

# **Serious Incident Framework**

Supporting learning to prevent recurrence

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# **Serious Incident Framework**

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## Foreword

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.

Over the last decade the NHS has made significant progress in developing a standardised way of recognising, reporting and investigating when things go wrong and a key part of this is the way the system responds to serious incidents. Serious incidents in health care are events 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 our particular attention to ensure these incidents are identified correctly, investigated thoroughly and, most importantly, trigger actions that will prevent them from happening again.

Following the implementation of the Health and Social Care Act 2012, a revised Serious Incident Framework was published in March 2013 to reflect the changed structures in the NHS. At the time we committed to review this Framework after a year of operation to understand how well the system was able to implement it. Therefore, over 2014 we have reviewed the Serious Incident Framework to ensure that it is fit for purpose and that it supports the need to take a whole-system approach to quality improvement.

As part of this review we have continued to promote and build on the fundamental purpose of patient safety investigation, which is to learn from incidents, and not to apportion blame. We have also continued to endorse the application of the recognised system-based method for conducting investigations, commonly known as Root Cause Analysis (RCA), and its potential as a powerful mechanism for driving improvement.

This revised Framework has been developed in collaboration with healthcare providers, commissioners, regulatory and supervisory bodies, patients and families and their representatives, patient safety experts and independent expert advisors for investigation within healthcare. While the fundamental principles of serious incident management remain unchanged, a number of amendments have been made in order to;

- emphasise the key principles of serious incident management;
- more explicitly define the roles and responsibilities of those involved in the management of serious incident;
- highlight the importance of working in an open, honest and transparent way where patients, victims and their families are put at the centre of the process;
- promote the principles of investigation best practice across the system; and

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- focus attention on the identification and implementation of improvements that will prevent recurrence of serious incidents, rather than simply the completion of a series of tasks.

In order to simplify the process of serious incident management, two key operational changes have also been made:

1. Removal of grading – we found that incidents were often graded without clear rationale. This causes debate and disagreement and can ultimately lead to incidents being managed and reviewed in an inconsistent and disproportionate manner. Under the new framework serious incidents are not defined by grade - all incidents meeting the threshold of a serious incident must be investigated and reviewed according to principles set out in the Framework.
2. Timescale – a single timeframe (60 working days) has been agreed for the completion of investigation reports. This will allow providers and commissioners to monitor progress in a more consistent way. This also provides clarity for patients and families in relation to completion dates for investigations.

We ask that the leaders of all organisations consider this refreshed Framework and that Medical and Nursing Directors in particular within provider and commissioning organisations ensure that it is used to support continuous improvement in the way we identify, investigate and learn from serious incidents in order to prevent avoidable harm in the future.

**Dr Mike Durkin**  
**Director of Patient Safety**  
**NHS England**

## Serious Incident Management at a glance

Serious Incidents in health care are adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified. This Framework describes the circumstances in which such a response may be required and the process and procedures for achieving it, to ensure that Serious Incidents are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again.

Serious Incidents include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services.

The needs of those affected should be the primary concern of those involved in the response to and the investigation of serious incidents. Patients and their families/carers and victims' families must be involved and supported throughout the investigation process.

Providers are responsible for the safety of their patients, visitors and others using their services, and must ensure robust systems are in place for recognising, reporting, investigating and responding to Serious Incidents and for arranging and resourcing investigations. Commissioners are accountable for quality assuring the robustness of their providers' Serious Incident investigations and the development and implementation of effective actions, by the provider, to prevent recurrence of similar incidents.

Investigation's under this Framework are not conducted to hold any individual or organisation to account, as there are other processes for that purpose including; criminal proceedings, disciplinary procedures, employment law and systems of service and professional regulation, such as the Care Quality Commission (CQC) and the Nursing and Midwifery Council, the Health and Care Professions Council, and the General Medical Council. Investigations should link to these other processes where appropriate.

Serious Incidents must be declared internally as soon as possible and immediate action must be taken to establish the facts, ensure the safety of the patient(s), other services users and staff, and to secure all relevant evidence to support further investigation. Serious Incidents should be disclosed as soon as possible to the patient, their family (including victims' families where applicable) or carers. The commissioner must be informed (via STEIS and/or verbally if required) of a Serious Incident within 2 working days of it being discovered. Other regulatory, statutory and advisory bodies, such as CQC, Monitor or NHS Trust Development Authority, must also be informed as appropriate without delay. Discussions should be held with other partners (including the police or local authority for example) if other externally led investigations are being



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undertaken. This is to ensure investigations are managed appropriately, that the scope and purpose is clearly understood (and those affected informed) and that duplication of effort is minimised wherever possible.

The recognised system-based method for conducting investigations, commonly known as Root Cause Analysis (RCA), should be applied for the investigation of Serious Incidents. This endorses three levels of investigation (for which templates and guidance are provided); 1) concise investigations - suited to less complex incidents which can be managed by individuals or a small group of individuals at a local level 2) comprehensive investigations - suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators 3) independent investigations - suited to incidents where the integrity of the internal 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. The level of investigation should be proportionate to the individual incident. Concise and comprehensive investigations should be completed within 60 days and independent investigations should be completed within 6 months of being commissioned.

Serious Incidents should be closed by the relevant commissioner when they are satisfied that the investigation report and action plan meets the required standard. Incidents can be closed before all actions are complete but there must be mechanisms in place for monitoring on-going implementation. This ensures that the fundamental purpose of investigation (i.e. to ensure that lessons can be learnt to prevent similar incidents recurring) is realised.

## Policy statement

This revised Serious Incident<sup>1</sup> Framework builds on and replaces the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation issued by the National Patient Safety Agency (NPSA, March 2010) and NHS England's Serious Incident Framework (March 2013). It also replaces and the NPSA Independent investigation of serious patient safety incidents in mental health services, Good Practice Guide (2008). The Department of Health is currently reviewing its 2005 guidance 'Independent investigation of adverse events in mental health services'<sup>2</sup> and further guidance may be provided in relation to issues associated with Article 2 of the European Convention on Human Rights – the right to life. Until the 2005 guidance is replaced, it should be read in conjunction with this Framework.

This Framework is designed to inform staff providing and commissioning NHS funded services in England<sup>3</sup> who may be involved in identifying, investigating or managing a

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<sup>1</sup> The terms 'serious incident requiring investigation (SIRI)', 'serious incident (SI)' or 'serious untoward incident (SUI)' are often used interchangeably. This document will refer to 'SIs' and serious incidents.

<sup>2</sup> This guidance replaced paragraphs 33 –36 in HSG (94) 27 (LASSL(94)4)

<sup>3</sup> Serious incidents involving NHS patients from England receiving care in Welsh provider organisations are covered by the requirements of this Framework. The Welsh provider organisation is required to notify the commissioner for patients' care in England. Where serious incidents involve NHS patients from Wales receiving care in English provider organisations, the commissioner of these patients' care in Wales must be informed. This will be the local health board, unless it is specialist care being provided in which case Welsh Health Specialised Services Committee (WHSSC) must be informed.

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serious incident. It is relevant to all NHS-funded care in the primary, community, secondary and tertiary sectors. This includes private sector organisations providing NHS-funded services.

Investigations carried out under this Framework 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 as 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.

## Acknowledgements

This Framework has been developed in collaboration with healthcare providers, commissioners, regulatory and supervisory bodies, patients, patient and victim's families and their representatives, patient safety experts and independent expert advisors for investigation within healthcare. The Patient Safety Domain sincerely thanks all individuals and groups of individuals who contributed towards the development of this Framework.

## Purpose

The Framework seeks to support the NHS to ensure that robust systems are in place for reporting, investigating and responding to serious incidents so that lessons are learned and appropriate action taken to prevent future harm.

The Framework is split into three parts;

- **Part One: Definitions and Thresholds** - sets out what a serious incident is and how serious incidents are identified. This section also outlines how the Framework must be applied in various settings.
- **Part Two: Underpinning Principles** - outlines the principles for managing serious incidents. It also clarifies the roles and responsibilities in relation to serious incident management, makes reference to legal and regulatory requirements and signposts to tools and resources.
- **Part Three: Serious Incident Management Process** - outlines the process for conducting investigations into serious incidents in the NHS for the purposes of learning to prevent recurrence. It covers the process from setting up an investigation team to closure of the serious incident investigation. It provides information on timescales, signposts tools and resources that support good practice and provides an assurance Framework for investigations.

The Framework aims to facilitate learning by promoting a fair, open, and just culture that abandons blame as a tool and promotes the belief that 'incidents cannot simply be linked to the actions of the individual healthcare staff involved but rather the system in

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which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring<sup>b</sup>.

It is recognised that serious incidents that require investigation extend beyond those which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The Framework describes the process for undertaking systems-based investigations that explore the problem (what?), the contributing factors to such problems (how?) and the root cause(s)/fundamental issues (why?). It endorses the recognised approach applied within the NHS (currently referred to as Root Cause Analysis investigation) and recognises that 'serious incidents' span a vast range of healthcare providers and settings, extending into social care and the criminal justice system.

The Framework acknowledges the interfaces with other organisations, particularly those with a statutory responsibility to investigate specific types of incidents which may involve the delivery of healthcare and therefore can coincide with serious incident investigations led by the health service. In doing so, it recognises that a variety of investigation methodologies may be applied and promotes the ever increasing need to work collaboratively in an effort to draw lessons to inform systematic learning and improvement.

Local operational guidance for serious incident management (within commissioning and provider organisations) must be consistent with this Framework.

## Introduction

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. This revised Framework takes account of the changes and acknowledges the increasing importance of taking a whole-system approach to quality<sup>4</sup>, 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<sup>ii</sup>.

Whilst it may be appropriate to performance-manage, or even regulate organisations on the basis of their responses to serious incidents, it is not appropriate to performance-manage or regulate organisations only on the basis of the number or type of serious incidents that they report. Doing so will only discourage reporting, disincentivise information sharing and inhibit learning.

Neither is it appropriate to sanction organisations simply for reporting serious incidents or to set performance targets based on decreasing the number of serious incidents that are reported. Simply counting the number of serious incidents reported by an organisation does not tell you how safe they are and should not be used to make isolated judgements about the safety of care.<sup>5</sup>

It is, however, appropriate for commissioners and regulators to expect serious incidents to be reported in a timely manner, to be effectively and appropriately investigated, robust action plans to be developed and implemented and learning

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<sup>4</sup> Quality in healthcare is defined as care that is safe, effective, and that provides as positive an experience for the patient as possible.

<sup>5</sup> Local Risk Management Systems (LRMS) and the National Reporting and Learning System (NRLS) together with other systems provide a means to record general safety and patient safety incidents and should form part of local risk management processes.

shared as appropriate. Where this is not happening – for example where serious incidents are not being reported to commissioners or regulators within the required timescales once organisations are aware of them (or event not reported at all) or where investigations and action plans are not effective and robust, it is appropriate to undertake regulatory action or performance management of the organisation. Information about serious incidents should also be triangulated with other information and intelligence; for example, that obtained through Quality Surveillance Groups.<sup>6</sup>

## Part One: Definitions and Thresholds

### 1. What is a Serious Incident?

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<sup>7</sup> 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 signalling 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 judgement of the people involved (see section 1.1).

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<sup>6</sup> Guidance on running Quality Surveillance Groups can be found at: <http://www.england.nhs.uk/wp-content/uploads/2014/03/quality-surv-grp-effective.pdf>

<sup>7</sup> 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 of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery ); or
- Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).

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<sup>8</sup> of one or more people. This includes
    - suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past<sup>9</sup> (see Appendix 1);
  - 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<sup>10</sup>; 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. See Never Events Policy and Framework for the national definition and further information;<sup>11</sup>
- An 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:

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<sup>8</sup> Caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice.

<sup>9</sup> This includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually - it may be appropriate to declare a serious incident for a homicide by a person discharged from mental health care more than 6 months previously.

<sup>10</sup> This may include failure to take a complete history, gather information from which to base care plan/treatment, assess mental capacity and/or seek consent to treatment, or fail to share information when to do so would be in the best interest of the client in an effort to prevent further abuse by a third party and/or to follow policy on safer recruitment.

<sup>11</sup> 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. See the Never Events Policy and Framework available online at:

<http://www.england.nhs.uk/ourwork/patientsafety/never-events/>



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- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 2 for further information);
  - Property damage;
  - Security breach/concern;<sup>12</sup>
  - Incidents in population-wide healthcare activities like screening<sup>13</sup> 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<sup>14</sup>); or
  - Activation of Major Incident Plan (by provider, commissioner or relevant agency)<sup>15</sup>
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation<sup>16</sup>.

### 1.1. 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 or not 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)

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<sup>12</sup> This will include absence without authorised leave for patients who present a significant risk to themselves or the public.

<sup>13</sup> Updated guidance will be issued in 2015. Until that point the Interim Guidance for Managing Screening Incidents (2013) should be followed.

<sup>14</sup> It is recognised that in some cases ward closure may be the safest/ most responsible action to take but in order to identify problems in service/care delivery, contributing factors and fundamental issues which need to be resolved an investigation must be undertaken

<sup>15</sup> For further information relating to emergency preparedness, resilience and response, visit: <http://www.england.nhs.uk/ourwork/epr/>

<sup>16</sup> As an outcome loss in confidence/ prolonged media coverage is hard to predict. Often serious incidents of this nature will be identified and reported retrospectively and this does not automatically signify a failure to report.

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 (see Part Three, section 3 for further details relating to reporting).

## **1.2. Can a 'near miss' be a serious incident?**

It may be appropriate for a 'near miss' to be 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 or not 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.

## **1.3. 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;
- 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 (see Part One; section 1 and 1.1. for further details);
- Information shared at Quality Surveillance Group meetings;
- Complaints;
- Whistle blowing;
- Prevention of Future Death Reports issued by the Coroner.<sup>17</sup>

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<sup>17</sup> Caution: when replying to section letters from the Coroner, the response must clearly state in what capacity the respondent writes i.e. a Sub-region should clearly state that actions are specific to its part of the organisation and not NHS England more widely.



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 Framework 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.

## **1.4. Risk management and prioritisation**

Managing, investigating and learning from serious incidents in healthcare 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 sufficient time and attention.

### **1.4.1. Prioritising**

Organisations should have processes in place to identify incidents that indicate the most significant opportunities for learning and prevention of future harm. This is not achieved by having prescribed lists of incidents that count as serious incidents. For example, blanket reporting rules that require every grade 3 and 4 pressure ulcer, every fall or every health care acquired infection to be treated as serious incidents can lead to debilitating processes which do not effectively support learning.

### **1.4.2. Opportunities for investing time in learning**

The multi-incident investigation root cause analysis (RCA) model<sup>18</sup> 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

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<sup>18</sup> Further information for multi-incident investigations is available online:  
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=75355>

the delivery of improvement work rather than initiating another investigation. This would need careful assessment, engagement with those affected<sup>19</sup> and agreement on a case-by-case basis.

### 1.4.3. Prevalence

It is acknowledged that prevalence is an important part of risk and safety management and it is important that all incidents (including those that do not meet the threshold for a serious incident and/or where a full investigation is not required) are documented and recorded. All incidents should be recorded on local risk management systems (LRMS) and, where the incident is a patient safety incident (see glossary) it should be reported to the National Reporting and Learning System<sup>20</sup>

## 1.5. Framework application and interfaces with other sectors

This Framework applies to serious incidents which occur in all services providing NHS funded care, including independent providers where NHS funded services are delivered. The infrastructure within each healthcare setting will largely determine how the Framework is applied in practice. It is acknowledged that some providers, particularly small providers, may be less well equipped to manage serious incidents in line with the principles and processes outlined in this Framework. Where this is the case commissioners and providers must work together to identify where there are gaps in resources, capacity, accessibility and expertise. Arrangements for supporting providers should be agreed on a local basis. Whilst commissioners should offer support where there is capacity to do so, providers are ultimately responsible for undertaking and managing investigations and consequently incur the cost for this process. This includes paying for independent investigations of the care the provider delivered and for undertaking its own internal investigations.

The principles and processes outlined in this Framework are relevant for the majority of serious incidents that occur in healthcare. However, there are occasions (outlined below) where the processes described in this Framework will coincide with other procedures. In such circumstances, co-operation and collaborative working between partner agencies is essential for minimising duplication, uncertainty and/or confusion relating to the investigation process. Ideally, only one investigation should be undertaken (by a team comprising representatives of relevant agencies) to meet the needs/requirements of all parties. However, in practice this can be difficult to achieve. Investigations may have different aims/ purposes and this may inhibit joint investigations. Where this is the case efforts must be made to ensure duplication of effort is minimised.<sup>21</sup>

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<sup>19</sup> Those affected must be involved in a manner which is consistent with the principles outlined in Part Two of this Framework.

<sup>20</sup> Further information is available online: <http://www.england.nhs.uk/ourwork/patientsafety/report-patient-safety/>

<sup>21</sup> Relevant organisations (i.e. those who co-commission and /or co-manage care) should develop a memorandum of understanding or develop, in agreement with one another, incident investigation policies about investigations involving third parties so that there is a clear joint understanding of how such circumstances should be managed. The Department of Health Memorandum of Understanding: investigating patient safety incidents involving unexpected death or serious untoward harm (2006) provides a source for reference where a serious incident occurs and an investigation is also required by the police, the Health and Safety Executive and/or the Coroner. However this guidance is currently under review.

Wherever possible, serious incident investigations should continue alongside criminal proceedings but this should be considered in discussion with the police. In exceptional cases (i.e. following a formal request by police, Coroner or judge) the investigation may be put on hold and this should be discussed with those involved.<sup>22</sup>

### **1.5.1. Deaths in Custody- where health provision is delivered by the NHS**

People in custody, including either those detained under the Mental Health Act (1983) or those detained within the police and justice system, are owed a particular duty of care by relevant authorities. The obligation on the authorities to account for the treatment of an individual in custody is particularly stringent when that individual dies<sup>iii</sup>.

In prison and police custody, any death will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations. Healthcare providers must fully support these investigations where required to do so. The PPO has clear expectations in relation to health involvement in PPO investigations into death in custody. Guidance published by the PPO<sup>23</sup> must be followed by those involved in the delivery and commissioning of NHS funded care within settings covered by the PPO.

In NHS mental health services, providers must ensure that any death of a patient detained under the Mental Health Act (1983) is reported to the CQC without delay. However providers are responsible for ensuring that there is an appropriate investigation into the death of a patient detained under the Mental Health Act (1983) (or where the Mental Capacity Act (2005) applies). In circumstances 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 managed in accordance with best practice - including suicide and self-inflicted death (see Part One; section 1) - then the death must be reported to the provider's commissioner(s) as a serious incident and investigated appropriately. Consideration should be given to commissioning an independent investigation as outlined in Appendix 3.

### **1.5.2. 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*<sup>24</sup> (2013) the LSCB will commission Serious Case Reviews and in circumstances set out in guidance for adult safeguarding concerns<sup>25</sup> the LSAB will commission Safeguarding Adult Reviews. The Local Authority will also

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<sup>22</sup> Investigations linked to complaints must be considered and agreed in line with guidance issued by the Department of Health

<sup>23</sup> Guidance is available online: <http://www.ppo.gov.uk/updated-guidance-for-clinical-reviews/>

<sup>24</sup> Available online:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/281368/Working\\_together\\_to\\_safeguard\\_children.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/281368/Working_together_to_safeguard_children.pdf)

<sup>25</sup> Available online: <http://careandsupportregs.dh.gov.uk/category/adult-safeguarding/>

initiate Safeguarding Adult Enquiries, or ask others to do so, if they suspect an adult is at risk of abuse or neglect.

Healthcare providers must contribute towards safeguarding reviews (and enquiries) as required to do so 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.

### **1.5.3. 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. See Appendix 4 for further details

### **1.5.4. Homicide by patients in receipt of mental health care**

Where patients in receipt of mental health services commit a homicide, NHS England will consider and, if appropriate, commission an investigation. This process is overseen by NHS England's Regional investigation teams. The Regional investigation teams have each established an Independent Investigation Review Group (IIRG) which reviews and considers cases requiring investigation. Clearly there will be interfaces with other organisations including the police and potentially the Local Authority (as there may be interfaces with other types of investigation such as DHRs and/or SCRs/SARs, depending on the nature of the case). To manage the complexities associated with such investigations (and to facilitate joint investigations where possible), a clearly defined investigation process has been agreed. Central to this process is the involvement of all relevant parties, which includes the patient, victim(s), perpetrator and their families and carers, and mechanisms to support openness and transparency throughout. See Appendix 1 for further details.

### **1.5.5. Serious Incidents in National Screening Programmes**

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Serious Incidents in NHS National Screening Programmes must be managed in line with the guidance: *Managing Safety Incidents in National Screening Programmes*,<sup>26</sup> which is aligned with the principles and processes set out in this Framework. 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.

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<sup>26</sup> Updated guidance will be issued in 2015. Until that point the Interim Guidance for Managing Screening Incidents (2013) should be followed.

## Part Two: Underpinning Principles

### 1. Seven Key Principles

This Framework 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
<b>Open and Transparent</b>	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 NHS Being Open guidance and the NHS contractual Duty of Candour <sup>27</sup> must be applied in discussions with those involved. This includes staff and patients, victims and perpetrators, and their families and carers.

<sup>27</sup> The Department of Health has introduced regulations for the Duty of Candour. It requires providers to notify anyone who has been subject (or someone lawfully acting on their behalf, such as families and carers) to a 'notifiable incident' i.e. incident involving moderate or severe harm or death. This notification must include an appropriate apology and information relating to the incident. Failure to do so may lead to regulatory action. Further information is available from [http://www.cqc.org.uk/sites/default/files/20141120\\_doc\\_fppf\\_final\\_nhs\\_provider\\_guidance\\_v1-0.pdf](http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf)

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	<p>Openness and transparency (as described in 'Being Open') means:</p> <ul style="list-style-type: none"> <li>• Acknowledging, sincerely apologising and explaining when things have gone wrong;</li> <li>• Conducting a thorough investigation into the incident, ensuring patients, their families and carers are satisfied that lessons learned will help prevent the incident recurring;</li> <li>• Providing support for those involved to cope with the physical and psychological consequences of what happened<sup>iv</sup></li> </ul> <p>Saying sorry is not an admission of liability and is the right thing to do. Healthcare organisations should 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.</p> <p>The NHS Litigation Authority provides advice on saying sorry available online from: <a href="http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf">http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf</a></p> <p>Part three; section 4.2 outlines the steps required to support this principle.</p>
<p><b>Preventative</b></p>	<p>Investigations of serious incidents are undertaken to ensure that weaknesses in a system and/or process are identified and analysed to understand what went wrong, how it went wrong and what can be done to prevent similar incidents occurring again<sup>v</sup>.</p> <p>Investigations carried out under this Framework 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.</p> <p>Organisations must advocate justifiable accountability and a zero tolerance for inappropriate blame. The Incident Decision Tree<sup>28</sup> should be used to promote fair and consistent staff treatment within and between healthcare organisations.</p>

<sup>28</sup> The Incident Decision Tree (first published by the NPSA) aims to help the NHS move away from attributing blame and instead find the cause when things go wrong. The goal is to promote fair and consistent staff treatment within and between healthcare organisations. NHS England is planning the re-launch of the Incident Decision Tree during 2015/16.



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<p><b>Objective</b></p>	<p>Those involved in the investigation process must not be involved in the direct care of those patients affected nor should they work directly with those involved in the delivery of that care. Those working within the same team may have a shared perception of appropriate/safe care that is influenced by the culture and environment in which they work. As a result, they may fail to challenge the ‘status quo’ which is critical for identifying system weaknesses and opportunities for learning.</p> <p>Demonstrating that an investigation will be undertaken objectively will also help to provide those affected (including families/carers) with confidence that the findings of the investigation will be robust, meaningful and fairly presented.</p> <p>To fulfil the requirements for an independent investigation, the investigation must be both commissioned and undertaken independently of the care that the investigation is considering (see Appendix 3)</p>
<p><b>Timely and responsive</b></p>	<p>Serious incidents must be reported without delay and no longer than 2 working days after the incident is identified (Part Three; section 3 outlines the process for reporting incidents).</p> <p>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.</p>
<p><b>Systems based</b></p>	<p>The investigation must be conducted using a recognised systems-based investigation methodology that identifies:</p> <ul style="list-style-type: none"> <li>○ The problems (the what?);</li> <li>○ The contributory factors that led to the problems (the how?) taking into account the environmental and human factors; and</li> <li>○ The fundamental issues/root cause (the why?) that need to be addressed.</li> </ul> <p>Within the NHS, the recognised approach is commonly termed Root Cause Analysis (RCA) investigation.<sup>29</sup> The investigation must be undertaken by those with appropriate skills, training and capacity.</p>
<p><b>Proportionate</b></p>	<p>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 (see Part One; section 1.1) and ensures that organisations are focusing resources in an appropriate way</p>

<sup>29</sup> Tools and training resources to support robust systems investigation in the NHS are available to download from <http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/>



	<p>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 (see Appendix 3 for further details). In exceptional circumstances a regional or centrally-led response may be required (see Part Three, section 3.2).</p>
<p><b>Collaborative</b></p>	<p>Serious incidents often involve several organisations. Organisations must work in partnership to ensure incidents are effectively managed.</p> <p>There must be clear arrangements in place relating to the roles and responsibilities of those involved (see Part Two, section 2 and 3 below). Wherever possible partners should work collaboratively to avoid duplication and confusion. There should be a shared understanding of how the incident will be managed and investigated and this should be described in jointly agreed policies/procedures for multi-agency working.</p>

## 2. 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.

### 2.1. Involvement of multiple commissioners

In a complex commissioning landscape where multiple commissioners may commission services from multiple providers spanning local and regional geographical boundaries, this model (i.e. where providers report incidents to the commissioner holding the contract who then assumes responsibility for overseeing the response to the serious incident) is not always practicable so a more flexible approach is required. Commissioners must work collaboratively to agree how best to manage serious incidents for their services.

In all cases, a RASCI (Responsible, Accountable, Supporting, Consulted, Informed) model should be agreed in relation to management of serious incidents<sup>vi</sup> (see Appendix 5 for further details). This will ensure that it is clear who is responsible for

leading oversight of the investigation, where the accountability ultimately resides and who should be consulted and/or informed as part of the process. This allows the 'accountable commissioner', i.e. the commissioner holding the contract to clearly delegate responsibility for management of serious incident investigations to an appropriate alternative commissioning body, if that makes sense. It should be noted that this does not remove the overall accountability of the commissioner who holds the relevant contract.

The RASCI model supports the identification of a single 'lead commissioner' with responsibility for managing oversight of serious incidents within a particular provider. This means that a provider reports and engages with one single commissioning organisation who can then liaise with other commissioners as required. This approach is particularly useful where the 'accountable commissioner' is geographically remote from the provider (and therefore removed from other local systems and intelligence networks) and/or where multiple commissioners' commission services from the same provider. It facilitates continuity in the management of serious incidents, removes ambiguity and therefore the risk of serious incidents being overlooked and reduces the likelihood of duplication where there is confusion regarding accountability and/or responsibility and general management of the serious incident process.

## **2.2. 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 co-ordinating the investigation process. Commissioners themselves should provide support in complex circumstances. Where no one provider organisation is best placed to assume responsibility for co-ordinating an investigation, the commissioner may lead this process<sup>30</sup>.

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,

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<sup>30</sup> Please note in some circumstances the Local Authority or another external body may be responsible for managing and co-ordinating the investigation process. Where this is the case, providers and commissioners must contribute appropriately and must gain assurance that problems and solutions relating to healthcare issues will be identified and appropriately actioned.

implementation and monitoring of subsequent action plans by the relevant organisations must be undertaken in line with guidance outlined in part three of this Framework.

### 3. Roles and Responsibilities for Managing Serious Incident

Different parts of the system have distinct functions in relation to serious incident management- effective management and learning requires a collective effort throughout the system.

The nature of the serious incident largely determines who has a role to play and what that role is. This section outlines the key roles and responsibilities of providers, commissioners, key regulatory and supervisory bodies. Reference must be made to Appendix 2 which outlines other bodies that must be involved, depending on the nature and circumstances of the case.

#### 3.1. Providers of NHS-funded care

The leadership at a provider organisation is ultimately responsible for the quality of care that is provided by that organisation.<sup>31</sup> Serious incident management is a critical component of corporate and clinical governance, and providers are responsible for arranging and resourcing investigations and must ensure robust systems are in place for recognising, reporting, investigating and responding to serious incidents. The principles and processes associated with robust serious incident management must be endorsed within an organisation's Incident Reporting and Management Policy.

There must be clear procedures for:

- Timely reporting and liaison with their commissioning bodies (incidents must be recorded on STEIS within 2 working days of being identified). Particular types of incidents may require additional reporting to other systems. See appendix 2.
- Compliance with reporting and liaison requirements with regulators and other agencies/partners. See appendix 2
- Mechanisms to support robust serious incident investigations, including processes to ensure the following:
  - Early, meaningful and sensitive engagement with affected patients and/or their families/carers, from the point at which a serious incident is identified, throughout the investigation, report formulation and subsequent action planning through to closure of the investigation process. A specific person should be assigned to engage with the family to provide a single point of contact.
  - Clear procedures for taking immediate action following a serious incident including the collection and retention of evidence i.e. notes/clinical records,

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<sup>31</sup> Quality in the New Health System, *Maintaining and Improving Quality*. National Quality Board, January 2013

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written accounts/statements<sup>32</sup> from those involved, equipment involved, information from the location (site visit) and interviews with relevant individuals.

- Investigations are undertaken by appropriately trained and resourced staff and/or investigation teams that are sufficiently removed from the incident to be able to provide an objective view.
- Investigations follow a systems-based approach to ensure any issues/problems with care delivery are fully understood from a human and systems factors perspective and that the 'root causes' are identified (where it is possible to do so) in order to produce focused recommendations that result in SMART (specific, measurable, attainable, relevant, time-bound) actions and learning to prevent recurrence.
- Access to relevant specialists/ experts, communications expertise, administrative support and/or additional resources to support investigations where required.
- Mechanisms to ensure that actions from action plans are monitored until implemented and there is evidence of whether or not the action plan has resulted in the practice / system improvement anticipated. This should include oversight of implementation by organisation leaders.
- Mechanisms to support investigations being led by external agencies such as the police, HSE or local authority. Where required, providers must submit evidence to contribute towards external investigations.
- Processes (including interagency investigation policy and/or memorandum of understanding with relevant organisations) to support collaboration and partnership working where joint investigations are required to avoid duplication of activity or confusion of responsibility.
- Quality assurance processes to ensure completion of high quality investigation reports and action plans to enable timely learning and closure of investigations and to prevent recurrence.
- Mechanisms and effective communication channels to facilitate the sharing of lessons learned across the organisation and more widely where required.

### **3.2. Commissioners of NHS- funded care**

Commissioners are responsible for securing a comprehensive service within available resources, to meet the needs of their local population. They must commission 'regulated activities' from providers that are registered with the CQC, and should contract with the provider to deliver continuously improving quality care. They must

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<sup>32</sup> Statements taken to support the serious incident investigation do not need to be signed. They are written as aides-memoir to support the investigation process to inform learning. Where formal statements are required (as part of court/criminal proceedings) staff must receive the appropriate support and guidance from the organisations risk manager and legal advisors. Clear policies and procedures must be in place to support formal statement writing.

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assure themselves of the quality of services they have commissioned, and should hold providers to account for their responses to serious incidents. This means commissioners quality assure the robustness of their providers' serious incident investigations and the action plan implementation undertaken by their providers. Commissioners do this by evaluating investigations and gaining assurance that the processes and outcomes of investigations include identification and implementation of improvements that will prevent recurrence of serious incidents (see Part Three; section 4.4-5 for further details).

Commissioning Support Units (CSUs) assist some Clinical Commissioning Groups (CCGs) in some of the practical aspects of their role, for example, by ensuring there is timely reporting of serious incidents by the provider and quality assuring the robustness of the serious incident investigation undertaken by the provider. Delegating activity to the CSU does not remove a CCG's overall accountability for this activity.

Commissioners should use the details of serious incident investigation reports, together with other information and intelligence achieved via day to day interactions with providers to inform actions that continuously improve services (where this is required). Commissioners must establish mechanisms for sharing intelligence with relevant regulatory and partner organisations.

Commissioning organisations have a responsibility to work together to determine how best to manage oversight of serious incidents in all the services they commission, particularly where multiple commissioners commission services from the same provider and/or where commissioning teams may be geographically remote. Commissioners should establish a RASCI ('Responsible, Accountable, Supporting, Consulted, Informed,') model for the management of serious incidents in their commissioned services as set out in Appendix 5. A 'lead commissioner' role should be agreed in relation to serious incident management in providers with multiple commissioners in order to provide a clear communication channel between the provider and commissioning system.

As previously described, commissioners will typically manage serious incidents by overseeing investigations that are actually led and resourced by the provider(s) of care in which the serious incident occurred. However, in complex situations where multiple providers are involved or where the provider requires support with the investigation, commissioners may need to take a more hands-on approach to the investigation process itself.

Commissioners should develop and agree procedures for managing concerns raised to them in relation to the management of the investigation process. They should take responsibility for communicating clearly and effectively with those raising concerns through a single person and ensure issues are effectively resolved.

Commissioners also need access to resources/expertise and access to competent independent investigators to support investigations in which they have an obligation to assist (for example PPO investigations require the input of clinical reviewers to support the investigation of death in prison custody), or where they recognise an independent investigation may be required (see Appendix 3).

Commissioners must also have procedures for managing serious incidents within their own organisations including mechanisms to support the quality assurance and closure of investigations reports.<sup>33</sup> They must also have procedures to support their providers in reporting serious incidents onto the STEIS system where this is required.

### **3.3. NHS England**

NHS England has a direct commissioning role as well as a role in leading and enabling the commissioning system. As part of the latter role, NHS England maintains oversight and surveillance of serious incident management within NHS-funded care and assures that CCGs have systems in place to appropriately manage serious incidents in the care they commission. They are responsible for reviewing trends, analysing quality and identifying issues of concern. They have a responsibility for providing the wider system with intelligence gained through their role as direct commissioners and leaders of the commissioning system. NHS England must maintain mechanisms to support this function, including exploiting opportunities provided by their involvement and participation in local and regional Quality Surveillance Groups.<sup>34</sup>

In certain circumstances (for example with many incidents relating to mental health homicide, see Appendix 1) NHS England may be required to lead a local, regional or national response (including the commissioning of an independent incident investigation) depending on the circumstances of the case. See Part Three, section 3.2 and Appendix 3 for further details.

#### **3.3.1. Care Quality Commission (CQC)**

The CQC makes authoritative judgements on the quality of health and care services, according to whether they are safe, effective, caring, responsive and well-led. The chief inspectors rate the quality of providers accordingly, and clearly identify where failures need to be addressed. They have a role in encouraging improvement and may use the details of incident reports, investigations and action plans to monitor organisations' compliance with essential standards of quality and safety, to assess risks to quality and to respond accordingly. The CQC works closely with commissioners and providers to gather intelligence and information as part of their pre-inspection process. The Health and Social Care Act sets specific requirements for registered organisations in relation to the type of incidents that must be reported to them. Further details are published online: <http://www.cqc.org.uk/organisations-we-regulate/registered-services/notifications>

#### **3.3.2. Monitor**

Monitor will rely on commissioners' information and intelligence to inform both their monitoring of existing NHS Foundation Trusts, and the authorisation process for new NHS Foundation Trusts. Monitor will use the details of serious incident reports, investigations and action plans to monitor Foundation Trusts' compliance with essential standards of quality and safety and their licence terms. Monitor can take

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<sup>33</sup> CCGs can ask their respective sub-region to review investigation reports. Regions and sub-regions must establish appropriate mechanisms for review of their own investigations this can include establishing peer review arrangements with neighbouring regional and sub-regional teams.

<sup>34</sup> For further information on: How to make your Quality Surveillance Group effective visit: <http://www.england.nhs.uk/wp-content/uploads/2014/03/quality-surv-grp-effective.pdf>

action where there are quality problems as a result of poor governance within Foundation Trusts. This is usually triggered by findings from CQC, but commissioners can refer issues directly to Monitor. Monitor will work with partners to facilitate learning and sharing throughout the healthcare system. Monitor requires NHS foundation Trusts to inform them about relevant serious incidents (i.e. any incidents which may reasonably be regarded as raising potential concerns over compliance with their licence).

#### **3.3.4. NHS Trust Development Authority (TDA)**

The TDA will support NHS trusts in ensuring they have effective systems and processes in place to report, investigate and respond to serious incidents in line with national policy and best practice. It will work in partnership with the relevant commissioner (s) responsible for holding trusts to account for their responses to serious incidents.

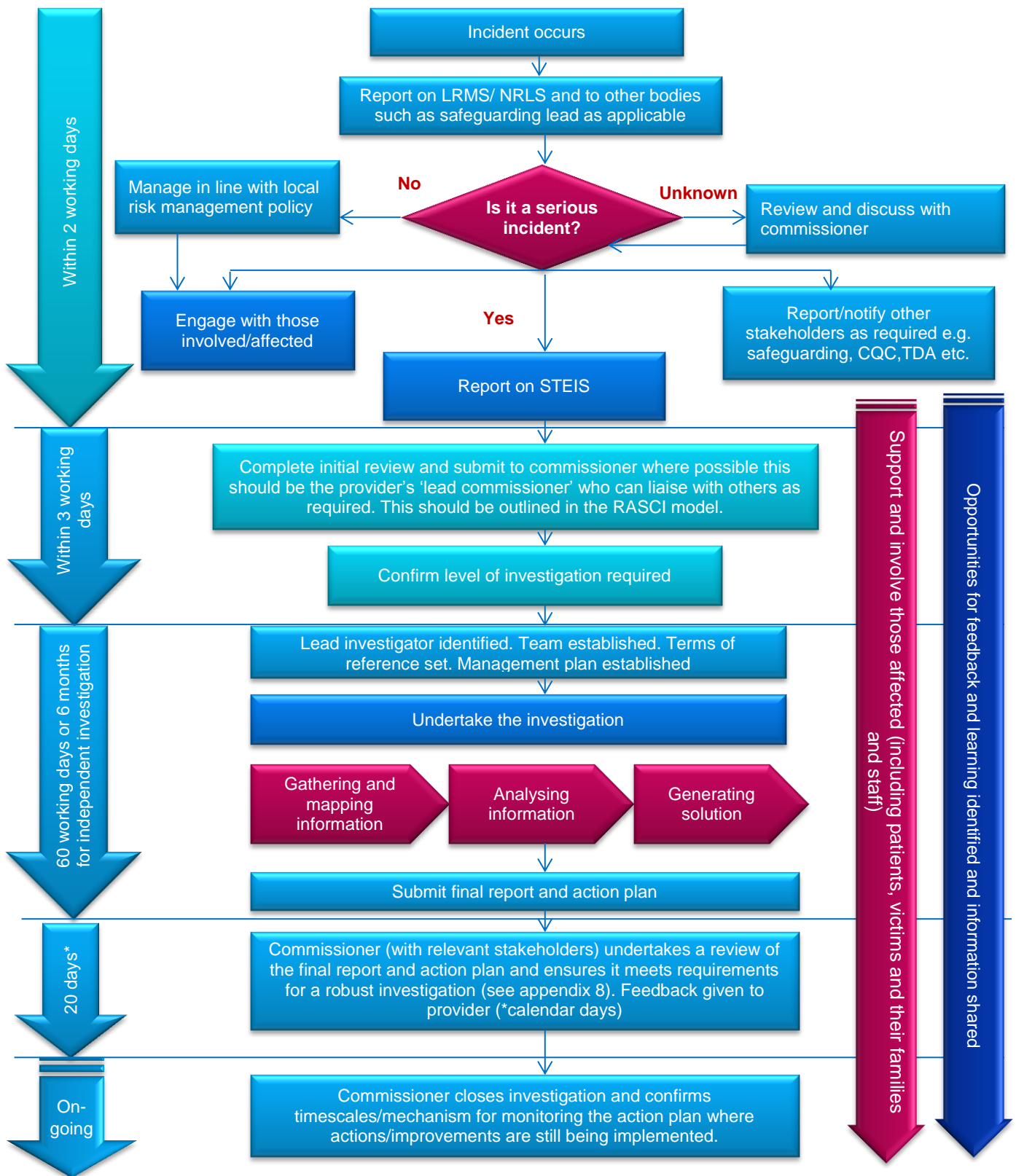
The TDA will specifically:

- Ensure that NHS Trusts have appropriate systems and processes in place to respond to serious incidents, undertake credible investigations and follow through on action plans;
- Ensure NHS Trusts have formal arrangements in place with commissioners to secure appropriate and timely closure of serious incident investigations;
- Ensure NHS Trusts have mechanisms in place to learn from incidents which are disseminated throughout the organisation;
- Where appropriate, review Trusts' Serious Incident policies and support Trusts to develop their policies to achieve desired improvements relating to the reporting and management of Serious Incidents;
- Use information about serious incidents as a component of the overall surveillance of quality; in particular, the analysis of serious incident data is used to provide information about provider organisations, to assure the quality of care and inform the assessment of NHS trust applications for Foundation Trust status;
- Share information and liaise with NHS England, CQC, professional regulators and other stakeholders, especially those associated with quality surveillance groups;
- Work with NHS Trusts to improve the quality of investigations



## Part Three: The Serious Incident Management Process

### 1. Overview of the Serious Incident Management Process





## 2. Identification and immediate action

Serious incidents or suspected serious incidents must be declared internally as soon as the healthcare provider becomes aware of the incident. A senior manager or clinician should be identified by the health care provider's chief executive or equivalent, 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.<sup>35</sup>
- Identify witnesses, including staff, and other service users, to ensure they receive effective support.
- Identify an appropriate specialist/clinician<sup>36</sup> to conduct an initial incident review (characteristically termed the 72-hour review) 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 the provider 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 within the provider organisation.
- 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 (the Strategic Executive Information System, NHS England's web-based serious incident management system) or its successor system (see Part Three; section 3 below). Some incident types require additional reporting to other systems. See appendix 2 for further details.

As discussed in Part One of this guidance, it is often clear that a serious incident has occurred but where this is not the case providers should engage in open and honest discussions with their commissioners (and others as required) to agree the appropriate and proportionate response. Where it is not known whether or not an incident is a

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<sup>35</sup> Advice from Information Governance leads should be sought early on to help support this process. They can advise on what information can/should be used and what needs to be done to support the use of personal and patient confidential information. Appropriate use of information that might relate to court or judicial proceedings should also be discussed and understood as appropriate.

<sup>36</sup> A clinician with relevant expertise who is not involved in delivery of care to the patient

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<sup>37</sup>. Any downgrading must be agreed with the relevant commissioner 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 the organisation's risk management and patient safety policies if appropriate.

### 3. Reporting a Serious Incident

Serious incidents must be reported by the provider to the commissioner 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 the relevant commissioning organisation upon identification. This should be done by telephone as well as electronically:

- Incidents which activate the NHS Trust or Commissioner 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:

Out-of-hours, the local on-call management procedures must be followed.

Reporting a serious incident must be done by recording the incident on the NHS serious incident management system, STEIS,<sup>38</sup> or its successor system. 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 2 for a list of other organisations that must be considered. In some circumstances, where a serious incident or multiple serious incidents raise profound concerns about the quality of care being provided, organisations should consider calling a Risk Summit, which provides a mechanism for key stakeholders in the health economy to come together to collectively share and review information.<sup>39</sup> Most serious incidents will not warrant this level of response however.

All serious incidents which meet the definition for a patient safety incident should also be reported separately to the NRLS for national learning. Organisations with local risk

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<sup>37</sup> This may depend on local procedures and capacity to ensure de-logging of incidents is performed in a timely manner.

<sup>38</sup> Providers require an N3 connection and authorisation from their local NHS England Area Team in order to set up a STEIS account. Where providers are unable to access STEIS the commissioner must report the serious incident on the system on the provider's behalf. A suitable Serious Incident Review Form (example provided in Appendix 6) should be completed in these circumstances in order to inform the relevant commissioner.

<sup>39</sup> Guidance available online at <http://www.england.nhs.uk/ourwork/part-rel/nqb/>

management systems that link to the NRLS can report via their own systems. Organisations without this facility should report using the relevant NRLS e-form<sup>40</sup>

### **3.1. Follow up information**

An initial review (characteristically termed a '72 hour review') should be undertaken and uploaded onto the STEIS system by the provider (offline submission may be required where online submission is not possible, see Appendix 6). This should be completed within 3 working days of the incident being identified. 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.

### **3.2. Alerting the system: escalation and information sharing**

Where a serious incident indicates an issue/problem that has (or may have) significant implications for the wider healthcare system, or where an incident may cause widespread public concern, the relevant commissioner (i.e. lead commissioner receiving the initial notification) must consider the need to share information throughout the system i.e. with NHS England Sub-regions and Regions and other partner agencies as required. This is a judgement call depending on the nature of the incident, although the scale of the incident and likelihood of national media attention will be a significant factor in deciding to share information.

Where the commissioner receiving the initial notification recognises the need to share information, they must liaise with and alert NHS England (where they are not the commissioner receiving the initial notification). Commissioners should share information with members of their local Quality Surveillance Group (QSG), which bring together different parts of the system to proactively share intelligence on real or actual quality failures. A Risk Summit may be required to share information if very serious concerns about the quality of care being provided to patients remain. When these requirements to share information entail sharing confidential personal information they are subject to the law relating to privacy and confidentiality and the Data Protection Act. Advice should be sought from the relevant Caldicott Guardian, Information Governance leads and legal team, as required.

NHS England at Sub-region and then Regional level must make an informed decision about whether or not to inform national directorate leads within NHS England Central Team. Communication should be managed by an appropriately designated regional

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<sup>40</sup> Further information available online: <http://www.england.nhs.uk/ourwork/patientsafety/report-patient-safety/>

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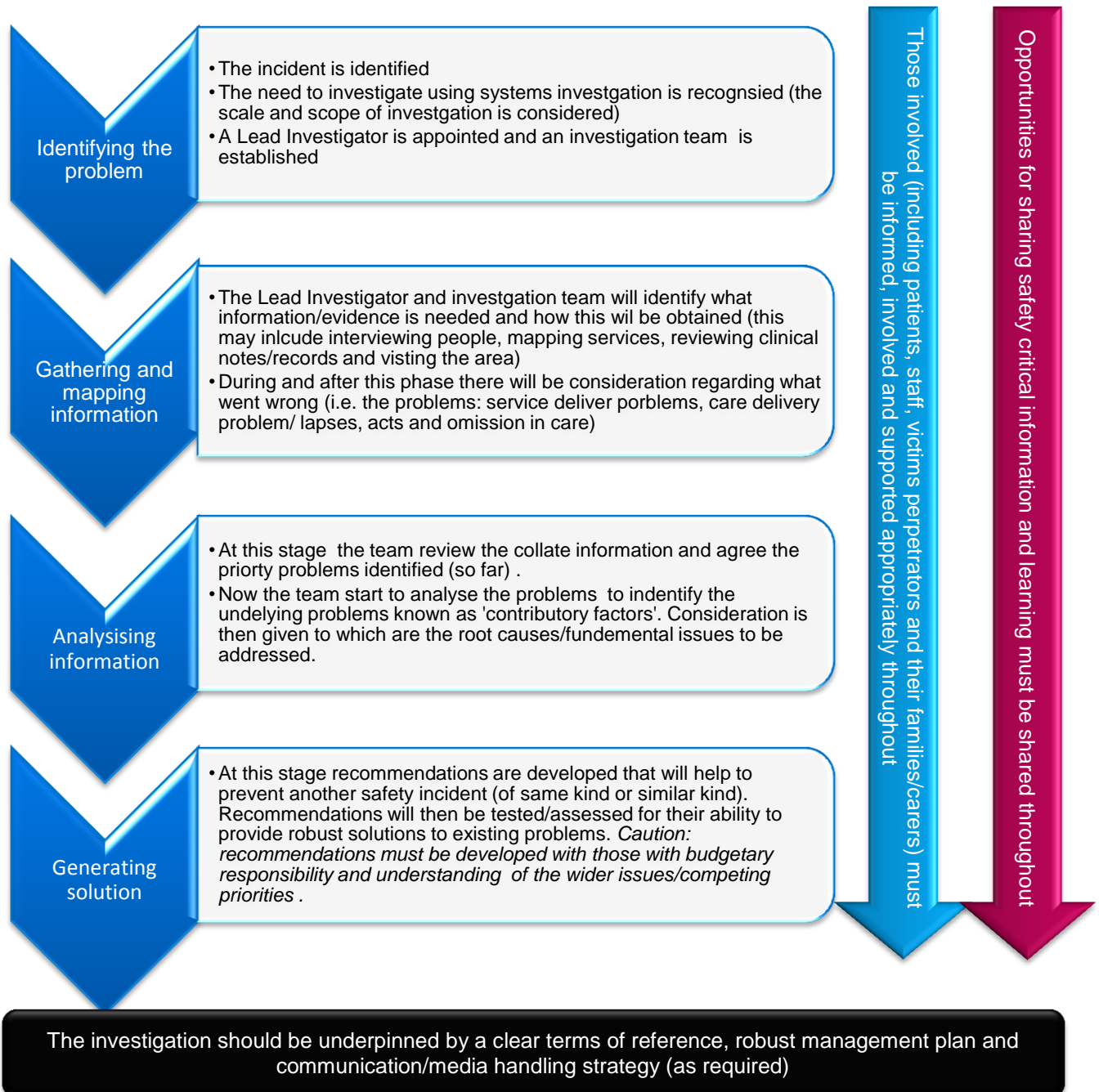
lead. A briefing which describes the issue and the current position in terms of incident management and investigation (where applicable) should be provided. The organisation responsible for preparing this information will depend on the incident and must be agreed on a case by-case-basis. The briefing should be disseminated by the relevant regional lead through the appropriate professional accountability and commissioning routes including Nursing, Medical, Operational and Commissioning Teams. A decision to inform the Department of Health must be agreed with NHS England directorate leads as appropriate. Communication with the Department of Health must be co-ordinated through NHS England Central Communications.

NHS England, in rare and exceptional circumstances (for example, where an incident has the potential to cause significant harm throughout the system and/or where investigation of the commissioning system or configuration of services is required), may identify the need for a regionally or centrally led response, initiated by the commissioning of an independent investigation. Where this is the case an appropriate incident management plan (overseen by appropriate Officer/ Responsible Owner at either regional or national level) must be developed and implemented in line with the principles in this Framework. Appendix 3 provides further details relating to the commissioning on independent investigations.

## 4. Overview of the investigation 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',<sup>vii</sup> and uses recognised tools and techniques<sup>41</sup> to identify:

- The problems (the what?) including lapses in care/acts/omissions; and
- 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.



<sup>41</sup> The investigation toolkit which can be accessed from <https://report.nrls.nhs.uk/rcatoolkit/course/index.htm> provides a wealth of tools, techniques and resources to support each stage of the investigation.

## **4.1. 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 appropriate Manager/ Director/ Chief Executive. 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 organisation’s 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.

## **4.2. 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.

### **4.2.1. Involving patients, victims and their families/carers**

Involvement begins with a genuine apology. The principles of honesty, openness and transparency (as set out in Part Two of this Framework which endorses the NHS Being Open guidance) 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.

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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 to someone else?

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;
- Have 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<sup>42</sup>
- 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;

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<sup>42</sup> This may disclose confidential personal information for which consent has been obtained, or where patient confidentiality is overridden in the public interest. This should be considered by the organisation's Caldicott Guardian and confirmed by legal advice, where required. NHS England is currently seeking advice in relation to the development of national guidance available to further support this matter. In the meantime, advice should be sought in relation to each case.



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- 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 make contact with those affected. This should be clearly explained to the patients/ victims and families as required. A co-ordinated 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.

### **4.2.2. 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 Incident Decision Tree<sup>43</sup> 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.<sup>44</sup>

## **4.3. Agreeing the level/type of investigation**

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<sup>43</sup> The Incident Decision Tree aims to help the NHS move away from attributing blame and instead find the cause when things go wrong. The goal is to promote fair and consistent staff treatment within and between healthcare organisations. NHS England is currently redeveloping the Incident Decision Tree with a plan to re-launch 2015/16

<sup>44</sup> Healthcare organisations should also encourage staff to seek support from relevant professional bodies such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Pharmaceutical Council (GPhC) see <http://www.professionalstandards.org.uk/regulators/statutory-regulators-directory> for further information.



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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 the table below.

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Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (currently referred to as RCA investigation). Within the NHS, most serious incidents are investigated internally using a comprehensive investigation approach. Resources to support systems-based investigation in the NHS are available online from: <http://www.england.nhs.uk/ourwork/patientsafety/root-cause/> For further information relating to the circumstances and requirements for commissioning independent investigations see appendix 3.

Level	Application	Product/ outcome	Owner	Timescale for completion
Level 1 <b>Concise internal investigation</b>	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	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 2 <b>Comprehensive internal investigation</b>  (this includes those with an independent element or full independent investigations commissioned by the provider)	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	Provider organisation (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	
Level 3 <b>Independent investigation</b>	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 (see Appendix 1 and 3 for further details)	Comprehensive investigation report including all elements of a credible investigation	The investigator and <b>all</b> 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

National reporting templates should be used unless agreed that adaptations are required. National templates will be reviewed on a continuous basis. Recommendations to inform changes should be sent to [england.RCAinvestigation@nhs.net](mailto:england.RCAinvestigation@nhs.net)

## 4.4. 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. Each NHS organisation 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 if guidance is needed about the disclosure of patient identifiable information.

### 4.4.1. 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<sup>45</sup>;
- 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 (see section 4.4.2. below);
- 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 incident.

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<sup>45</sup> It may be appropriate to separate confidential material, in part or full, into a confidential annexe to ensure the report can be shared effectively and appropriately with and without this information as required. A clearly defined distribution list should be developed.

NHS England recommends use of national reporting templates, available online: <http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/> . National templates should be used unless agreed adaptations are required<sup>46</sup>.

#### **4.4.2. Action plan**

NHS England recommends use of the NPSA Action Plan template available online: <http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/>

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;

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<sup>viii</sup>.

## **4.5. Submission of Final Report, Quality Assurance and Closure**

### **4.5.1. Submission of Final Report**

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

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

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<sup>46</sup> Recommendations to inform changes to the national reporting templates should be sent to [england.RCAinvestigation@nhs.net](mailto:england.RCAinvestigation@nhs.net)

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- 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 within the serious incident management system and included in the serious incident report.

As described in Part One; section 1.5, 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, commissioners should review/agree the date for completion once the investigation can recommence<sup>47</sup>.

Providers 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 appropriate commissioner 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.

### **4.5.2. 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.

It may be necessary to involve several commissioning organisations in the quality assurance and sign-off process depending on the nature and circumstance of the incident. This should be established when developing the RASCI model. The relevant Director (or equivalent) within the commissioning organisation responsible for managing oversight of the serious incident must ensure a robust and transparent process is in place for assurance and closure of serious incidents. This must preclude the involvement of members of the investigation team. There may be occasions where commissioners wish to make arrangements for another internal team or a separate commissioning organisation to undertake an additional quality assurance

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<sup>47</sup> Within the current SI system (STEIS) commissioners may 'stop the clock' where there is a formal request to suspend the investigation. The date for completion should be reviewed and agreed again once the investigation can recommence.

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review where there is a risk of conflict of interest.<sup>48</sup> This does not remove their overall responsibility to ensure that the report, action plan and implementation of necessary actions meet the required standard. The serious incident report, closure process and meeting minutes must clearly describe the roles and responsibilities of those involved in the reporting, investigation, oversight and closure of the serious incident to demonstrate good governance and provide a clear audit trail.

The commissioner must seek assurance that the report fulfils the required standard for a robust investigation and action plan. See Appendix 8 for supporting information. Any concerns or areas requiring further action should be highlighted to the provider at the earliest opportunity to facilitate timely action and resolution of issues raised.

It may be acceptable to close the incident before all preventative actions have been implemented and reviewed for efficacy. For example where actions are continuous or long term, the commissioner may consider closure once there is evidence that such actions have been initiated. Where this is considered acceptable, robust arrangements should be put in place to ensure implementation is regularly reviewed.

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.

## 5. Next steps

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 behavioural and cultural change. It is not unreasonable for improvements to take many months or even years in some cases.

It is important that providers and commissioners invest time and resources into monitoring and progressing with long term actions, particularly where these address the causes contributing to other incidents across the system. A mechanism for the monitoring and review of actions should be agreed by the provider and commissioner.

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<sup>48</sup> For example where a commissioner assists and/or provides advice or support to a small independent provider in the investigation process.

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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 by providers on a regular basis. A more collective approach can help to make the delivery of multiple action plans more manageable and can also help inform wider strategic aims for the organisations involved.

## Appendix 1: Regional Investigation Teams: Investigation of homicide by those in receipt of mental health care

### Introduction

This Standard Operating Model has been developed by NHS England's regional teams with contributions from a wide range of stakeholders including families, carers, NHS England Regional and Area Team Directors of Nursing, regional investigation team leads and independent investigators. It describes the process overseen by NHS England's regional investigation team to ensure an appropriate approach is undertaken when responding to mental health care-related homicides. It must be read in conjunction with the main Framework.

### Scope

This appendix covers the process for investigating mental health care related homicides only. Other circumstances that may require an independent investigation and the process that should be followed in such circumstances are described in Appendix 3.

The regional investigations team should commission an independent investigation of mental health care related homicides when a homicide has been committed by a person who is, or has been, subject to a care programme approach, or is under the care of specialist mental health services, in the past 6 months<sup>49</sup> prior to the event.

Regional involvement in other circumstances requiring independent investigation is described in Appendix 3.

Investigations carried out under this Framework are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how a person died as this is a matter for Coroners. Neither are they conducted to hold any individual or organisation to account. Other systems exist for that, 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.

### Purpose

Homicides committed by those in receipt of mental health care have devastating consequences for the family of the victim (s), patients and their families and a profound impact for all parties involved. These incidents often require complex, multi-agency investigations involving internal and external stakeholder across geographical and organisational boundaries. The purpose of having a regionally led standardised approach to investigating such incidents is to:

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<sup>49</sup> 6 months is included as a guide and each case should be considered individually- it may be appropriate to declare a serious incident and commission an independent investigation for a homicide by a person discharged from mental health care more than 6 months prior to the event.



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- Ensure that mental health care related homicides are investigated in such a way that lessons can be learned effectively to prevent recurrence;
- Explicitly consider and if necessary, commission independent investigations into the wider commissioning system and configuration of services that may have contributed to the incident in question;
- Facilitate further examination of the care and treatment of patients in the wider context and establish whether or not an incident could have been predicted, or prevented, and if any lessons can be learned for the future to reduce the chances of recurrence;
- Provide additional objectivity required due to the significant impact of these events on the victim's family and carers, plus the wider public concern that can arise following such an event;
- Ensure that any resultant recommendations are implemented through effective action planning and monitoring by providers and commissioners;
- Ensure families (to include friends, next-of-kin and extended families) of both the deceased and the perpetrator are fully involved. Families should be at the centre of the process and have appropriate input into investigations;
- Improve the quality, consistency and timeliness of commissioning independent investigations into such cases through the use of a national Framework of approved investigators;
- Ensure that there is early consideration for joint investigations if other agencies will be carrying out investigations into the same event(s) e.g. in cases of the death of a child. Wherever possible agencies involved should consider if it is possible to commission a single investigation. The regional investigations team will ensure that, together with police, Health and Safety Executive, Local Safeguarding Boards and/or other agencies, agreement is reached regarding an approach to:
  - The timing of investigations;
  - Sharing of information and confidentiality issues; and
  - Communications with families, carers, staff and the media.

The regional investigations team will also ensure that the necessary consent, to access information for the purpose of the investigation and also to share information with the victim's family, is sought as required at the earliest opportunity.

### The Standard Operating Model

The reporting requirements and information exchange within the model has three defined stages:

1. Providers report an incident through the NHS serious incident management system (STEIS) or its successor mechanism and conducts an initial review and produce a 72 hour report:
2. Providers conduct an internal investigation and produces an investigation report within 60 days:
3. The NHS England Regional Investigation Teams in conjunctions with the Independent Investigations Review Group (IIRG) reviews these reports and considers commissioning an independent investigation.

#### **Stage 1 - Incident reporting to the NHS serious incident management system, STEIS, or its successor, the initial 72-hour service management review and report**

- In the event of an incident the provider should enter all relevant and known details about the incident on the NHS serious incident management system (STEIS or its successor). The provider should inform the NHS England Sub-region quality lead, and the relevant CCG incident/quality lead<sup>50</sup>.
- The NHS England sub-region quality lead will alert the Regional investigations team via the Regional investigations team e-mail account and work with an identified lead in the CCG who will ensure an initial 72-hour review is completed by the provider.
- The aim of the review is to cover necessary immediate action with respect to;
  - Identifying and providing assurance that the safety of staff, patients and the public is protected;
  - Assessing the incident in more detail (and to confirm if the incident requires a full investigation);
  - Proposing the appropriate level of investigation; and
  - Communicating with relevant individuals and organisation including the families (of victims and perpetrators) Police, CQC, Monitor, TDA, Coroner, HSE as required.
- Providers should actively seek the details of all victims and their families through the appropriate channels at an early stage.
- The 72 hour review report should be shared with the CCG lead, Sub-region quality lead, and the Investigation Team.

<sup>50</sup> Where there are multiple commissioning organisations involved, this Framework encourages providers and commissioners to establish a lead commissioning model (wherever possible) so that the provider engages with one commissioner on a frequent basis. See Part Two, section 2 of this Framework for further details.

## **Stage 2 – Provider focussed internal investigation and 60-day investigation report**

- The relevant commissioner (typically the quality lead within the CCG) will ensure that the service provider undertakes a robust and thorough internal investigation. The Regional Investigations Team will be available to support and help develop the terms of reference with the commissioner and other stakeholders as necessary. An opportunity must be given to the family members of the victim and the alleged perpetrator to have input in to the terms of reference and raise concerns where possible.
- The internal investigation should be completed within 60 working days (from the date in which the incident is reported), be of good quality and underpinned by clear terms of reference. It should demonstrate the application of robust investigative methodologies which result in effective recommendations to prevent recurrence as outlined in part three of the main Framework.
- All investigative material should be retained and be readily available to share with the Independent Investigators if required.
- In addition to established local reporting procedures the 60 day report should also be shared with the CCG lead, sub-region quality lead and the Investigation Team and affected families.

## **Stage 3 - Independent Investigations Review Group (IIRG)**

- An IIRG has been established by each NHS England Regional Investigations Team. Its purpose is to review and help determine cases which require independent investigations. Each IIRG will have representation from experts in the field of mental health and/or investigation as well as lay members. Upon receipt of the 60 day report the relevant NHS England Regional Investigation Team will make arrangements for a review by the IIRG to take place. They will consider the scope and quality of the internal investigation, provide feedback and determine whether an independent investigation is required.
- It should be noted that there is no automatic bar on conducting independent investigations whilst criminal proceedings are underway. There should be an early discussion with relevant partners (e.g. police, Coroner) to ensure that investigations can commence at the earliest opportunity. The Regional Investigations Team will advise the provider of the IIRG decision and inform them if an investigation is required and at what level.

## **Commissioning the independent investigation**

- The regional investigations team will ensure the families of both the perpetrator and the victim are fully informed about the investigation and its parameters, what they can expect from it and how they can contribute.
- The regional investigations team will then draw up the terms of reference for the independent investigation following liaison with all appropriate stakeholders.
- A tender process will then take place to identify a suitable independent investigator to conduct the investigation.
- The regional investigations team will seek the consent of the perpetrator for access to their medical records to be released to the independent investigators

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(NB: agreement to access to the victims medical records may also be required in some cases).

### **Conducting the independent investigation**

- The regional investigations team will arrange a start-up meeting with key stakeholders to be involved in the investigation process. The purpose is to;
  - Introduce the stakeholders to the Independent investigators:
  - To establish links with each of the stakeholders in order to facilitate the investigation process;
  - To refine the terms of reference;
  - Set timescales for monitoring purposes; and
  - Discuss issues of concern
- The independent investigation should be completed in 6 months from the date it is commissioned.
- Throughout the investigation, monthly reports will be provided by the independent investigator to the NHS England Regional Investigations Team and bi-monthly reports to all stakeholders.
- The first draft of the final report will be shared by the investigator with stakeholders to check its factual accuracy. Commissioners and providers should then meet to begin the development of the action plan to address the report's recommendations. Comments from stakeholders during this process will also be considered by the Independent Investigators for inclusion in the final draft.
- The final draft report will be submitted to the Regional Investigations team which will ensure the necessary steps are undertaken to agree sign-off, publication and closure of the investigation.

### **Information Governance**

- In undertaking and commissioning investigations, personal information and records are shared as necessary by providers, CCGs, NHS England and independent investigators. Personal information relating to patients and staff will be treated in line with NHS England's policies on confidentiality, data protection and information governance.
- Access to personal identifiable information about patients in these cases will be restricted to staff working in investigation teams, the legal advisors and internally within NHS England when necessary for the purposes of the investigation.
- Internal and independent investigation reports will be shared with stakeholders, including the family of the victims involved. Independent investigation reports (and action plans) will be published, so issues concerning anonymity and consent for disclosure of personal information must be considered at an early stage in the investigation process. Each NHS organisation has a Caldicott Guardian who is responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. Advice from the Caldicott Guardian should be sought if guidance is needed about the disclosure of patient identifiable information.
- Information Governance must not stand in the way of a thorough investigation process that involves the victim's and their families. Those undertaking investigations should be aware of how to access the support of their Information

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Governance Leads, who can provide guidance in relation to the requirements of the duty of confidentiality, Data Protection Act and Human Rights Act, particularly where patients have expressed relevant views about access to their information. Organisations have a responsibility to understand these issues and deliver an open and transparent report.

### Legal opinion

- When the final draft independent investigation report is received by the Regional Investigation Team, it will be sent for legal review (to examine compliance with the law and to determine whether it is susceptible to legal challenge). The review will need to consider a number of issues, including:
  - Whether the terms of reference have been met;
  - Whether conclusions are supported with evidence;
  - Whether the report is defamatory; and
  - Whether confidentiality and data protection protocols have been followed.
- Following this process the review findings will be shared with the Independent Investigators to amend their report as necessary.
- The final report will then be submitted to the IIRG for acceptance on behalf of NHS England. NB: any issues/concerns must be discussed and where further action is required the investigator/investigating team must be informed.

### Pre-publication

- The Regional Investigations Team will arrange a pre-publication meeting with stakeholders to ensure that, prior to the report's publication;
  - legal issues have been addressed;
  - recommendations have been considered by all parties, an action plan developed and, stakeholders have had the opportunity to comment on it;
  - victim's, families, perpetrators and their families have had an opportunity receive a hard copy of the report in good time to review and understand its findings and recommendations;
  - individuals cited in the report have had the opportunity to comment;
  - a communications, media handling plan and publication date have been agreed; and
  - a date to present for sign off and closure have been agreed.

### Sign off and closure

- A meeting with relevant commissioners, NHS England Regional and Sub-regional leads must be convened. The victim's family or their advocates should be invited to attend. The perpetrator and the family and/or their representatives should also have an opportunity to discuss the sign-off and closure of investigation with relevant parties.
- The commissioners should advise the providers senior leadership team (i.e. Chief Executive, the Medical Director and/or Director of Nursing) that they will be required to attend to present their action plan for sign off.
- Sign off and closure should be agreed. Clearly any concerns/issues highlighted by any interested party must be considered by those responsible for commissioning

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the investigation (i.e. the regional investigation team). The regional investigation team must seek to understand the issue, consider and appropriately agree what further action is required.

- The commissioners will share the report with the Sub-region Quality Surveillance Group.
- It is important to recognise that the closure of the investigation does not mark the end of the case. Implementing actions and improvement can take a considerable amount of time. Providers and commissioners must ensure there are robust processes for monitoring the implementation of long term actions (see part three, section 4.5-5 for further details).

### **Publication**

- Reports should be made public in the interests of learning and transparency. NHS England will publish and share the independent investigation reports on its website. In order to encourage greater local accountability and ownership, independent reports will also be published by the relevant commissioners and the provider organisation.
- Independent Investigation reports are publicised in an anonymised format. Perpetrators can be named at their request, as can victims or where the families make a request.
- Resultant action plans will be published on the provider organisations website and be updated until completion.

## Appendix 2: 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<sup>viii</sup>.

## **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 focussed 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



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Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation and subsequent guidance<sup>ix</sup>.

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 have to 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 particular 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)**

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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**

The vast majority of 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 Incident Decision Tree should be used to determine if action is required in relation to individuals<sup>51</sup>

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

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<sup>51</sup> The Incident Decision Tree aims to help the NHS move away from attributing blame and instead find the cause when things go wrong. The goal is to promote fair and consistent staff treatment within and between healthcare organisations. NHS England is currently redeveloping the Incident Decision Tree with a plan to re-launch in early 2015.

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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 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. This process is described in appendix 1. This appendix should be read in conjunction with the main Framework.

### Scope

Investigations carried out under this Framework 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.

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Within each Regional Team of NHS England a Regional investigation team has been established. This team, with input from an Independent Investigation Review Group (IIRG)<sup>52</sup> is responsible for commissioning independent investigation into incidents involving homicide by those in receipt of mental health care (as outlined in Appendix 1). 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:

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<sup>52</sup> A group established by the regional investigation team to review cases requiring independent investigation which includes members with relevant subject expertise (in clinical practice and/or investigation) as well as lay members.

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- 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<sup>53</sup> 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<sup>54</sup>.
- 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.
- As detailed in Appendix 1, an independent investigation should be commissioned by NHS England's regional investigations team when a homicide has been committed by a person who is, or has been, subject to a care programme approach, or is under the care of specialist mental health services, in the past six months<sup>55</sup> prior to the event. Appendix 1 describes the procedures that must be followed in such circumstances.

### **Declaration and Immediate Action**

The processes/actions described in Part Three; section 2 must be followed. 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,

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<sup>53</sup> E.g. cases where the relevant provider organisation has assumed responsibility (including exercising control) for the patient's welfare and safety: *Rabone v Pennine Care NHS Foundation Trust* [2012] UKSC 2. Further advice should be sought in relation to such matters as outlined on page 66 of this guidance.

<sup>54</sup> The final decision will rest with the commissioner although advice may be sought from the Regional Investigations Team. The quality of the provider's internal investigation should be considered in terms of its content and particularly in relation to how well the concerns of the patients and their families have been taken into consideration and addressed (refer to the assessment tool, appendix 8).

<sup>55</sup> Six months is a guide and each case should be considered individually as it may be appropriate to declare a serious incident for a homicide by a person discharged from more than 6 months prior to the event.

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then the commissioner should take the necessary action to commission an independent investigation to ensure that action is taken without delay. In 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 (see part three; section 4.2 for further details).

### **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, in line with section three of this Framework) 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**



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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<sup>56</sup>.
- 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 team**

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

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<sup>56</sup> Issues concerning anonymity and consent for disclosure of personal information are important and should be considered at an early stage in the investigation process. Each NHS organisation 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 the advice from the Caldicott Guardian if guidance is needed about the disclosure of patient identifiable information. NHS England is seeking advice in relation to the development of national guidance to support this issue. In the meantime, advice from the Caldicott Guardian and specific legal advice (where required) must be sought on a case by case basis.

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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;
- 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<sup>x</sup>.

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<sup>57</sup>. The commissioner of the investigation will send a copy of the draft report to the relevant bodies to check

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<sup>57</sup> The report may disclose confidential personal information for which consent has been obtained, or if patient confidentiality has been breached, this is balanced against public interest. This should be considered by the organisations Caldicott Guardian and confirmed by legal advice where required. NHS England is currently seeking advice in relation to national guidance available to further support this matter. In the meantime, advice should be sought in relation to each case.

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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**

As outlined in Part Three; section 5, 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<sup>58</sup>.

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<sup>iii</sup>’.

Not all incidents being investigated under this guidance will trigger a duty for the investigation to be Article 2 compliant<sup>59</sup>. 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.

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<sup>58</sup> Further information is available online at:

[http://www.equalityhumanrights.com/sites/default/files/documents/humanrights/hrr\\_article\\_2.pdf](http://www.equalityhumanrights.com/sites/default/files/documents/humanrights/hrr_article_2.pdf)

<sup>59</sup> The requirements of such an investigation are:

- the authorities must act of their own motion;
- the investigation must be carried out by a person who is independent of those implicated in the events being investigated;
- the investigation must be effective in the sense that it must be conducted in a manner that does not undermine its ability to establish the relevant facts;
- the investigation must be reasonably prompt;
- there must be ‘a sufficient element of public scrutiny of the investigation or its results to secure accountability in practice as well as in theory’
- the degree of public scrutiny required may well vary from case to case;
- there must be involvement of the next of kin to the extent necessary to safeguard his or her legitimate interests.

## 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<sup>xi</sup>.

### **Providers (including GPs and Primary Care)**

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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

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for contact (for example, in London via [ENGLAND.LondonInvestigations@nhs.net](mailto: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 the guidance in part one, section 1-1.5 of this Framework. 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<sup>60</sup>. The four regional leads will produce, with appropriate support, an Annual Report for NHS England on Domestic Homicide and the NHS.

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<sup>60</sup> Home Office Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews (2013) [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/209020/DHR\\_Guidance\\_refresh\\_HO\\_final\\_WEB.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209020/DHR_Guidance_refresh_HO_final_WEB.pdf)



## 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<sup>61</sup> 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

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<sup>61</sup> GP services, community pharmacy, and primary ophthalmic services (mainly NHS sight tests); all dental services - primary, community, hospital; specialised services; high-secure psychiatric services; offender health; some aspects of healthcare for members of the armed forces and their families; and public health services (screening, immunisation, services for children aged 0-5 including health visiting) on behalf of Public Health England

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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<sup>xii</sup>
- **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.

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

<b>Provider:</b>		<b>Services And Service Address:</b>							
	<b>Key stakeholders</b>								
			NHS England						
	Geographical I 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:
Organisatio n name:									
Function for Serious Incident Oversight (RASCI)									
<b>RASCI Definitions<sup>62</sup></b>									
<i>Responsible</i> - (Doer) - The team assigned to do the work									
<i>Accountable</i> - (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									

<sup>62</sup> NHS England (2014) Principles for managing quality in specialised commission

## Appendix 6: Example incident reporting forms (either template can be used)

<b>Serious Incident Reference Number:</b>	
<b>STEIS Identification Number:</b>	
<b>Date/Time/Location of Incident including hospital / ward / team level information</b>	
<b>Incident type</b>	
<b>Type of investigation expected to be required: Level 1, 2 or 3</b>	
<b>Description of incident including reason for admission and diagnosis (for mental health please include Mental Health Act status and date of referral and last contact)</b>	
<b>Details of any police or media involvement/interest</b>	
<b>Details of contact with or planned contact patient/family or carers</b>	
<b>Immediate actions taken including actions to mitigate any further risk</b>	
<b>Details of other organisations/individuals notified</b>	
<b>Lead Commissioner</b>	
<b>Report completed by</b>	
<b>Designation</b>	
<b>Date / time report completed</b>	
A brief chronology of key events (to be inserted) if required	

Choose an item.

**NHS England North Yorkshire and Humber Sub-region serious incident example reporting form** (incorporates details required within 72 hour template- either template can be used to generate 72 hour report)

This template has been kindly provided by NHS England North Yorkshire and Humber Sub-region and may be adapted for local application			
CCG Area			
Reporting organisation			
Reporter Details			
Reporter name		Reporter Job Title	
Reporter Tel. no		Reporter E-mail	
Incident Details			
Date of incident?		Date Incident Identified?	
Incident Site? (if other than reporting org)		Incident Location?	Click to select Location
Who Was Involved			
Type of Patient?	click to Select Type		
GP Practice?			
Gender?	Male <input type="checkbox"/> Female <input type="checkbox"/>		
Date Of Birth? (dd/mm/yyyy or N/A)			
Ethnic Group?			
Persons Notified?	Patient <input type="checkbox"/> Family <input type="checkbox"/> Carer <input type="checkbox"/>		
Degree of Harm	None <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Death <input type="checkbox"/>		
Junior Doctor Involvement?	Include Specialty and Grade		
What Happened			
Type of Incident			
Actual/Near Miss?			
Never Event?	Yes <input type="checkbox"/>	Expected level of investigation	

Choose an item.

Description of Incident					
Immediate Action Taken					
Media Interest?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Comms informed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Externally reportable?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Externally reported to?		
Any Other Comments: e.g. multiagency incident, police and /or HSE investigation, Coroner's inquest, CQC involvement.					

## 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<sup>63</sup>;
- 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.

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<sup>63</sup> Patients and families also have rights under information legislation, such as the Freedom of Information Act, the Data Protection Act (Subject Access Provisions), and Access to Health Records Act (where not superseded) to access information as applicable.

Choose an item.

### **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)**



Choose an item.

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;

Choose an item.

- 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;

Choose an item.

- 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.

Choose an item.

## Appendix 8: Closure checklist

This checklist provides a tool which can be used by providers and commissioners in their assessment of systems investigation into serious incidents. The STEIS report must be fully completed including date investigation is completed, lesson learned and actions taken			
Phase of investigation	Element	Answer (yes/no)	If no, was there a robust rationale and that prevents this affecting the quality of the investigation?
Set up/ preparation	Is the Lead Investigator appropriately trained?		
	Was there a pre-incident risk assessment?		
	Did the core investigation team consist of more than one person?		
	Were national, standard NHS investigation guidance and process used?		
Gathering and mapping	Was the appropriate evidence used (where it was available) i.e. patients notes/records, written account?		
	Were interviews conducted?		
	Is there evidence that those with an interest were involved ( <i>making use of briefings, de-briefings, draft reports etc.</i> )?		
	Is there evidence that those affected ( <i>including patients/staff/ victims/ perpetrators and their families</i> ) were involved and supported appropriately?		
	Is a timeline of events produced?		
	Are good practice guidance and protocols referenced to determine what should have happened?		
	Are care and service delivery problems identified? ( <i>This includes what happened that shouldn't have, and what didn't happen that should have. There should be a mix of care (human error) and service (organisational) delivery problems</i> )		
	Is it clear that the individuals have not been unfairly blamed? ( <i>Disciplinary action is only appropriate for acts of wilful harm or wilful neglect</i> )		
Analysing information	Is there evidence that the contributory factors for each problem have been explored?		
	Is there evidence that the most fundamental issues/ or root causes have been considered?		
Generating solutions	Have strong (effective) and targeted recommendations and solutions (targeted towards root causes) been developed? Are actions assigned appropriately? Are the appropriate members i.e. those with budgetary responsibility involved in action plan development? Has an options appraisal been undertaken before final recommendation made?		
Throughout	Is there evidence that those affected have been appropriately involved and supported?		
Next steps	Is there a clear plan to support implementation of change and improvement and method for monitoring?		
Overall assessment and feedback			

## 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<sup>xiii</sup>

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

Choose an item.

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. It will be extended to all other providers from 1 April 2015, subject to Parliamentary process and approval.

This regulation requires an NHS body to:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity
- Tell the relevant person in person as soon as reasonably practicable after becoming aware that a ‘notifiable safety incident’<sup>64</sup> has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident which, to the best of the health service body’s knowledge, is true of all the facts the body knows about the incident as at the date of the notification.
- Advise the relevant person what further enquiries the health service body believes are appropriate.
- Offer an apology.
- Follow this up by giving the same information in writing, and providing an update on the enquiries.
- Keep a written record of all communication with the relevant person

Further information is available online at

<http://www.legislation.gov.uk/ukdsi/2014/978011117613/regulation/20> and [http://www.cqc.org.uk/sites/default/files/20141120\\_doc\\_fppf\\_final\\_nhs\\_provider\\_guidance\\_v1-0.pdf](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.

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<sup>64</sup> means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

- (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or
- (b) severe harm, moderate harm or prolonged psychological harm to the service user

Choose an item.

**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

Choose an item.

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.



Choose an item.

**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.

**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

## References

<sup>i</sup> National Patient Safety Agency, 'Seven Steps to Patient Safety', 2004 – 2009. Available at <http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/>

<sup>ii</sup> Royal College of Surgeons (2014) Building a culture of candour: A review of the threshold for the duty of candour and of the incentives for care organisations to be candid. Available online <https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

<sup>iii</sup> Human Rights Review (2012) Article 2: The Right to Life [http://www.equalityhumanrights.com/sites/default/files/documents/humanrights/hrr\\_article\\_2.pdf](http://www.equalityhumanrights.com/sites/default/files/documents/humanrights/hrr_article_2.pdf)

<sup>iv</sup> National Patient Safety Agency, 'Being Open: communicating patient safety incidents with patients, their families and carers', November 2009, available at: <http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83726>

<sup>v</sup> Maria Dineen (2011) *Six Steps to Root Cause Analysis* (third edition) ISBN:978-0-9544328-2-9

<sup>vi</sup> NHS England (2014) Principles for managing quality in specialised commissioning (including RASCI template) available at: [https://nhs.uk/sharingpoint.com/TeamCentre/Operations/\\_layouts/15/WopiFrame.aspx?sourcedoc={1CAE2D20-BB4F-47A3-BFB6-3371A4D7AE6A}&file=Principles%20for%20managing%20quality%20in%20specialised%20commissioning%20including%20RASCI%20template.docx&action=default](https://nhs.uk/sharingpoint.com/TeamCentre/Operations/_layouts/15/WopiFrame.aspx?sourcedoc={1CAE2D20-BB4F-47A3-BFB6-3371A4D7AE6A}&file=Principles%20for%20managing%20quality%20in%20specialised%20commissioning%20including%20RASCI%20template.docx&action=default)

<sup>vii</sup> NPSA, RCA toolkit, available at: <https://report.nrls.nhs.uk/rcatoolkit/course/iindex.htm>

<sup>viii</sup> Work related deaths: A protocol for liaison (England and Wales). Available at: <http://www.hse.gov.uk/pubns/wrdp1.pdf>

<sup>ix</sup> Health and Social Care Information Centre guidance HSCIC Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (2015) Available at: <https://www.igt.hscic.gov.uk/KnowledgeBaseNew/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf>

Choose an item.

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<sup>x</sup> Independent Schools Inspectorate (ISI) 2012- Integrated Handbook-framework

<sup>xi</sup> Home Office Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews (2013)  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/209020/DHR\\_Guidance\\_refr\\_esh\\_HO\\_final\\_WEB.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209020/DHR_Guidance_refr_esh_HO_final_WEB.pdf)

<sup>xiii</sup> Department of Health, No Secrets, available at  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4008486](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008486)