Lincolnshire Community Health Services
NHS Trust

Serious Incident Policy

(Including the Never Event Framework)

Supporting learning to prevent recurrence

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Lincolnshire Community Health Services Trust
Version Control Sheet

Serious Incident Policy

Version	Section/Para/ Annex	Version/Description of Amendments	Date	Author/Amended by
1.			August 2008	J Christmas
2.	Entire document	Review date extended on authorisation of Information Governance to enable reviewed documents to be submitted to suitable approving Committee	April 2010	S Barnes
3.	Entire document	Update criteria and procedure	May 2010	J Christmas
4.	Point 32	Reflect Tissue Viability reporting criteria	August 2010	J Christmas
	Page 26	Identify staff support leaflet	August 2010	J Christmas
	Appendix 9	Insert updated copy	August 2010	J Christmas
	Appendix 10	Inserted Director on Call Serious incident	August 2010	J Christmas
	Changes to index, chronological numbering and appendices within text & appendices	Chronological Numbering updated	August 2010	J Christmas
4.1	Minor formatting organisation name changes	Extension agreed at QSG 15th August to allow for upcoming changes in collaboration With external agencies	August 2014	Diane Bainbridge
4.2		Extension agreed to allow for benchmarking information from CCG.	May 2015	Sarah McKown

5.	Entire document	Separate policy developed for use by LCHS in line with SI Framework guidelines	July 2015	Lisa Green
5.1	Appendix 6 Page 46	Revision to Never Event Framework and Never Event list	Feb 2018	Joanne Gooch
5.1	Section 16 Page 18	Contact details updated	Feb 2018	Joanne Gooch
6	Section 29 Page 26	Addition: actions to be added to team's quality improvement plans	June 2018	Joanne Gooch
	Appendix 8	Closure checklist removed as not used as part of process	January 2021	Joanne Gooch
	Section 16 Page 17	Escalation of potential serious incident process updated	January 2021	Joanne Gooch
	Section 21 Page 21	NPSA incident decision tree replaced by A just culture guide	January 2021	Joanne Gooch
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Background

Responding appropriately when things go wrong in healthcare is a key part of the way that the NHS can continually improve the safety of the services we provide to our patients. We know that healthcare systems and processes can have weaknesses that can lead to errors occurring and, tragically, these errors sometimes have serious consequences for our patients, staff, services users and/or the reputation of the organisations involved themselves. It is therefore incumbent on us all to continually strive to reduce the occurrence of avoidable harm.

Lincolnshire Community Health Services (LCHS) must ensure that serious incidents (SIs) are identified, reported and managed in an effective and timely way and learning is shared internally and externally.

Statement

LCHS is committed to the timely and effective reporting and management of serious incidents, to promote patient and organisational safety and individual and organisational learning.

Responsibilities

Operational oversight of the process for managing serious incidents within LCHS is delegated through the LCHS Chief Executive to the Director of Nursing, AHPs and Operations

All staff must ensure that serious incidents are reported immediately to their line manager or Head of Clinical Services or if not immediately available, to the appropriate Quality Assurance Manager.

Training

Training will be provided to staff through the LCHS induction programme. This training will be supplemented for both clinical and non-clinical staff by mandatory training updates.

Dissemination

The policy will be available on the organisation's website and staff intranet.

Resource Implications

The successful implementation of incident reporting requires robust staff training and access to appropriate information systems and analytical tools.

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Section 1 - Foreword

The potential for learning from some incidents in healthcare is so great, or the consequences to patients, families and carers, staff or organisations so significant that these incidents warrant using additional resources to mount a comprehensive response, following consistent and clearly defined principles and procedures, with a significant management focus and formal governance arrangements around reporting, investigation, learning, action planning, implementation and closure.

The National Patient Safety Agency (NPSA) established the building blocks for doing this in the first National Framework for Reporting and Learning from Serious Incidents Requiring Investigation published in 2010. This was supplemented by the Serious Incident Framework produced by NHS England in March 2013, which reflected the changes within the NHS landscape following the Health and Social Care Act 2012. Since the publication of this guidance there have been further changes, particularly within NHS England. In order to continue building on the foundations set by the NPSA, NHS England has developed a revised Serious Incident Framework which replaces previous versions. The revised Framework takes account of the changes and acknowledges the increasing importance of taking a whole-system approach to quality, where cooperation, partnership working, thorough investigation and analytical thinking are used to understand where weaknesses/ problems in service and/or care delivery exist, in order to draw learning that minimises the risk of future harm.

Serious incidents in healthcare are rare, but it is acknowledged that systems and processes have weaknesses and that errors will inevitably happen. But, a good organisation will recognise harm and the potential for harm and will undertake swift, thoughtful and practical action in response, without inappropriately blaming individuals[i].

Section 2: LCHS Responsibilities

LCHS is responsible for identifying and reporting serious incidents onto the Strategic Executive Information System (StEIS) using a unique identifier and notifying the commissioners within 48 hours of the incident being identified as a serious incident.

Where the risk identified from a serious incident relates to another Trust or to the commissioners, LCHS will ensure that the incident is notified to the clinical risk management team of West Lincolnshire Clinical Commissioning Group (CCG).

Duties:

- The Chief Executive of LCHS is ultimately responsible for managing serious incidents identified

- Strategic oversight of this process is delegated to the Director of Nursing, AHPs and Operations

- The Director of Nursing, AHPs and Operations is responsible for receiving; risk assessing; aggregating and analysing; and managing the investigation and reporting of “own reported” SIs.

- The RCA Investigation Manager is responsible for leading the RCA for a SI. The RCA Investigation Manager will be nominated by the Director of Nursing, AHPs and Operations, or delegated Head of Clinical Service, to complete an initial fact find (IFF) of the case within 3 working days of the incident being reported, and thereafter oversee a full RCA (where required) for completion within 60 days.

- RCA Managers will be selected for their specialist expertise, they will interview staff; collate and analyse evidence and write the final RCA report.

- All staff / line managers are responsible for managing and reporting serious incidents and risk within their own service area to their line manager and to the Quality Assurance Manager. They are required to be familiar with the SI reporting policy and to be able to identify and escalate incidents which fall within the SI criteria in accordance with this policy.

Section 3: If more than one NHS organisation is involved in a Serious Incident (SI)

If more than one NHS organisation is involved in a SI, the organisation that has identified the incident will report it in the first instance notify the incident to the CCG, they will then confirm the lead agency / organisation.

The lead agency / organisation will be responsible for reporting the incident onto the StEIS system; for the investigation and coordination of the risk management response. The lead agency / organisation will oversee the production of a comprehensive Root Cause Analysis report (RCA). The RCA will be shared with key stakeholders / agencies, to enable these organisations to discharge their separate responsibilities in relation to the incident.

If the police or Health and Safety Executive (HSE) are involved in any SI, the principles outlined in the memorandum of understanding between the police, HSE and Department of Health should be followed. If the police are involved, the parameters of the local investigation will be guided by them in the first instance. If any restrictions are placed on organisation investigators by either the Police or HSE these should be clearly documented in the Datix record, in associated reports to the organisation and reflected on StEIS.

Section 4: Definition of a serious incident (SI)

In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm[1] to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident

occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signaling systemic failures within a commissioning or health system.

There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list.

The definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that rely on the judgment of the people involved (see section 1.1).

Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death[2] of one or more people. This includes
        - suicide/self-inflicted death; and
    - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
    - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:—
        - the death of the service user; or
        - serious harm;
    - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
        - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring[3]; or
        - where abuse occurred during the provision of NHS-funded care.

      This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident (see Part One; sections 1.3 and 1.5 for further information).
- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. Please see Appendix 6 for more information.

- n incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

    - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 8 for further information);
    - Property damage;
    - Security breach/concern
    - Incidents in population-wide healthcare activities like screening[4] and immunisation programmes where the potential for harm may extend to a large population;
    - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
    - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
    - Activation of Major Incident Plan (by provider, commissioner or relevant agency)

- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation[5].

Section 5: Assessing whether an incident is a serious incident
In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a human factors and systems-based approach) and what may be done to address the weakness to prevent the incident from happening again.

Whilst a serious outcome (such as the death of a patient who was not expected to die or where someone requires on going/long term treatment due to unforeseen and unexpected consequences of health intervention) can provide a trigger for identifying serious incidents, outcome alone is not always enough to delineate what counts as a serious incident. The NHS strives to achieve the very best outcomes, but this may not always be achievable. Upsetting outcomes are not always the result of error/ acts and/ or omissions in care. Equally some incidents, such as those which require activation of a major incident plan for example, may not reveal omissions in care or service delivery and may not have been preventable in the given circumstances. However, this should be established through thorough investigation and action to mitigate future risks should be determined.

Where it is not clear whether an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omissions in care) caused or contributed towards a serious outcome, but the simplest and most defensible position is to discuss openly, to investigate proportionately and to let the investigation decide. If a serious incident is declared but further investigation reveals that the definition of a serious incident is not fulfilled- for example there were no acts or omissions in care which caused or contributed towards the outcome- the incident can be downgraded.

This can be agreed at any stage of the investigation and the purpose of any downgrading is to ensure efforts are focused on the incidents where problems are identified and learning, and action are required

Section 6: Can a near miss be a serious incident?

It may be appropriate for a near miss to be a classed as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be caused should the incident (or a similar incident) occur again. Deciding whether a near miss should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- The likelihood of the incident occurring again if current systems/process remain unchanged; and
- The potential for harm to staff, patients, and the organisation should the incident occur again.

This does not mean that every near miss should be reported as a serious incident but, where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk.

Section 7: How are serious incidents identified?

As described above, serious incidents are often triggered by events leading to serious outcomes for patients, staff and/or the organisation involved. They may be identified through various routes including, but not limited to, the following:

- Incidents identified during the provision of healthcare by a provider e.g. patient safety incidents or serious/distressing/catastrophic outcomes for those involved e.g. risk assessed as moderate harm or above;
- Allegations made against or concerns expressed about a provider by a patient or third party;
- Initiation of other investigations for example: Serious Case Reviews (SCRs), Safeguarding Adult Reviews (SARs), Safeguarding Adults Enquires (Section 42 Care Act) Domestic Homicide Reviews (DHRs) and Death in Custody Investigations (led by the Prison Probation Ombudsman) NB: whilst such circumstances may identify serious incidents in the provision of healthcare this is not always the case and SIs should only be declared where the definition above is fulfilled Complaints;
- Whistle blowing;
- Prevention of Future Death Reports issued by the Coroner.

If an incident is identified by an organisation that is not involved in the delivery of care in which the incident occurred, then that organisation must take action to ensure that the relevant provider(s) and commissioner(s) are informed to ensure the incident is reported, investigated and learned from to prevent future risk of reoccurrence. Where the identifying organisation is another provider it must raise concerns with its commissioner, who can assist in the necessary correspondence between other organisations as required.

Serious incidents identified (or alleged) through the complaints route, or any other mechanism, must be treated in line with the principles in this policy to ensure that it is investigated and responded to appropriately. If the investigation reveals that there were no weaknesses/problems within health's intervention which either caused or contributed to the incident in question, the incident can be downgraded by the commissioners and

removed from StEIS.

Section 8: Risk management

Evaluation of risk is a key component of SI management. It is the responsibility of all staff to be vigilant to risks. On identification of an incident staff should to respond to manage any identified risks and escalate through their line management or directly to the relevant Quality Assurance Manager, in line with LCHS Incident reporting and Risk Management policy.

LCHS maintains a risk register which contains details of all agreed risks. As a minimum, organisational risks assessed as extreme or high should be considered for inclusion on the relevant directorate or service level register.

Section 9: Opportunities for investing time in learning

Managing, investigating and learning from serious incidents requires a considerable amount of time and resource. Care must be taken to ensure there is an appropriate balance between the resources applied to the reporting and investigation of individual incidents and the resources applied to implementing and embedding learning to prevent recurrence. The former is of little use if the latter is not given enough time and attention.

The multi-incident investigation root cause analysis (RCA) model provides a useful tool for thoroughly investigating reoccurring problems of a similar nature (for example, a cluster of falls or pressure ulcers in a similar setting or amongst similar groups of patients) in order to identify the common problems (the what?), contributing factors (the how?) and root causes (the why?). This allows one comprehensive action plan to be developed and monitored and, if used effectively, moves the focus from repeated investigation to learning and improvement.

Where an organisation has identified a wide-spread risk and has undertaken (or is undertaking) a multi-incident investigation and can show evidence of this and the improvements being made, then this can be used as a way of managing and responding to other similar incidents within an appropriate timeframe. This means that if another similar incident occurs before the agreed target date for the implementing of preventative actions/improvement plans, a separate investigation may not be required. Instead consideration should be given to whether resources could be better used on the delivery of improvement work rather than initiating another investigation. This would need careful assessment, engagement with those affected and agreement on a case-by-case basis.

Section 10: Serious case reviews and safeguarding adult reviews

The Local Authority via the Local Safeguarding Children Board or Local Safeguarding Adult Board (LSCB, LSAB as applicable), has a statutory duty to investigate certain types of safeguarding incidents/ concerns. In circumstances set out in *Working Together to Safeguard Children*[6] (2013) the LSCB will commission Serious Case Reviews and in circumstances set out in guidance for adult safeguarding concerns[7] the LSAB will commission Safeguarding Adult Reviews. The Local Authority will also initiate Safeguarding Adult Enquiries, or ask others to do so, if they suspect an adult is at risk of abuse or neglect.

LCHS must contribute towards safeguarding reviews (and enquiries) as required by the

Local Safeguarding Board. Where it is indicated that a serious incident within healthcare has occurred (see Part One, section 1), the necessary declaration must be made.

Whilst the Local Authority will lead SCRs, SARs and initiate Safeguarding Enquiries, healthcare must be able to gain assurance that, if a problem is identified, appropriate measures will be undertaken to protect individuals that remain at risk and ultimately to identify the contributory factors and the fundamental issues (in a timely and proportionate way) to minimise the risk of further harm and/or recurrence. The interface between the serious incident process and local safeguarding procedures must therefore be articulated in the local multi-agency safeguarding policies and protocols. Providers and commissioners must liaise regularly with the local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating and responding to safeguarding concerns, which is agreed by relevant partners. Partners should develop a memorandum of understanding to support partnership working wherever possible.

Section 11: Domestic Homicide Reviews

A Domestic Homicide is identified by the police usually in partnership with the Community Safety Partnership (CSP) with whom the overall responsibility lies for establishing a review of the case. Where the CSP considers that the criteria for a Domestic Homicide Review (DHR) are met, they will utilise local contacts and request the establishment of a DHR Panel. The Domestic Violence, Crime and Victims Act 2004, sets out the statutory obligations and requirements of providers and commissioners of health services in relation to domestic homicide reviews.

Section 12: National Screening Programmes

Serious Incidents in NHS National Screening Programmes must be managed in line with the guidance: *Managing Safety Incidents in National Screening Programmes,* which is aligned with the principles and processes set out in this policy. The guidance provides further clarity with regards to the accountabilities, roles and processes for managing screening safety incidents and serious incidents in national screening programmes. These are often very complex, multi-faceted incidents that require robust coordination and oversight by Screening and Immunisation Teams working within Sub-regions and specialist input from Public Health England's Screening Quality Assurance Service.

The Screening Quality Assurance Service is also responsible for surveillance and trend analysis of all screening incidents. It will ensure that the lessons identified from incidents are collated nationally and disseminated. Where appropriate these will be used to inform changes to national screening programme policy and education/training strategies for screening staff.

Section 13: Seven key principles

This policy endorses the application of 7 key principles in the management of all serious incidents:

Figure 1: Principles of Serious Incident Management

Key Principle	Supporting Information
Open and Transparent	The needs of those affected should be the primary concern of those involved in the response to and the investigation of serious incidents. The principles of openness and honesty as outlined in the LCHS Open and Honest Care Policy must be applied in discussions with those involved. This includes staff and patients, victims and perpetrators, and their families and carers. Openness and transparency mean: • Acknowledging, sincerely apologising and explaining when things have gone wrong; • Conducting a thorough investigation into the incident, ensuring patients, their families and carers are satisfied that lessons learned will help prevent the incident recurring; • Providing support for those involved to cope with the physical and psychological consequences of what happened[ii] Saying sorry is not an admission of liability and is the right thing to do. Please refer to LCHS Open and Honest Care policy to decide on the most appropriate members of staff to give both verbal and written apologies and information to those involved. This must be done as early as possible and then on an ongoing basis as appropriate.

Preventative	Investigations of serious incidents are undertaken to ensure that weaknesses in a system and/or process are identified and analyses to understand what went wrong, how it went wrong and what can be done to prevent similar incidents occurring again. Investigations carried out under this policy are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how a person died (where applicable) as this is a matter for Coroners, neither are they conducted to hold any individual or organisation to account. In circumstances where the actions of other agencies are required then those agencies must be appropriately informed and relevant protocols must be followed. LCHS must advocate justifiable accountability and a zero tolerance for inappropriate blame. The NHS Improvement Just Culture Guide should be used to promote fair and consistent staff treatment.
Timely and responsive	Serious incidents must be reported without delay and no longer than 2 working days after the incident is identified. Every case is unique, including: the people/organisations that need to be involved, how they should be informed, the requirements/needs to support/facilitate their involvement and the actions that are required in the immediate, intermediate and long term management of the case. Those managing serious incidents must be able to recognise and respond appropriately to the needs of each individual case.
Systems based	The investigation must be conducted using a recognised systems-based investigation methodology that identifies: ○ The problems (the what?); ○ The contributory factors that led to the problems (the how?) taking into account the environmental and human factors; and ○ The fundamental issues/root cause (the why?) that need to be addressed. Within the NHS, the recognised approach is commonly termed Root Cause Analysis (RCA) investigation. The investigation must be undertaken by those with appropriate skills, training and capacity.
Proportionate	The scale and scope of the investigation should be proportionate to the incident to ensure resources are effectively used. Incidents which indicate the most significant need for learning to prevent serious harm should be prioritised. Determining incidents which require a full investigation is an important part of the process and ensures that resources are focused in an appropriate way. Typically, serious incidents require a comprehensive investigation, but the scale and scope (and required resources) should be considered on a case by-case-basis. Some incidents may be managed by an individual (with support from others as required) whereas others will require a team effort, and this may include members from various organisations and/or experts in certain fields. In many cases an internally managed investigation can fulfil the requirements for an effective investigation. In some circumstances (e.g. very complex or catastrophic incidents spanning multiple organisations and/or where the integrity of the investigation

	would be challenged/ undermined if managed internally) an independent investigation may be required. In exceptional circumstances a regional or centrally led response may be required.
Collaborative	Serious incidents often involve several organisations. LCHS must work in partnership to ensure incidents are effectively managed. There must be clear arrangements in place relating to the roles and responsibilities of those involved. Wherever possible partners should work collaboratively to avoid duplication and confusion and there should be a shared understanding of how the incident will be managed and investigated.
Objective	Utilise a range of information sources including data records and written statements.

Section 14: Accountability

The primary responsibility in relation to serious incidents is from the provider of the care to the people who are affected and/or their families/carers.

The key organisational accountability for serious incident management is from the provider in which the incident took place to the commissioner of the care in which the incident took place. Given this line of accountability, it follows that serious incidents must be reported to the organisation that commissioned the care in which the serious incident occurred.

Section 15: Involvement of multiple providers

Often more than one organisation is involved in the care and service delivery in which a serious incident has occurred. The organisation that identifies the serious incident is responsible for recognising the need to alert other providers, commissioners and partner organisations as required in order to initiate discussions about subsequent action. All organisations and agencies involved should work together to undertake one single investigation wherever this is possible and appropriate.

Commissioners should help to facilitate discussions relating to who is the most appropriate organisation to take responsibility for coordinating the investigation process. Commissioners themselves should provide support in complex circumstances. Where no one provider organisation is best placed to assume responsibility for coordinating an investigation, the commissioner may lead this process.

Often in complex circumstances separate investigations are completed by the different provider organisations. Where this is the case organisations (providers and commissioners and external partners as required) must agree to consider cross boundary issues i.e. the gaps in the services that may lead to problems in care. The contributing factors and root causes of any problems identified must be fully explored in order to develop effective solutions to prevent recurrence. Those responsible for coordinating the investigation must ensure this takes place. This activity should culminate in the development of a single investigation report. Development, implementation and monitoring of subsequent action plans by the relevant organisations must be undertaken.

Section 16: **Escalation of potential serious incident process**

If you think this is a serious incident e.g. unexpected patient death, sudden/unexpected patient deterioration, fall with harm

Escalation 8am – 8pm

1.	Incident Identified
2.	Contact Matron/Service Lead to commence escalation
3.	Identfier to complete on Datix immediately
4.	Matron/Service Lead to notify Head of Service and Bronze on-call (to log in on-call log)
5.	Bronze on-call to record in on-call log to include time, location, brief description, who this has been escalated to and the Datix reference
6.	Matron/Service Lead to escalate to Deputy Director of Nursing and Quality (Susan Ombler) or Deputy Director of AHPs (Angela Shimada) and Quality HocS (Lorna Adlington and Sarah McKown)
7.	Inform/seek advice from Quality Assurance Manager (9am – 5pm Monday to Friday)

Escalation 8pm – 8am

1.	Incident Identified
2.	Contact Bronze on-call if immediate support is required e.g • Unexpected patient death • Sudden/unexpected patient deterioration • Cardiac arrest Bronze on-call to record in on-call log to include time, location, brief description, who this has been escalated to (if required)
3.	Identfier to complete on Datix immediately
4.	Matron/Service Lead to be informed of inicdent on handover
5.	Matron/Service Lead to escalate to Deputy Director of Nursing and Quality (Susan Ombler) or Deputy Director of AHPs (Angela Shimada) and Quality HocS (Lorna Adlington and Sarah McKown)
6.	Inform/seek advice from Quality Assurance Manager (9am – 5pm Monday to Friday)

Section 17: Identification and immediate action

Serious incidents or suspected serious incidents must be declared internally as soon as they are identified. A senior manager or clinician should be identified by the Director of Nursing, AHPs and Operations, or the officer with relevant delegated authority to undertake the following:

- Arrange for any immediate actions required to ensure the safety of the patient(s), other services users and staff.
- Obtain all relevant physical, scientific and documentary evidence, and make sure it is secure and preserved. Initial actions of local managers in the collection and retention of information are important for the overall integrity of the investigation process
- Identify witnesses, including staff, and other service users, to ensure they receive effective support.
- Identify an appropriate specialist/clinician to conduct an initial incident review (the initial fact find, IFF) to confirm whether a serious incident has occurred and if applicable, the level of investigation required and to outline immediate action taken (including where other organisations/partners have been informed)
- Ensure commissioners and other relevant parties (for example: police, safeguarding professionals, the Information Commissioner's Office) are informed at the earliest opportunity and within 2 working days of a serious incident being identified.
- Agree who will make the initial contact with those involved, or their family/carer(s). Where an individual(s) has been harmed by the actions of a patient, particular thought should be given to who is best placed to contact the victim and/or their family. Where necessary LCHS must contact the police and agree with them who will make the initial contact with the victim(s), their family/carer(s) and/or the perpetrator's family. Those involved should have a single point of contact
- Arrange appropriate meeting(s) with key stakeholders, including patients/victims and their families/carers as required.
- Ensure the incident is appropriately logged on the serious incident management system StEIS, this is the responsibility of the Quality Assurance Manager.

Where it is not known whether an incident is a serious incident, it is better to err on the side of caution and treat the incident as a serious incident until evidence is available to demonstrate otherwise. Serious incident reports can be downgraded, and relevant records amended at any stage in the investigation. Any downgrading must be agreed with the CCG on a case by case basis. Incidents that are found to not meet the threshold of a serious incident must be managed in line with other appropriate LCHS policies if appropriate.

Section 18. Reporting a serious incident

Serious incidents must be reported to the CCG without delay and no later than 2 working days after the incident is identified. Incidents falling into any of the serious incident categories listed below should be reported immediately to CCG upon identification. This should be done by telephone as well as electronically:

- Incidents which activate the major incident plan:
- Incidents which will be of significant public concern:
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies:

Reporting a serious incident must be done by recording the incident on the NHS serious incident management system, StEIS by the Quality Assurance Manager. The serious incident report must not contain any patient or staff names and the description should be clear and concise.

Other regulatory, statutory, advisory and professional bodies should be informed about serious incidents depending on the nature and circumstances of the incident. Serious incident reports must clearly state that relevant bodies have been informed. See Appendix 1 for a list of other organisations that must be considered. All serious incidents

which meet the definition for a patient safety incident should also be reported separately to the NRLS for national learning.

Section 19: Follow up information

An initial review (known as the initial fact find (IFF) or preliminary report) should be undertaken and emailed to the Deputy Director of Nursing and Quality and copied to the Quality Assurance Manager within 3 working days of the incident. The report should be approved by the Deputy Director of Nursing and Quality prior to being sent to the CCG clinical risk team by the Quality Assurance Manager.

The aim of the initial review is to:

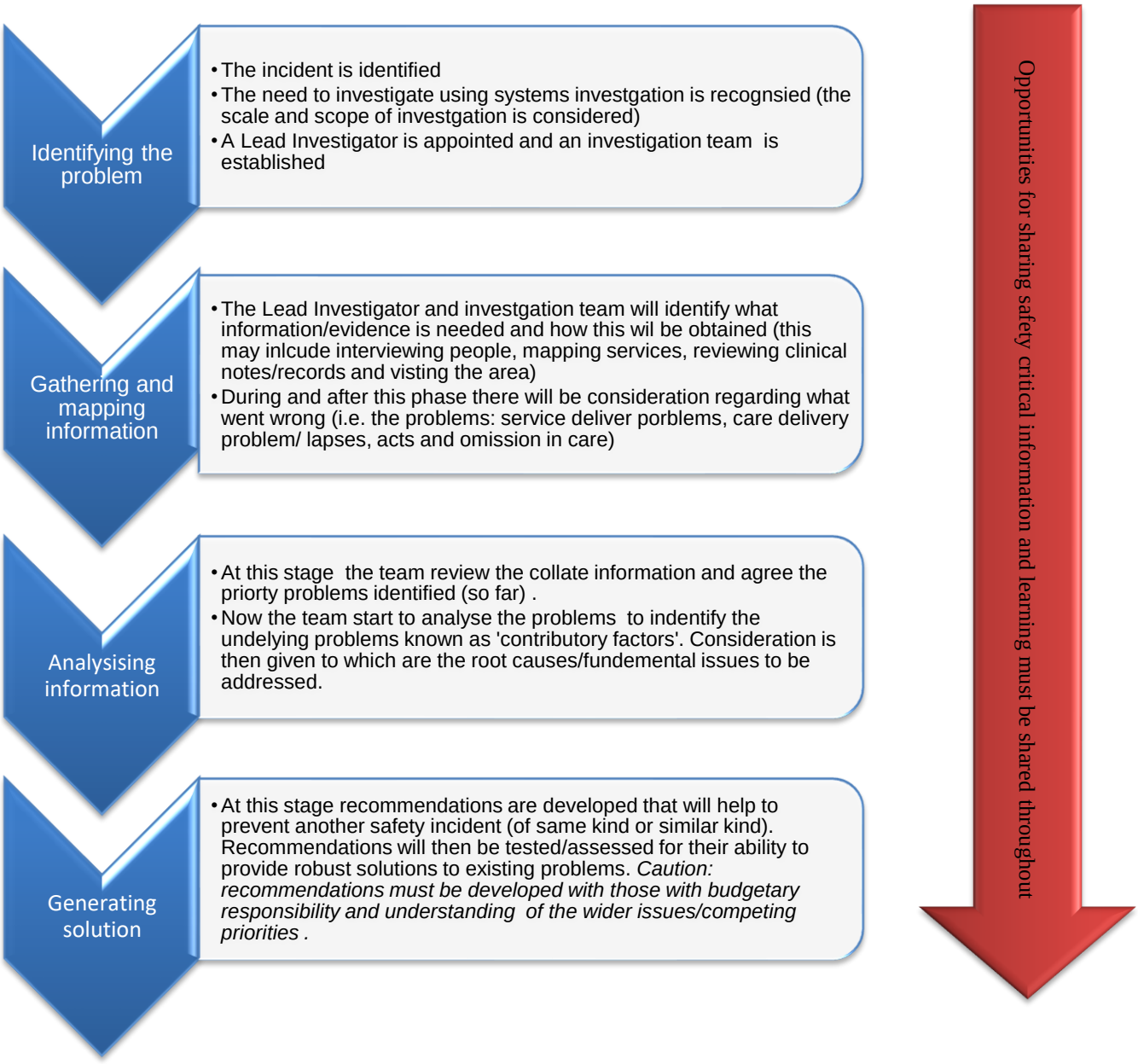
- Identify and provide assurance that any necessary immediate action to ensure the safety of staff, patients and the public is in place;
- Assess the incident in more detail (and to confirm if the incident does still meet the criteria for a serious incident and does therefore require a full investigation); and
- Propose the appropriate level of investigation.

The information submitted as part of the initial review should be reviewed by the appropriate stakeholders and the investigation team (once in operation) in order to inform the subsequent investigation.

Section 20: Overview of the investigation/RCA process

This schematic provides a brief overview of a systems investigation for investigating serious incidents in the NHS. It requires a 'questioning attitude that never accepts the first response', and uses recognised tools and techniques to identify:

  - The problems (the what?) including lapses in care/acts/omissions; and
  - The contributory factors that led to the problems (the how?) considering the environmental and human factors; and
  - The fundamental issues/root cause (the why?) that need to be addressed.


Identifying the problem
• The incident is identified
• The need to investigate using systems investgation is recognsied (the scale and scope of investgation is considered)
• A Lead Investigator is appointed and an investigation team is established
Gathering and mapping information
• The Lead Investigator and investgation team will identify what information/evidence is needed and how this wil be obtained (this may inlcude interviewing people, mapping services, reviewing clinical notes/records and visting the area)
• During and after this phase there will be consideration regarding what went wrong (i.e. the problems: service deliver porblems, care delivery problem/ lapses, acts and omission in care)
Analysising information
• At this stage the team review the collate information and agree the priorty problems identified (so far) .
• Now the team start to analyse the problems to indentify the undelying problems known as 'contributory factors'. Consideration is then given to which are the root causes/fundemental issues to be addressed.
Generating solution
• At this stage recommendations are developed that will help to prevent another safety incident (of same kind or similar kind). Recommendations will then be tested/assessed for their ability to provide robust solutions to existing problems. *Caution: recommendations must be developed with those with budgetary responsibility and understanding of the wider issues/competing priorities .*
Opportunities for sharing safety critical information and learning must be shared throughout

Section 21: A just culture guide

In March 2018 NHS Improvement published 'A just culture guide' which replaced the NPSA incident decision tree.

The fair treatment of staff supports a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame.

Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated.

The guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely.

- it asks a series of questions that help clarify whether there truly something is specific about an individual that needs support or management versus whether the issue is wider, in which case singling out the individual is often unfair and counter-productive
- it helps reduce the role of unconscious bias when making decisions and will help ensure all individuals are consistently treated equally and fairly no matter what their staff group, profession or background.

The guide should not be used routinely. It should only be used when there is already suspicion that a member of staff requires some support or management to work safely, or as part of an individual practitioner performance/case investigation. Remember, you have moved into individual practitioner performance investigation when it is suggested a single individual needs support to work safely (including training, supervision, reflective practice, or disciplinary action), as opposed to where a whole cohort of staff has been identified, which would be examined as part of a safety investigation.

The guide does not replace the need for patient safety investigation and should not be used as a routine or integral part of a patient safety investigation. This is because the aim of those investigations is system learning and improvement. As a result, decisions on avoidability, blame, or the management of individual staff are excluded from safety investigations to limit the adverse effect this can have on opportunities for system learning and improvement.

Section 22: Setting up the team

The provider declaring the incident (unless otherwise agreed) must ensure that an appropriate serious incident investigation team is established. It is the responsibility of all team members to keep their own organisation fully briefed about the incident and actions being taken. The investigation team is also responsible for identifying valuable/ safety-critical learning to be shared at any stage of the investigation process. The team should not wait until completion of the investigation to highlight system weaknesses/ share valuable learning which may prevent future harm.

The investigation team should have a Lead Investigator with accountability to the Director of Nursing, AHPs and Operations. It is essential to identify team members with:

- Knowledge of what constitutes an effective systems investigation process, and the skills/ competencies to lead and deliver this;
- Skills/ competencies in effective report writing and document formulation;

- Expertise in facilitating patient/family involvement
- Understanding of the specialty involved – this often requires representation from more than one professional group to ensure investigation balance and credible;
- Responsibility for administration and documentation (or for there to be adequate administrative and IT support);
- Knowledge/ expertise in media management and a clear communication strategy – or access to this specialist support via the communications team (see Appendix 7);
- Access to appropriate legal and/or information governance support where appropriate;
- Access to competent proof-reading services where required; and
- Appropriate links/mechanisms to share lesson locally and nationally during the investigation as required.

Section 23: Involving and supporting those affected

The needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents. It is important that affected patients, staff, victims, perpetrators, patients/victims' families and carers are involved and supported throughout the investigation.

All communication with those involved should be recorded promptly and factually on to Datix.

Please refer to LCHS Open and Honest Care policy for more information.

Section 24: Involving patients, victims and their families/carers

Involvement begins with a genuine apology. The principles of honesty, openness and transparency as set out in LCHS Open and Honest Care policy must be applied. All staff involved in liaising with and supporting bereaved and distressed people must have the necessary skills, expertise, and knowledge of the incident in order to explain what went wrong promptly, fully and compassionately. The appropriate person must be identified for each case. This can include clinicians involved in the incident, but this is not always appropriate and should be considered on a case-by-case basis.

An early meeting must be held to explain what action is being taken, how they can be informed, what support processes have been put in place and what they can expect from the investigation. This must set out realistic and achievable timescales and outcomes.

Those involved will want to know:

- What happened?
- Why it happened?
- How it happened?
- What can be done to stop it happening again?

They must also have access to the necessary information and should:

- Be made aware, in person and in writing, as soon as possible of the process of the investigation to be held, the rationale for the investigation and the purpose of the investigation;
- Be given the opportunity to express any concerns and questions. Often the family offer invaluable insight into service and care delivery and can frequently ask the key questions;

- Have an opportunity to inform the terms of reference for investigations;
- Be provided with the terms of reference to ensure their questions are reflected;
- Know how they will be able to contribute to the process of investigation, for example by giving evidence;
- Be given access to the findings of any investigation, including interim findings
- Have an opportunity to respond/comment on the findings and recommendations outlined in the final report and be assured that this will be considered as part of the quality assurance and closure process undertaken by the commissioner;
- Be informed, with reasons, if there is a delay in starting the investigation, completing the investigation or in the publication of the final report; and be offered media advice, should the media make enquiries.

It is important that appropriate treatment and support is provided for patient and victims and their families and carers. This should be considered on an individual basis. However, the following needs should be considered:

- The need for an independent advocate with necessary skills for working with bereaved and traumatised individuals;
- Support with transport, disability, and language needs;
- Support during and after the investigation. This may include counselling or signposting to suitable organisation that can provide bereavement or post-traumatic stress counselling;
- Further meetings with the organisations involved or support in liaising with other agencies such as the police;

Depending on the nature of the incident, it may be necessary for several organisations to contact those affected. This should be clearly explained to the patients/ victims and families as required. A coordinated approach should be agreed by the partner agencies in discussion with those affected.

It is important to acknowledge that other patients/ service users may have been involved or affected by the incident and they must also be offered the appropriate level of support and involvement.

Section 25: Supporting staff

It is important to recognise that serious incidents can have a significant impact on staff who were involved or who may have witnessed the incident.

Like victims and families, they will want to know what happened and why and what can be done to prevent the incident happening again.

Staff involved in the investigation process should have the opportunity to access professional advice from their relevant professional body or union, staff counselling services and occupational health services. They should also be provided with information about the stages of the investigation and how they will be expected to contribute to the process.

Provider organisations should make it clear that the investigation itself is separate to any other legal and/or disciplinary process. Organisations must advocate justifiable accountability but there must be zero tolerance for inappropriate blame and those involved must not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or

any threat to their registration by virtue of involvement in the investigation process.

The Just Culture Guide should be used to promote fair and consistent staff treatment within and between healthcare organisations. In the very rare circumstances where a member of staff has committed a criminal or malicious act, the organisation should advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation.

Section 26: Agreeing the level/type of investigation

The nature, severity and complexity of serious incidents vary on a case-by-case basis and therefore the level of response should be dependent on and proportionate to the circumstances of each specific incident. The appropriate level of investigation should be proposed by the provider as informed by the initial review. The investigations team and, where applicable, other stakeholders will use the information obtained through the initial review to inform the level of investigation. The level of investigation may need to be reviewed and changed as new information or evidence emerges as part of the investigation process. Within the NHS there are three recognised levels of systems-based investigation (currently referred to as RCA investigation). These are described in Appendix 2.

Section 27: Final report and action plan

Serious incident investigation reports must be shared with key interested bodies including patients, victims and their families. It is recommended that reports are drafted on the basis that they may become public, so issues concerning anonymity and consent for disclosure of personal information are important and should be considered at an early stage in the investigation process. LCHS has a Caldicott Guardian who is responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. Those investigating serious incidents can seek advice from the Caldicott Guardian or the information governance team if guidance is needed about the disclosure of patient identifiable information.

Section 28: Final report

The investigation concludes with an investigation report and action plan. This needs to be written as soon as possible and in a way that is accessible and understandable to all readers.

The report should:

- Be simple and easy to read;
- Have an executive summary, index and contents page and clear headings;
- include the title of the document and state whether it is a draft or the final version;
- Include the version date, reference initials, document name, computer file path and page number in the footer;
- Disclose only relevant confidential personal information for which consent has been obtained, or if patient confidentiality should be overridden in the public interest. This should however be considered by the Caldicott Guardian and where required confirmed by legal advice
- Include evidence and details of the methodology used for an investigation (for example timelines/cause and effect charts, brainstorming/brain writing, nominal group technique, use of a contributory factor framework and fishbone diagrams, five whys and barrier analysis);
- Identify root causes and recommendations;
- Ensure that conclusions are evidenced and reasoned, and that recommendations are implementable
- Include a description of how patients/victims and families have been engaged in the process;
- Include a description of the support provided to patients/victims/families and staff following the incidents
- Include the lessons learned and how these will be shared internally (and externally if applicable)

Section 29: Action plan

The minimum requirements for an action plan include the following:

- Action plans must be formulated by those who have responsibility for implementation, delivery and financial aspects of any actions (not an investigator who has nothing to do with the service although clearly their recommendations must inform the action plan);

- Every recommendation must have a clearly articulated action that follows logically from the findings of the investigation;
- Actions should be designed and targeted to significantly reduce the risk of recurrence of the incident. It must target the weaknesses in the system (i.e. the 'root causes' /most significant influencing factors) which resulted in the lapses/acts/omissions in care and treatment identified as causing or contributing towards the incident;
- A responsible person (job title only) must be identified for implementation of each action point;
- There are clear deadlines for completion of actions;
- There must be a description of the form of evidence that will be available to confirm completion and also to demonstrate the impact implementation has had on reducing the risk of recurrence;
- Any actions identified need to be added to the relevant teams quality improvement plan

A SMART approach to action planning is essential. That is, the actions should be: Specific, Measurable, Attainable, Relevant and Time-bound. To ensure that the most effective actions/solutions are taken forward, it is recommended that an option appraisal of the potential actions/solutions is undertaken before the final action plan is developed and agreed.

Details should also be included on where the action plan will be reviewed and monitored until signed off as completed.

Section 30: Submission of Final Report

Serious incident reports and action plans must be submitted to the CCG within 60 working days of the incident being reported, unless an independent investigation is required, in which case the deadline is 6 months from the date the investigation commenced.

In certain circumstances, it may be difficult to complete a final report within these timescales. This might be due to:

- Enforced compliance with the timetable of an external agency, such as police, Coroner, Health and Safety Executive or Local Children Safeguarding Board or Safeguarding Adult Board;
- Investigation of highly specialised and multi-organisation incidents, such as those involving a national screening programmes; or
- Incidents of significant complexity.

In such circumstances the commissioner and investigations team can agree an alternative timeframe. This should be clearly recorded on Datix and included in the serious incident report. The Quality Assurance Manager should be notified if you are aware of a reason why the investigation will take longer than 60 days and they will contact the CCG to discuss an alternative timeframe.

There is no automatic bar on investigating incidents where criminal proceedings are underway. Wherever possible, serious incident investigations should continue alongside criminal proceedings. This should be considered in discussion with the police. Following a formal request by the police, a coroner or a judge, the investigation may be put on hold, as it may potentially prejudice a criminal investigation and subsequent proceedings (if any). Where this is the case, the CCG

should review/agree the date for completion once the investigation can recommence.

LCHS can request extensions to the report submission deadline, but there must be compelling reasons for doing so; for example, new information coming to light which requires further investigation. This must be agreed and confirmed by the CCG in advance of the original deadline. Extensions are effective from the day on which the serious incident report was due for submission.

Clear management plans should be developed at the start of the process to avoid delays. Those involved (including patients, staff, victims and their families/carers where applicable) must be informed of management plans and any reasons for deviation.

Section 31: Quality assurance and closure of the investigation

On receipt of the final investigation report and action plan from the provider, the commissioner should acknowledge receipt by email. They will then undertake a quality assurance review of the report within 20 calendar days. Where necessary an alternative timescale may be agreed.

Cases can be re-opened where there is a requirement to do so i.e. upon receipt of new information derived from any of the mechanism previously outlined in Part One, section 1.3 of this guidance.

Publication of serious incident investigation reports and action plans is considered best practice. To support openness and transparency, local commissioners should work with their providers to encourage and support publication of reports and action plans. Where reports are published there, must be robust processes in place for proof reading and steps must be taken to protect the anonymity of persons involved. Reports should not contain confidential personal information unless consent has been obtained or there is an overriding public interest (as described in section 4.4). The content must be considered by the organisation's Risk Manager (or relevant officer) with support from the organisations Caldicott Guardian and legal advisor/ team as required. It is important to share information safely for the purposes of learning whilst maintaining the principle of openness and transparency.

Section 32: Dissemination of lessons learned

LCHS quality team will report incidents and lessons learned to the service line quality assurance groups and provide monthly information relating to incidents, trends and learning to the CCG's clinical risk management team.

Where appropriate, issues will also be highlighted within the CCG contract and quality meetings to support performance management and promote patient safety and service quality.

Section 33: Process for review/monitoring/sign off

It is important to recognise that the closure of an incident marks only the completion of the investigation process. The delivery and implementation of action and improvement may be in its infancy at this stage. Implementing change and improvement can take time, particularly where this relates to behavioral and cultural change. It is not unreasonable for improvements to take many months or even years in some cases.

Patients and families involved may also wish to maintain their involvement with the organisations after the investigation is closed in order to seek assurance that action is being taken and that lessons are really being learned. Opportunities for future involvement should be made available where this is the case.

In order to prevent issues from being considered in isolation and common trends from being missed, investigation reports and action plans should be reviewed collectively on a regular basis.

Section 34: References

Information Resource to Support the Reporting of Serious Incidents, NPSA, April 2010
Seven steps to patient safety, NPSA
East Midlands Policy for reporting and handling serious incidents in the East Midlands January 2010
Provider Guidance Serious Incident Reporting, DoH, October 2007
Policy for managing and investigating the most serious events in mental health services May 2008.
Information Governance – Reporting Serious Incidents, East Midlands Strategic Health Authority, May 2008
Being Open, NPSA, 15 September 2005
Never Events. Framework: Update for 2010/11. Policies and Action for Primary Care; NPSA, National Reporting and Learning Service

Appendix 1: Notification of interested bodies

Serious incidents must be notified without delay (or within specified timescales) to all relevant bodies via the appropriate routes. Guidance produced by specific bodies should be referred to in order to ensure compliance with their requirements. Commissioners should be notified of serious incidents no later than 2 working days after the incident is identified.

CQC

HSCA notification must be made by all services registered under the Health and Social Care Act (HSCA). This includes all NHS Trusts, independent healthcare, adult social care, primary dental care and independent ambulance providers.

The way in which notifications are made will depend on their nature and the type of service. The process differs slightly for NHS Trusts than for other providers

For NHS Trusts, the requirement to report incidents is typically met by reporting incidents to the National Reporting and Learning System. Please refer to the CQC's notification guidance which outlines how each type of notification needs to be made:
http://www.cqc.org.uk/content/notifications

Controlled Drugs

Serious incidents relating to controlled drugs must be reported to the provider's Accountable Officer.

Coroner

An unexpected death (where natural causes are not suspected) and all deaths of detained patients must be reported to the Coroner by the treating clinician. This should be done immediately. It is recognised that, following an unexpected death, a serious incident may not be identified until the issuing of the coroner's report.

Coroners make two sorts of referral to the police:

- For an investigation under the Coroner's Act where the Coroner expects a police officer to investigate the death and prepare a file for the inquest by obtaining witness statements and other evidence.
- For a criminal investigation where the Coroner is concerned that the circumstances of the death may involve criminal liability.

Investigating police officers should be clear with the NHS and other organisations when they are acting on behalf of the Coroner to establish the cause of death, rather than investigating a crime. If the matter becomes a criminal investigation, the investigating officer should make it clear to the NHS organisation and others that the status of the investigation and their role in it has changed.

Defects and Failures

Where incidents relate to a defect or failure involving engineering plants, infrastructure and/or non-medical devices, a defect and failure report should also be submitted by the organisation to the Department of Health via the defect and failure reporting portal http://efm.hscic.gov.uk/

Health and Safety Executive (HSE)

The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 (HSWA) and ensuring that "risks to people's health and safety from work activities are properly controlled". Serious incidents may need to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). The trigger point for RIDDOR reporting is over 7days' incapacitation (not counting the day on which the accident happened). Further information on reporting is available at http://www.hse.gov.uk/riddor/report.htm

Incidents involving work-related deaths (or cases where the victim suffers injuries in such an incident that are so serious that there is a clear indication, according to medical opinion, of a strong likelihood of death) should be reported under RIDDOR and managed in accordance with the Work-Related Deaths Protocol. In the first instance the incident should be reported within the organisation in the normal way and to the commissioning organisation[iii].

Health Education England

Directors of Education and Quality (DEQ) in Health Education England (HEE) and its Local Education and Training Boards are responsible for the quality of the education and training provided to medical, nursing, dental and Allied Health Professionals (AHP) students and others, and training grade doctors. These students may be involved in serious incidents and HEE have a duty of care to them. Also, they are an excellent source of feedback on the standard of patient care experienced in their placement.

HEE DEQs should therefore be informed about serious incidents where trainees are involved. The provider should ensure that the responsible DEQ is made aware of the incident as soon as possible. This does not, however, alter the serious incident management process which should be undertaken in line with national serious incident Framework.

Care must be taken to ensure all parties understand that notification of serious incidents involving trainees is focused on supporting those trainees and ensuring the standards of training are appropriate. It is very rare that serious incidents are the result of individual failings and notifications sent to DEQs are not intended as a comment or judgement on the capability of trainees.

Information governance serious incidents, Caldicott and data protection

When reporting serious incidents, providers must comply with Caldicott, data protection and information governance requirements. Where incidents relate to information governance (IG) issues they should be reported within the IG toolkit, in line with the Health and Social Care Information Centre guidance HSCIC Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation and subsequent guidance.

The severity of the incident must be assessed using the scale and severity factors outlined within the HSCIC guidance. All incidents which reach the threshold for a level 2 IG related serious incidents are reported publicly via the IG toolkit and should be reported and investigated as serious incidents under this Framework. Serious incidents relating to information governance must be reported on the NHS serious incident management system, StEIS or its successor, as well as the IG toolkit.

Organisations must be registered to access the HSCIC IG toolkit. Login details will be provided when the organisation undertakes the initial IG assessment which is a dual functionality of the toolkit and provides NHS organisations with a means of self-assessing performance against key aspects of information governance. For further information relating to the assessment and reporting process please refer to the HSCIC guidance or contact your regional information governance lead.

Organisations must be aware that the information reported to the IG toolkit will be published within the public domain. Consequently, the transfer of StEIS reports to the IG toolkit is not recommended unless the content has been approved for publication and a separate report is typically required. It is acknowledged that reporting to both the IG toolkit and StEIS represents duplication of reporting, however the IG toolkit does not currently provide a mechanism for informing relevant commissioners of IG serious incidents and so StEIS reporting is required to ensure that information is shared.

Local Authorities

Local authorities are responsible for commissioning specific public health services including health protection, health improvement and population healthcare. Responsibility for the quality of care being provided is recognised by the governance arrangements within the local authority. Local Authority commissioners must use their interactions with health care providers and commissioners to identify any actual or potential quality problems.

As part of the local Quality Surveillance Groups, Local Authorities will share information and intelligence and learning in relation to serious incidents. Health and Wellbeing Boards also provide a link to the Local Authorities' quality agenda where intelligence should be shared to inform local leadership for quality improvement.

Local Authorities also have a role to play in safeguarding adults and children and young people in vulnerable circumstances. Providers and commissioners must ensure that information about abuse or potential abuse is shared with Local Authority safeguarding teams.

The interface between the serious incident process and local safeguarding procedures must therefore be articulated in the local multi-agency safeguarding protocol and policies. Providers and commissioners must liaise regularly with the local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating safeguarding concerns, which is agreed by relevant partners.

Medicines and Healthcare products Regulatory Agency (MHRA)

Organisations should report suspected problems ('adverse incidents') with a medicine or medical device to the MHRA using the Yellow Card Scheme as soon as possible if:

- A medicine causes side effects
- Someone's injured by a medical device, either because its labelling or instructions aren't clear, it's broken or has been misused
- A patient's treatment is interrupted because of a faulty device
- Someone receives the wrong diagnosis because of a medical device
- A medicine doesn't work properly
- A medicine is of a poor quality
- You think a medicine or medical device is fake or counterfeit

Further details are available at:
http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Monitor

NHS Foundation Trusts are required to inform Monitor about relevant serious incidents (i.e. any incidents which may reasonably be regarded as raising potential concerns over compliance with their licence) requiring investigation.

NHS Protect

NHS Protect, through their contractual standards, stipulate that appropriate security management arrangements must be in place. This includes the provider employing or contracting a qualified person to undertake and/or oversee the delivery of the full range of security management work. The qualified person (the Local Security Management Specialist (LSMS)) works with the Area Security Management Specialist (ASMS) to ensure robust arrangements are in place.

The Security Incident Reporting System (SIRS) is an electronic tool which allows NHS health bodies to report security incidents occurring on their premises to NHS Protect, enabling the creation of a national picture of such incidents across the NHS in England, for use in detecting and preventing crime in a national, regional and sector specific context.

Where a serious incident occurs to a member of staff resulting from a physical or non-physical assault, there is a requirement to report this to NHS Protect via the Security Incident Reporting System (SIRS). The same reporting requirement relates to incidents involving loss or damage to property and assets of NHS organisations, staff and patients.

Users can access an online web portal for incidents to be added or edited, and SIRS can also integrate with local NHS risk management systems to allow a single or bulk upload of records.

More information can be found here http://www.nhsbsa.nhs.uk/4247.aspx

NHS Trust Development Authority

NHS Trusts should directly inform the TDA of all serious incidents

Police

The police are likely to investigate incidents where there is;

- evidence or suspicion that the actions leading to harm (including acts of omission) were reckless, grossly negligent or wilfully neglectful;
- evidence or suspicion that harm/adverse consequences were intended

In the first instance the incident should be reported within the organisation in the normal way and to the commissioning body. Referral to the police should be undertaken by a senior member of staff in the reporting organisation.

Professional regulators and professional misconduct

Most serious incidents are caused by the failure of systems and not the actions of individuals and this must be recognised by the team handling the investigation. Serious incident management process should be followed and progressed in line with the national Serious Incident Framework even if grounds arise to suggest that a serious incident may have occurred as a result of ‘professional misconduct’. If grounds for professional misconduct are

suggested it is important that the appropriate lead (e.g. the Responsible Officer/Medical or Nursing Director) within the provider organisation is alerted (within 2 days) to ensure that appropriate action is taken as and when required. Appropriate action includes the investigation and/or HR team taking time to carefully assess or refer on to experts the actions or omissions in question, within the context of the incident, to identify whether these are considered reckless or malicious, as opposed to slips, lapses, or a situation where there are others routinely taking the same route or in need of similar levels of support, supervision or training. Systems failures are most likely to be at the core of the problem and, the most effective place to target improvements/solution to prevent recurrence.

The Just Culture Guide should be used to determine if action is required in relation to individuals.

Information relating to all Statutory Regulators and the process for managing professional misconduct can be found in the statutory regulators directory

http://www.professionalstandards.org.uk/regulators/statutory-regulators-directory

Public Health England

Public Health England (PHE) Screening and Immunisation Leads, based within NHS England Sub-regions, have a system leadership role for screening and immunisation programmes. They have a responsibility to support the oversight and management of incidents which occur within these programmes and will liaise with other PHE experts to ensure that the investigation and response to an incident is managed appropriately. PHE's Screening Quality Assurance team also has a key role in the investigation and management of serious incidents within screening programmes. Screening and Immunisation Leads within NHS England must ensure the Screening Quality Assurance team is notified when incidents occur within screening programmes.

PHE also has a broader role in supporting the management of serious incidents that occur within other NHS services, where there is a potential for the incident to have adversely affected the health of a wider population. Such incidents may include decontamination failures; inadvertent contact on NHS premises of patients and staff with someone with a transmissible infectious disease such as measles or TB; outbreaks of health care associated infections; the finding of a Health Care Worker infected with a blood borne virus; failure of microbiological laboratory practice; release/widespread exposure to harmful chemicals or a source of radiation.

Where the potential exists for the health of a wider group of people to be adversely affected by an incident in the NHS, the responsible NHS provider must contact the relevant Public Health England Centre through their Health Protection Team and involve PHE as part of the local incident control team. Commissioners must work with the providers of services which they directly commission to ensure this is the case. Public Health England will provide expert input to the assessment of population risk and advice on the management of public health aspects of the incident. The local team will draw on regional and national expertise within PHE as necessary.

Serious Adverse Blood Reactions and Incidents (SABRE)

The UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive require that serious adverse incidents and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety. This information is vital to the work that the Serious Hazards of Transfusion (SHOT) uses to compile its reports. Further details on reporting can be found at:
http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm

Appendix 2

Information in this table provides an outline of the levels of systems-based investigations:				
Level	**Application**	**Product/ outcome**	**Owner**	**Timescale for completion**
Level 1 **Concise internal investigation IR1 and IR2**	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact report which includes the essentials of a credible investigation	Chief Executive/relevant deputy in which the incident occurred, providing principles for objectivity are upheld	IR1s should be reviewed immediately on notification to ensure all necessary actions have been taken. IR2 should be completed within 30 days of the incident being reported.
Level 2 **Comprehensive internal investigation** **Root cause analysis**	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Trust Chief Executive/relevant deputy in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan.
Level 3 **Independent investigation**	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved	Comprehensive investigation report including all elements of a credible investigation	The investigator and **all** members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.	6 months from the date the investigation is commissioned

Appendix 3: Independent Investigation (level 3)

Introduction

This appendix describes the process for undertaking independent investigations for the purposes of learning to prevent recurrence. It describes the circumstances in which an independent investigation may be required and the process for commissioning and managing these types of investigation. It also outlines the potential scope of independent investigations and the circumstances where it may be necessary to involve the expertise of NHS England Regional investigation teams. It does not describe the regional process that has been established for investigating homicide by those in receipt of mental health care.

Scope

Investigations carried out under this policy are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how a person died (where applicable) as this is a matter for Coroners. Neither are they conducted to hold any individual or organisation to account. Other processes exist for that purpose including: criminal or civil proceedings, disciplinary procedures, employment law and systems of service and professional regulation, such as the Care Quality Commission and the Nursing and Midwifery Council, the Health and Care Professions Council, and the General Medical Council. In circumstances where the actions of other agencies are required then those agencies must be appropriately informed and relevant protocols, outside the scope of this Framework, must be followed.

An independent investigation is an investigation into an incident which is both commissioned and undertaken independently of those directly responsible for and directly involved in the delivery of the elements that the investigation is considering.

This guidance considers two types of independent investigation:

1. The first is an independent provider-focussed investigation considering the specific care given to a patient or patients by one or more providers. This type of investigation should be commissioned by the commissioner of the care within which the serious incident occurred and undertaken by individuals who are all independent of the provider(s) in question.

2. The second type is a wider independent investigation of the role of the commissioning system or the configuration of services, which must be commissioned and undertaken independently of the aspects of the system that are under investigation, including independently of any directly involved commissioners. Incidents requiring this type of investigation will usually require a regionally or centrally led response. The most appropriate organisation to commission and quality assure the investigation must be agreed on a case by case basis.

Within each Regional Team of NHS England a Regional investigation team has been established. This team, with input from an Independent Investigation Review Group (IIGR)[8] is responsible for commissioning independent investigation into incidents involving homicide by those in receipt of mental health care . This team can also help to assess cases that may require independent investigations because the incident indicates a need to commission a wider independent investigation into the role of the commissioning system or the configuration of services or where it is agreed a regionally led response is required due to

the scale, complexity (i.e. number of patients/services users affected/involved, level of public concern/ media interest and number of organisations and partner agencies involved) and the potential for cross sector learning. The commissioning of an investigation into the commissioning system itself and/or an investigation led at the regional level is ultimately a decision for the Regional investigation team in conjunction with the IIRG.

Although the regional team may offer support where it is necessary to do so, independent investigations, and the decision to commission independent investigations, should be managed locally by the commissioner of the care in which the incident occurred wherever possible. Local management and ownership of Serious Incidents is of fundamental importance to ensuring appropriate and timely action.

When to conduct an independent investigation?

Independent investigations are required where the integrity of the internal investigation and its findings are likely to be challenged or where it will be difficult for an organisation to conduct a proportionate and objective investigation internally due to the size of organisation or the individuals or number of organisations involved. Independent investigations avoid conflicts of interest and should be considered if such conflicts exist or are perceived to exist.

An independent investigation can be used as a means of assessing whether a provider's account of an incident has been fairly presented to give credit to the findings and assurance that lessons will be learnt to prevent recurrence, or it can be used to obtain an objective assessment of the nature and causes of an incident irrespective of whether or not any investigative work has been or is to be undertaken by the service provider.

An independent investigation should be considered for the following circumstances:

- A serious incident where the organisation is unable to conduct an effective, objective, timely and proportionate investigation. This is particularly relevant to incidents where the obligation on the authorities to account for the treatment of an individual is particularly stringent including:
    - Deaths (and near deaths resulting in severe harm) of those detained under the Mental Health Act (1983) and, in certain circumstances, the deaths of informal psychiatric in-patients[9] where;

        - the cause of death is unknown; and/or
        - where there is reason to believe the death may have been avoidable or unexpected i.e. not caused by the natural course of the patient's illness or underlying medical condition when this is managed in line with best practice. This includes suicide and self-inflicted death (NB: this also includes the death of recently transferred prisoners. Healthcare providers must inform the relevant prison service if there is reason to suggest that the care they received in prison could have contributed towards their death.)

- Where the commissioner(s) or provider(s) or the patient/family feel that the nature of the potential causes of an incident warrant independent scrutiny in order to ensure lessons are identified and acted upon in a robust, open and transparent manner[10].

- Where incidents represent a significant systemic failure leading to wide-spread public concern and independent investigation is required to ensure public confidence in the findings.

- Where it is necessary to examine the role of the wider commissioning system or configuration of services (involving multi-agencies/organisations) in the causation of a serious incident or multiple serious incidents.

Declaration and Immediate Action

In some cases it will be immediately possible to identify from the initial review, or even before, that an incident requires an independent investigation. Where this is the case, then the commissioner should take the necessary action to commission an independent investigation to ensure that action is taken without delay. It most cases however, the provider will complete their own internal investigation and this will be reviewed by the relevant commissioners before the need to commission an independent investigation is agreed.

It is fundamental that the patients/services users and/or family/carers are involved from the very beginning of the process and that their needs are assessed to ensure they are appropriately supported.

Commissioning an independent Investigation

The decision to commission an independent investigation can be made at any stage of the incident management process, depending on the nature and circumstances of the incident.

For provider-focused independent investigations, it is the commissioner of the care within which the serious incident occurred who should make the final decision on the type of investigation required. Commissioners may wait until they have received the provider's internal report (which should be completed within 60 days), before making the decision as to whether or not to commission an independent investigation.

In exceptional circumstances (where either the scale, severity or overall complexity means the investigation cannot be managed locally) or those which must consider the wider commissioning system or the configuration of services, where the decision to undertake and commission an investigation must be taken independently of the aspects of the system that are under investigation, including any directly involved commissioners, a regionally or centrally led response may be required.

For a regionally led response, the Regional Investigation Team (in consultation with the Independent Investigation Review Group) will make the final decision on the type of investigation required. The Central Team (including appropriate national directors) will agree a response for national issues. The appropriate response must be considered on an individual basis. Independent investigations of this nature will usually commence after the relevant provider-focussed (either internal or independent) investigations are complete. It is important that all proceeding investigation reports are made available to the independent investigating team to help inform their investigation.

Multi-agency working

The principles for collaboration and partnership working as set out in part one of this the Framework must be followed. In line with this there should be no automatic bar to prevent a 'health-led' investigation because there is a parallel police investigation underway but there

may be exceptional cases and agencies should cooperate with one another to ensure the investigation can be managed appropriately (refer to part one; section 1.5 for further details).

Starting the commissioning process

A designated individual within the appropriate organisation must be identified to lead commissioning and project management activity including allocation of the cost of the investigation.

Appropriate steps must then be taken including the following;

- Listing all the agencies that have a stake in the care of those involved in the incident and ensuring that they are aware of the process and are involved in the commissioning process if appropriate.
- Identifying any legal issues that may be relevant to the independent investigation, or any court proceedings, and obtaining the appropriate legal advice.
- Obtaining fully informed, written consent (if appropriate) from the service user(s) involved in the incident for the release of their medical records to the investigation team, and agreement that any personal details can be included in a public report[11].
- In the event of the service user not giving consent or lacking capacity to consent the commissioner will need legal advice and advice from Caldicott Guardian to agree a way forward.
- Arranging a meeting between the investigation team, trust representatives, the police and representatives from any other agencies who have agreed to participate in the investigation. Timescales, ground rules, sharing of information and terms of reference should be agreed and shared. Victims/family/carers must also be involved and kept fully informed regarding discussion about the scale and scope of the investigation
- Early discussion with the local Coroner
- Early identification of those affected and their families
- Informing the patients, carers and families about the investigative process and how they can be involved. Arranging for them to meet the commissioner and then the investigation team if wanted.
- Agreeing the timescale for the investigation, timings and setting a date for receipt of the final report.
- If the commencement of the investigation has to be delayed, the reasons must be clearly explained to the patients and families affected.

The investigation teams

In order to ensure independence and avoid any conflict of interest, no member of the independent investigation team can be in the employment of the provider or commissioner organisations under investigation, nor should they have had any clinical involvement with the individual(s) to whom the investigation relates.

Investigators must declare any connectivity that might, or might appear to, compromise the integrity of the investigation. They must adhere to the principles set out below and uphold the highest professional standards in relation to all who are involved in the process before, during and after the investigation.

Investigators must:

- Carry out their work with professionalism, integrity, sensitivity and courtesy;

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- Evaluate the standard of care delivered by the provider objectively;
- Report fairly and without favour;
- Communicate clearly and objectively using accessible language;
- Act in the best interests of patients;
- Respect the confidentiality of information received and judgements made before, during and after the investigation;
- At all times adhere to the requirements outlined in the Terms of Reference; and
- Pay close regard to legal requirements for safeguarding the welfare of patients.

Investigators must ensure that their recommendations are;

- Comprehensive, in that they cover all the requirements of the investigations Terms of Reference;
- Consistent, in that the evaluations of the evidence do not contradict one another;
- Reliable, in that they are based on consistent application of the evaluative criteria i.e. extent to which that care corresponded with statutory obligations, relevant national guidance, Trust policies, including any team or service operational policies and professional standards; and
- Objective, in that the actions of the provider are fully and fairly evaluated and recommendation are made in the best interests of patients.

Members of investigation teams need to be properly appointed with formal appointment letters and a Lead Investigator must be identified from the outset[iv].

The skills and expertise of the independent investigation team appointed must include the following:

- Relevant clinical, social care and managerial expertise.
- Expert investigation skills such as Root Cause Analysis.
- Interviewing and communication skills.
- Understanding of the independent investigation process.
- Excellent report writing skills.
- An understanding of the treatment of witnesses.
- Other specific skills and expertise may be required as is specific to each case, and should be determined by the commissioner and/or the Regional Investigations Team.
- Verbal communication skills including, if required, giving evidence in Court.

It is recommended that as part of the contract held with the investigators there is an agreement that the team will undertake an independent audit to assess how far the recommended actions have been implemented 6-12 months after the investigation. The audit should highlight areas where providers need additional support from other areas of the system to deliver change and improvement.

Terms of Reference

The commissioner of the investigation in discussion with the Lead Investigator is responsible for ensuring that the investigation is underpinned by a clear terms of reference, taking into consideration any findings from internal review, recommendations from the panels review and the patients/family's concerns/ questions.

The Terms of Reference are likely to include;

- Examining the care and treatment provided, including risk assessment and risk management;

- Providing a chronology of the events leading up to the incident;
- Identifying care or service delivery issues, along with the factors that might have contributed to them;
- Identifying underlying causes; and
- Making clear, implementable recommendations for the local health community.

If an independent investigation of the wider commissioning system and the configuration of services is required, then this will involve consideration of whether the causes of the serious incident may have related to, or included the range, availability or configuration of health care service provision within a local health care economy. Such investigations will also take into account any other issues raised by the preceding provider-focussed investigations. The Terms of Reference are likely to include:

- Consideration of the findings of the preceding provider-focussed investigations;
- Further investigation of the care or services provided as required;
- Identifying care or service delivery issues, along with the factors that might have contributed to them;
- Identifying underlying causes; and
- Making clear, implementable recommendations for the local health community..

The work of the investigation team should stay within the terms of reference unless the terms are renegotiated with the commissioner.

Closure and publication of independent investigations

The independent investigation must be completed by the investigation team within 6 months of the date it is commissioned.

The draft report must be sent to the organisations that commissioned it who will send it to the relevant stakeholders including the patient/family involved[12]. The commissioner of the investigation will send a copy of the draft report to the relevant bodies to check for factual accuracy only. There should not be any amendments to any outcomes or recommendations detailed within the report. The provider(s) must review the report and provide an updated action plan based on recommendations/ findings. This must be done in line with the guidance set out in Part Three; section 4.4.2 of this guidance. The action plan must be submitted to the commissioner of the investigation (and the lead commissioners if different) as soon as possible and within 10 working days.

Commissioners of the investigation will make arrangements for a meeting with relevant key stakeholders to approve the draft report and action plan once submitted. Once agreed, the commissioner of the investigation will liaise with the legal advisors, investigators, families, Trusts/providers, other commissioners/ stakeholders to agree closure of the investigation and publication the final report.

Before the final report and action plan is published all pre-publication checks must be complete. This includes ensuring:

- The report and action plan has been subject to legal review;
- Recommendations have been agreed by all interested parties;
- Those affected i.e. patients and their families have had an opportunity to understand the report and its recommendations;
- Agree media handling plan;

- Anyone that may be seen to be criticised should have an opportunity to comment;
- A robust, effective action plan is in place, including a process for review of delivery/implementation of agreed actions; and
- Final sign off by the commissioner of the investigation.

Once signed-off, the report and action plan should be published on the websites of the relevant commissioner, the Trust/provider and NHS England in a prominent and easy to access area as soon as possible and within 21 days. This system should bring greater openness and accountability.

Next steps

It is important to recognise that the closure of an incident marks the completion of the investigation process only. The delivery of action and improvement at this stage may be in its infancy. Implementing change and improvement can take time, particularly where this relates to behavioural and cultural change. It is not unreasonable for improvement to take many months or even years in some cases.

It is important that providers and commissioners invest time in monitoring and progressing with long term actions, particularly where these may addresses the causes contributing to other incidents across the system. Patients and families involved may also wish to maintain their involvement with the organisations after the investigation is closed to seek assurance that action is being taken and that lessons are really being learned. Opportunities for future involvement should be offered where this is the case.

Implications of the Human Rights Act

The Human Rights Act 1998, which gives effect in the UK to the European Convention on Human Rights (ECHR), may impact investigations carried out in relation to serious incidents. The relevant Article of the ECHR is Article 2 – right to life[13].

Article 2 have been interpreted in the case law of UK courts and the European Court of Human Rights as imposing both positive and procedural (investigative) obligations on the State. This means that 'the state must never arbitrarily take someone's life and must also safeguard the lives of those in its care. In addition, the state must carry out an effective investigation when an individual dies following the state's failure to protect the right to life, or the use of force by government officials'.

Not all incidents being investigated under this guidance will trigger a duty for the investigation to be Article 2 compliant[14]. On the one hand, the duty does not, for example, arise in every case where someone dies in hospital. On the other hand, it will almost always arise where there is an unexpected death in custody (including those detained under the Mental Health Act (1983)) and where there are real concerns that there were failures of care. It may also arise as a consequence of the control of and responsibility assumed for the individual, so Article 2 could apply to the death of an informal psychiatric patient. However, every case will depend on its own facts and legal advice should be sought.

It is important to note that any duty to carry out an Article 2 compliant investigation covers the whole span of investigations following death or incident, and not simply an investigation under this guidance in isolation. Normally, the coroner's inquest will ensure Article 2 compliance either on its own or with an investigation carried out under this guidance and/or civil or criminal proceedings. An investigation under this guidance may contribute towards to the coroner's inquest as part of the State's overall response to its Article 2 obligations.

Again, legal advice may be needed to determine the scope of and proper procedures for any investigation under this guidance that involves significant Article 2 issues.

Appendix 4: Domestic Homicide Reviews

Adapted with kind permission from NHS England, London

A Domestic Homicide is defined as:

The death of a person aged 16 or over which has, **or appears to have**, resulted from violence, abuse or neglect by—

a) a person to whom s/he was related or with whom s/he was or had been in an intimate personal relationship, or
b) a member of the same household as him/herself, held with a view to identifying the lessons to be learnt from the death.

A Domestic Homicide is identified by the police usually in partnership with the Community Safety Partnership (CSP) with whom the overall responsibility lies for establishing a review of the case.

Where the CSP considers that the criteria for a Domestic Homicide Review (DHR) are met and should be undertaken, they will utilise local contacts and request the establishment of a DHR Panel. An independent chair will be appointed.
The Review Panel must include individuals from the statutory agencies listed under section 9 of the Domestic Violence, Crime and Victims Act 2004, this includes NHS England, and Clinical Commissioning Groups.

Domestic Homicide Reviews

The purpose of a Domestic Homicide Review is to;

a) establish what lessons are to be learned from the domestic homicide regarding the way in which local professionals and organisations work individually and together to safeguard victims;
b) identify clearly what those lessons are both within and between agencies, how and within what timescales they will be acted on, and what is expected to change as a result;
c) apply these lessons to services including changes to policies and procedures as appropriate; and
d) prevent domestic violence and abuse and improve service responses for all domestic violence and abuse victims and their children through improved intra and inter-agency working.

DHRs are not inquiries into how the victim died or into who is culpable; that is a matter for coroners (as to how?) and criminal courts (as to culpability), respectively, to determine as appropriate[v].

Providers (including GPs and Primary Care)

The Domestic Violence, Crime and Victims Act (2004) requires provider organisations to respond to requests for Individual Management Reports (IMR) in a timely manner, reflecting on any learning which might be gained from the issues raised in the IMR.
The IMR must be completed by a third party, rather than any persons involved in the care of the victim, perpetrator or family members. For small providers, this may mean making reciprocal arrangements with partner organisations or commissioning an independent organisation to complete the IMR. If requested by the Chair the provider organisation must

provide a panel member.

Clinical Commissioning Groups

The CCG must provide a panel member and work with the Community Safety Partnership to ensure that action plans are implemented locally, and learning shared across NHS providers.

CCGs may be directed by the Secretary of State to participate in a Domestic Homicide Review, under Section 9(3) of the Domestic Violence, Crime and Victims Act (2004).

NHS England

NHS England will provide a panel member, provide oversight of IMR's at panel meetings, ensure that recommendations and actions are achievable, and disseminate learning across the NHS in England.

NHS England may support panel Chairs where obstacles to full NHS participation are experienced, using a range of relationship, contractual and regulatory influences.
NHS England may work in partnership with CCGs to identify victim and perpetrator GPs, through whom other NHS providers involved in the care of the victim and/or perpetrator may be identified.

NHS England may be directed by the Secretary of State to participate in a Domestic Homicide Review, under Section 9(3) of the Domestic Violence, Crime and Victims Act (2004).

NHS England will work in partnership with the CCGs to ensure that local services deliver high quality, safe and effective services through the implementation of action plans.

NHS England will collate learning from Domestic Homicides and make recommendations to Education Commissioning organisations for professional development opportunities for all professions.

Management of the Domestic Homicide Process

The authority to request Individual Management Reports from NHS provider organisations lies with the Chair of the Panel, or the Community Safety Partnership who exercise this authority under the Domestic Violence, Crime and Victims Act 2004.

Where agreed NHS England's Regional Offices will designate a regional lead and provide a co-ordination role for Domestic Homicide Reviews, providing a central point for contact (for example, in London via ENGLAND.LondonInvestigations@nhs.net) to minimise the burden on non-NHS partners.

It is the responsibility of the Community Partnership to inform NHS England of a Domestic Homicide; however CCGs must inform the relevant Regional Lead (and their Sub-region) if they are informed of a Domestic Homicide.

The panel member from NHS England should be selected by the appropriate Sub-region Director of Nursing in collaboration with the regional lead facilitating/coordinating the DHR management process. The panel member will provide an update to the relevant (regional and Sub-region) leads on monthly basis (or as agreed).

When to declare a serious incident?

A serious incident should be declared and managed in line with this policy The initiation of a DHR does not automatically constitute a serious incident in the healthcare service.

On-going assistance and oversight for DHRs

NHS England regional teams must keep a library of recommendations for panel members to access, and panel member must work with regional leads to ensure recommendations are consistent and achievable. This can then fed into an annual Domestic Homicide report.

All regional leads should liaise closely with colleagues in the Home Office to support the review and evaluation of the Home Office Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews. The four regional leads will produce, with appropriate support, an Annual Report for NHS England on Domestic Homicide and the NHS.

Appendix 5: Assigning Accountability: RASCI model

1. Providers of NHS funded care often deliver services commissioned by different commissioning organisations. These may include, NHS England, multiple CCGS and Local Authorities. This can lead to uncertainty and ambiguity in relation to serious incident management.

2. Therefore, within each provider (where there are multiple commissioners), it is recommended that a 'lead commissioner' (usually the commissioner with the greatest contract value) is identified to lead oversight of serious incident management across the organisation. This should be formally agreed for each contract (e.g. through a collaborative agreement).

3. Accountable commissioners (i.e. contract signatory) must work collaboratively with and through other commissioners, to ensure the reporting arrangements are included within contracts. Whilst they may delegate responsibilities for serious incident management to other commissioners they remain accountable for quality assuring the robustness of the serious incident investigation, learning and action plan implementation undertaken by their providers.

4. It is recommended that each contract should have a RASCI (Responsible; Accountable; Supporting; Consulting; Informed) matrix (see table below) to support the robust and effective oversight management of serious incidents. The matrix must clearly identify the Accountable (Contracting) Commissioner (whether NHS England or a CCG) regardless of any delegation of management responsibilities.

5. Where serious incidents occur within services without a RASCI model, it is recommended that a model is developed and agreed by the relevant commissioning organisations to ensure roles and responsibilities in relation to managing the incident are clearly set out.

6. Involving NHS England as direct commissioners:

    a. NHS England has direct commissioning responsibilities[15] which are discharged via its sub-regions. The commissioning functions within the sub-regions vary (some have specific functions in commissioning specialised services or healthcare within the health and justice system for example). Wherever possible however, NHS England is working towards a consistent approach where quality and safety concerns are managed at a local level providing this is feasible given the level of local resource and expertise to manage such concerns.

    b. The functions of NHS England Sub-regions are described as follows:

        - **Originating Sub-region** – Sub-region where the patient comes from.

        - **Geographical Host Sub-region** (or Local Sub-region) – the Sub-region in whose local boundary a service is located.

- **Functional Host Sub-region** – Sub-regions with additional commissioning responsibilities i.e. specialised commissioning. These Sub-regions have an extended functional boundary. For specialised commissioning it has been agreed that the Functional Host will support the Geographical host to manage responsibility for quality concerns. The Functional Host will therefore populate a RASCI template (Responsible; Accountable; Supporting;Consulting; Informed) for each provider within their "functional" area in readiness to support the Geographical Host Sub-region to undertake their quality assurance functions[vi]

- **Accountable (contracting) Sub-region** – the Sub-region which negotiates and holds the contract for NHS England and is accountable for quality assuring the robustness of the serious incident investigation, learning and action plan implementation undertaken by their providers accountable for the quality of the services. This Sub-region may also be the geographical and/or functional host.

7. In some circumstances the originating, geographical host, functional host and accountable (contracting) Sub-region are all located in different Sub-regions and in such circumstance a RASCI model proves fundamental for ensuring serious incident are appropriately managed.

Appendix 6: Never Events

The Never Events policy and framework sets out the NHS's policy on Never Events.

It explains what they are and how staff providing and commissioning NHS funded service should identify, investigate and manage the response to them. It is relevant to all NHS funded care.

Never Events are serious incidents that are entirely preventable because guidance or safety recommendations providing strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers**.**

The revised Never Events policy and framework and updated Never Events list was published in January 2018, to become active upon initiation of the update to the 2017–2019 NHS Standard Contract on 1 February 2018.

Summary of January 2018 revisions

Revisions to the Never Events policy and framework have been made following a consultation with stakeholders at the end of 2016.

In response to the consultation and to further support learning from Never Events, the main changes to the revised policy and framework are:

- the removal of the option for commissioners to impose financial sanctions on trusts reporting Never Events
- to align the Never Events policy and framework with the Serious Incident framework, to achieve consistency across the two documents (a revised Serious Incident framework will be published later in 2018)
- revisions to the list of Never Events, including two additional types of Never Event.*
- *Details of the rationale for amendments to the Never Events list can be found in appendix C of the Never Events list.

The January 2018 revised Never Events policy and framework supersedes the previous version published by NHS England in March 2015

Never Events policy and framework (Revised January 2018)

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

Learning from what goes wrong in healthcare is crucial to preventing future harm, but it requires a culture of openness and honesty to ensure staff, patients, families and carers feel supported to speak up in a constructive way.

The revised Never Events policy and framework are designed to support the NHS to do that, and are part of continuing efforts to build a learning culture and maximise opportunities to keep our patients safe.

Our revision of the framework has been informed by your response to the consultation at the end of 2016. The consultation asked if the previous Never Events policy and framework were fit for purpose, and if the list of incidents continued to reflect the definition of a Never Event – that is, incidents on the list should be avoidable if available preventative measures have been implemented.

One of the key changes we have made in response to what you told us is to remove the option to impose financial sanctions associated with Never Events. We heard that allowing commissioners to impose financial sanctions following Never Events reinforced the perception of a 'blame culture'. Our removal of financial sanctions should not be interpreted as a weakening of effort to prevent Never Events. It is about emphasising the importance of learning from their occurrence, not blaming.

The revised Never Events framework will be aligned with a new Serious Incident framework due to be published later in 2018. We will shortly be launching an engagement exercise around the Serious Incident framework, but the plan to align the two documents will go ahead as Never Events should always be treated as Serious Incidents.

We have also looked at the list of Never Events. A reference group comprising NHS Improvement and NHS England regional quality leads, members of the patient safety team at NHS Improvement and clinical advisors reviewed the list alongside all the new suggestions that were made for Never Events in response to the consultation. Two types of Never Event have been added – unintentional connection of a patient requiring oxygen to an air flowmeter and undetected oesophageal intubation – and the definitions of some existing Never Events have been revised. Further detail is provided in the Never Events list 2018.

This document is a resource for patients, boards and all healthcare clinical and management staff. However, we particularly ask that all board members and other leaders of healthcare organisations consider this revised framework, and that medical and nursing directors in provider and commissioning organisations ensure that all relevant guidance is followed – both to prevent Never Events and to learn from Never Events when they do occur.

Celia Ingham Clark - Interim National Director of Patient Safety NHS Improvement

1. Policy statement

1.1. Never Events are incidents that require investigation under the Serious Incident framework. In 2018 the Never Events policy and framework will be merged with the revised Serious Incident framework. Until then, this policy should always be read in conjunction with the current Serious Incident framework.

1.2. The Never Events policy and framework is relevant to all NHS-funded care.

2. Acknowledgements

2.1. The Never Events policy and framework have been revised following a wide consultation of patients, healthcare providers, commissioners, regulatory and supervisory bodies, patient safety experts, professional organisations and royal colleges. We thank everyone for their contribution.

3. Purpose

3.1. Never Events are defined as Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. Strong systemic protective barriers are defined as barriers that must be successful, reliable and comprehensive safeguards or remedies – for example, a uniquely designed connector that stops a medicine being given by the wrong route. The importance, rationale and good practice use of relevant barriers should be fully understood by and robustly sustained throughout the system, from suppliers, procurers, requisitioners, training units to frontline staff.

3.2. The Never Events policy and framework are designed to provide healthcare workers, clinicians, managers, boards and accountable officers with clarity on their responsibilities and on the principles of Never Events. In particular, these people should know what they are expected to do to prevent Never Events and how they must respond if they occur, including how they report a Never Event.

3.3. Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes and so this policy and framework provide the NHS with an essential lever for improving patient safety.

3.4. NHS Improvement's vision of high quality, compassionate and constantly improving healthcare requires us to nurture the necessary culture and conditions, including openness and transparency, evidence-based decision- making and a commitment to lifelong learning. As Don Berwick noted: "…standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning."(1)[16]

3.5. The Never Events policy and framework support our vision by requiring honesty, accountability and learning in response to a group of incidents that can be prevented if accepted practice (including available preventative measures) has been implemented.

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[16] **(1)** Department of Health (August 2013) A promise to learn – a commitment to act: improving the safety of patients in England August 2013. Available at: www.gov.uk/government/publications/berwick-review-into-patient-safety

3.6. In this context, it is important that when a Never Event occurs, regardless of the outcome, the problems in care are identified and analysed through full investigation using a systems-based investigation method (such as root cause analysis – RCA) to understand how and why they occurred (from a systems perspective), as described in the Serious Incident framework. This will mean effective and targeted action can be taken to prevent recurrence.

3.7. Supporting staff to recognise Never Events is essential so that the opportunity to investigate, learn and improve can be identified in a timely way before vital information is lost.

4. Definition

4.1. The types of incident defined as Never Events using the criteria below are listed in the Never Events list 2018.

4.2. Never Events are incidents that meet all the criteria given in 4.3 to 4.6 below, and require full investigation under the Serious Incident framework.

4.3. Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations[17] that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

4.4. Each Never Event type has the potential to cause serious patient harm or death. However, serious harm [18]or death does not need to have happened as a result of a specific incident for that incident to be categorised as a Never Event.

4.5. For each Never Event type, there is evidence that the Never Event has occurred in the past – for example, through reports to the National Reporting and Learning System (NRLS) – and that the risk of recurrence remains.([19]

4.6. Each Never Event type must be able to be clearly defined and its occurrence easily recognised – this requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.

4.7. The Never Event list is reviewed regularly by NHS Improvement.

4.8 The NHS Improvement patient safety team does not act as an arbiter of whether a particular incident is a Never Event. This is agreed between provider and commissioner. The national team can advise on whether a type of Serious Incident qualifies as a Never Event as defined in the framework.

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[17] As compiled by NHS Improvement patient safety experts and healthcare professionals, and referenced in the Never Events list 2018. These include: physical barriers (eg equipment that makes it impossible to connect medications via the wrong route); time and place barriers (eg withdrawal of concentrated medications from settings to prevent them being accidentally selected) or systems of double or triple checking where these are supported by visual or computerised warnings, standardised procedures or memory/communication aids. As all human action is vulnerable to human error, particularly where there is a risk of staff becoming overloaded, processes that rely solely on one staff member checking the actions of another or referring to written policies are not strong barriers.

[18] Serious harm: severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care); chronic pain (continuous, long-term pain lasting more than 12 weeks or beyond the time that healing post trauma or surgery should have occurred) or psychological harm; impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is unlikely to be temporary (that is, has lasted or is likely to last for a continuous period of at least 28 days).

[19] As this policy aims to drive patient safety improvement, it excludes incident types eradicated by technical, medical or scientific advances.

5. Learning from incidents

5.1. Learning from incidents requires timely incident reporting in a fair, open and just culture. Blame is not a useful lever for learning because: "…a patient safety incident cannot simply be linked to the actions of the individual healthcare staff involved. All incidents are also linked to the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring"[20].

6. Organisational leadership

6.1. This policy and framework apply nationally, and all levels of healthcare organisations – from 'ward to board' – must play their part. Ultimately, however, and for clarity, an organisation's leadership is accountable for the occurrence of Never Events and crucially for the organisation's response.

6.2. The chief executive, all board members, other relevant organisation leaders and all relevant teams should know about any Never Event occurring in their organisation, and view each as an opportunity to investigate effectively and take meaningful targeted action(s) that measurably reduces risk of recurrence to improve patient safety. Repeated Never Events, particularly of the same type, signal ongoing problems in systems that previous investigations may not have identified or their recommendations (and resulting actions) have failed to address. Leaders should focus on maintaining systems that prevent Never Events from occurring in the first place. However, leaders must also provide support, investment and attention to enable effective investigation and meaningful improvement action (which measurably reduces the risk of recurrence) when Never Events do occur.

7. Requirements – when a Never Event is identified

7.1. Never Events are incidents that require full investigation under the Serious Incident framework. The requirements for reporting, principles for investigation, and the roles and responsibilities associated with the management and oversight of other Serious Incidents apply, including the need to fully and meaningfully engage patients, families and carers at the beginning of and throughout any investigation. Further information can be found in the Serious Incident framework.

7.2. As with other incidents that are classified as Serious Incidents, Never Events must be reported to both the strategic executive information system (StEIS) and the NRLS until the new patient safety incident management system is in place. Crucially, reports to both the NRLS and StEIS must clearly label the incident as a Never Event, even if this status is uncertain at the time of reporting (both systems contain a Never Events field). If necessary, and with provider and commissioner agreement, incident reports on StEIS can be retrospectively amended if it is found that the incident did not meet the definition of a Never Event. A clear audit trail explaining the rationale for the change and who authorised this should be recorded.

7.3. Organisational leaders (board or equivalent) are responsible for ensuring that any occurrence of a Never Event is analysed fully using a systems- based investigation method (such as RCA) to understand how and why it occurred (from a systems perspective). Leaders must then ensure that actions which measurably reduce the risk of recurrence are taken. Monitoring processes must support implementation and delivery of effective actions – this is the crucial aspect of this policy and framework.

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[20] National Patient Safety Agency (2004–2009) Seven steps to patient safety. Available at: www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

7.4. Incidence of Never Events must be identified in the commissioner's annual report and the provider's quality accounts (ensuring patient confidentiality). This should include:

- data on the type and number of Never Events, including historical context and related incidents
- the learning stemming from the incidents, with a focus on the system changes made to reduce the probability of recurrence
- how learning has been shared at all levels in the organisation and externally.

7.5. In some instances, Never Events may be identified sometime after they occurred. While delayed identification is not a factor in determining whether an incident is a Never Event, it may have a bearing on the improvements deemed necessary following investigation (e.g. where subsequent procedural changes mean that additional action may be unnecessary).

7.6. Where a Never Event is discovered by one organisation but appears to be the responsibility of another, the 'discovering' organisation should inform the originating organisation and is not required to report the incident as its own.

7.7. Some definitions of Never Events have changed in this revision of the framework. Where incidents that used to meet the definition of a Never Event but no longer do so (for example, wrong level spinal surgery) are identified after publication of the new framework, they should not be reported as Never Events even if they occurred before publication. Previously reported Never Events, even if they no longer meet the definition of a Never Event, should not be retrospectively downgraded.

7.8. As a rule, local healthcare organisations should consider the status of the incident at the time it occurred, particularly whether it met the Never Event criteria. If the incident pre-dated clear, easy to apply guidance on prevention or the introduction of the Never Event framework in 2009, it is not a Never Event. But if such guidance was available at the time but not acted on, the incident could be considered a Never Event in all but name, and treated appropriately.

8. Failure to report a Never Event

8.1. Failure to report a Never Event is unacceptable and can signal cultural and safety failings in an organisation. The reporting and investigation of Never Events may be an indicator of the organisation's attitude to patient safety and openness. As noted by Sir Liam Donaldson: "to err is human, to cover up is unforgivable, and to fail to learn is inexcusable". (6)

8.2 In some circumstances it may not be apparent that an incident is a Never Event until there has been some degree of investigation. In these circumstances, the possibility that a Never Event has occurred should be reported as soon as it is identified.

8.3. Failure to report a Never Event should be thoroughly investigated by the relevant organisational lead, with support from commissioners as required, to understand what prevented the recognition and/or reporting of the incident. This may lead to efforts to develop knowledge/awareness about incident reporting (and Never Events more specifically) and/or broader initiatives to measure and improve reporting culture as part of a wider safety culture in the organisation. If the failure to report was a deliberate act, this is likely to constitute a serious failing by the staff and organisation involved and will likely constitute a breach of Care Quality Commission (CQC) requirements (regulations 16 and 18 of the CQC (Registration) Regulations 2009).

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

Surgical

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post procedure

Medication

4. Mis-selection of a strong potassium solution
5. Administration of medication by the wrong route
6. Overdose of insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis-selection of high strength midazolam during conscious sedation

Mental health

9. Failure to install functional collapsible shower or curtain rails

General

10. Falls from poorly restricted windows
11. Chest or neck entrapment in bed rails
12. Transfusion or transplantation of ABO-incompatible blood components or organs
13. Misplaced naso- or oro-gastric tubes
14. Scalding of patients
15. Unintentional connection of a patient requiring oxygen to an air flowmeter
16. Undetected esophageal intubation

Appendix A: Wrong implant/prosthesis
Appendix B: Retained foreign object post procedure
Appendix C: Rationale for amendments to the Never Events list (including consideration of the October 2016 open consultation)

All organisations providing NHS care should use the following list that becomes active on initiation of the updated 2017-19 NHS Standard Contract on 1 February 2018.

Surgical

1. Wrong site surgery

An invasive procedure[21] performed on the wrong patient or at the wrong site (e.g. wrong knee, eye, limb, tooth). The incident is detected at any time after the start of the procedure.

Excludes:

- removal of wrong primary (milk) teeth unless done under a general anesthetic
- interventions where the wrong site is selected because the patient has unknown/unexpected anatomical abnormalities; these should be documented in the patient's notes
- wrong level spinal surgery*
- wrong site surgery due to incorrect laboratory reports/results or incorrect referral letters
- contraceptive hormone implant in the wrong arm.

***Excluded from the current list while NHS Improvement works with the relevant professional organisations to ensure development of robust national barriers to prevent this incident.**

Setting: All settings providing NHS-funded care.

National safety requirement:

- Safer Practice Notice – Wristbands for hospital inpatients improves safety (2005). The key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safer Practice Notice – Standardising wristbands improves patient safety (2007). The key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – WHO surgical safety checklist (2009). The key points in the alert are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safe Anaesthesia Liaison Group – Stop before you block (2011).
- The Royal College of Radiologists – Standards for providing a 24-hour interventional radiology service (2008).
- Faculty of Pain Medicine – Safety checklist for interventional pain procedures under local anesthesia or sedation (2017).
- Royal College of Surgeons (Faculty of General Dental Practice) – Toolkit for the prevention of wrong tooth extraction (2017).
- National safety standards for invasive procedures (NatSSIPs) (2015).
- Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).

2. Wrong implant/prosthesis

Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient.

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[21] The start of an invasive procedure is when a patient's anatomy begins to be permanently altered. For example, this is when the first incision is made that will scar the patient and take time to heal and recover from.
Includes: Interventions that are considered to be surgical but may be done outside a surgical environment – for example, wrong site block (including blocks for pain relief), biopsy, interventional radiology procedure, cardiology procedure, drain insertion and line insertion (eg peripherally inserted central catheter (PICC)/ Hickman lines). This also includes teeth extracted in error that are immediately reimplanted.

Excludes:

- placed implant/prosthesis is intentionally different from that specified in the surgical plan, based on clinical judgement at the time of the procedure
- specified implant/prosthesis is placed as planned but later found to be **suboptimal**
- implant/prosthesis is different from the one specified due to incorrect preprocedural measurements or incorrect interpretation of the preprocedural data – for example, wrong intraocular lens placed due to wrong biometry or using wrong dataset from correct biometry.

Includes:

- implantation of an intrauterine contraceptive device different from the one in the procedural plan.

See Appendix A for examples of correct application of this Never Event definition.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Safer Practice Notice – Wristbands for hospital inpatients improves safety (2005). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safer Practice Notice – Standardising wristbands improves patient safety (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – WHO surgical safety checklist (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- National safety standards for invasive procedures (NatSSIPs) (2015).
- Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).

3. Retained foreign object post procedure

Retention of a foreign object in a patient after a surgical/invasive procedure.

'Surgical/invasive procedure' includes interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside the surgical environment – for example, central line placement in ward areas.

'Foreign object' includes any items subject to a formal counting/checking process at the start of the procedure and before its completion (such as for swabs, needles, instruments and guidewires) except where items:

- not subject to the formal counting/checking process are inserted any time before the procedure, with the intention of removing them during the procedure but they are not removed
- subject to the counting/checking process are inserted during the procedure and then intentionally retained after its completion, with removal planned for a later time or date as clearly recorded in the patient's notes
- are known to be missing before completion of the procedure and may be inside the patient (eg screw fragments, drill bits) but action to locate and/or retrieve them is

impossible or more damaging than retention.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – WHO surgical safety checklist (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safer Practice Notice – Reducing the risk of retained throat packs after surgery (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – Reducing the risk of retained swabs after vaginal birth and perineal suturing (2010). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- National safety standards for invasive procedures (NatSSIPs) (2015).
- Patient Safety Alert – Supporting the introduction of the national safety standards for invasive procedures (2015).

Medication

4. Mis-selection of a strong potassium solution

Mis-selection refers to:

- when a patient is intravenously given a strong2 potassium solution rather than the intended medication.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – Potassium chloride concentrate solutions (2002; updated 2003). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

5. Administration of medication by the wrong route

The patient is given one of the following:

- intravenous chemotherapy by the intrathecal route
- oral/enteral medication or feed/flush by any parenteral route
- intravenous medication that was intended to be administered by the epidural route.*

* During the transition period for the introduction of NRFit™ devices, the ‘intravenous administration of a medicine intended to be administered by the epidural route’ cannot be considered a Never Event. An update will be provided when this period ends.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – Promoting safer measurement and administration of liquid medicines via oral and other enteral routes (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

2 ≥10% potassium w/v (eg ≥0.1 g/mL potassium chloride, 1.3 mmol/mL potassium chloride).

- Patient Safety Alert – Safer practice with epidural injections and infusions (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

6. Overdose of insulin due to abbreviations or incorrect device

Overdose refers to when:

- a patient is given a 10-fold or greater overdose of insulin because the words 'unit' or 'international units' are abbreviated; such an overdose was given in a care setting with an electronic prescribing system [22]
- a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin
- a healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Rapid Response Report – Safer administration of insulin (2010). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – Risk of severe harm and death due to withdrawing insulin from pen devices (2016).

7. Overdose of methotrexate for non-cancer treatment

Overdose refers to when:

- a patient is given a dose of methotrexate, by any route, for non-cancer treatment that is more than the intended weekly dose; such an overdose was given in a care setting with an electronic prescribing system.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – Improving compliance with oral methotrexate guidelines (2006). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

8. Mis-selection of high strength midazolam during conscious sedation

[22] Electronic prescribing, dispensing and administration systems are an evidence-based method to reduce patient harm from medicines. All NHS organisations should introduce them as soon as possible. When the definitions for the insulin and methotrexate overdose Never Events were revised in 2015, it was agreed that those for insulin given in overdose because of the use of abbreviations
for 'unit' and for all methotrexate overdose incidents would only apply to care settings with electronic prescribing systems as indicated. The systemic protective barriers for these two types of Never Event were found not to be strong enough in care settings where electronic barriers do not exist. For example, even though most acute hospitals do use a preprinted insulin prescription to try and prevent prescribers using the abbreviations 'iu' or 'u', this is not the case in all care settings. Also, preprinted prescriptions on their own are not a reliably strong enough barrier to prevent a potential 10-fold dosing error as prescribers can still prescribe insulin on general prescriptions.

Mis-selection refers to when:

- a patient is given an overdose of midazolam due to the selection of a high strength preparation (5 mg/mL or 2 mg/mL) instead of the 1 mg/mL preparation, in a clinical area performing conscious sedation
- excludes clinical areas where the use of high strength midazolam is appropriate; these are generally only those performing general anaesthesia, intensive care, palliative care, or areas where its use has been formally risk-assessed in the organisation.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Rapid Response Report – Reducing risk of overdose with midazolam injection in adults (2008). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

Mental health

9. Failure to install functional collapsible shower or curtain rails

Involves either:

- failure of collapsible curtain or shower rails to collapse when an inpatient attempts or completes a suicide
- failure to install collapsible rails and an inpatient attempts or completes a suicide using non-collapsible rails.

Setting: All settings providing NHS-funded mental health inpatient care.

National safety requirement:

Health building notes:

- Health building note 03-01 – Adult acute mental health units (2013).
- Health building note 03-02 – Facilities for child and adolescent mental health services (CAMHS) (2017).

Estates and facilities alerts:

- NHS England SN 01 – Cubicle rail suspension system with load release support systems (2002).
- NHS England 03 – G-rail 2301, window curtain tracking system (2004).
- NHS England 08 – Cubicle rail tracking and PVC dustcovers (2004).
- NHS England 10 – Bed cubicle rails, shower curtains rails, and curtain rails in psychiatric in-patient settings (2004).
- Department of Health 08 – Cubicle curtain track rail (2007).
- EFA/2010/003 – Anti-ligature curtain rails (including shower curtains): Risks from incorrect installation or modification (2010).
- EFA/2010/10 – Flush fitting anti-ligature curtain rails: ensuring correct installation (2010).

General

10. Falls from poorly restricted windows

A patient falling from a poorly restricted window[23]. This applies to:

- windows 'within reach' of patients; this means windows (including the window sills) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to climb out of the window
- windows located in facilities/areas where healthcare is provided and that patients can and do access
- where patients deliberately or accidentally fall from a window where a fitted restrictor is damaged or disabled, but not where a patient deliberately disables a restrictor or breaks the window immediately before they fall
- where patients can deliberately overcome a window restrictor using their hands or commonly available flat-bladed instruments as well as the 'key' provided.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Health Building Note 00-10 Part D – Windows and associated hardware.
- Department of Health Estates and Facilities Alert – Window restrictors of cable and socket design (2014).
- Health and Safety Executive Risk of falling from windows (2016).

11. Chest or neck entrapment in bed rails

Entrapment of a patient's chest or neck between bedrails or in the bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance.

Setting: All settings providing NHS-funded care including care homes, and patients' own homes where equipment for their use has been provided by the NHS.

National safety requirement:

- Medicines and Healthcare products Regulatory Agency – Safe use of bed rails (2013).

12. Transfusion or transplantation of ABO-incompatible blood components or organs

Unintentional ABO-mismatched solid organ transplantation.

Unintentional transfusion of ABO-incompatible blood components.

Excludes:

- where ABO-incompatible blood components are deliberately transfused with appropriate management.

Excludes:

[23] This includes windows where the provider has not put a restrictor in place in accordance with guidance.

- situations in which clinically appropriate ABO-incompatible solid organs are deliberately transplanted.

In this context, 'incompatible' antibodies must be clinically significant. If the recipient has donor-specific anti-ABO antibodies and is therefore likely to have an immune reaction to a specific ABO-compatible organ, the inadvertent transplantation of that organ without appropriate management is a Never Event.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Department of Health CEM/CMO/2017/005 – Safe transfusion practice: use a bedside checklist (2017).
- British Society for Histocompatibility and Immunogenetics and British Transplantation Society – Guidelines for the detection and characterisation of clinically relevant antibodies in allotransplantation (2014).
- British Transplantation Society – Guidelines for antibody incompatible transplant (2015).
- Safer Practice Notice – Wristbands for hospital inpatients improves safety (2005). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

- Safer Practice Notice – Standardising wristbands improves patient safety (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

13. Misplaced naso- or oro-gastric tubes

Misplacement of a naso- or oro-gastric tube in the pleura or respiratory tract that is not detected before starting a feed, flush or medication administration.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – Nasogastric tube misplacement: continuing risk of death and severe harm (2016).
- NHS Improvement – Initial placement checks for nasogastric and orogastric tubes: resource set (2016).

14. Scalding of patients

Patient scalded by water used for washing/bathing.

Excludes:

- scalds from water being used for purposes other than washing/bathing (eg from kettles).

Setting: All settings providing NHS-funded care.

National safety requirement:

- HTM 04-01 – Safe water in healthcare premises (2006, updated 2017).

- Health Building Note 00-10 Part C – Sanitary assemblies (2013).
- Health and Safety Executive – Managing the risks from hot water and surfaces in health and social care (2012).
- Health and Safety Executive – Scalding and burning (2012).

15. Unintentional connection of a patient requiring oxygen to an air flowmeter

This applies when a patient who requires oxygen is connected to an air flowmeter when the intention was to connect them to an oxygen flowmeter.

Excludes:

- unintentional connection to an air cylinder instead of an oxygen cylinder as robust barriers to prevent this have not yet been identified.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – Reducing the risk of oxygen tubing being connected to air flowmeters (2016).

16. Undetected oesophageal intubation

Ventilation of a patient following oesophageal intubation instead of the intended tracheal intubation, which is not identified because capnography is not used or capnography readings indicating the need for tracheal intubation are not acted on.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Association of Anaesthetists of Great Britain and Ireland (AAGBI) – Standards of monitoring during anaesthesia and recovery (2015).

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Wrong implant/prosthesis

Earlier definitions of the Never Event type 'wrong implant/ prosthesis' were not consistently applied with regard to wrong intraocular lenses (IOL). The examples below assist with consistent application of the current clarified definition. They are intended solely as **examples of the principles of the definition**, and are not a complete list of circumstances where the definition applies.

Circumstances	Does this fit the Never Event definition?
A patient attended hospital for a right phacoemulsification and IOL procedure. The surgeon – a senior trainee – discussed the risks and benefits of right cataract surgery and the target refractive outcome with the patient, who consented to the procedure with the aim of achieving an emmetropic (no distance glasses) outcome. A +20.5 dioptre (D) IOL was chosen and the IOL selection sheet was completed accordingly. At the WHO sign in the surgeon confirmed with the team he wanted a +20.5D IOL. A +20.0D IOL was presented during the time out section of the WHO checklist, which was completed by the consultant (not the surgeon), scrub nurse and operating department practitioner. The team did not identify that the lens power did not match that selected on the biometry and IOL selection sheet, and previously stated at the sign in. The senior trainee continued with surgery supervised by the consultant and a +20.0D IOL was implanted in error.	This is a Never Event. The surgeon clearly stated the surgical plan for a +20.5D IOL to the team. A different IOL was inserted.

A patient was admitted for right phacoemulsification and IOL. A toric IOL was planned to correct astigmatism. The IOL power was circled correctly on the biometry sheet and this was also correctly transcribed onto an IOL selection sheet. (continued on next page)	This is a Never Event. The surgeon stated in the surgical plan the wish to implant a certain model of lens but implanted a different model, which could not correct the astigmatism.

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The operation was cancelled as the list was running late and the patient was admitted a few days later for surgery by a different consultant. This surgeon confirmed at sign in and again at time out with the surgical team that a 19D model SN6AT (toric) lens was required as detailed in the notes, but did not confirm that a toric lens was required as planned. The lens presented to the surgeon was a 19D SA60AT (non-toric) and this was opened and inserted into the patient's eye.	
A patient attended hospital for a left phaocemulsification and IOL procedure. The surgeon confirmed with the patient that the aim of the procedure was emmetropia and circled a +17.5D IOL on the biometry sheet. The sheet had unexpectedly been printed in a different format, moving the data for the most commonly used IOL from where it normally appeared. This meant the wrong type of IOL was circled, an anterior chamber not a posterior chamber lens. All WHO checks were appropriately completed by the surgeon and the team, and a lens power of +17.5D was confirmed verbally by the surgeon to the team as the surgical plan. A +17.5D posterior chamber lens was inserted. At the postoperative review the patient was noted to be 3.5D hypermetropic and not emmetropic.	This is **not** a never event. The IOL inserted was the one stated in the surgical plan by the consultant. However, this surgical plan was wrong because the surgeon had chosen the power for a posterior chamber lens using data pertaining to an anterior chamber lens.

A patient was admitted for left phacoemulsification and IOL. The surgeon discussed the refractive aim with the patient; emmetropia was agreed and a +22D lens was circled on the biometry sheet. The IOL power was then unclearly transcribed onto an IOL selection sheet and later misread as 27D, not 22D. The surgeon confirmed the IOL as 27D to the team and all checks were completed. It was not noted that the original biometry sheet indicated a 22D IOL. A 27D lens was inserted. The patient was noted postoperatively to be myopic rather than emmetropic.	This is **not** a never event. The IOL inserted was that stated in the surgical plan by the consultant, but the surgical plan was based on information incorrectly transcribed from a poorly written document.

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Retained foreign object post procedure

Earlier definitions of the Never Event type ‘retained foreign object post operation’ were not consistently applied. The examples below assist with consistent application of the current clarified definition. They are intended solely as **examples of the principles of the definition** and are not a complete list of circumstances where the definition applies.

Note that the principles of the definition relate to items that should be subject to a formal counting or checking process at the start of the procedure and before its completion. The size of the retained foreign object and the potential for harm from the retained foreign object are irrelevant to the incident’s designation as a Never Event.

Circumstances	Does this fit the Never Event definition?

A patient underwent gynaecological surgery and a vaginal pack/vaginal tampon was intentionally left in place at the end of surgery, with removal planned for 48 hours after surgery. Unfortunately, the pack was not removed as planned and the patient was sent home with the pack still in place. She went to her GP complaining of vaginal discomfort and discharge. He examined her and found the pack.	This does **not** meet the definition of a Never Event as the vaginal pack was intentionally retained after the procedure. Once outside the controlled counting processes in theatre, the Never Event principle of being eminently preventable if existing guidance is followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via StEIS and the NRLS, with all possible steps taken to prevent similar events in future.

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A patient needed suturing after an episiotomy during a vaginal delivery. To create a clear view for the suturing procedure, three swabs were placed in the patient's vagina, to be removed as soon as suturing was complete. Only two swabs were removed. This error was realised when the swab fell out a few days after the patient and her baby went home.	This meets the definition of a Never Event. The swab was not intentionally retained. The number of swabs inserted and removed should have been counted at the time of the procedure.
A patient undergoing eye surgery as a day case had a pledget (a small swab) inserted under her eyelid an hour preoperatively to deliver topical medication. The pledget should have been removed during surgery but was not. The patient telephoned for advice about her painful eye the day after her procedure. When she returned to the unit to be examined the pledget was found and removed.	This does **not** meet the definition of a Never Event as the pledget was inserted outside the controlled counting processes in theatre. The Never Event principle of being eminently preventable if existing guidance is followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via StEIS and the NRLS, with all possible steps taken to prevent similar events in future.
A patient undergoing eye surgery as a day case had a pledget inserted under her eyelid at the beginning of the procedure. The pledget should have been removed at the end of the surgery but was not. The patient telephoned for advice the day after her procedure because her eye was painful. When she returned to the unit to be examined the pledget was found and removed.	This meets the definition of a Never Event. The pledget was not intentionally retained and the number of pledgets inserted and removed should have been counted at the time of the procedure.

A patient had an interventional cardiology procedure using a guidewire. When the doctor tried to withdraw the guidewire, it appeared to be stuck. It was left in place so that X-rays could be taken and expert advice sought before attempting to remove it.	This does **not** meet the definition of a Never Event as the guidewire was known to be retained before the procedure was completed, and immediate action to retrieve it was impossible or more damaging than retention. (continued)

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	This incident is still likely to fit the definition of a Serious Incident and should be reported via StEIS and the NRLS, with all possible steps taken to prevent similar events occurring in future. If an equipment fault is likely to be responsible, the incident should also be reported to the MHRA.
A patient had an interventional cardiology procedure using a guidewire. No problems with the procedure were noticed at the time, but an X-ray taken for another reason several days later revealed a broken-off guidewire tip lodged in a blood vessel.	This meets the definition of a Never Event as the guidewire should have been checked for completeness when it was withdrawn at the end of the procedure.

Rationale for amendments to the Never Events list (including consideration of the October 2016 open consultation)

Never Event	Amendment	Rationale
Wrong site surgery	Include pain relief blocks.	New guidance is available from the Faculty of Pain Medicine – *Safety checklist for interventional pain procedures under local anaesthesia or sedation* (2017).
Wrong site surgery	Clarification that the extraction of primary (milk) teeth is excluded unless done under a general anaesthetic.	The extraction of milk teeth is extremely unlikely to result in severe harm/death unless it is done under a general anaesthetic when the potential risks of anaesthesia could apply.
Wrong site surgery	Exclude spinal surgery.	There is no specific guidance available relating to preoperative identification/marking of the spinal level. NHS Improvement will be working with the British Orthopaedic Association to develop guidance.
Wrong site surgery	Exclude contraceptive hormone in the wrong arm.	Severe harm/death is extremely unlikely.
Wrong implant/ prosthesis	Includes the implantation of an intrauterine contraceptive device that differs from the one in the procedural plan.	The existing barriers to prevent implantation of the wrong implant/prosthesis also apply to intrauterine devices.

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Wrong implant/ prosthesis	Excludes where the implant/prosthesis differs from the one intended due to incorrect preprocedural measurements or incorrect interpretation of the preprocedural data, eg wrong intraocular lens due to wrong biometry or using the wrong dataset from correct biometry.	There are currently no robust barriers to prevent this from occurring.
Overdose of insulin due to abbreviations or incorrect device	Include when a healthcare professional withdraws insulin from an insulin pen or an pen refill and then administers it using a syringe and needle.	New guidance is available in the Patient Safety Alert *Risk of severe harm and death due to withdrawing insulin from pen devices* (2016).
Unintentional connection of a patient requiring oxygen to an air flowmeter	New Never Event.	New guidance is available in the Patient Safety Alert *Reducing the risk of oxygen tubing being connected to air flowmeters* (2016).
Undetected oesophageal intubation	New Never Event.	New guidance is available to prevent the ventilation of a patient following intended tracheal intubation and subsequent oesophageal intubation that is not recognised or acted on: Association of Anaesthetists of Great Britain and Ireland – *Standards of monitoring during anaesthesia and recovery* (2015).

Annexe1: RASCI Template (example only- to be adapted locally)

Provider:		Services And Service Address:							
	Key stakeholders								
			NHS England						
	Geographical Host CCG	Geographical Host Local Authority	Geographical Host Sub-region	Functional Host Sub-region	Contracting Sub-region	Originating Sub-region	CQC	Monitor/ TDA	Other- please state:
Organisation name:									
Function for Serious Incident Oversight (RASCI)									

RASCI Definitions[24]

Responsible - **(**Doer) - The team assigned to do the work

Accountable - (Buck stops here) - The team making the final decision with ultimate ownership

Supporting - (Here to help) - The functional host Sub-region that will support the geographical host Sub-region and the contracting host Sub-region in undertaking their quality assurance functions including ensuring there is timely reporting, investigation and learning and action plan implementation undertaken by the provider in response to serious incidents

Consulted - (In the Loop) - The team that must be consulted before a decision or action is taken

Informed - (For Your Information) - The team which must be informed that a decision or action has been taken

Appendix 7: Communications

A well-planned, structured communications plan is vital in managing serious incidents effectively. This should include a comprehensive proactive and reactive communications strategy for internal and external communication. The relevant staff should be briefed to ensure that they can appropriately respond to internal and external communication requirements.

The investigations team should;

- ensure openness and transparency is the default position – while patient confidentiality and data protection considerations must be maintained, any organisation using public money should be open and accountable to the public for its performance.
- ensure there is regular communication between the provider, the commissioner, the patient, victim, their family and other stakeholders. Communication should be tailored to the needs of the recipient(s) (see correspondence checklist below);
- have a clear plan for sharing information about serious incidents with staff and external partner organisations, the public and the media;
- have a clear plan for managing concerns that arise (helplines may be required for incidents effecting large populations);
- have a clear ongoing communications and engagement strategy, including clear arrangements for sign-off processes and spokespeople;
- inform communications leads in other local organisations in a timely and efficient manner (for example local authorities, CCGs, police);
- inform relevant sector or national stakeholders of what is happening; and
- monitor and track the impact of the communications strategy.

In forensic/criminal cases, all communications with the media should be led by the police in partnership with the relevant agencies involved with the incident.

Information relating to serious incidents (including information held on national systems such as StEIS, local databases and internal reports, investigation reports and root cause analysis and other documents), could be subject to a request for disclosure under the Freedom of Information Act. A request for information regarding a serious incident should follow Freedom of Information Act policies of the organisation that received the request.

Communication checklist

Regular communication will be necessary between the trust, the commissioner, the patients, victims, families and other stakeholders. Communication should be tailored to the needs of the recipient(s). The following are suggested issues to be considered when writing to different stakeholders.

Initial letter from the Trust to patients, families, victims and perpetrators

The initial correspondence should consider the following areas:

- Expression of condolence and regret:

- Describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police):
- Describe the current position in the investigation process:
- Describe factors that will influence the timescale of the investigation:
- Describe how the family will be involved in the investigation process:
- Describe how the information about the event will be assimilated and disseminated:
- Provide contact information for the person who will link with the family from the trust:
- Provide information on support systems/agencies for the family available from the trust and independently including the police family liaison officer.

Initial letter from the Trust to staff

The initial correspondence to staff should consider the following areas:

- Expression of condolence and regret about the incident:
- Acknowledgement of the impact on staff:
- Describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police):
- Describe the current position in the investigation process:
- Describe factors that will influence the timescale of the investigation:
- Describe how staff will be invited to be involved in the investigation process:
- Describe how the information about the event will be assimilated and disseminated:
- Provide contact information of the person who will link with the trust:
- Provide information on staff support systems available within the trust and independently.

Initial letter to the victim's family from the commissioner, where family liaison is transferred from the Trust (when for example, an independent investigation is required)

The initial correspondence to the family of the victim should consider the following areas:

- Expression of condolence and regret:
- Explain why the commissioner is the point of liaison and not the trust:
- Describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police):
- Describe the current position in the investigation process:
- Describe factors that will influence the timescale of the investigation:

- Describe how the family will be invited to be involved in the investigation process:
- Describe how the information about the event will be assimilated and disseminated:
- Provide contact information of the person who will link with the family from the commissioner:
- Provide information on the support systems/agencies available to the family, available from the trust and independently, including the police family liaison officer.

Initial letter to the perpetrator's family, where family liaison is transferred from the Trust (where applicable; for example, when an independent investigation is required following homicide committed by a patient in receipt of Mental Health Services)

The initial correspondence to the family of the perpetrator should consider the following areas;

- expression of condolence and regret;
- explain why the commissioner is the point of liaison and not the trust;
- describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police);
- describe the current position in the investigation process;
- describe factors that will influence the timescale of the investigation;
- describe how the family of the victim will be invited to be involved in the investigation process (if appropriate);
- describe how the information about the event will be assimilated and disseminated;
- provide contact information of the person who will link with the family of the perpetrator from the commissioner;
- provide information on independent support systems/agencies available to the family.

Letters inviting participation in the independent investigation

Receiving such correspondence may be very difficult for some people involved in the independent investigation. Consideration should be given to other methods of inviting participation- for example by a face-to-face request- in the presence of people who the recipient will find supportive.

Letters requesting participation in the independent investigation to families of victims and perpetrators, staff and other agencies' personnel

Correspondence inviting families, staff and other individuals to participate in the independent investigation should consider;

- acknowledging that participation may be difficult but may also be helpful to the person;
- describing the form of participation that is being requested and methods of participation available, for example one-to-one interview, with all family members

together, in the presence of other supporters such as staff representatives, advocates or friends, written submissions, use of video links;

- describing the status of written statements provided to the investigation;
- offering the person an opportunity to discuss the process with a named person before making a decision to participate;
- suggesting that the person discusses participation with an advocate or supporter who is independent of the process;
- describing the implications for the investigation process of participating or not participating;
- describing what will happen to the information that is provided after the independent investigation has been completed;
- describing how poor practice issues and whistle-blowing will be dealt with;
- detailing any limits to confidentiality for all participants in the process; and
- reaffirming messages contained within earlier correspondence.

Letters prior to publication of the independent investigation report to families of the victim, the perpetrator and other independent investigation participants

Consideration should be given to;

- acknowledging that the process of publication will be difficult for many involved in the independent investigation;
- describing how and where publication will occur, for example hard copy report, press statements,
- anticipated media involvement;
- anticipated response from the media and others with an interest in the published independent investigation report;
- stating that publication is the end of the independent investigation process;
- describing the process of how the investigation's recommendations will be enacted;
- describing how wider learning may occur, for example collation of reports for annual thematic review by the Regional Investigations Advisory Panel/National Confidential Inquiry
- inviting participants, particularly the family of the victim, to meet the independent investigation team or team leader, who can outline the findings of the report, recommendations, action plan;
- Reiterating forms of support that will be available to participants after publication of the independent investigation report.

Glossary

Abuse - A violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent. Abuse can occur in any relationship and may result in significant harm, or exploitation, of the person subjected to it[vii]

Specific forms of abuse are described in detail within *Working together to safeguard children (2010)* and guidance for safeguarding adults

Adverse Event/Incident - See Patient Safety Incident.

Being Open - Open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare.

Carers - Family, friends or those who care for the patient. The patient has consented to their being informed of their confidential information and to their involvement in any decisions about their care.

Child - The Children Act 1989 and the Children Act 2004 define a child as being a person up to the age of 18 years. The Children Act 2004 states that safeguarding, protection and cooperation between services may, in certain circumstances, be continued through to a young person's 19th birthday or beyond.

Clinical Governance - A Framework 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.

Commissioner - An organisation with responsibility for assessing the needs of service users, arranging or buying services to meet those needs from service providers in either the public, private or voluntary sectors, and assuring itself as to the quality of those services.

Clinical Commissioning Group - Clinically-led organisation that commissions most NHS-funded healthcare on behalf of its relevant population. CCGs are not responsible for commissioning primary care, specialised services, prison healthcare, or public health services.

Contributory Factors – the Root Cause Analysis Investigation tools, Contributory Factors Classification Framework available at: http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/ provides a breakdown of factors (e.g. patient or task related factors) and their components (e.g. co-morbidities, complexity of condition or out of date policy) which contributed to the problems in care or service delivery. The contributory factors should be identified as part of the investigation process before the root causes and solution are explored.

Culture - Learned attitudes, beliefs and values that define a group or groups of people.

Data Loss - There is no simple definition of a serious data loss incident. What may at first appear to be of minor importance may, on further investigation, be found to be serious and vice versa. Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.

Duty of Candour – a statutory requirement has been introduced to ensure health care providers operate in a more open and transparent way. The regulation for Duty of Candour applied to health service bodies from 27 November 2014.

Further information is available online at http://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20 and

http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf

NB: not all 'notifiable incidents' will meet the threshold for a serious incident

Equipment - Machines and medical devices used to help, prevent, treat or monitor a person's condition or illness. The term may also be used to refer to aids that may support a person's care, treatment, support, mobility or independence, for example, a walking frame, hoist, or furniture and fittings. It excludes machinery or engineering systems that are physically affixed and integrated into the premises.

General Practitioner - A medical practitioner who provides primary care to meet the general health needs of a registered population. General practitioners treat acute and chronic illnesses and provide preventative care and health education for all ages.

Healthcare - The preservation of mental and physical health by preventing or treating illness through services offered by the health professions, including those working in social care settings.

Healthcare Professional - Doctor, dentist, nurse, pharmacist, optometrist, allied healthcare professional or registered alternative healthcare practitioner.

Incident - an event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public.

Independent Healthcare - private, voluntary and not-for-profit healthcare organisations that are not part of the NHS.

Investigation - act or process of investigating – a detailed enquiry or systematic examination.

Major surgery – a surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, or tissue (if an extensive orthopaedic procedure is involved, the surgery is considered 'major').

Medical Device - Any instrument, apparatus, appliance, software, material or other article (whether used alone or in combination) (including software intended by its manufacturer to be used for diagnostic and/or therapeutic purposes and necessary for its proper application), intended by the manufacturer to be used for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, alleviation of or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy of a physiological process;
- control of conception

and which does not achieve its physical intended action on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

Never Events - Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike.

NHS-Funded Healthcare - Healthcare that is partially or fully funded by the NHS, regardless of the provider or location.

Notification - The act of notifying to one or more organisations/bodies.

Patient Safety - The process by which an organisation makes patient care safer. This should involve risk assessment, the identification and management of patient-related risks, the reporting and analysis of incidents, and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring. The term 'patient safety' is replacing 'clinical risk', 'non-clinical risk' and the 'health and safety of patients'.

Patient Safety Incident - Any unintended or unexpected incident that could have led or did lead to harm for one or more patients receiving NHS-funded healthcare.

Permanent Harm - Permanent lessening of bodily functions, including sensory, motor, physiological or intellectual.

Primary Care - Refers to services provided by GP practices, dental practices, community pharmacies and high street optometrists and commissioned by the NHS England from April 2013

Professional Body - An organisation that exists to further a profession and to protect both the public interest, by maintaining and enforcing standards of training and ethics in their profession, and the interest of its professional members.

Provider (or Healthcare provider) - Organisation that provides healthcare including NHS trusts, NHS Foundation Trusts, general medical practices, community pharmacies, optometrists, general dental practices and non-NHS providers.

Risk - The chance of something happening that will have an undesirable impact on individuals and/or organisations. It is measured in terms of likelihood and consequences.

Risk Management - Identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefit and cost.

Risk Summit - A meeting of high-level leaders called to shape a programme of action, which is focused on sharing information willingly to help achieve a consensus about the situation under scrutiny and the actions required to mitigate the identified risks

Root Cause Analysis (RCA) - A systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

Safety - A state in which risk has been reduced to an acceptable level.

Safeguarding - Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights. Children, and adults in vulnerable situations, need to be safeguarded. For children, safeguarding work focuses more on care and development; for adults, on empowerment, independence and choice.

Secondary care - Defined as a service provided by specialists who generally do not have first contact with patients. Secondary care is usually delivered in hospitals or clinics and patients have usually been referred to secondary care by their primary care provider (usually their GP). Most secondary care services are commissioned by CCGs.

Severe Harm - A patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.

Significant Event Audit - An audit process where data is collected on specific types of incidents that are considered important to learn about how to improve patient safety.

Specialised services - Specialised services are commissioned by NHS England and are services provided in relatively few hospitals, to catchment populations of more than one million people. The number of patients accessing these services is small, and a critical mass of patients is needed in each treatment centre in order to achieve the best outcomes and maintain the clinical competence of NHS staff. These services tend to be located in specialist hospital trusts in major towns and cities.

Tertiary Care - Specialised consultative health care, usually for inpatients and on referral from a primary or secondary health professional, in a facility that has personnel and facilities for advanced medical investigation and treatment, such as a tertiary referral hospital.http://en.wikipedia.org/wiki/Health_care - cite_note-11#cite_note-11

Treatment - Broadly, the management and care of a patient to prevent or cure disease or reduce suffering and disability.

Unexpected Death - Where natural causes are not suspected. Local organisations should investigate these to determine if the incident contributed to the unexpected death.

Working Day - Days that exclude weekends and bank holiday

Appendix 8.

Reporting of Personal Data Related Incidents

Principles

Serious Incidents involving data are classified in terms of severity on a scale of 0-5 in terms of either/both risk to reputation and risk to individuals as identified in figure 1 below:

Figure 1

<table>
<tr><th>0</th><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th></tr>
<tr><td>No significant reflection on any individual or body. Media interest very unlikely.</td><td rowspan="2">Damage to An individual's reputation. Possible media interest, e.g. celebrity involved. Potentially serious breach. Less than 5 people affected or risk assessed as low, e.g. files were encrypted.</td><td rowspan="2">Damage to a team's reputation. Some local media interest that may not go public. Serious potential breach and risk assessed high e.g. unencrypted clinical records lost. Up to 20 people affected.</td><td>Damage to a services reputation/ low key local media coverage.</td><td>Damage to an organisation's reputation/ local medial coverage.</td><td>Damage to NHS reputation/ national medial coverage.</td></tr>
<tr><td>Minor breach of confidentiality. Only single individual affected.</td><td>Serious breach of confidentiality e.g. up to 100 people affected.</td><td>Serious breach with either particular sensitivity e.g. sexual health details or up to 1000 people affected.</td><td>Serious breach with potential for ID theft or over 1000 people affected.</td></tr>
</table>

Incidents classified as a severity rating of 3 or above should also be reported to the Information Commissioner.

Section 1 – to be completed for all policies

Equality Analysis

NB - It is the responsibility of the author / reviewer of this document to complete / update the Equality Analysis each time it has a full review and to contact the Equality Diversity and Inclusion Lead if a full equality impact analysis is required

Equality Impact Analysis Screening Form

Title of activity	Serious incident policy		
Date form completed	January 2021	Name of lead for this activity	Joanne Gooch

Analysis undertaken by:		
Name(s)	Job role	Department
Joanne Gooch	Quality Assurance Manager	Quality Team

What is the aim or objective of this activity?	This policy outlines the arrangements for reporting, managing, analysing and learning from serious incidents, including support for patients and their families/carers and staff.
Who will this activity impact on? *E.g. staff, patients, carers, visitors etc.*	The policy is intended to benefit all population groups by improving the quality of patient care.

Potential impacts on different equality groups:

Equality Group	Potential for **positive** impact	**Neutral** Impact	Potential for **negative** impact	Please provide details of how you believe there is a potential positive, negative or neutral impact (and what evidence you have gathered)
Age	☒	☐	☐	
Disability	☒	☐	☐	
Gender reassignment	☒	☐	☐	
Marriage & civil partnerships	☒	☐	☐	
Pregnancy & maternity	☒	☐	☐	
Race	☒	☐	☐	
Religion or belief	☒	☐	☐	

Sex	☒	☐	☐	
Sexual Orientation	☒	☐	☐	
Additional Impacts ***(what other groups might this activity impact on? Carers, homeless, travelling communities etc.)***	☒	☐	☐	

If you have ticked one of the above equality groups please complete the following:

Level of impact

	Yes	No
Could this impact be considered direct or indirect discrimination?	☐	☒
If yes, how will you address this?		

	High	Medium	Low
What level do you consider the potential negative impact would be?	☐	☐	☐

If the negative impact is high, a full equality impact analysis will be required.

Action Plan

How could you minimise or remove any negative impacts identified, even if this is rated low?
How will you monitor this impact or planned actions?
Future review date: When policy is next reviewed.