The Board has three core roles in relation to safety:

- **Formulating strategy:** clear vision and purpose that puts quality, reliability and safety at its heart including strategic aims for safety – 'Will care be safe in the future?'
- **Ensuring accountability:** for delivering the strategy, for seeking assurance that systems are in place and working effectively, and for the organisation operating with openness, transparency and candour.
- **Shaping culture:** modelling and promoting values and standards of conduct for everyone.

The Board will seek assurance that the systems in place support the effective management of adverse events by scrutinising and monitoring locally developed measures that have been developed, agreed and implemented. The Board will be kept informed of serious and ongoing issues and recognise the links between staffing, quality outcomes and safety.

Governance committees

The Clinical and Care Governance and the Healthcare Governance and Audit Committees will demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open:

- Responsible for assuring the Board that there are established and effective measures in place to record and manage adverse events, including meeting duty of candour requirements, and that learning and improvement have taken place to reduce the risk of recurrence.
- Ensure preventative measures and processes are in place to effectively undertake risk assessment, identify potential harm and manage risks to an acceptable level. The aim being to minimise the likelihood of an event occurring and/or the level of harm.
- Ensure actions contained within improvement plans have been completed and contribute to organisational learning by sharing and adopting key learning points.

Non-Executive Directors:

- Will demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Seek assurance that effective systems for reporting, managing, reviewing, learning and improving from adverse events and Duty of Candour procedures are in place and working well within the organisation.

Chief Executive:

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- Create a culture to support staff to safely express concerns and for these to be listened to, discussed and acted on as appropriate.

- Will demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open
- Ensure robust and effective policies and procedures are in place for adverse event management and meeting duty of candour requirements.
- Ensure effective systems are in place for reporting, learning and improvement.
- Delegate roles and responsibilities to executive team members.

Corporate Management Team will:

- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to Being Open.
- Have a role in determining the level of review of adverse events.
- Ensure compliance with adverse event policies and procedures, including the Duty of Candour requirements.
- Engage with patients, service users and families, including through Duty of Candour processes.
- Ensure staff support and training.

Operational Management Teams will:

- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Senior clinicians have a responsibility to set an example and encourage openness and honest in reporting adverse events. Clinical leaders should actively foster a culture of learning and improvement.
- Ensure compliance with adverse event and Duty of Candour policies and procedures.
- Review and manage adverse events.
- Progress improvement plans and follow-up, providing clear evidence of delivery and implementation.
- Disseminate learning points and provide support to turn learning into action.
- Engage with patients, service users and families, including through duty of candour processes.
- Support staff.

Managers/Team Leaders will:

- Be responsible for implementing required actions and improvements.
- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Ensure staff awareness and compliance with policies and procedures.
- Manage adverse events including Duty of Candour processes, review, progress of actions, dissemination of learning points and implementation of improvement actions.
- Engage with patients, service users and families, including through duty of candour processes.
- Engage with and support staff.

All staff will

- Report and action personal data breaches.
- Report and action Cyber security breaches.
- Report adverse events.
- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Attend Risk Management training.
- Follow policy and procedures, including adhering to timescales.
- Participate in reviews and duty of candour processes.
- Understand learning points and implement recommended improvement actions.
- Engage with patients, service users, families and carers.

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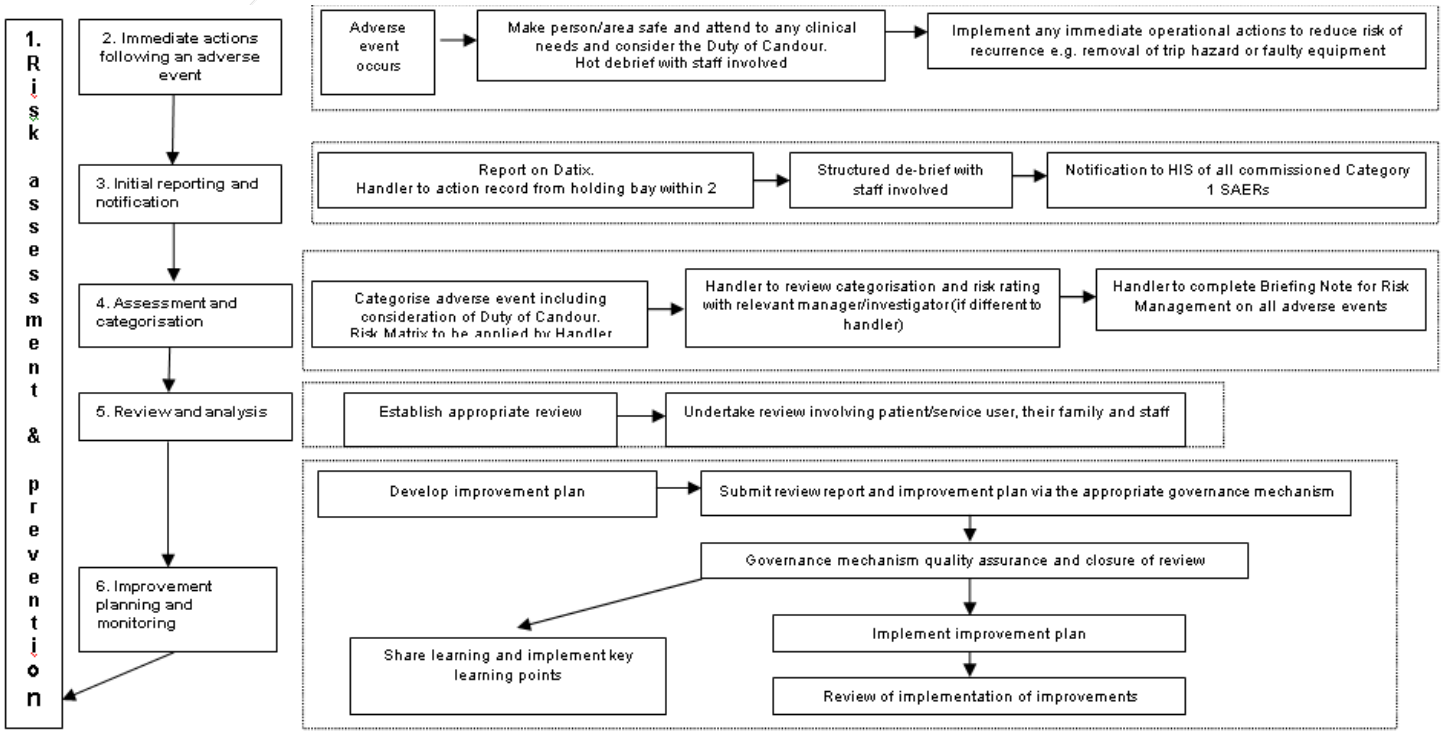
Duty of Candour Procedure (Scotland) Regulations 2018
Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016
HSE RIDDOR and Falls Guidance
NHSS Scotland Quality Strategy. Putting People at the heart of our NHS. May 2010.

6 Appendices/Related Documents

6.1 Appendix 1 – Guide to Levels of Review

Guide to levels of review Adverse event category	Suggested minimum level of review	Review team	Reporting of findings and learning	Guidance timescale
Category I	**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.	Full review team: commissioning manager 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 an objective view).	Via division/service governance structures with evidence of improvement plans as required. The development of the improvement plan should sit within the team/department where the adverse event took place.	Commission review within 10 working days of the adverse event being reported on incident management system. Commence and close review (report submitted for approval) within 90 working days of the commissioning date. 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 II	**Level 2:** local management team review.	Service manager with multidisciplinary team input.	Via local governance structures with evidence of improvement plans as required.	Commence and close review (report submitted for approval) within 30 working days of the adverse event being reported on incident 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 III	**Level 3:** local review by line manager in discussion with staff.	Managers/staff locally. If further review required then local management review process.	Via aggregated reports and learning points to management and governance structures.	Adverse event approved and closed within 10 working days of adverse event being reported on incident management system.

6.2 Appendix 2 Flowchart of actions to be taken to effectively manage Adverse Events



Notify the on-call Executive Manager at the earliest opportunity after a Category 1 Adverse Event.

6.3 Appendix 3 – Briefing Note

BRIEFING NOTE FOR POTENTIAL SAER (SIGNIFICANT ADVERSE EVENT REVIEW)

Alert the Nurse/Medical Director in their role as commissioners for a Significant Adverse Event Review to enable effective decision making on whether a SAER should be commissioned

This Briefing Note (BN) **must** be submitted to the Risk Manager as soon as possible but no later than **2 working days** of the adverse event occurring/notification of the adverse event via the below Risk Management e-mail address:

{input email box when set up}

Site adverse event occurred: .....

Location (exact): .....

Adverse event date: __/__/____ **date of notification to Risk Management**: __/__/____

Date Briefing Note sent to Nurse/Medical Director from Risk Management: __/__/____

Datix Reference: W.....

Handler of Adverse Event record: .....

ADVERSE EVENT DETAILS:			
CHI number:	Patient Name:		
Patient outcome/condition following adverse event:			
Is the patient outcome a known complication of a disease/treatment	Yes	No	
Did this incident trigger the legislation for Duty of Candour	Yes	No	Not yet known
BRIEF SUMMARY OF ADVERSE EVENT *Include details of -*			
***What** happened, **when, where, who** was involved, who reported it and to whom, including detail if any concerns and issues that were evident* *Any **pertinent background information** related to the situation e.g. patients admission dates, interventions/procedures, previous medical history, etc*			

Severity of the adverse event *(injury requiring further treatment, long term incapacity/disability, extreme impact resulting in death or major incapacity*

Recommendations *to inform development of actions for improvement and should a Significant Adverse Event Review (SAER) be commissioned?*

ASSESSMENT QUESTIONS *(consider the following questions to support decision)*	**Yes**	**No**	**Unknown**
Other national or legislative requirements for reporting adverse events (RIDDOR, IRIC, Health Improvement Scotland, MHRA, Mental Welfare Commission, Information Commissioner)			
Was there a problem with any equipment involved in this case? *(consider need for safety alert)*			
Has there been a breach of policy or procedure?			
Is there something you think should have been done differently in this case?			
Do you feel there is any learning to be gained from investigating this event? *(Would something be done differently next time?)*			
Are there any patient/family concerns regarding the treatment/care/outcome?			
Are there any management concerns related to the events or individuals involved?			
Is there currently any interest from the Procurator Fiscal?			

If you have answered Yes to any of the assessment questions please give further detail below:

Electronic Signature of handler completing the Briefing Note:

Risk Management use only:

Electronic signature of Risk Management team escalating the Briefing Note:

COMMISSIONING MEETING OUTCOME			
Date of meeting with Risk Management and Nurse/Medical Director to discuss briefing note for potential SAER __/__/_____			
Briefing Note review:			
Is there further information required? YES/NO			
Outcome of decision:	Commisioned	Not commissioned	
Rationale for decision:			
Causation code (1,2,,3,4, if known at this stage)			
Causation codes: 1. Appropriate care/services: well planned and delivered/unavoidable outcome 2. Issues identified but they did not contribute to the event 3. Issues identified which may have caused or contributed to the event 4. Issues identified that directly related to the cause of the event			
Duty of Candour?	Yes	No	Not yet known

Scope of Review: (be cautious not to go back too far, review is of the adverse event, not the patients full health history, timeline should contain details of the core chain of events leading up to the adverse event)

Ensure all questions are answered and as much detail as possible captured on this Briefing Note document (continue on additional pages if required)

When complete this document can be accepted as a Review Report, providing evidence and assurance that a review has been carried out

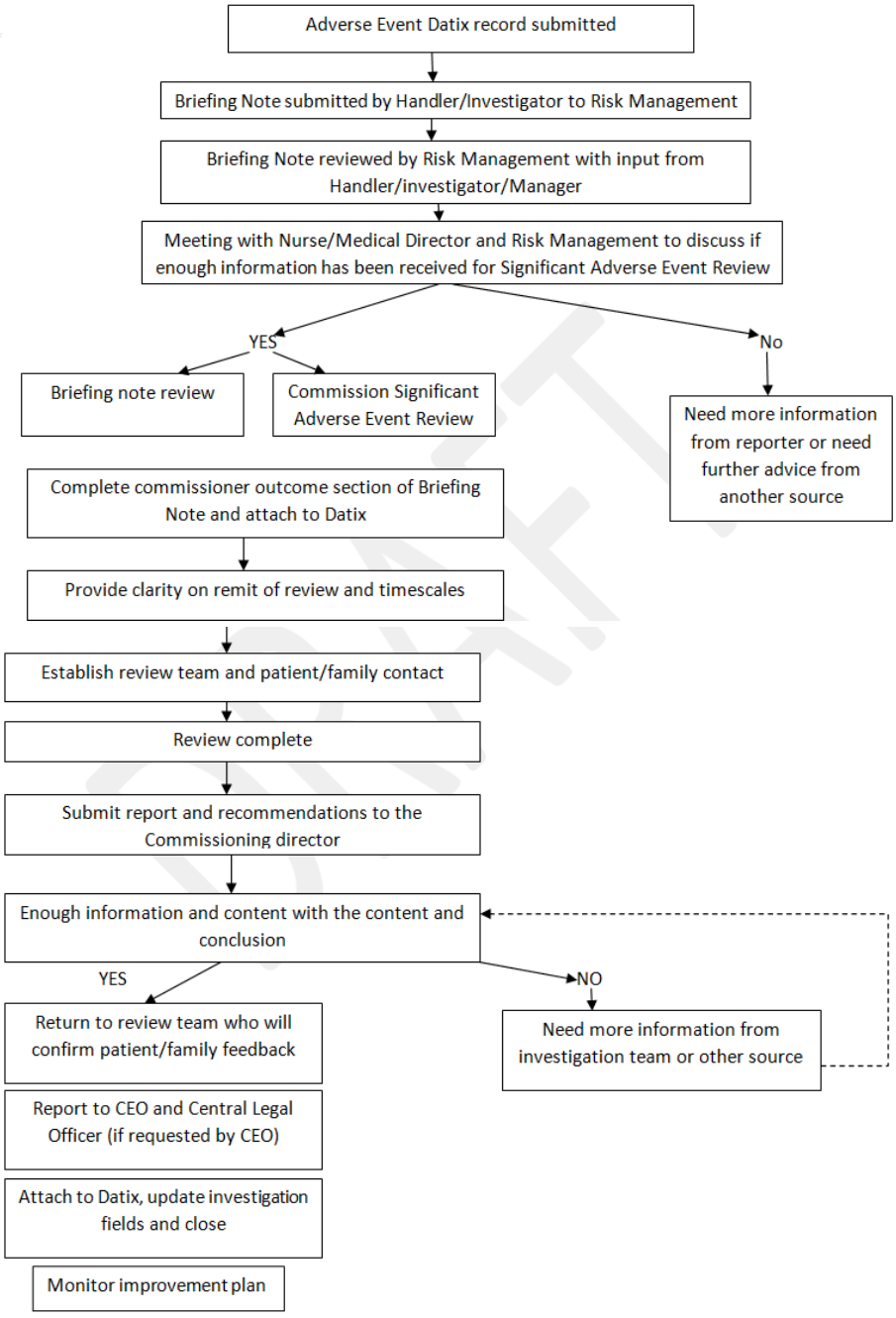
Electronic Signature(s) of Nurse/Medical Director

Consider whether this adverse event is reportable to external agencies:
(RIDDOR, IRIC, Health Improvement Scotland, MHRA, Mental Welfare Commission, Information Commissioner)

REMEMBER TO ATTACH THIS DOCUMENT TO DATIX WHEN COMPLETE AS A RECORD OF THE DECISION MAKING

(whether SAER COMMISSIONED or NOT)

6.4 Appendix 4 – Significant Adverse Event and Report Review Pathway



Pathway Guidance

The purpose of this pathway is to improve flow and timescales by reducing bottlenecks in the system whilst maintaining external scrutiny and access for advice.

Process

The aim with this process and guidance is to:

- Achieve timely commissioning of Significant Adverse Event Reviews
- Achieve timely sign off of Significant Adverse Event Review reports
- Ensure the handlers/investigators/managers are responsible for the management of their own events by Nursing/medical Directors to be kept informed and can intervene if required
- Ensure the handler/investigator/manager have access to help if required in decision making for both commissioning and report endorsement
- To standardise across NHS Western Isles what events should have a Significant Adverse Event Review
- To ensure Duty of Candour legislation is met

Briefing note of adverse event review describes an explanation of what happened and an initial assessment to assist in the decision of requesting further information or commissioning a Significant Adverse Event Review.

Ownership of the process and timescales is with the handler/investigator/manager who should encourage and operate an open, supportive reporting culture. It is important that all appropriate documentation is completed such as the decision making on briefing note with commissioned date etc.

Reminder of Conversation from Complaint

Any Significant Adverse Event Review's that have been converted from a Complaint need to be entered on the adverse event module of Datix as an adverse event to allow the recording, monitoring and storing of Significant Adverse Event Review information.

Reminder of Patient/Family communication

- Notify – what happened
- Apologise

- Explain there will be a review
- Ask if there are questions for the review
- Give contact information
- Investigate
- Keep in touch if there is likely to be a delay
- Share the results (what, why, now what)
- Offer a meeting
- Consider ongoing support

Reminder of Duty of Candour definitions of serious harm

- Death & Permanent damage
- Increase to treatment (significant)
- Changes to body structure
- Shortened life expectancy
- Impairment of function lasting 28 days
- Pain or psychological harm lasting 28 days
- Requiring treatment to prevent: death and the other outcomes

Reminder of Causation Codes

1. Appropriate care/services: well planned and delivered/unavoidable outcome
2. Issues identified but they did not contribute to the event
3. Issues identified which may have caused or contributed to the event
4. Issues identified that directly related to the cause of the event

Reminder of what to look for in the report

The report should:

- Identify, analyse and prioritise problems/key issues to identify fundamental root causes.
- Conclude if the event was preventable/ avoidable and assign causation codes.
- Conclusions should convey the review team's assessment of what happened and should directly link to what is being recommended
- Recommendations need to:
    - Relate directly to the event (for example training is sometimes a recommendations but no knowledge gap is established in the report)
    - Be sensible (for example the recommendation is too broad and could not be assigned to anyone)
    - Be agreed with those assigned to do them (it should not be a surprise to a specialty to receive recommendations from a Significant Adverse Event Report as they should be involved in the review.)

6.5 Appendix 5 – National Notification Data

Healthcare Improvement Scotland

Adverse Events:

Guidance on national notification data

Purpose of this document

The purpose of this document is to provide guidance to the NHS boards in Scotland on the specific dataset that Healthcare Improvement Scotland (HIS) requires for the national notification system in relation to Category I Significant Adverse Event Reviews. The aim is to ensure consistency of process and quality in the data submitted.

Data is essential for quality management purposes at national, regional and local levels. The national notification system will allow data to be collated and analysed centrally which will facilitate the recognition of trends and themes at a national level and to inform the planning of national improvement programmes.

The initial dataset submitted to HIS will change over time. Improvement in the data set will be informed by review of the outputs in partnership with stakeholders to achieve the aims of the national notification system. Data will initially be reviewed monthly to assess the quality of the data.

Background

This document should be read alongside Learning from adverse events through reporting and review: A national framework for Scotland, published by Healthcare Improvement Scotland, and revised in December 2019. The national framework aims to support a consistent approach in health and care services to reviewing and learning from adverse events, and to facilitate learning and improvement at national level. It recognises that adverse events can have a major effect on the people who are involved in them. An **adverse event** is defined as **an event that could have caused or did result in harm to people or groups of people.**

In September 2019 HIS published Adverse Event Management: NHS boards self-evaluation report.

This report highlighted areas of good practice in adverse event management within NHS boards in Scotland but also identified variations and inconsistencies between these organisations.

In response to the report the Cabinet Secretary for Health and Sport instructed Healthcare Improvement Scotland (HIS) to work with all NHS Boards to ensure that boards notify HIS when a category 1 Significant Adverse Event Review (SAER) is commissioned, and to move towards standardising terminology and definitions, including the implementation across all NHS boards of the consistent use of 'Significant Adverse Event Review'.

This document was informed by engagement with representatives from NHS boards, including an expert reference group, and discussions with Scottish Government officials.

Aim

Establish a robust national notification system for the NHS boards in Scotland to report the commissioning of any Significant Adverse Events Reviews for category 1 adverse events.

Objectives

The primary objective of this work is to support improvement, and achieve greater consistency, in the management and review of the most serious adverse events (Category I) that occur in healthcare services; and to enable effective learning at national level. This in turn should support the aim of safe, effective and person-centred healthcare services, and a culture of openness and learning.

The national notification system will develop and evolve over time and the first year will enable an initial dataset to be tested and refined to meet the primary objective outlined above.

Operational objectives for year 1 include:

January 2020 – January 2021

- To achieve the aim, review data submitted monthly to assess consistency and appropriateness of the information.
- Seek feedback from users with a review of the submission process after 3 months of launch.
- Analyse data to understand the national harms across Scotland which result in Significant Adverse Event Reviews.
- Identify patterns of national consistency and variation in the data reported from NHS boards, to determine the reasons for these patterns and generate actions that will support improvement in collective practice.

- Engage and collaborate with relevant stakeholders, including NHS boards and national organisations with a shared interest in this work, to develop and refine the approach, and to seek opportunities to maximise impact of any work undertaken. Assess for national trends, and identify recurring national themes which could support national improvement work.
- Develop a clearer national picture of significant adverse event processes in healthcare in Scotland.

- Develop a revised guidance document to improve consistency with regard to nationally submitted data.
- Share good practice relating to the process of significant adverse event reporting nationally utilising information from the national notification data.

What will the data be used for?

The data will be used to meet the objectives outlined above. NHS boards will submit non-identifiable data to protect patient confidentiality. HIS will use this data to inform existing improvement programmes nationally including Scottish Patient Safety Programme (SPSP) and the wider work done by the Improvement Hub (iHub).

There will be a future focus on the learning from the data submitted by the boards that will be shared nationally.

HIS will provide feedback and support to boards on areas of improvement identified from data collected through the notification system, with the potential to commission national pieces of work in response to identified improvement opportunities.

The data will help inform an evolving list of key harms to further assist NHS boards in Scotland to reduce any unacceptable variation regarding the application of the national adverse events framework.

A national view of adverse events reporting will support NHS boards in Scotland to continuously improve adverse event management approaches.

Data and submission process

Data will be submitted monthly via a reporting spreadsheet template until a national digital solution is available.
(Two NHS boards will be piloting the web-based CRM system. Notifications can to be submitted instantly onto the CRM system.)

In the event of an NHS Multi-Board Significant Adverse Event Review, the NHS board leading the review will be responsible for notifying Healthcare Improvement Scotland of the commissioning of the review and the outcome of the review process.

NHS boards will notify HIS of **all Significant Adverse Event Reviews commissioned for category 1 events from 01.01.2020**.
The first data submission will be expected to be received by **06.02.20**.
The deadline for data submission in subsequent months will also be by the 6th of the subsequent month, for example:

Commissioned SAERs	Deadline for initial notification to HIS
01.01.2020 - 31.01.2020	06.02.2020
01.02.2020 - 29.02.2020	06.03.2020
01.03.2020 – 31.03.2020	06.04.2020

Boards will be asked to submit their data monthly, via a newly created email address: hcis.aenotificationteam@nhs.net with reminders sent out by HIS in advance of the submission date.

If no SAERs have been commissioned in that month, then a nil report is expected to be returned to HIS to signify this.

It is recognised that notification of an SAER at point of commission alone will not support national learning and therefore there will be a two-stage data submission process to support national learning. Once a review has been completed, boards will be asked to update the initial notification record, and submit the outcomes from the SAER process. This will be reported as part of the monthly return.

All SAERs commissioned for a category I event will require notification to HIS, as per the cabinet secretary's instruction.

Definitions as per national Framework

Adverse event category	Suggested minimum level of review	Review team	Reporting of findings and learning	Guidance timescale
Category I – events that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHS Scotland risk assessment matrix, or Category G, H or I on National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP) index).	**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.	Full review team: commissioning manager 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 an objective view).	Via division/service governance structures with evidence of improvement plans as required. The development of the improvement plan should sit within the team/department where the adverse event took place.	Commission review within 10 working days of the adverse event being reported on incident management system. Commence and close review (report submitted for approval) within 90 working days of the commissioning date. 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.

Two stage data submission

Initial notification: date the decision is made to commission an SAER → **Learning and outcomes: outcome of the event after review completion**

Stage 1	
Initial notification system	
Data	**Definition/ explanation**
Unique identifier	Datix number or other identifier from local board incident reporting system
Date SAER commissioned	Date decision made to progress to SAER
Category of event	Free text summarising the type of event e.g. suicide, medicines
PLEASE ENSURE * NO PATIENT IDENTIFIABLE DATA IS SENT TO HIS	

Stage 2	
Learning and outcomes POTENTIAL DATA FIELDS FOR DISCUSSION JANUARY 2020	
Data	**Definition/ explanation**
Date review completed	Date final sign off by appropriate governance group
Speciality related to event	Area of speciality if relevant (*free text*)
Brief description of event	Short descriptor of incident
Review Outcome of event	Refer to Appendix 1, and grade outcome code accordingly
***PLEASE ENSURE *** NO PATIENT IDENTIFIABLE DATA IS SENT TO HIS	

Appendix 1: Review Outcomes

Learning from adverse events through reporting and review: a national framework for Scotland (Page 23)

Review outcomes

Not all adverse event reviews will identify system failures and may find proper care was delivered. A review may conclude that the care delivered was appropriate and an event was unavoidable. The potential for learning in these cases should still be recognised and areas of good practice shared appropriately. An outcome code can be applied to adverse event reviews to indicate the findings of the review in relation to the link between care and outcome which will allow identification of those events where improvements are required. The following codes can be used.

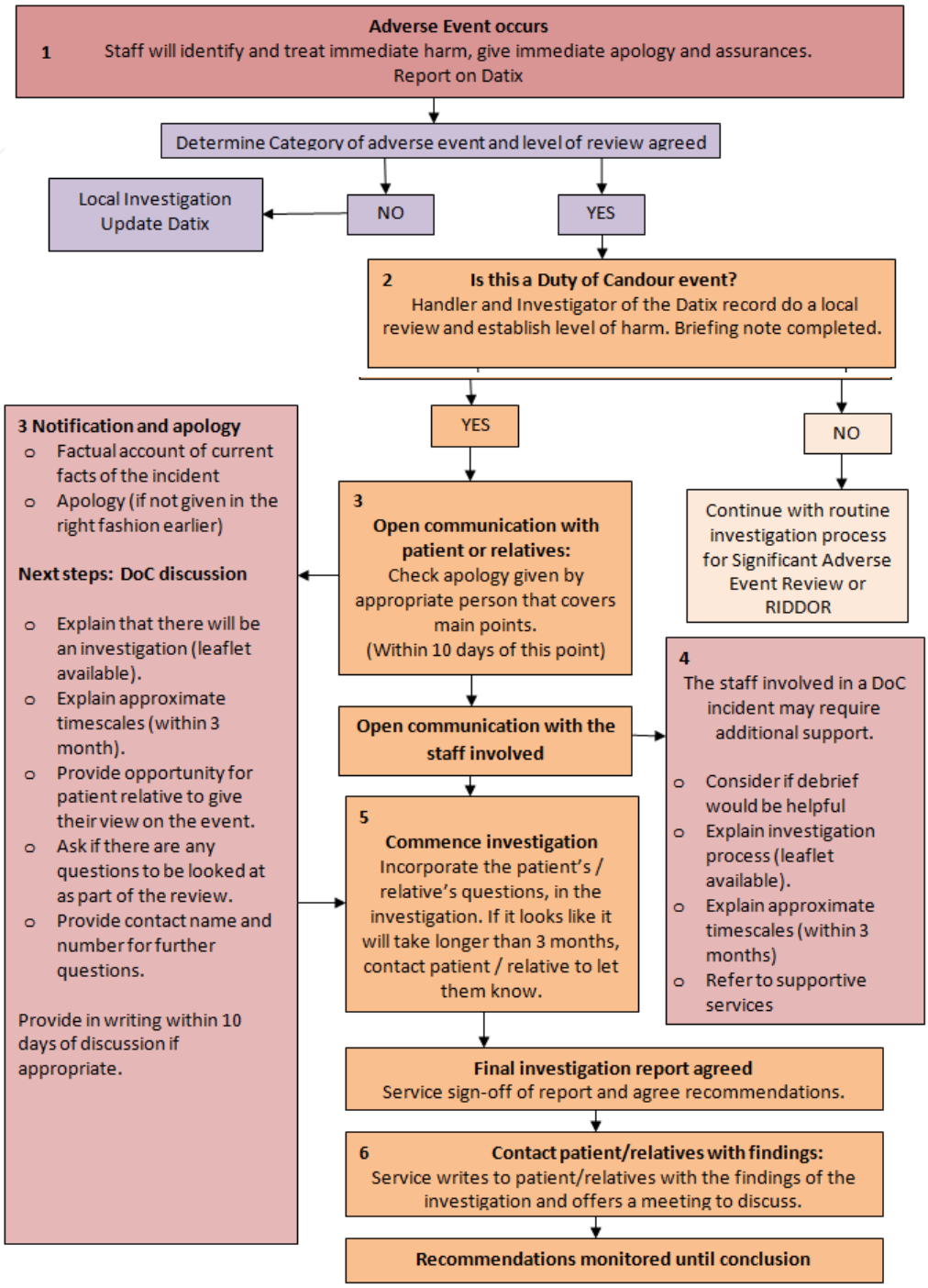
1. **Appropriate care** - The adverse event review concluded that the care and/or service was well planned and appropriately delivered; no care or service delivery problems were identified; and the adverse event outcome was ultimately unavoidable. However, it is likely there are still learning points (especially good practice points).

2. **Indirect system of care issues** - The adverse event review identified indirect or incidental sub-optimal care or service issues and lessons that could be learned (and good practice points). However, these were unlikely to have affected the final outcome. For example, a protocol was not strictly followed or there was a delay in accessing the case notes, but these were unlikely to have affected the final outcome.

3. **Minor system of care issues** - The adverse event review identified minor or sub-optimal care or service provision and that a different plan or delivery of care/service may have resulted in a different outcome. For example, system or management factors were identified (such as incomplete records or a delay in transferring the patient or service user), but there was uncertainty regarding their impact on the final outcome. Learning points have been identified and improvement plans developed.

4. **Major system of care issues** - The adverse event review identified that a different plan and/or delivery of care or service would, on the balance of probability, have been expected to result in a more favourable outcome. Factors were identified which negatively influenced or contributed to the adverse event outcome. For example, how the case was managed had a significant impact on the level of harm. Learning points have been identified and improvement plans developed.

6.6 Appendix 6 – Duty of Candour flowchart

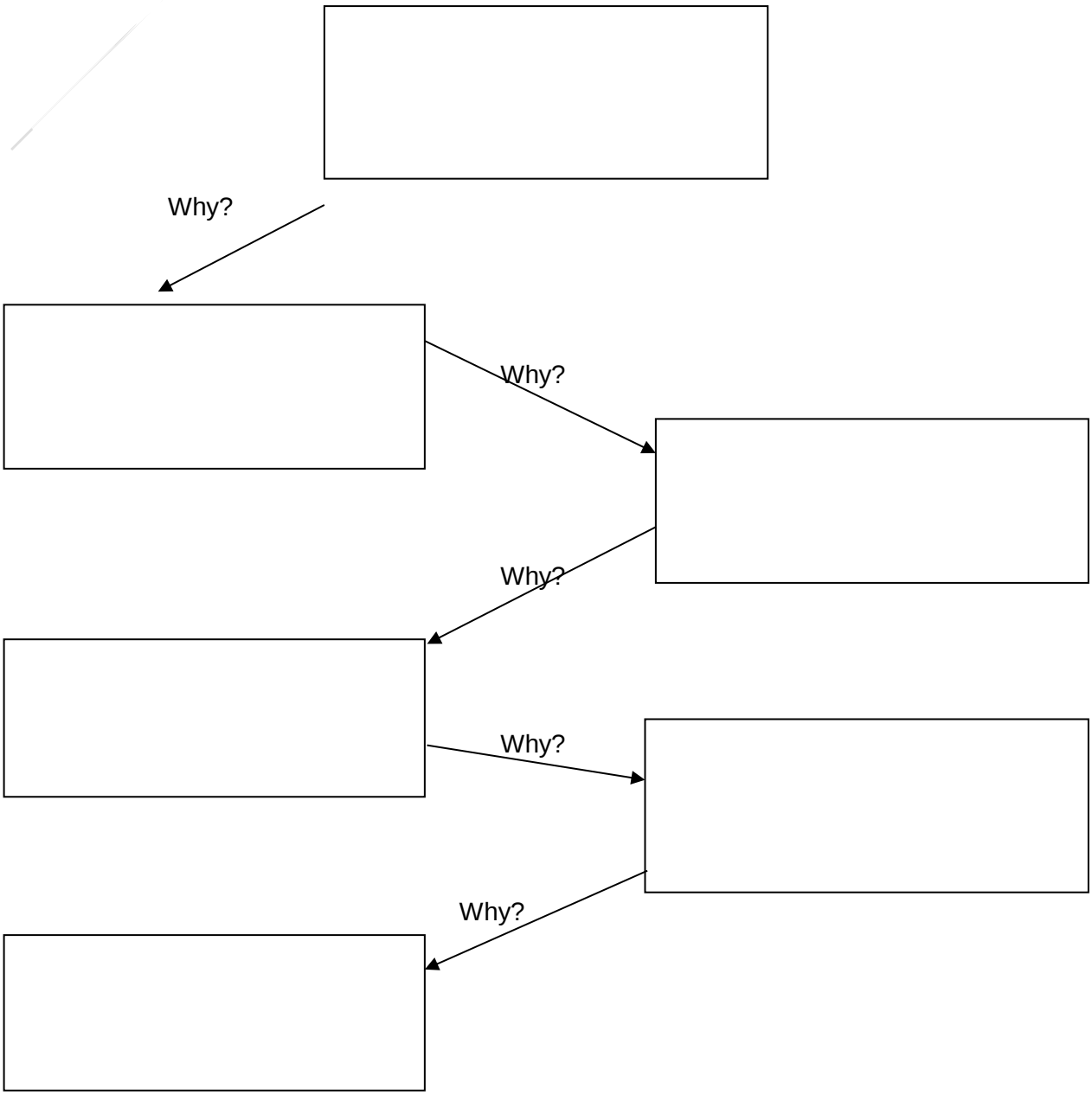


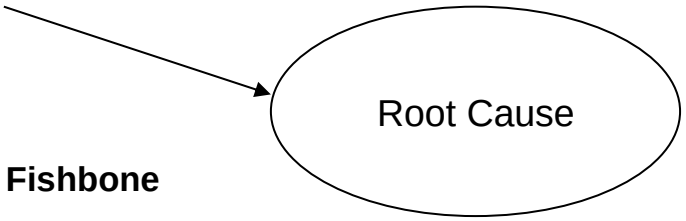
6.7 Appendix 7 - RCA Tool – Tabular Timeline

Event Date				
Event Time				
Event				
Supplementary Information				
Good Practice				
Care/Service Delivery Problem				

6.8 Appendix 8- RCA Tool – Five Why's

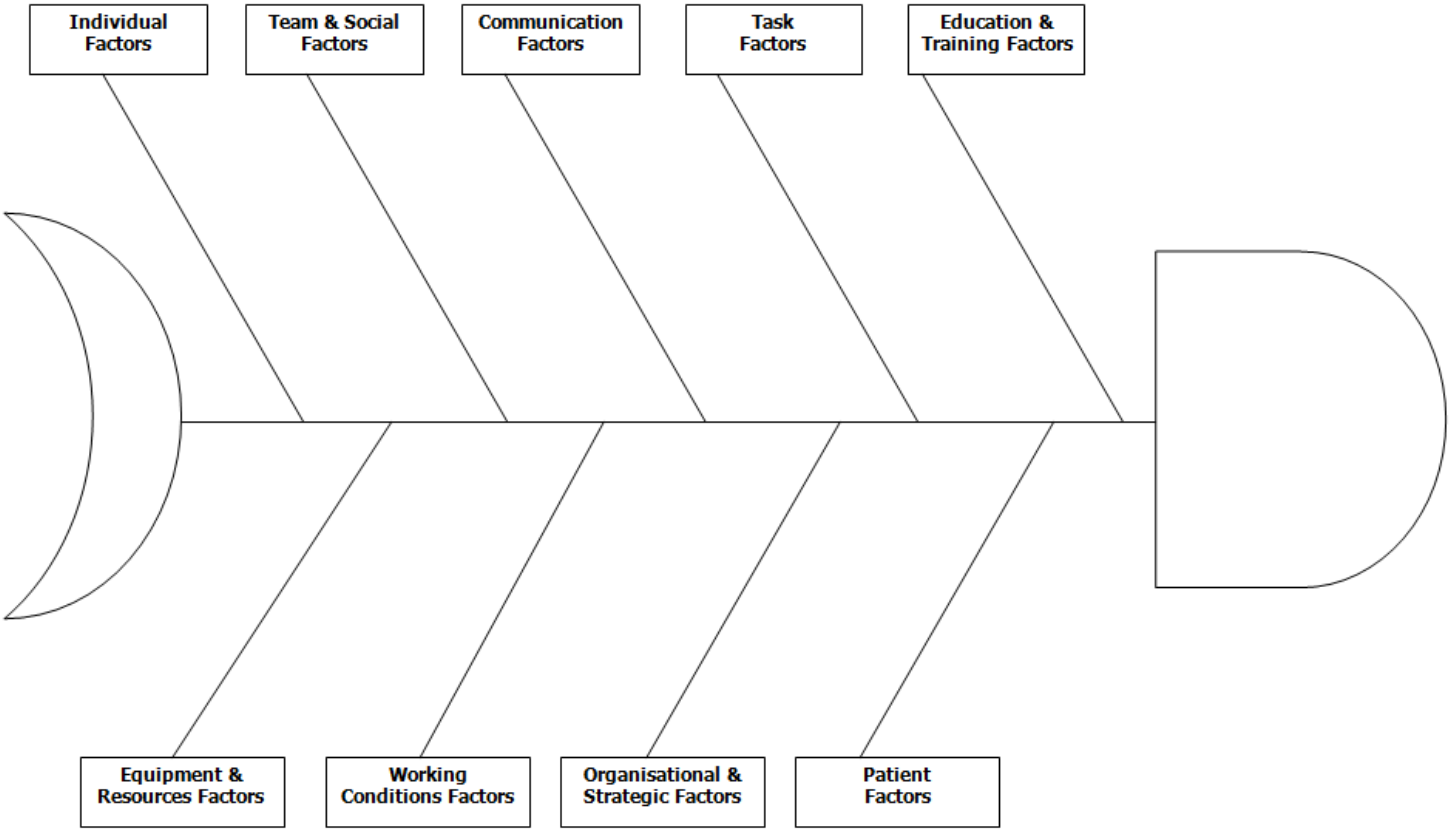
Problem:





6.9 Appendix 9 - RCA Tool – Fishbone Template

RCA Tool – Fishbone Template



6.10 Appendix 10 – Risk Matrix

Likelihood Definitions Descriptor	Rare	Unlikely	Possible	Likely	Almost Certain
Likelihood	Can't believe this event would happen – will only happen in exceptional circumstances	Not expected to happen, but definite potential exists – unlikely to occur	May occur occasionally, has happened before on occasions – reasonable chance of occurring	Strong possibility that this could occur – likely to occur	This is expected to occur frequently / in most circumstances – more likely to occur

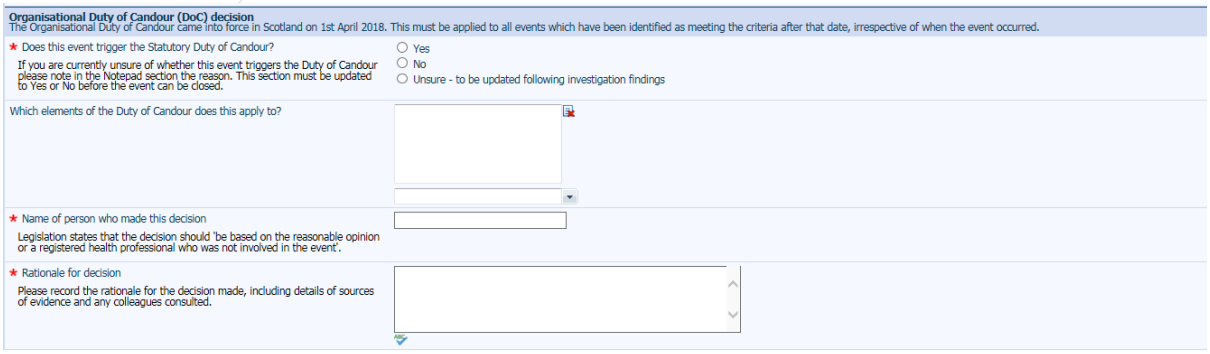
Risk Matrix

Likelihood	Consequences / Impact				
	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	Medium	High	High	V High	V High
Likely (4)	Medium	Medium	High	High	V High
Possible (3)	Low	Medium	Medium	High	High
Unlikely (2)	Low	Medium	Medium	Medium	High
Rare (1)	Low	Low	Low	Medium	Medium

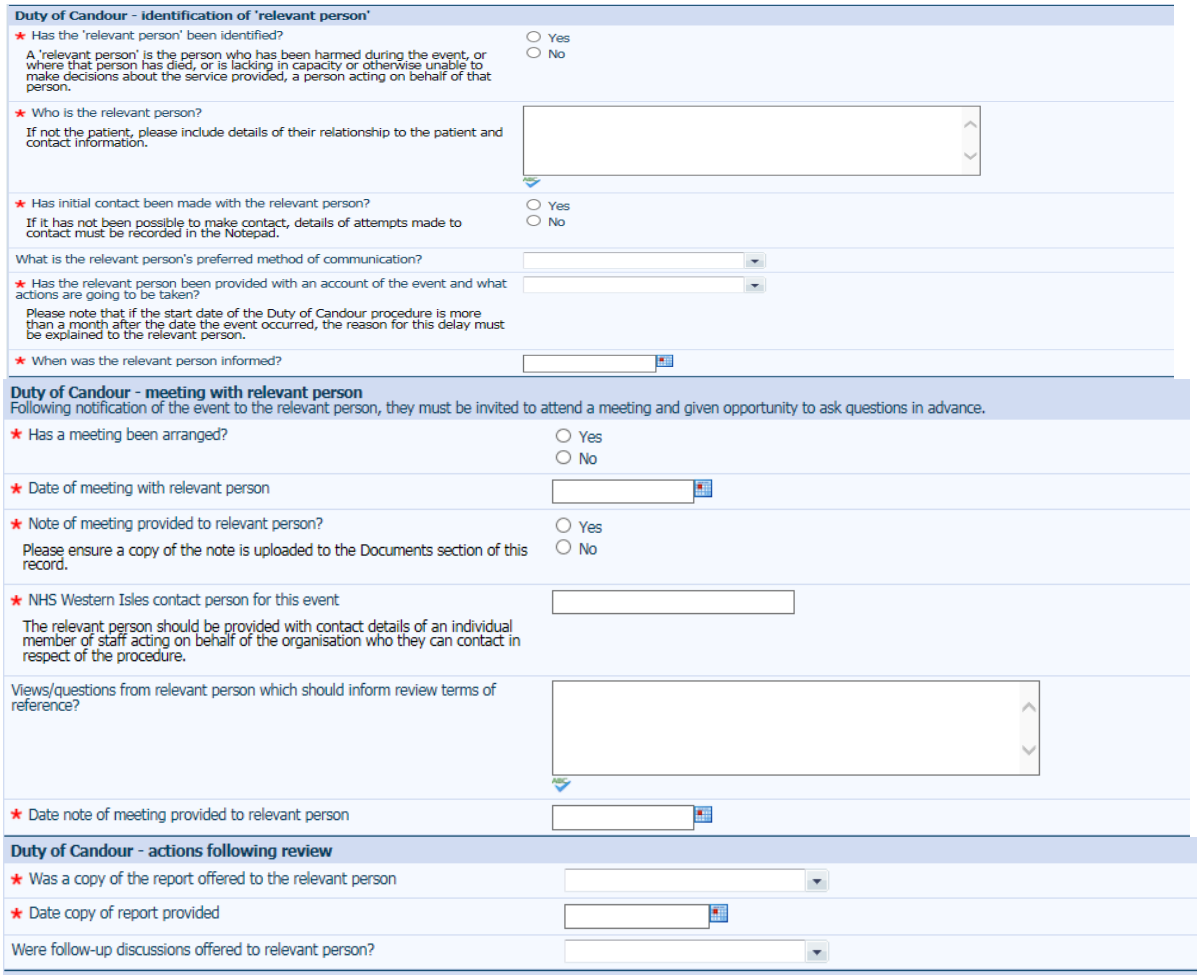
- **Very High:** Senior Management Action to confirm the level of risk identified and produce an action plan to eliminate/reduce or transfer the risk
- **High:** Service Head Action to confirm the level of risk identified and produce an action plan to eliminate/reduce or transfer the risk
- **Medium:** Ward/Dept Head to confirm the level of risk identified and produce an action plan to eliminate/reduce or transfer the risk
- **Low:** Ward/Dept Head to confirm the level of risk identified and manage using routine procedures

Impact/Consequence Definitions Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient Experience	-Reduced quality patient experience/clinical outcome not directly related to delivery of clinical care	-Unsatisfactory patient experience/clinical outcome directly related to care provision – readily resolvable	- Unsatisfactory patient experience/ clinical outcome, short term effects – expect recovery less than 1wk -Increased level of care/stay less than 7 days	-Unsatisfactory patient experience /clinical outcome, long term effects - expect recovery over more than 1week - Increased level of care/stay more than 7 -15 days	-Unsatisfactory patient experience/clinical outcome, continued ongoing long term effects
Objectives/ Project	-Barely noticeable reduction in scope/quality/schedule	- Minor reduction in scope/quality/ schedule	- Reduction in scope/quality/project objectives or schedule	-Significant project over-run	-Inability to meet project/corporate objectives, reputation of the organisation seriously damaged
Injury /illness (physical and psychological) to patient/visitor/staff	-Adverse event leading to minor injury not requiring first aid -No staff absence	- Minor injury or illness, first aid treatment required - Up to 3 days staff absence	- Agency reportable, e.g. Police (violent and aggressive acts) -Significant injury requiring medical treatment and/or counselling -RIDDOR over 7-day absence due to injury/dangerous occurrences	-Major injuries/long term incapacity /disability (e.g. loss of limb), requiring, medical treatment and/or counselling -RIDDOR over 7-day absence due to major injury/dangerous occurrences	-Incident leading to death(s) or major permanent incapacity
Complaints/Claims	- Locally resolved verbal complaint	- Justified written complaint peripheral to clinical care	- Below excess claim. - Justified complaint involving lack of appropriate care	- Claim above excess level. - Multiple justified complaints	- -Multiple claims or single major claim - Complex Justified complaint
Service/ Business Interruption	- Interruption in a service which does not impact on the delivery of patient care or the ability to continue to provide service	- Short term disruption to service with minor impact on patient care/service provision	- Some disruption in service with unacceptable impact on patient care -Temporary loss of ability to provide service - Resources stretched - Potentially impaired operating capability -Pressure on service provision	-Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked -Potentially impaired operating capability -Temp service closure	- Permanent loss of core service/ facility - Disruption to facility leading to significant "knock on" effect -- -Inability to function
Staffing and Competence	- Short term low staffing level temporarily reduces service quality (less than 1 day) - Short term low staffing level (>1 day), where there is no disruption to patient care	- Ongoing low staffing level reduces service quality **-** Minor error due to lack of/ ineffective training/ implementation of training	- Late delivery of key objective/service /care due to lack of staff **-** Moderate error due to lack of/ ineffective training/implementation of training - Ongoing problems with staffing levels	- Uncertain delivery of key objective/service/care due to lack of staff **-** Major error due to lack of/ ineffective training/implementation of training	- Non-delivery of key objective/ service/care due to lack of staff. - Loss of key staff -Critical error due to lack of/ ineffective training/ implementation of training
Financial (including Damage/Loss/Theft/ Fraud	- Negligible organisational/ personal financial loss up to £100k	- Minor organisational/ personal financial loss of £100k - £250K	- Significant organisational/personal financial loss of £250k - £500k	- Major organisational/personal financial loss of £500k - £1m	-Severe organisational financial loss of more than £1m
Inspection/ Audit	- Small number of recommendations which focus on minor quality improvement issues	-Recommendations made which can be addressed by low level of management action	- Challenging recommendations that can be addressed with appropriate action plan - Improvement Notice	-Enforcement/prohibition action -Low Rating - Critical report	-Prosecution -Zero rating - Severely critical report
Adverse Publicity/ Reputation	- Rumours, no media coverage - Little effect on staff morale	- Local media coverage – short term -Some public embarrassment - Minor effect on staff morale/public attitudes	- Local media - long-term adverse publicity - Significant effect on staff morale/public perception of the organisation Local MSP/SEHD interest	- National media adverse publicity less than 3 days - Public confidence in the organisation undermined - Use of services affected	- National/International media/ adverse publicity, more than 3 days - MSP/MP/SEHD concern (Questions in Parliament) - Court Enforcement/Public

6.11 Appendix 11 – Duty of Candour Screenshots from Datix



If Yes is selected in the first question above then the following panels are triggered:



6.12 Appendix 12 – Personal Data Breach Screening Questions:

Cyber Security Incident Reporting

Reporter Section:

Essential Information

Please answer either *YES* or *NO* to all of the following questions.

If yes, please complete relevant detailed section immediately below.

★ **Has this incident resulted in a Personal Data Breach?**  A breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed	

Personal Data Breach details

★ **Choose the most appropriate Personal Data Breach Category**	
★ **Categories of information**	
★ **How many individuals have been affected?**	
★ **Are the affected people aware that incident has occurred**	
★ **Has the data placed at risk now been recovered?**	
★ **Has there been a delay in reporting this incident?**	

Investigator Section:

Personal Data Breach details

* Choose the most appropriate Personal Data Breach Category	
* Categories of information	
* How many individuals have been affected?	
* Are the affected people aware that incident has occurred	
* What are the potential consequences and adverse effects	
Has the data placed at risk now been recovered?	
Provide details of where the information/data was found	
* Have you informed the Police about this incident?	
* Have you informed any other regulatory bodies about this incident?	
* Has the Board taken any action to minimise/mitigate the effect	

* Have you informed any other regulatory bodies about this incident?	No
* Has the Board taken any action to minimise/mitigate the effect	No
* Please provide details of any actions to minimise/mitgate	
* Has there been a delay in reporting this incident?	
* What measures did the Board put in place to prevent recurrence	

CYBER SECURITY INCIDENT REPORTING - https://www.ncsc.gov.uk/reporting-cyber-security-incident

Your Name *

Your Phone *

Your Contact Email Address *

The email address from an **uncompromised** system that all further correspondence should be sent to.

Your Company Email Address *

The company email address for reference purposes (this may be compromised, but will not be used for correspondence)

What Sector is the organisation in? *

- Select -

What is your Role? *

Summary of Incident *

Are you sharing this with us for information or do you require advice and assistance? *

- Select -

Do you have an Internal ID for the incident? *

Investigation so far *

Impact *

- Select -

Description of Impact

Current state of incident *

- Select -

Who else has been notified? *

e.g. Law Enforcement, Action Fraud, Lead Government Department, Incident Response Company, Information Commissioner's Office (ICO) and NIS Directive Competent Authority, plus related incident reference numbers.

Have you reported this to the Information Commissioner's Office (ICO) as a GDPR obligation?

☐ Yes

Have you reported this to the relevant Competent Authority (CA) as a NIS Directive obligation?

☐ Yes

Do you have any further data or samples to aid this incident?

☐ Yes

6.13 Appendix 13 – Cyber Security Breaches

Notifiable Scottish Public Sector Cyber Incidents are defined as incidents or attacks against Scottish public sector network information systems which:

- Have the potential to disrupt the continued operation of the organisation or delivery of public services and/or;
- Carry a likelihood that other public, private or third sector organisations may experience a similar attack, or that the incident could spread to these organisations and/or;
- Could have a negative impact on the reputation of the Scottish public sector or Scottish Government and/or;
- Carry the likelihood of Scottish Parliament or social media interest.

The NCSC defines a cyber security incident as:

- A breach of a system's security policy in order to affect its integrity or availability
- The unauthorised access or attempted access to a system

Activities commonly recognised as security policy breaches include:

- attempts to gain unauthorised access to a system and/or to data
- the unauthorised use of systems and/or data
- modification of a system's firmware, software or hardware without the system-owner's consent
- malicious disruption and/or denial of service

NHS Western Isles staff will use the electronic adverse event reporting system (Datix), as a reporting mechanism for cyber/network information security incidents. Incidents must be reported on Datix without delay.

The incident will be risk assessed and investigated by the Information eHealth Lead/Head of IT and if deemed to be of a serious nature, a **Notifiable Cyber Incident Security Form** will be completed and shared with the relevant agencies (Scottish Government e-health Department, The National Cyber Security Centre (NCSC), the Scottish Government Cyber Resilience Unit (CRU), Information Commissioners Office (ICO) and Police Scotland. Lower level threat incidents should be dealt with internally as per Board Policies. Lower risk threats may also be shared with the Information Security community across Scotland for information and learning.

Under Regulation 12(8) of NIS, the ICO is required to share incident notifications with the National Cyber Security Centre (NCSC), and relevant law enforcement agencies.

PERSONAL DATA BREACHES

The General Data Protection regulation (GDPR), requires us all to ensure personal information, in relation to patients and staff, is processed and stored securely at all times. Personal Data is any information that can identify a person, either directly or indirectly. In particular their Name, CHI number, Date of Birth, Address, Diagnosis, description of physical appearance, genetics, fingerprints or even technical identifiers such as computer IP address.

A personal data breach is 'a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed' (Art 4 of GDPR). Breaches can be categorised based on the following information security principles;

- Confidentiality breach – where there is an unauthorised or an accidental disclosure of, or access to, personal data. Integrity breach – where there is an unauthorised or an accidental alteration of personal data.
- Availability breach – where there is an accidental or an unauthorised loss of access to or, destruction of, personal data.
- Loss or destruction breach – where personal data is lost or stolen.

It should be noted that, depending on the circumstances, a breach can concern confidentiality, availability and integrity of personal data at the same time, as well as any combination of these. Personal data security breaches which would fall into the above categories would include the following for examples:

- disclosing confidential data to unauthorised individuals;
- loss or theft of portable devices containing personal or special category personal data e.g. laptops, PCs, mobile phones, USB, disks, etc.;
- loss or theft of paper records;
- inappropriate access controls on electronic folders/files/drives which allows unauthorised access/use of personal data;
- suspected breach of the NHS Western Isles IT Security and Acceptable Use policies;
- attempts to gain unauthorised access to computer systems e.g. hacking;
- records altered or deleted without appropriate consent/authorisation from the data subject;
- viruses or other attacks on ITS equipment, systems or networks;
- breaches of physical security e.g. breaking into secure rooms or filing cabinets where confidential personal data is stored;
- confidential personal data left unlocked in accessible areas;
- unsecure disposal of confidential paper waste;
- leaving PCs unattended when logged on to a user account without locking the screen
- disclosing passwords to colleagues or others who could then gain unauthorised access to data; publication of confidential personal data onto websites or internet in error;
- misdirected e-mails containing personal, confidential or special category data.

Reporting a Personal Data Breach:

- All personal data breaches should be reported through DATIX without delay,
- The Data Protection Officer will ensure that the relevant parties are notified, for example; Chief Executive, eHealth Manager, Caldicott Guardian, Clinical Governance, on call member of Executive Team, Communications Manager, HR and any other party relevant to that incident.
- A risk assessment will be completed by the Information Governance Manager/DPO/IT Security Team to assess any risks associated with the breach, the potential adverse consequences for individuals; how serious or substantial these are; and how likely they are to happen again. A containment and recovery plan will be drawn up to prevent an escalation and to make efforts to recover and secure any lost or compromised data.
- If the breach is deemed notifiable, when large scale or significant distress/harm/embarrassment likely, a full investigation of the incident will be carried out.
- When is becomes apparent that a breach may require to be reported out with NHS Western Isles, and or to the Information Commissioners Office (ICO), the Chief Executive NHS Western Isles will be notified without delay.
- The DPO will be responsible for reporting data breaches to the appropriate regulatory body such as the Information Commissioner, Scottish Government or the Police. Reports will be

made without delay and in any case, when notifying the Information Commissioner, within 72 Hours.

The electronic Adverse Event Reporting Management System has a mandatory question for reporters to state whetted a Data Breach has occurred – please see Appendix 9 for DATIX screening questions.