NHS England

Serious Incident Framework - frequently asked questions (March 2016)

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Serious Incident Framework - frequently asked questions (March 2016)

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Contents

1 Are 'Serious Incidents' limited to isolated events which result in harm?

No. Serious incidents can include those where patients could have been seriously harmed but, for a stroke of luck or heroic action on the part of an individual, this was avoided. Where very significant consequences may have resulted and there is a strong likelihood that the incident could be repeated, it may be justified to declare a serious incident in order to ensure the incident is learned from. Also, see questions 10 and 11 for further details.

Equally, serious incidents can include incidents which do not directly result in patient harm but do present risks to an organisation's ability to deliver safe ongoing healthcare (Part 1: Section 1 of the Framework provides details relating to the circumstances in which serious incidents may be identified). For example, an isolated event or the occurrence of a series of events, signalling systemic failures within a commissioning or health system, can trigger a Serious Incident investigation.

It is also possible that a seemingly minor local incident, particularly those within screening programmes, can trigger the need for a Serious Incident investigation due to their ability to have a major service or population impact if, for example, the incident affects an entire care pathway for a patient or multiple patients.

Incidents like this have the potential to cause wide-spread concern- the consequences and impact often become increasingly significant as information emerges through the course of an investigation- and must be carefully managed.

The response, as with any Serious Incident investigation, should follow 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 fundamental principles (Part 2; section1)

and overarching process (described in Part 3; section1) should be applied appropriately to ensure the response is proportionate.

Involving the appropriate individuals/organisations, clearly articulating roles and responsibilities in relation to an agreed investigation, communication and media management plan will be essential for a coordinated and effective response. Specific guidance is provided for managing safety incidents in NHS screening programmes available online at https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes [1]

The Serious Incident Framework, Part 2; Section 2 (and appendix 5), outlines an approach (using the RASCI[2] model) to help establish the roles and responsibilities for those involved in the management and oversight of investigations involving multiple organisations (including providers, commissioner and other supervisory bodies).

Part 3; section 2 outlines immediate actions that should be undertaken in response to a serious incident including what to do in circumstances where an SI is suspected but the scale and severity is unknown (also see question 11).

NB: guidance on initial fact finding procedures following incidents (and potential serious incidents) in screening programmes can be found within the screening guidance.

Part 3; section 4 (of the Serious Incident Framework) describes the investigation process, how to set up an appropriate investigation team and how to support those affected including patients, families and staff. Appendix 7 provides additional information to support a communication plan and communication materials for those involved.

2 Are Serious Incident investigations intended to determine if there is personal or organisational culpability?

No. It is important the Serious Incident investigation process is used for the purpose of learning and not to apportion blame. In rare circumstances, where there is evidence to suggest an individual has caused intended harm, is unfit to carry out their duties, or has acted in a grossly negligent manner[3] appropriate referral (through established HR and professional regulatory routes, etc.) should be made and separately progressed. The Serious Incident investigation must focus of identifying the learning (i.e. contributing factors and root causes) and subsequent actions that once implemented would prevent a similar incident occurring again.

[1] This guidance explains the different stages (and associated procedures) of incident management and the roles and responsibilities of those likely to be involved in these circumstances.
[2] Responsible, Accountable, Supporting, Consulted, Informed
[3] We intend to refresh the NPSA's Incident Decision Tree to reflect the current NHS landscape, but the principles within it of the deliberate harm test; ill health test; foresight test; and substitution test remain helpful for identifying the circumstances when HR advice may be required.

The NHS Litigation Authority (NHS LA) agrees that it is important for healthcare organisations to investigate and identify root cause(s) to understand what action can be taken to prevent the likelihood of future recurrence. The identification of one or more root causes would not necessarily result in a finding of civil liability. This is because the claimant would need to establish that the care fell below the reasonable standard and that, as a result, they suffered a reasonably foreseeable injury.

The NHS LA's Saying Sorry guidance clearly states that cover for a claim would never be withheld because an apology or explanation has been given. NHS LA is fully supportive of both Being Open[4] and the Duty of Candour[5]. The NHS LA "Saying Sorry" guidance is available online via: http://www.nhsla.com/Claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf). Further information is also available via: http://www.nhsla.com/Safety/Pages/Home.aspx

3 Are 'avoidable' deaths that are identified via routine retrospective case record review Serious Incidents?

Yes. Research by Hogan et al[6],[7] shows that when retrospective case record review of patients who have died in hospital identifies an apparently avoidable death, that death tends to be due to a series of incidents, primarily omissions and delays, none of which would be likely to have caused the death in isolation but which in combination can result in the death of a patient.

The fact that a death was due to a number of omissions and delays for example, rather than a single catastrophic error does not mean it does not count as a 'Serious Incident'. Deaths that were probably avoidable on the basis of retrospective case record review almost certainly meet Serious Incident criteria.

It is acknowledged that typically, deaths of this kind will be reported at the point the avoidable death was identified rather than at the point where individual incidents contributing to the death occurred.

4 Must all deaths of detained patients, including deaths of patients in custody[8] be reported as Serious Incidents?

All unexpected deaths of detained patients, where the death might have been caused by problems in healthcare, should be reported as Serious Incidents (just as for unexpected deaths where there might have been problems in healthcare in any other setting). If, following an initial review or further investigation it is identified that the

[4] Guidance available online at: http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726

[5] Care Quality Commission (CQC) Regulation 20: Duty of Candour available online https://www.cqc.org.uk/content/regulation-20-duty-candour

[6] Hogan et al. Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. *BMJ Qual Saf2012*:21:737-45.

[7] Hogan et al. Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record BMJ 2015;351:h3239

[8] This refers to custodial settings (e.g. prisons) where healthcare is commissioned by NHS England

Serious Incident definition is not upheld (i.e. the death resulted from a patient's underlying condition which was managed in line with accepted practice) then the incident can be downgraded. This can be done at any point in an investigation.

Some deaths may be expected (i.e. as a result of natural causes / course of patient's underlying illness when managed in line with accepted practice) and in such circumstances should not be reported as Serious Incidents.

5 What is meant by the phrase 'unexpected or avoidable' in the Serious Incident definition?

This phrase is intended to ensure that death or injury that was an expected or inevitable consequence of the patient's medical condition or healthcare, does not trigger a Serious Incident investigation. It is not intended to support a search for reasons why harm could not have been avoided and does not mean that an injury resulting in serious harm or death can be said to be '*unavoidable*' just because the prevention of this particular type of harm can be challenging.

The judgement of avoidability requires careful review of the care that was provided against the care that would have been expected given our understanding of acceptable clinical practice at the time of the incident and the wider circumstances within which the incident occurred.

It is not acceptable to locally define in advance certain types of incident, such as certain pressure ulcers or inpatient falls, as 'unavoidable' as long as some routine prevention measures have been undertaken. Caution should also be taken not to automatically assume that all cases of injury resulting in serious harm or death during a surgical or invasive procedure can be assumed to be an 'expected complication' even if such complications are listed in the literature or consent formats. This is because the likelihood of complications occurring will be influenced by the safety of local systems; each case needs to be considered individually.

Any Serious Incident investigation which seeks to conclude that an incident was either 'avoidable' or 'unavoidable' rather than focusing on what could be learned to prevent future harm is not compliant with Root Cause Analysis methodology.

The phrase 'unexpected' when applied to unexpected deaths is not intended to indicate that all deaths of patients not in receipt of end of life care should be considered Serious Incidents; death may be expected because of wider health conditions, continued substance abuse, or other issues, even though end of life care was not in place.

Equally, the fact that a patient was receiving end of life care does not in itself mean there is never a need to declare a Serious Incident (for example, a major opiate medication error may be the direct cause of death and meet Serious Incident criteria). Whilst health conditions that can cause sudden death (such as a cardiac arrhythmia) are more likely to be 'unexpected' than conditions where health tends to deteriorate over time (such as chronic obstructive pulmonary disease), there are no clinical diagnoses that in themselves define a death as expected or unexpected; the circumstances have to be individually considered.

To be ‘unexpected’ a death must be unexpected to all relevant providers of the patient’s healthcare. For example, the death of a patient who occasionally attends a dementia clinic in a mental health trust may not have been anticipated by the mental health trust, but if it was expected by the GP who sees the patient more frequently to treat their heart failure, it was not an ‘unexpected’ death.

6 There is no list of specific incidents that should be reported as Serious Incidents, should a local list be created?

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 criteria included within the Serious Incident framework describes the general circumstance in which providers and commissioners should expect serious incidents to be reported. Providers and commissioners should work together to ensure they are applied appropriately.

It is also important to highlight that historically certain incidents have been classified as SIs so they can be counted (as part of local initiatives and/or incentives) and this is not the purpose of the SI framework (or STEIS) so alternative methods of data collection should be sought where there is a desire to count certain types of incident.

7 Are 12 hour waits for admission automatically classed as Serious Incidents?

No. It is possible that a 12 hour wait could result in serious harm to a patient and in such circumstances should be reported and investigated appropriately. However, this may not always be the case. Additionally, in some circumstances patients could suffer serious harm from delays much shorter than 12 hours depending on their condition. This is why an incident should be considered on a case by case basis as described in detail in question 6 above.

8 Should pressure ulcers be reported as Serious Incidents?

Where the definition of a Serious Incident is met, the incident should be reported and investigated according to the principles set out in the Serious Incident Framework.

Often organisations report all category 3 and 4 pressure ulcers as Serious Incidents. Clearly some will meet the definition but categorising all category 3 and 4 pressure ulcers as Serious Incidents may lead to a 'burden of investigation that makes it difficult to move forward quickly and implement learning'[9]. Consideration must be given to the circumstances of each case since the category of a pressure ulcer does not always indicate the severity of the wound. For example, an infected category 2 pressure ulcer may lead to septicaemia and death whereas a very small category 3 pressure ulcer on the ear (designated as category 3 because cartilage will be exposed with any loss of overlying skin) may not have serious consequences for the patient.

Grading pressure ulcers can also be difficult, particularly when differentiating between a category 2 and 3 pressure ulcer and also between a category 3 and 4. This is another reason why grading alone should not be relied on for determining overall severity.

Any pressure ulcer that meets, or potentially meets, the threshold of a Serious Incident should be thoroughly investigated to ensure any problems in care are identified, understood and resolved to prevent the likelihood of future recurrence. This requires an assessment of whether any acts of omission or commission may have led to the pressure ulcer developing. It is not acceptable to locally define, in advance, certain types of pressure ulcer that are 'unavoidable' as long as some routine preventative measures have been undertaken. As stated in questions 4 above any Serious Incident investigation which seeks to conclude that an incident was either 'avoidable' or 'unavoidable' rather than focusing on what could be learned to prevent future harm is not compliant with Root Cause Analysis (RCA) methodology.

It is important to note that if the patient was clearly not, nor should have been, in receipt of any NHS funded healthcare (including part NHS-funded or co-funded care) at the time the pressure ulcer developed then it would not meet criteria for Serious Incident reporting. For example, a healthy adult who is injured in an accident at home but not found until after a 'long lie' during which a pressure ulcer developed would not meet the criteria of a Serious Incident.

It is important that all pressure ulcers, except in people who were unknown to NHS funded services, are recognised as patient safety incidents and reported accordingly. All patient safety incidents should be reported to the National Reporting and Learning System (NRLS) for the purposes of national learning. See questions 15 for further information relating to the NRLS.

9 Why are Never Events classed as Serious Incidents?

Never Events arise from the 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. Therefore, where such

[9] Tissue Viability Society, 2012, Achieving Consensus in Pressure Ulcer Reporting. Available online at: http://tvs.org.uk/wp-content/uploads/2013/05/TVSConsensusPUReporting.pdf

a Never Event occurs, this highlights that there are weaknesses in a system or process which must be investigated, understood and addressed to prevent the likelihood of future recurrence and harm to patients.

10 Should 'near misses' be reported as Serious Incidents?

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.

Clearly, this is a judgement call 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.

11 What should happen where incidents occur that might be Serious Incidents but it is not immediately clear?

It is acknowledged that unexpected outcomes are not always the result of error/ acts and/ or omissions in care. It may be unclear initially whether an unexpected outcome is potentially related to any weaknesses in a system or process (including acts or omissions in care) or was related to natural disease processes or issues unrelated to healthcare. 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. Often a more informed judgement can be made as more information becomes available (for example, post-mortem examination and toxicology results in the case of an unexpected death).

Incidents that are reported as Serious Incidents can be downgraded at any stage where it is found that the Serious Incident criteria is not met and further investigation is not required. Equally, incidents that initially appear unrelated to healthcare can be reported as Serious Incidents if at any point new information is obtained to suggest they may be related to any weaknesses in a system or process (including acts or omissions in care).

12 Does it matter if an incident is discovered a long time after it happened, or at a different organisation to where it happened?

Serious Incidents may, on occasion, be discovered some time, even years, after the incident itself occurred. The delay between the incident and its discovery is not in itself a factor in determining whether an incident is a Serious Incident or not. It may however, have a bearing on the improvements that are deemed necessary following investigation, for example where changes in procedures since the incident mean that additional actions may no longer be necessary.

Where a Serious Incident is discovered by one organisation, but appears to be the responsibility of another, it is the 'discovering' organisation's responsibility to ensure that the appropriate organisations are alerted in the first instance. The incident should then be recorded and responded to by the organisation where the incident occurred provided they are identifiable. This process is intended to facilitate the investigation, learning and resolution of issues where it matters most. It is not about the attribution of fault or blame.[1] Changes within the STEIS system, to facilitate notification of Serious Incidents occurring in other organisations, have been made to enable organisations to document serious incidents which need to be investigated by others. Commissioners should assist their providers to ensure relevant organisations are made aware of any such incident so that the necessary action can be taken.

13 What should Commissioners and Providers do if they cannot agree on whether something is or is not a Serious Incident?

Agreement must be established locally between the Provider and the Commissioner. It is important that the Provider and Commissioner maintain a two-way discussion until agreement is achieved. NHS England Regional Teams may advise in circumstances where local resolution is unsuccessful but they are not responsible for acting as arbiters in relation to individual cases.

Neither the Department of Health, NHS England Central or NHS Improvement will act as arbiters of whether a particular incident is a serious incident or not.

14 Can the numbers, rates or types of Serious Incident reports be used for performance management?

No. Providers and their commissioners would be expected to routinely discuss whether Serious Incident reporting is conforming to the principles of the Serious Incident framework, but this discussion needs to be based on the nature of reporting, investigation and action, rather than numbers of Serious Incidents reported.

Ultimately we do not know what is (or even if there can be such a thing as) a 'tolerable/expected' number of SIs (for any organisation): Average numbers or rates may not represent desirable practice, while very high numbers or rates of Serious Incidents may indicate a dilution of the resource available for meaningful investigation. So, it would be inappropriate to benchmark against a perceived correct or an average

number or rate. If you benchmark the wrong example, the copied organisational model may only set you back in your efforts to improve[10].

Serious incident reporting has been used for different purposes across different organisations, so there is significant variation in reporting practice. Often the incidents that are reported may reflect historical reporting requirements set out in local lists (defining SIs) rather than an organisation's ability to recognise harm or the potential for harm.

It is also important to note that a provider's size, structure and function is not reflected in Serious Incident data. SI data does not therefore provide a useful indication of risk when considered in isolation.

15 How does Serious Incident reporting align with the National Reporting and Learning System (NRLS) and NRLS categories of harm?

The National Reporting and Learning System (NRLS) captures all patient safety incidents[11] reported to local risk management systems such as Datix or Ulyses. When reporting patient safety incidents to the NRLS the actual (not potential) level of harm caused must be reported.

The Strategic Executive Information System (STEIS) captures all Serious Incidents. Serious Incidents (as defined in the Serious Incident Framework) can include but are not limited to patient safety incidents. Whilst almost all patient safety incidents that have been reported to the NRLS with correct use of the NRLS categories for death or severe harm[12] would be likely to meet the definition of a Serious Incident, the Serious Incident definition must be directly applied when considering if reporting via STEIS is required.

Some organisations have expressed their confusion when reporting serious incidents to STEIS and the NRLS because it is difficult to imagine that a Serious Incident can be reported as a no or low harm incident. However, the outcomes (i.e. actual harm) of Serious Incidents can cover all degrees of harm. For example, all Never Events are Serious Incidents but not all will result in severe harm or death. Therefore the actual outcome that is reported to the NRLS may in fact be no or low harm, even though it's declared as a Serious Incident. Additionally some Serious Incidents may not involve actual or potential harm to any patient (e.g. an incident related to loss of confidential information affecting staff).

All Serious Incidents which meet the definition of a patient safety incident should be reported to STEIS and to the National Reporting and Learning System (NRLS).

[10] G.L.Neilson et al (2015) 10 Principles of Organisational Design

[11] Any unintended or unexpected incident that could have led or did lead to harm for one or more patients receiving NHS-funded healthcare.

[12] A patient safety incident that appears to have resulted in permanent harm (i.e. permanent lessening of bodily functions, including sensory, motor, physiological or intellectual) to one or more persons receiving NHS-funded care.

Organisations with local risk 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. Further information available online: http://www.england.nhs.uk/ourwork/patientsafety/report-patient-safety/

An easy to access reporting form and further guidance to support the reporting of patient safety incidents in general practice is also available online from: http://www.england.nhs.uk/ourwork/patientsafety/general-practice/

16 Must a full investigation be undertaken for every Serious Incident?

The scale and scope of the investigation should be proportionate to the incident to ensure resources are effectively used. 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.

Within the NHS, Root Cause Analysis (RCA) is the recognised standard systems based approach for conducting investigations. As part of the RCA model there are two templates for constructing investigation reports;

- a concise template- suited to less complex incidents which can be managed by individuals or a small group at a local level ; and
- a comprehensive template- suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable

National reporting templates should be used unless agreed that adaptions are required. National templates will be reviewed on a continuous basis. Recommendations to inform changes should be sent to england.RCAinvestigation@nhs.net

17 When is it appropriate to use multi-incident or aggregate RCA methodology?

The multi-incident investigation root cause analysis (RCA) model provides a useful tool for thoroughly investigating reoccurring problems of a similar nature (for example, a cluster of falls that occur 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 deeper learning and improvement.

Using this methodology for investigation of Serious Incidents (including Never Events) should be considered with caution. It may be appropriate in some scenarios e.g. where an organisation has identified a wide-spread risk and has demonstrated their ability to

determine common causal factors by undertaking investigation, which is compliant with best practice, and can show evidence of this and the improvements being made to reduce the likelihood of recurrence. However, this would need careful assessment, engagement with those affected and agreement on a case-by-case basis.

18 How does the SI framework align with the Serious Case Review and Safeguarding Adult Review process?

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[13] (2013) the LSCB will commission Serious Case Reviews and in circumstances set out in guidance for adult safeguarding concerns[14] the LSAB will commission Safeguarding Adult Reviews. The Local Authority will also initiate Safeguarding Adult Enquiries, or ask others to do so, if they suspect an adult is at risk of abuse or neglect.

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, 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.

It is recommended that if one (joint) investigation is to be undertaken by multiple agencies (NB: the terms of reference must be the same; investigations for learning cannot be undertaken jointly with investigations seeking to identify criminal culpability/ professional misconduct etc.) then a common methodology should be consistently applied. Separate investigations can be undertaken if different approaches are required e.g. the health service may conduct their own investigation using the Root Cause Analysis methodology (if a serious incident / potential serious incident) is identified as this will enable well defined recommendations to be develop which are based on specific care and delivery problems, contributory factors and fundamental root causes. However, given the multi-agency nature of safeguarding concerns, it is

[13] Available online: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/281368/Working_together_to_safeguard_children.pdf

[14] Available online: http://careandsupportregs.dh.gov.uk/category/adult-safeguarding/

essential that investigations and not undertaken in isolated and responsibility is assigned for reviewing all aspects of care in order to identify the gaps between and within different services/ sectors.

19 What constitutes a good quality investigation?

A good quality investigation allows organisations to identify:

- The problems (the what?) including lapses in care/acts/omissions that may have contributed towards an incident; 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; and
- Enables the development of solutions which effectively address problems to reduce the likelihood of recurrence.

The Framework endorses the application of the recognised systems-based method for conducting investigations, commonly known as Root Cause Analysis (RCA). Investigations must effectively engage those affected and must not inappropriately blame anyone involved.

There are many elements to a good quality investigation. These are underpinned within the framework and outlined as part of the assessment tool included within the appendices.

20 The closure checklist includes 'Is the Lead Investigator appropriately trained?' What are the criteria for determining this?

For staff leading a Root Cause Analysis, Patient Safety Investigation this should include:

1. A 2-day training course which offers a practical element to the training, in particular the analysis section.

The course should:

- cover effective solution generation and implementation
- follow and promote the Serious Incident framework
- follow and endorse the National Patient Safety Agency (NPSA) guidance and toolkit (for further information visit: https://www.england.nhs.uk/patientsafety/root-cause/)
- specifically promote the use of the NPSA final report templates.

2. The individual should undertake a full RCA patient safety investigation within 12 months of the training

3. Individuals continuing to conduct investigations should complete advanced training within 2- 3 years of their initial 2-day course. (Having attended a two day course investigators should be aiming to advance analytical and improvement skills; and the subsequent quality of investigations and reports).

4. The individual should have updates to the training every three years.

Staff assisting or quality assuring the investigation should also have received appropriate training. For staff assisting in a Root Cause Analysis, Patient Safety Investigation this includes:

1. A 1-day training course which offers a practical element to the training, in particular the analysis section.

The course should:

- follow and promote the Serious Incident framework
- follow and endorse the NPSA guidance and toolkit
- specifically promote the use of the NPSA final report templates.

2. The individual should assist with an RCA patient safety investigation within 12 months of the training

3. The individual should have updates to the training every 3 years.

For staff quality assuring a Root Cause Analysis, Patient Safety Investigation this includes:

1. A 1 or 2-day training course which offers a practical element to the training, in particular the analysis section and focuses on the key elements of how to critique an RCA investigation report.

   - follow and promote the Serious Incident framework
   - follow and endorse the NPSA guidance and toolkit
   - specifically promote the use of the NPSA final report templates.

2. The individual should undertake or shadow an RCA patient safety investigation to consolidate their training

3. The individual should have updates to the training every 3 years.

The NPSA guidance on: human error, fair blame, human factors, cognitive interviewing, being open and effective solution generation and implementation should all be part of the courses for all of the above.

21 Is it necessary to include a pre-investigation and post-investigation risk assessment in the investigation report?

The full detail of a pre and post investigation risk assessment (i.e. full details relating to how the likelihood and severity where agreed) does not have to be included in the final report, but the results (risk ratings) should be.

A pre investigation risk assessment identifies the perceived risk and therefore the level of investigation required, and any immediate actions that may be needed to protect those at risk of harm. The post RCA risk assessment a. reviews / revisits this assessment for learning; (for example, during and/or following the investigation you may learn that the consequence of an incident is more or less severe than initially anticipated and this would affect the perceived level of risk) and b. Provides a baseline from which efficacy of remedial actions can be measured/monitored.

The pre and post investigation risk assessment forms part of the investigation good practice guidance endorsed within the Serious Incident Framework (available online at https://www.england.nhs.uk/patientsafety/root-cause/).

22 When should Serious Incidents be closed?

Closure of an incident marks the completion of the investigation process only. Commissioners should close incidents on receipt of the final investigation report and action plan if they are satisfied that the requirements outlined within the serious incident framework are fulfilled. Incidents can be closed before all preventative actions have been implemented and reviewed for efficacy, particularly if actions are continuous or long term. Mechanisms must be in place within provider and commissioning organisations for the monitoring implementation of long term/on-going actions.

Cases can be re-opened where there is a requirement to do so i.e. upon receipt of new information.

23 Why was the new framework developed and what changed?

Further to the changes in the NHS landscape in 2013 NHS England published a revised Serious Incident Framework. This supplemented the National Reporting and Learning Framework for Incidents Requiring Investigation, produced by the National Patient Safety Agency[15] in 2010, and it was agreed that a further review would be undertaken to develop one overarching framework which would provide clarity and consistency for providers and commissioners in relation to managing serious incident in NHS funded care. The revised framework replaces the previous versions published by the NPSA and NHS England.

This review has provided an opportunity to reinforce;

[15] responsibilities and key functions of the NPSA were transferred to NHS England on 1 June 2012

- the fundamental purpose and principles of serious incident management, which it to learn from incidents to prevent the likelihood of recurrence of harm;
- the process, procedures and ethos that facilitate organisations in achieving this fundamental purpose;
- key accountabilities of those involved in serious incident management, which is to support those affected including patients, victims, their families and staff and to engage with them in an open, honest and transparent way;
- key organisational accountabilities where the provider is responsible for their response to serious incidents and where commissioners are responsible for assuring this response is appropriate.

In order to simplify the process two key operational changes have been made:

1. Removal of grading – we found that incidents are 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.

24 Does the Serious Incident Framework apply to maternity?

Yes. The Framework applies to all NHS funded care.

Historically, some maternity services have used detailed criteria or lists of incident types to direct the reporting of Serious Incidents. However, the 2015 Serious Incident Framework made clear that incidents must be considered on a case by case basis when deciding whether to declare a Serious Incident. For example, whilst it is acknowledged that an unexpected admission to NICU would be expected to trigger consideration as to whether this was the result of earlier problems in healthcare (as would unexpected admission to ITU and PICU care in adult and children's services) it is inappropriate to assume all unplanned admissions to Neonatal Intensive Care Unit (NICU) automatically meet the criteria of Serious Incidents.

See question 11 for further details.

25 Does the Framework take into account changes in the commissioning landscape, particularly in relation to new co-commissioning arrangements for primary care services?

Yes, the framework describes the key organisational accountability which 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. However, it is acknowledged that in a complex commissioning landscape multiple organisations may be involved. The framework therefore endorses the RASCI (Responsible, Accountable, Supporting, Consulted, Informed) model as a means of helping organisations to determine who does what in relation to serious incident management. 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 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.

26 Will there be opportunities for further future development?

Yes. Work to monitor and review the application of this framework will be ongoing. It is anticipated that the framework will be updated as required.

27 Will there be changes to the reporting system STEIS?

Modifications have been made to the existing system to take account of changes in the commissioning landscape and to support implementation of the new Framework. Information relating to any future updates will be made available via the STEIS homepage and cascaded by the STEIS technical support team.

There is a long-term programme of work currently being undertaken by NHS England to develop a new Patient Safety Incident Management System. Further information is available from http://www.england.nhs.uk/ourwork/patientsafety/dpsims-dev/