NHS England

Serious Incident Framework 2015/16- frequently asked questions

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Serious Incident Framework 2015/16

Frequently asked questions

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1 Why has a new framework been developed and what has 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[1] 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;

- 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 clarify for patients and families in relation to completion dates for investigations.

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

2 Will there be opportunities for further future development?

Yes. Work to monitor and review the application of this framework will continue during 2015/16. It is anticipated that the framework will be reviewed annually and updated as required.

3 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 within the 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.

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

This phrase is intended to ensure that death or injury resulting in serious harm, that was an expected or inevitable consequence of the patient's medical condition or healthcare, does not trigger a Serious Incident investigation. For example, some types of radiotherapy will almost certainly cause infertility. It 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. 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, as 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.

5 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'[2]. 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 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 7 for further information relating to the NRLS.

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

Also see question 11 regarding discovery of a Serious Incident at a different organisation to where it occurred.

6 Why are Never Events classed as Serious Incidents?

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. Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes and can provide the NHS with an essential lever for improving patient safety. Regardless of the outcome of an individual Never Event, Never Events are always considered Serious Incidents.

7 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 which are reported as Serious Incidents can be downgraded at any stage where the Serious Incident criteria is not meet and further investigated is not required.

8 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[3]. 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

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

severe harm[4] would be likely to meet the definition within the Serious Incident Framework, 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). 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/

9 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.

[4] 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.

10 Does the new 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.

11 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 Sub-regional and 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 nor NHS England Central Patient Safety Domain will act as arbiters of whether a particular incident is a Serious Incident.

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. The 'discovering' organisation does not have to report the incident as their own[5]. Commissioners should assist their providers to ensure appropriate organisations are made aware so that the necessary action can be taken.

13 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

14 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

[5] Changes within the STEIS system, to facilitate notification of Serious Incidents occurring in other organisations, are being explored to enable organisations to document Serious Incidents which need to be investigated by others (see questions 15).

- 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.

15 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 for 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.

16 Will there be changes to the reporting system STEIS?

Modifications will be made to the existing system to take account of changes in the commissioning landscape and to support implementation of the new Framework. Information 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/