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Standard Operating Model for Managing Serious Incidents within Services Directly Commissioned by NHS England

Supplementing the NHS England Serious Incident Framework March 2013

Working draft for internal testing only

Patient Safety Domain
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Introduction

Serious incidents (SI) requiring investigation\(^1\) is defined as an incident that occurred during NHS funded healthcare (including in the community), which resulted in one or more of the following;

- unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- a never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death\(^2\). The *Never Events Framework* provides further information
- a scenario that prevents, or threatens to prevent, an organisation’s ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- allegations, or incidents, of physical abuse and sexual assault or abuse; and/or
- loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

In order to provide national consistency in the definition of a Serious Incident and ensure clarity about roles, responsibilities and timescales for managing SIs, NHS England published a national Serious Incident Framework in March 2013\(^3\).

This Standard Operating Model aims to supplement the national Serious Incident Framework March 2013 by providing further details relating to procedures for managing serious incidents occurring within services directly commissioned by NHS England. It aims to help establish processes which ensure that care is provided as safely as possible and, if things do go wrong, that the right action is taken.

This model should be read in conjunction with the national *Serious Incident Framework in March 2013*.

Purpose

NHS England has a responsibility for assurance, oversight and scrutiny of responses to SIs in providers of services that it directly commissions. This document intends to support the national Serious Incident Framework by focussing more closely on the roles and responsibilities of NHS England as commissioners, in relation to the management SIs within these services.

This document also recognises the wider role of NHS England in the oversight and surveillance of serious incidents within services which are commissioned by Clinical Commissioning Groups (CCGs). This includes; acute, community, ambulance care, mental

\(^1\) 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.
health and learning disabilities where the CCG is primarily responsible for assuring the quality of serious incident management. It also acknowledges the importance of commissioning organisations working in partnership in order to facilitate the most effective management of serious incidents.

This standard operating model does not fundamentally alter existing principles set out in the NPSA’s 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation\textsuperscript{iii} and elsewhere, but does update the framework to reflect the new commissioning arrangements. Organisations should continue to comply with their own local significant event or other reporting systems including reporting to the National Reporting and Learning System (NRLS) and other statutory bodies and regulators such as the CQC, MHRA, HSE etc.

**Scope**

This document is applicable to all services commissioned by the NHS England. This includes services which are commissioned via all areas teams:

- **Primary care independent contractors** - GPs, dentists, pharmacists and optometrists
- **National Screening and Immunisation programmes**
- **Public Health**

It also includes services commissioned by identified Lead Commissioning Area Teams:

- **Prescribed Specialised Services**
- **Health in the Justice System Services** - Prisons; Young Offender Institutions (YOIs); Immigration Removal Centres; Secure Training Centres; Secure Children’s Homes; Police Custody Suites; Court Liaison and Diversion Services; and Sexual Assault Services. Incidents outside of these settings are beyond the scope of this guidance however, this guidance supports the principles set out in the commissioning framework for offender health which recognise the importance of integrated care for offenders through engagement at a local level with Clinical Commissioning Groups (CCGs), other local Area Team and the prison service to manage the interface between services for patients and to manage the clinical service providers collectively.
- **Health care for armed forces and their families** - any serving member of the Armed Forces stationed in England and any family dependants who are registered with a Ministry of Defence, Defence Medical Services (DMS) Medical Centre. Reservists who require NHS health services and those stationed overseas who return to England to receive health services where registered with a DMS practice are also included.

This document covers the arrangements for reporting and investigating serious incidents that pertain to the NHS England itself in order to ensure that there is a clear and robust process for managing SIs that occur within this setting.

As described in securing excellence in commissioning for offender health and armed forces and their families\textsuperscript{iv, v} there are a number of interdependencies still being considered as part of the overall design and future responsibilities in the new commissioning landscape, this model
needs to be flexible in its approach to respond to this. This is a working draft. As the system learns and matures, changes will be made where appropriate.

**Responsibilities**

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider of NHS-funded care</td>
<td>Responding, reporting, investigating and implementing actions based on findings following a serious incident. Sharing Learning internally and externally as appropriate.</td>
</tr>
<tr>
<td>CCGs</td>
<td>Holding to account NHS funded acute, community, mental health and ambulance providers for their responses to SIs. This includes quality assuring the robustness of the SI investigation, by evaluating the investigation and ensuring that the process and outcomes of the investigation including identification and implementation of improvements are consistent with principles outlined in national guidance serious incident framework march 2013. Encouraging the sharing of learning as appropriate across the health community.</td>
</tr>
<tr>
<td>NHS England Area Teams (and London Regional Office) as direct commissioners</td>
<td>Holding to account providers of NHS funded primary care, specialised care and other directly commissioned services (e.g. screening and immunisation, healthy child) for their responses to serious incidents. This includes timely reporting, quality assuring the robustness of the SI investigation. Evaluating the investigation and gaining assurance that the process and outcomes including identification and implementation of improvements are consistent with principles outlined in national serious incident framework March 2013. Encouraging the sharing of learning as appropriate across the wider health community.</td>
</tr>
<tr>
<td>NHS England assurance through Area and Regional Teams.</td>
<td>Area Teams are responsible for the oversight and surveillance of serious incident investigations undertaken in NHS funded acute, community, mental health and ambulance care including reviewing trends, quality analysis and early warnings via Quality Surveillance Groups. This includes ensuring that CCGs have systems in place which ensures incidents are reported, investigated and managed in line with national serious incident framework March 2013. Regional teams have a responsibility to ensure that Area Teams have the appropriate systems in place for implementing and maintaining a robust quality assurance process. At both Regional and Area Team level NHS England has a responsibility for encouraging the sharing of learning as appropriate across the wider health community.</td>
</tr>
<tr>
<td>NTDA</td>
<td>Supporting NHS trusts in ensuring they have effective systems and processes in place in relation to serious incidents, coordinating responses where necessary alongside commissioners. Using relevant intelligence and information to inform their role in providing accountability of NHS trusts.</td>
</tr>
<tr>
<td>NHS England Central Patient Safety Domain Team</td>
<td>Identifying intelligence and learning to be shared at national level. Facilitate learning and sharing throughout the healthcare system. Develop systems to promote reporting by providers and to improve the effectiveness of reporting systems.</td>
</tr>
</tbody>
</table>

Table 1: Summary of responsibilities for SI management in the New NHS Structure

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2 The London region has specified that it will manage patient safety on a regional rather than Area Team basis so throughout this document, where we refer to Area Team, this means the London regional office for relevant SI reporting and management purposes that relate to the London region.
Serious Incident Reporting in services directly commissioned by NHS England.

*Please refer to the flowchart appendices 2-10 for a summary of the serious incident management process within specific services.*

The overarching principle is that SIs must be reported to the organisation that commissioned the care in which the SI occurred. So, for services directly commissioned by an Area Team (or London Regional Office), that Area Team must receive a report of the SI and is ultimately responsible for ensuring the SI is appropriately managed. Where an incident is identified in any of the services covered by this document then the processes outlined within this model should be followed. Area Teams have a responsibility to work with CCGs and providers to help ensure this is the case.

**Notification**

Reporting of an SI to the relevant Area Team must be done by recording the incident on STEIS (the NHS England’s web-based SI management system for which a log-on is necessary). SIs must be reported as soon as possible after the incident is detected and no later than two working days after the incident being identified. The report must not contain any patient or staff identifiable data (including initials of names) and the description should be concise.

Area Teams will manage STEIS accounts for providers within their geographical patch. Therefore when an a provider reports an SI on STEIS their Area Team (local) as well as their main commissioner, if this is not the Area Team (local), will be automatically informed. Where another commissioner is responsible for commissioning the care in which the SI occurred e.g. a Lead Commissioning Area Team for Specialised services (who might be geographically remote) there must be systems to ensure that this Area Team is also informed since, as commissioner, they are ultimately responsible for oversight of the SI process. The Area Team (local) must therefore work with other commissioners and providers to ensure that procedures for alerting the appropriate commissioners are in place.

The exception to this rule is where serious incidents occur within providers who do not provide a variety of healthcare services. An example of this is where an Area Team commissions forensic learning disability services from an independent provider. In this situation the provider will have a direct relationship with only one commissioning organisation. This may also be applicable to specific specialised services such as high secure psychiatric services which are designated to three Trust commissioned by 3 Lead Commissioning Area Teams for High Secure Services. See appendix 3 for further details.

Providers unable to set up a STEIS accounts must complete a Serious Incident Reporting form (Appendix 1- template form). The completed form must be sent to the Area Team who is responsible for commissioning the service in which the SI occurred. This must be done via the Area Teams designated inbox for serious incident reports using an NHS email account. The incident will then be logged onto the system by the Area Team using a STEIS account set up specifically for reporting SIs in directly commissioned services.
If a serious incident is identified by the Area Team by a letter of complaint from a patient or Ombudsman for example, the Assistant Director of Nursing (or appropriate deputy) should confirm that it reaches the threshold for an SI and inform the relevant provider who will be required to follow their usual process for reporting SIs.

Incidents falling into any of the serious incident categories listed below or where there is any doubt over the matter must be reported to the relevant Area Team Assistant Director of Nursing (or the Head of Patient Safety for the London Region) or appropriate deputy immediately by telephone as well as electronically.

- incidents which necessitate activation of 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

During out-of-hours the local on call management procedures must be followed.

**Information Sharing**

Further to identification of a serious incident which may cause widespread concern, the Area Team may recognise a need to share information with the relevant members of the regional team. This information should be shared directly with the appropriate Regional Lead who can then make an informed decision about whether or not to inform directorate leads within NHS England. Information should be disseminated through the appropriate professional accountability and commissioning routes including Nursing, Medical, Operational and Commissioning Teams. A briefing which describes the issue, current position in terms of incident management and investigation should be provided. A decision to inform the Department of Health should be agreed by NHS England directorate leads.

**Fact finding and follow up action**

The Area Teams should request a 72 hour interim report outlining the immediate actions taken for all grade 2 incidents where there is on-going or immediate threat to the public or where there is significant concern and interest from external bodies including media or other agencies.

Any changes to the initial report and any re-grading deemed necessary following fact finding by the provider must occur within 3 working days of incident being identified. The provider must also produce a concise summary of the issues identified.

All information must be clearly updated within STEIS by the provider or Area Team in cases where the provider cannot access STEIS.

**Reporting to the National Reporting and Learning System**

All patient safety incidents must be reported to the National Reporting and Learning System (NRLS). This data provides the NHS with a national perspective on risks and hazards which can be used to inform the development of tools and guidance at both local and national level.
By definition, a patient safety incident is any unintended or unexpected incident that could have led or did lead to harm for one or more patients receiving NHS-funded healthcare. Consequently incidents of abuse reported to the NRLS should include incidents which relate directly to NHS funded care i.e. not previous incidents which are discovered or disclosed during an inpatient stay for example. All incidents of abuse must be reported as a Safeguarding issue.

**Reporting Arrangements**

Upon receipt of an SI report, the Area Team Assistant Director (Quality Assurance) or appropriate Quality and Safety lead should confirm that the relevant Area Team Commissioning lead (Head of Primary Care, Head of Public Health, Head of Health and Justice, Head of Healthcare for Armed Forces and their families, Health or Head of Specialised Commissioning) is notified depending on the service within which the SI occurred. The relevant lead must be notified as soon as possible and no later than 2 working days after incident is identified.

The relevant Commissioning lead should have access to all information on the SI reported to the Area Team and be involved in the oversight and management of the SI wherever possible.

**Additional Reporting Requirements**

Area Teams as direct commissioners should work with providers to ensure that where applicable, additional reporting requirements are fulfilled.

- Regulators, professional bodies and safeguarding leads (where applicable) must be alerted via the appropriate routes within two working days of the incident being identified.
- Where the SI relates to a mental health homicide and requires investigation under HSG (94) 27 the Area Team must inform the Regional Investigations Team. The Regional Investigations Team need to be made aware of the circumstances of the homicide and any other statutory investigations that may be started at that time, for example Domestic Homicide Reviews, Serious Case Reviews, Children’s Serious Case Reviews. This early discussion would allow NHS England to explore opportunities to undertake joint reviews where appropriate. Further details will be made available following the publication of Guidance for Investigating Mental Health Homicide currently in development.
- Serious incidents relating to controlled drugs must be reported to the providers Accountable Officer.
- Where incidents relate to information governance issues they should also be reported in line with the Health and Social Care Information Centre guidance [HSCIC Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation](#). All level 2 information governance related serious incidents should be reported to the IG reporting toolkit. Organisations must be registered to access this toolkit. Login details will be provided when the organisation undertakes the initial IG assessment which is a dual functionality of the IG reporting 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.

- Where incidents which relate to a defect or failure of a non-medical device, a defect and failure report should be submitted by the organisation that is the originator of the report in accordance with the DH defect and failure reporting process

- Area Teams should also inform the relevant NHS England Projects Appraisal Unit (PAU) Senior Estates Manager when alerted to incidents which relate specifically to estate and facilities matters. See appendix 12 for further details.

Reporting to Public Health England

A number of SIs may have a wider adverse impact on population health e.g. decontamination failures, outbreaks of healthcare associated infectious diseases or incidents such as finding an infected Health Care Worker who has undertaken Exposure Prone Procedures, or a failure of microbiology laboratory practice.

Where SIs with the potential to adversely affect the health of a population are identified, Public Health England, local health protection team must be informed so that specialist support for the population risk assessment and subsequent management of the response to the incident can be provided.

Reporting to the Care Quality Commission (CQC) and other Regulatory and Professional Bodies

Area Teams as direct commissioners should work with providers to ensure that where it is necessary for other regulatory bodies to be informed, this is clearly stated within the SI report and the relevant bodies are informed within 2 days of incident being identified.

- **CQC**- registered organisations are required to notify CQC directly about events that indicate or may indicate risks to on-going compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in the CQC’s register. See Essential Standards of Quality and Safety vii. For CQC registered providers, most of these requirements are met by reporting via the National Reporting and Learning Service (NRLS), which will forward relevant information to CQC3. The exception is for independent sector providers and primary medical service providers who must report serious incidents directly to CQC. Independent providers should to report incidents via the NRLS to help inform national learning.

- **Other regulatory bodies**- including local Safeguarding Boards, the MHRA, the HSE, and the police will need to be notified depending on the type of incident and also the setting in which the incidents occurred and therefore needs to be considered on an

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3 For further information http://www.cqc.org.uk/organisations-we-regulate/registered-services/notifications
individual basis by provider and the commissioner. Where appropriate these organisations should be alerted as soon as possible but no later than 2 working days of a serious incident being identified.

- **Monitor** - NHS Foundation Trusts are also required to report relevant serious incidents requiring investigation to Monitor.

- **NTDA** - NHS Trusts should also directly inform the NTDA of Grade 2 serious incidents.

- **Responsible Officers** - Post Graduate Deans are the responsible officers for trainee doctors and should therefore be informed about serious incidents where trainee doctors are involved. The provider should ensure that the responsible Dean is made aware of the incident as soon as possible. This does not however, alter the SI management process which should be undertaken in line with national serious incident framework.

- **Professional misconduct** - The 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. SI management process should be followed and progressed in line with national Serious Incident Framework (March 2013) 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 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; In this case systems failures are likely to be at the core of the problem and, the most effective place to target improvements/solution to prevent recurrence.

Further advice for managing SIs should be sought via the [Serious Incident Framework in March 2013](#) or by contacting the relevant Area Team Assistant Director of Nursing or Regional Deputy Director of Nursing (Quality Assurance).

**Accountability for oversight and assurance for serious incidents within services directly commissioned by NHS England**

The principal accountability of all providers of NHS-funded care and commissioners is to patients and their families/carers. The needs of the patient and their family/ carers following a serious incident should be the first priority. The key organisational accountability for serious incident management is from the provider in which the incident took place to the commissioner of the care. NHS England Area Teams as direct commissioner are responsible for holding to account providers of NHS funded primary care, specialised care and other directly commissioned services (e.g. screening and immunisation) for their responses to serious incidents.
Delegating Commissioning Responsibilities Relating to Serious Incident Management in NHS England

The Area Team that commissioned the care in which an SI occurred may oversee an SI investigation process directly; however, they may also arrange for another commissioning organisation to oversee the SI investigation process on their behalf. This could be a CCG or another NHS England Area Team. This does not remove the responsibility of the commissioning Area Team to ensure the SI is appropriately managed. When for example, an Area Team is geographically remote or when services are commissioned from a large provider with multiple commissioners (e.g. CCGs and NHS England Area Teams) the commissioning Area Team may delegate the lead role for oversight of the SI investigation process.

Involvement of Clinical Commissioning Groups

There may be occasions where serious incidents occur within large providers who have a developed a close working relationship with a particular commissioner and this might be the CCG who commissions the majority of services delivered by that provider. The commissioner can be referred to as the provider’s main commissioner (although this can relate to volume of services commissioned rather than overall cost i.e. specialised services represent a large proportion of cost but might only represent a small proportion of available services). In such cases the commissioning Area Team can recommend that the CCG, as the providers ‘main commissioner’, leads the oversight of the SI investigation process since they are best placed to manage the response and maintain an inclusive overview of the quality of care delivered.

It is also important to consider the developmental role of CCGs within services that are commissioned primarily by NHS England. This includes, for example, working in partnership to improve safety within primary care. Whether acting as the main commissioner or supporting function, CCGs have an important role in the management of serious incidents across the healthcare service.

Area Teams must also liaise with CCGs to ensure they are informed about serious incidents which may relate to issues or impact services they directly commission, even if the incident occurs outside of this service. For example an incident may occur within an area which is commissioned by a CCG but initial fact finding may identify that an error in the admission process, which occurred in a service commissioned by NHS England, contributed to the incident. At this point there should be an agreement between the Area Team and CCG relating to who should lead oversight of the investigation.

Facilitating Commissioner Intelligence

Both the occurrence of an SI in a provider organisation and the management of the response to that SI by the provider are important sources of information that is relevant to the commissioning of a service by its commissioner. Ensuring serious incidents are reported in a way that facilitates commissioner intelligence about the provider is essential for quality assurance purposes.

Area Teams must work with providers and CCGs to ensure that incidents are reported in a way which ensures notification of the necessary commissioning organisations. For example if a member of the armed forces (who is registered with the DMS) is involved in a serious incident within secondary care, the provider must ensure that the patient is appropriately identified and the appropriate details are reported in STEIS. This will facilitate the appropriate notification...
process. See figure 1 and appendices for specific services. The STEIS report must include the providers local Area Team and their ‘main commissioner’ (if this is not the local Area Team). If the service in which the SI occurred is commissioned by another Area Team (i.e. Lead Commissioning Area Team) then this Area Team must also be informed to ensure they are fully informed. See figure 1 below.

The commissioner leading the investigation must ensure the CCG in which the patient’s GP is registered is also informed.

![Diagram](image.png)

**Figure 1:** Summary of incident notification process web (example only). NB: there should be regular exchange of information between commissioning functions to ensure that appropriate information and intelligence is shared.

Where a provider organisation is commissioned by multiple commissioning organisations, all those commissioning organisations should have access to all the SI reports that relate to that provider organisation. The Area Team (local) must facilitate access to a providers STEIS account for appropriate commissioners.

Area Teams should assess requests for access to a providers STEIS account on an individual basis. Area Teams should request a written application which confirms the requesting organisations details, reasons for requesting access, how the information will be used and who will be responsible for handling information and managing activity. Area Teams should also regularly monitor STEIS access arrangements in order to ensure that information is shared with appropriate commissioners.

Where multiple commissioners purchase services from a provider that crosses geographical and organisational boundaries, relevant information sharing agreements must be established within contracts to ensure that SI information can be shared while ensuring relevant Information Governance requirements are met.
Regional Responsibilities

Regional Teams should ensure that Area Teams have the appropriate systems and processes in place to ensure sufficient oversight and monitoring of serious incidents. They should ensure that serious incident trend data and other relevant statistical analysis methods are used to inform quality reviews and commissioning decisions.

Reporting Internal Incidents

Where serious incidents occur within NHS England Area Teams, these incidents must be reported to the Area Team’s respective Regional Team. The Regional team are responsible for the review and closure of serious incidents.

Serious Incidents which occur within NHS England Regional Teams must be reported to another Regional Team who will be responsible for the review and closure of serious incidents.

Within the National Team serious incidents will be reported to the Department of Health.

Investigating Serious Incidents in services directly commissioned by NHS England

Each provider organisation is responsible for investigating the incidents that have occurred.

The provider declaring the incident 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 should be chaired by the appropriate lead. There may be occasions where the nature of the SI warrants the chief executive of the provider (or nominated deputy) to chair the investigation team. It is essential to identify a team member with responsibility for administration and documentation and for there to be adequate administrative and IT support. Special consideration will be needed where there are multiple providers and commissioners. (See page 37, appendix D of the Serious Incident Framework re: multiple commissioners).

The investigation team must agree that the scale, scope and timescale of investigation are appropriate for the grading of the incident (see page 35, appendix C Serious Incident Framework March 2013). Ultimately the commissioner of the service must be satisfied that this is the case.

NHS England endorses the use of the NPSA’s root cause analysis (RCA) framework to investigate all SIs. It is recognised that some independent contractors may not yet have the capability to fully utilise these investigative tools. Where providers do not have the infrastructure or expertise to undertake investigations, support may be provided by the Area Team where appropriate and previously agreed. Support may also be provided by a member of the Area Team acting as a subject matter expert within the investigation team.

Whilst the Area Team may offer support where there is capacity to do so, the provider is responsible for undertaking the investigation and consequently incurs the cost for this process.
Where the Area Team is required to support the provider in the investigation of an SI, there must be clear segregation of responsibilities within the Area Team. This means that those participating in the reporting and investigation must not be involved in the oversight and closure of the SI on STEIS. The Director of Nursing within the Area Team must seek assurance that a robust and transparent process for the closure of serious incidents exists. Only members of the Area Team with sufficient distance from the investigation and appropriate level of seniority should be responsible for the closure of SIs. There may be occasions where Area Teams wish to make arrangements for another Area Team to undertake an additional quality assurance review. This does not however devolve their responsibility as commissioners to ensure that the report, action plan and implementation of necessary action 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.

Incidents where there is evidence, or suspicion of, a criminal offence having been committed are likely to be investigated by the police (before the provider is allowed to internally investigate), however, such incidents should still be reported by the provider organisation to the commissioning body in the usual way. When an incident requires investigation by the police and the Health and Safety Executive (HSE) jointly it should be managed in accordance with the Memorandum of Understanding (currently under review).

**Being Open and Duty of Candour**

Provider organisations must ensure that all SIs are disclosed to those affected in a timely manner, appropriately reported and investigated, with the findings being shared with those involved in accordance with the Being Open guidance and the contractual Duty of Candour requirements. Face to face meetings between the patient, their families/carers and provider organisation staff (including the staff involved where appropriate) must be actively supported and reasons for not undertaking such activity should be documented as part of the serious incident investigation by the provider.

**Report Format**

The [NPSA’s RCA Investigation Template](#) should be used.

**Action Plans**

NHS England recommends use of the [NPSA Action Plan template](#)

These are the minimum requirements for an action plan:

- every recommendation must have a clearly articulated action
- actions should be designed and targeted to significantly reduce recurrence of the incident
- a responsible person (job title only) must be identified for each action point
- there are dates for proposed completion of actions
- description of the form of evidence that will be available to confirm completion

A SMART approach to action planning is essential. That is, the actions should be: Specific, Measurable, Attainable, Relevant and Time-bound.
Submission of Final Reports

Grade 1 incident reports and action plans must be submitted within 45 working days of the incident being reported. Grade 2 reports and action plans must be submitted within 60 working days, unless an independent investigation is required, in which case the deadline is 6 months.

The words ‘Serious Incident Final Report’ must be used in the subject of the email.

Quality Assurance of SI Final Reports

On receipt of the final report and action plan from the provider, the Area Team will acknowledge receipt by email. It will then undertake a quality assurance review of the report within 20 working days. The NPSA credibility tool provides information relating to the quality assessment process.

Where necessary the Area Team may involve other commissioning and quality assurance leads for specific services in the process. For the purpose of development and learning it is also important to involve CCGs in this process.

For Grade 1 SIs, the Area Team will seek assurance that the report and action plan meets the required standard for a robust investigation the provider will be notified that this is the case and the SI will be marked as closed on STEIS.

If further information is necessary, this will be requested and must be submitted to the Area Team within 10 working days. Where necessary, an alternative timescale may be agreed between the provider and Area Team depending on the level of detail required.

For Grade 2 SIs the Area Team will seek assurance that the report meets the required standard for a robust investigation as well as confirmation that the action plan has been executed before the SI can be marked as closed on STEIS. It is important to have clarity on when it is acceptable to close the incident before all long term preventative actions have been implemented and reviewed for efficacy. Where this is considered acceptable robust arrangements should be put in place by to ensure implementation and review stages progress in full.

Extension of Submission Period

It is recognised that in certain circumstances trusts will find it difficult to complete a final report within the national framework timescales. i.e. due to:

- enforced compliance with the timetable of an external agency, such as a Coroner, Health and Safety Executive, Local Children Safeguarding Board
- investigation of highly specialised and multi-organisation incidents, such as those involving a national screening programme

Providers can request extensions to the report submission deadline for other reasons, but there must be a compelling reason, for example, new information coming to light which requires further investigation.
Requests for extensions should be communicated to the relevant Area Team and must include the reason for the extension and the extension period required. An extension should be considered in relation to each individual request. Following review by the Area Team, an extension may be granted. Extension periods should be requested and granted in relation to and effective from the day on which the SI report was due for submission.

The provider organisation will be informed of the decision once it has been made.

Any request for an extension must be made prior to the due date of the final report, otherwise an extension cannot be granted and the report will be recorded as overdue for submission.

**Monitoring of Action Plans**

The Area Team will close the incident when it is satisfied with the investigation, recommendations and action plan that have been submitted, and appropriate monitoring arrangements are in place and working efficiently. Where necessary the Area Team may involve other lead commissioners and quality assurance leads for specific services, in the monitoring of action plans.

Investigations will continue to be monitored until the Area Team are assured that actions have been completed.

Area Teams should monitor the response of their providers by seeking assurance and evidence from the provider that relevant policies and procedures are in place and implemented and by monitoring the relevant activities as necessary, for example by reviewing all incident investigations and action plans and monitoring serious incident data trends. This assurance process should be coordinated as part of other contract management.

**Coroner’s inquests, criminal investigations, and the involvement of other external agencies**

Where external investigations conducted by external agencies are on-going, for example police, safeguarding boards, HSE or Public Services Ombudsman investigations, coroner’s inquests etc. serious incident cases can remain open for very significant periods of time beyond the relevant deadline.

The Area Team will close those serious incident cases where all immediate actions for the health care services derived from internally conducted or commissioned investigations are satisfactorily in hand and where they are assured that there are external process for ensuring any outcomes from the external agency investigation will be communicated and acted upon. This can avoid unnecessary and potentially confusing duplication of activity or having cases open indefinitely, and is appropriate as the terms of reference for these investigations will often be very different. Where there is any doubt about the incident being appropriately coordinated managed and responded to by the external processes, the incident should remain open. If necessary, cases can be re-opened upon receipt of new information derived from the activities of external agencies.

If the Coroner issues a Rule 43, the provider should consider if it has implications for the SI report already submitted and where it does, the provider should update the SI report. Providers should also forward all Rule 43s issued by the Coroner to the Area Team and the provider’s response.
Appendix 1 - Example Serious Incident Reporting Form

(if the reporting organisation has a local form or reporting system and the relevant Area Team is satisfied that it captures the necessary level of detail and can easily be copied to the Area Team then this will be accepted)

**DO NOT INCLUDE PATIENT IDENTIFIABLE INFORMATION OR THAT OF INDIVIDUALS OTHER THAN THOSE OF THE REPORTER FOR COMMUNICATION PURPOSES**

<table>
<thead>
<tr>
<th>Type of Incident:</th>
<th>Reporting Organisation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Other, please specify:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Incident:</th>
<th>Reporter Name:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Time of Incident:</th>
<th>Reporter Job title/Role:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Location of Incident:</th>
<th>Reporter Tel No:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date Incident Identified:</th>
<th>Reporter Email:</th>
</tr>
</thead>
</table>

**Clinical Commissioning Group of Reporting Organisation:**

**Name of other Organisations Involved (where relevant):**
*eg: Hospital,Ambulance Service, OoH, Care Homes, Mental Health Services, Police, NRLS etc.*

**Care Sector:**
*eg: General Practice, Dentistry, Pharmacy, Optometrists, Other. If Other please specify.*
### Patient Details

- **Patient Date of Birth:**
- **Patient Gender:**

- **Patient registered GP Practice:**
- **Patient Ethnic Group:**

### What Happened?

- **Description of What Happened:**

- **Immediate Action Taken:**

- **Any Further Information:**

- **Details of any Police, Media Involvement/Interest:**

- **Any other organisations notified? (eg MHRA, CQC, CCG etc)**

- **Details of contact with or planned contact with patient/family or carers:**
**What impact or potential impact did the event have on the patient?**

**Apparent Outcome of Incident:**

*Please describe:*

*Please categorise significance/potential significance (tick A for actual harm and P for potential harm) Definitions of harm can be found in the National Framework*

<table>
<thead>
<tr>
<th>None</th>
<th>Low Harm</th>
<th>Moderate Harm</th>
<th>Severe Harm</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>A</td>
<td>P</td>
<td>A</td>
<td></td>
</tr>
</tbody>
</table>

**Likelihood of Reoccurrence:**

*Before reviewing this event – Please attempt to assess the likelihood of a similar event happening again.*

<table>
<thead>
<tr>
<th>Almost certain</th>
<th>Likely</th>
<th>Don’t know</th>
<th>Unlikely</th>
<th>Rare</th>
</tr>
</thead>
</table>
Appendix 2 - Serious Incidents within Primary Care

All patient Safety Incidents must be reported to NRLS

Within 2 working days of incident being identified

Within 3 working days of incident being identified

Submission of reports and action plans;

**Within 45 days** - Grade 1 (level 1 and 2)

**Within 60 days** - Grade 2 (level 2)

**Within 6 months** - Grade 2 (level 3 - independent RCA)

Within 20 days of receipt of report

Serious Incident Occurs

Report to Area Team (local) via managed inbox

Incident logged on STEIS by provider or Area Team (local) if provider cannot access

Any additional information submitted. Grading and level of investigation confirmed. Area Team (local) may request 72 hour report

Provider sets up investigation team

Provider completes incident investigation (RCA/SEA undertaken to RCA standard) Area Team (local) may provide support where applicable

Provider completes action plan which should be agreed by investigation team as effective means of preventing recurrence

Grade 1

Provider completes lessons learned to prevent recurrence of SI

Grade 2

Evidence of implementation provided to Area Team to support closure

Area Team (Patient Safety) undertake quality assurance review of report. This may involve primary care commissioning lead within Area Team and Clinical Commissioning Group

Practice records incident on local management system

Provider reviews need to report to other reporting/regulatory/professional bodies (MHRS, HSE, CQC, local Safeguarding authorities etc.) Report to information governance/project appraisal unit/Accountable Officer as required

Any additional information submitted. Grading and level of investigation confirmed. Area Team (local) may request 72 hour report

Area Team Patient Safety Team closes incident on STEIS*. Actions monitored as part of routine quality assurance activities. Dissemination of lessons learned.

*Those involved in the reporting and investigation of an SI must not be included in the closure process
Appendix 3 - Serious Incident Occurring within Specialised Commissioning

- All patient Safety Incidents must be reported to NRLS
- Serious Incident Occurs in Specialised Commissioning
  - Provider reports to main commissioner and Area Team (local) if not the main commissioner.
  - Lead Commissioning Area Team for Specialised Commissioning informed by appropriate lead within Area Team* (local)
  - Commissioner leading oversight agreed by commissioning organisations
  - Incident logged on STEIS by provider
- Provider reviews need to report to other reporting/regulatory/professional bodies and fulfil other reporting requirements (i.e. information governance/project appraisals unit/accountable officer)
- Provider submits any additional information to lead commissioner overseeing response. Grading and level of investigation confirmed. STEIS updated by provider if necessary
- Provider set ups investigation team
  - Provider completes incident investigation (RCA/SEA conducted to RCA standard)
  - Provider completes action plan which should be agreed by investigation team as effective means of preventing recurrence
  - Provider completes lessons learned to prevent recurrence of SI
  - If further information is needed this will be requested by the lead commissioner (within 10 days where possible)
  - Evidence of implementation provided to lead commissioner overseeing response to support closure
  - Area Team (Patient Safety) undertakes quality assurance review of report with Lead Commissioning Area Team and main Commissioner for Provider where necessary.
- Area Team (Patient Safety) Team closes incident on STEIS**. Actions monitored as part of routine quality assurance activities. Dissemination of lessons learned.

* Those involved in the reporting and investigation of an SI must not be included in the closure process
Appendix 4- Serious Incidents within for Healthcare Services for Armed Forces and their families (where registered with a DMS practice)

Serious Incident Occurs

Provider reports to main commissioner and Area Team (local) if not the main commissioner.

Lead Commissioning Area Team for Armed Forces and their families informed by appropriate lead within Area Team (local)

Commissioner leading oversight agreed by commissioning organisations

Incident logged on STEIS by provider

Within 2 working days

Provider submits any additional information to lead commissioner overseeing response. Grading and level of investigation confirmed. STEIS updated by provider if necessary

Within 3 working days

Submission of reports and action plans;

Within 45 days - Grade 1 (level 1 and 2)

Within 60 days - Grade 2 (level 2)

Within 6 months - Grade 2 (level 3-independent RCA)

Within 20 days of receipt of report

Provider set ups investigation team

Provider completes incident investigation (RCA/SEA conducted to RCA standard)

Provider completes action plan which should be agreed by investigation team as effective means of preventing recurrence

If further information is needed this will be requested by the lead commissioner (within 10 days if possible)

Evidence of implementation provided to lead commissioner overseeing response to support closure

Grade 1

Grade 2

Area Team (Patient Safety) undertake quality assurance review of report with Lead Commissioner Area Team and Lead Commissioner for Provider where necessary.

Area Team Patient Safety Team closes incident on STEIS*. Actions monitored as part of routine quality assurance activities Dissemination of lessons learned.

*Those involved in the reporting and investigation of an SI must not be included in the closure process
Appendix 5- Serious Incidents within Healthcare for Health and Justice

Prisons; Young Offender Institutions (YOIs); Immigration Removal Centres; Secure Training Centres; Secure Children’s Homes; Police Custody Suites; Court Liaison and Diversion Services; and Sexual Assault Services (excludes death in custody – see appendix 6)

1. Report to NRLS: Serious Incident Occurs in Offender Health

   2. Provider records incident on local management system

   3. Provider reviews need to report to other reporting/regulatory/professional bodies (MHRS, HSE, CQC, local Safeguarding authorities etc.) Report to information governance/project appraisal unit/Accountable Officer as required

   4. Incident logged on STEIS by provider

      5. Provider informs Lead Commissioning Area Team for Health and Justice

         6. Lead commissioning Area Team to consider need to report to other commissioners i.e. Area Team (local) or CCGs if interface/care pathway issue

      7. Incident logged on STEIS by provider

         8. Provider submits any additional information to lead commissioner overseeing response. Grading and level of investigation confirmed. STEIS updated by provider if necessary

         9. Provider set ups investigation team

             10. Provider completes incident investigation (RCA/SEA conducted to RCA standard)

             11. Provider completes action plan which should be agreed by investigation team as effective means of preventing recurrence

             12. Provider completes lessons learned to prevent recurrence of SI

             13. Evidence of implementation provided to lead commissioner overseeing response to support closure

             14. Area Team (Patient Safety) undertake quality assurance review of report with main Commissioner for Provider where necessary.

15. Area Team Patient Safety Team closes incident on STEIS*. Actions monitored as part of routine quality assurance activities. Dissemination of lessons learned.

*Those involved in the reporting and investigation of an SI must not be included in the closure process.
## Appendix 6- Death in Custody (in prison and other accommodation of prescribed description)

### Death in Custody Occurs

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Provider informs Prisoner Probation Ombudsman (PPO) If NHS healthcare provider, report death on STEIS (alternatively death reported on SI reporting form completed and submitted to Lead Commissioning Area Team via NHS mail/secure fax) within <strong>2 working days</strong></td>
</tr>
<tr>
<td>2.</td>
<td>PPO appoints PPO case manager and they inform the Lead Commissioning Area Team within <strong>1 working day</strong>. Area Team and case manager agree level of investigation. PPO Case Manager informs provider to make available notes and witnesses for the review.</td>
</tr>
<tr>
<td>3.</td>
<td>Area Team appoints the Clinical Reviewer within <strong>5 working days</strong> of initial PPO contact and informs PPO Case Manager of name and contact details of reviewer. Area Team supports the reviewer with access to personnel and information. Area team will contact provider to confirm name of reviewer and confirms that access will be given to notes and relevant witnesses.</td>
</tr>
<tr>
<td>4.</td>
<td>Clinical Reviewer submits the draft report submitted to Area Team for quality assurance within <strong>35 working days</strong>. Area Team will share with relevant commissioning manager and quality assess the report and return it to the reviewer with comments within <strong>10 working days</strong>. The Clinical Reviewer will return the updated report to the Area Team within <strong>50 working days</strong> of initial PPO contact. The Area Team will forward the final report to the PPO Case manager and PPO will publish their report.</td>
</tr>
<tr>
<td>5.</td>
<td>Once the report is final, the relevant Area Team Commissioning Manager, (CM) will discuss the recommendations with the healthcare provider and monitor implementation through the contract management process. Area Team are responsible for closing incident on STEIS Learning will be shared through the health economy via Quality Networks.</td>
</tr>
</tbody>
</table>

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1 Based on: Clinical Review Following a Death in Custody investigated by The Prisons and Probation Ombudsman Part 1 - Guidance for Commissioning Bodies. April 2013 and adapted from existing models with the kind permission from NHS England Kent and Medway Area Team and London Regional Office.
Appendix 7 - Serious Incidents within Screening Programmes:
NHS Breast Screening Programme, NHS Cervical Screening Programme, NHS Bowel Cancer Screening Programme, NHS Diabetic Eye Screening Programme, NHS Abdominal Aortic Aneurysm Screening Programme, NHS Fetal Anomaly Screening Programme, NHS Infectious Diseases in Pregnancy Screening Programme, NHS Sickle Cell and Thalassaemia Screening Programme, NHS Newborn Blood Spot Screening Programme, NHS Newborn Hearing Screening Programme, NHS Newborn and Infant Physical Examination Screening Programme

Interim Guidance for Managing Incidents in NHS National Screening Programmes in England

Screening and immunisation lead alert:
Director of PHE directors and the head of public health of the area team and area team quality assurance lead. Regional QA alert:
director NHS Cancer Screening Programmes
director of QA and operations manager English National Screening Programmes

Provider reports on STEIS

Area team confirm grading with provider. Provider updates STEIS if necessary

Chief executive/identified deputy, QA director/lead and commissioner (SIL) agree responsibilities and members of the serious incident management team.

Provider undertakes investigation. Serious incident management team ensures appropriate actions are undertaken and root cause (RCA) analysis produced.

Provider produces final incident report with incident chronology, RCA, actions taken, outcomes, recommendations for learning/policy/procedural changes to prevent reoccurrence and evaluation of the process of managing the incident. Agreed by serious incident management team.

Serious Incident management team send recommendation to Area Team that SI can be closed

Report to: CEO of provider/area team director Relevant national director of UK NSC Screening Programmes Regional QA Director of public health PHE centre director

Area Team (Patient Safety) will undertake quality review and decide whether to close SI on STEIS.

Lesson learned disseminated and actions monitored as part of routine activities. Regional QA provides objective report for national learning.

Incident must also be reported to the National Reporting and Learning System (NRLS) and regulators, including CQC, as appropriate

Within 2 working days

Within 3 working days

Submission of reports and action plans:
45 days:
Grade 1 (level 1 and 2)
60 days:
Grade 2 (level 2)
6 months:
Grade 2 (level 3-independent RCA)

Within 20 days of receipt of report

Within 2 working days

Within 3 working days

Appendix 7 - Serious Incidents within Screening Programmes: NHS Breast Screening Programme, NHS Cervical Screening Programme, NHS Bowel Cancer Screening Programme, NHS Diabetic Eye Screening Programme, NHS Abdominal Aortic Aneurysm Screening Programme, NHS Fetal Anomaly Screening Programme, NHS Infectious Diseases in Pregnancy Screening Programme, NHS Sickle Cell and Thalassaemia Screening Programme, NHS Newborn Blood Spot Screening Programme, NHS Newborn Hearing Screening Programme, NHS Newborn and Infant Physical Examination Screening Programme5

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5 Interim Guidance for Managing Incidents in NHS National Screening Programmes in England
This interim guidance is available at www.screening.nhs.uk/incidents.
Appendix 8 - Serious Incidents within Immunisation Programmes:

Neonatal hepatitis B immunisation programme; Neonatal BCG immunisation programme; Respiratory syncytial virus (RSV) immunisation programme; Immunisation against diphtheria, tetanus, poliomyelitis, pertussis, and Hib; Meningitis C (MenC) immunisation programme; Hib/MenC immunisation programme; pneumococcal immunisation programme; DTaP/IPV and dTaP/IPV immunisation programme; Measles, mumps and rubella (MMR) immunisation programme; Human papillomavirus (HPV) immunisation; Td/IPV (teenage booster) immunisation programme; Seasonal influenza immunisation programme. Further information relating to vaccine incidents is available from the Health Protection Agency, Guidance for Vaccine Incidents.

6 Refer to HPA, Vaccine Incident Guidance (March 2012) for further information http://www.hpa.org.uk/HPAwebFile/HPAweb.C/1267551139589
Appendix 9- Serious Incidents within NHS England Area Team

NHS England Area Team Incident

Report to Regional Team

Incident logged on STEIS by Area Team

Any additional information submitted. Grading, level of investigation and scope of Regional input required confirmed.

Area Team set up investigation team

Complete incident investigation (RCA/SEA to RCA standard)

Complete action plan to prevent recurrence

Complete lessons learned to prevent recurrence

If further information is needed this will be requested and must be submitted to the Area team with 10 working days (where possible)

Evidence of implementation provided to Regional Team to support closure

Regional Team undertake quality assurance review of report

Regional Team closes incident on STEIS. Dissemination of lessons learned

Review need to report to other reporting/regulatory bodies (MHRS, HSE, CQC, local Safeguarding authorities etc.) Report to information governance/ project appraisal unit as required

Submission of reports and action plans;

45 days- Grade 1 (level 1 and 2)

60 days- Grade 2 (level 2)

6 months- Grade 2 (level 3 independent RCA)

Within 2 working days

Within 3 working days

Within 20 days of receipt of final report
Appendix 10 - Serious Incident within NHS England Regional Teams

- **NHS England Regional Team Incident**
- **Report to Regional Team**
- **Incident logged on STEIS by Area Team**
- **Any additional information submitted. Grading, level of investigation and scope of Regional input required confirmed.**
- **Area Team set up investigation team**
- **Complete incident investigation (RCA/SEA to RCA standard)**
- **Complete action plan to prevent recurrence**
- **Complete lessons learned to prevent recurrence**
- **Within 2 working days**
- **Within 3 working days**

**Submission of reports and action plans:**

- **45 days**
  - Grade 1 (level 1 and 2)
- **60 days**
  - Grade 2 (level 2)
- **6 months**
  - Grade 2 (level 3 independent RCA)

**Within 20 days of receipt of report**

- **Regional Team closes incident on STEIS. Dissemination of lessons learned**
- **Evidence of implementation provided to Regional Team to support closure**
- **Regional Team undertake quality assurance review of report**
- **Review need to report to other reporting/regulatory bodies (MHRS, HSE, CQC, local Safeguarding authorities etc.) Report to information governance and project appraisal unit as required**

**Grade 1**

**Grade 2**

If further information is needed, this will be requested and must be submitted to the Area team with 10 working days (where possible).
Appendix 11-Examples of Serious Incidents
This list is not exhaustive and provides examples only.

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Appendix 12- NHS England Project Appraisal Unit (Senior Estates Manager)

Serious Incident Support
For incidents which relate to a defect or failure of a non-medical device, a Defect and Failure report must also be made by the organisation that is the originator of the report in accordance with the Department of Health’s Defects and Failures reporting process; [https://www.gov.uk/government/publications/reporting-of-defects-and-failures-and-disseminating-estates-and-facilities-alert](https://www.gov.uk/government/publications/reporting-of-defects-and-failures-and-disseminating-estates-and-facilities-alert)

Area Teams should also inform the NHS England Projects Appraisal Unit’s (PAU) Senior Estates Team where they are alerted to serious incidents that relate specifically to estates and facilities matters. Examples of estates related incidents can be found in appendix 11.1.

Incidents must only be reported to PAU Estates via email to England.SIRlestate@nhs.net with the email Subject being formatted as;

Region (North, Midlands, London, South) / Area Team reference / sending date;

*example*    North/ AT1 / ddmmyyyy

If the incident is being reported from a Regional Office replace *Area Team* with *Regional Office*

*example*    Midlands / Regional Office / ddmmyyyy

A member of the PAU Estates team will cover activity from each of the four NHS England regions and will:

- Log, review and report back on incidents to the originating team;
- Arrange to meet with Regional Office leads on a quarterly basis to review estates related incidents and any trends
- Meet with the NHS England national team annually to review activity and continued service support.
### Appendix 11.1 Estates related services / installation guide (not comprehensive)

<table>
<thead>
<tr>
<th>Estates related services/installation guide (not comprehensive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Air Conditioning</td>
</tr>
<tr>
<td>● Air Compressors</td>
</tr>
<tr>
<td>● Anti-terrorism</td>
</tr>
<tr>
<td>● Asbestos</td>
</tr>
<tr>
<td>● Assault (result of design deficiency)</td>
</tr>
<tr>
<td>● Boilers / Pressurised Vessels</td>
</tr>
<tr>
<td>● Bottled Medical Gas</td>
</tr>
<tr>
<td>● Building structural/ failure</td>
</tr>
<tr>
<td>● Chemical spillage</td>
</tr>
<tr>
<td>● Construction site accident</td>
</tr>
<tr>
<td>● Disability Discrimination</td>
</tr>
<tr>
<td>● Domestic Hot Water</td>
</tr>
<tr>
<td>● Enforcement notices (effects of)</td>
</tr>
<tr>
<td>● Electrical (generators / tests)</td>
</tr>
<tr>
<td>● Electrical (UPS units)</td>
</tr>
<tr>
<td>● Electrical supply</td>
</tr>
<tr>
<td>● Electrical wiring</td>
</tr>
<tr>
<td>● Environmental / Sustainability</td>
</tr>
<tr>
<td>● Equipment (failure)</td>
</tr>
<tr>
<td>● Explosion</td>
</tr>
<tr>
<td>● Fire Safety</td>
</tr>
<tr>
<td>● Flooding (effects of)</td>
</tr>
<tr>
<td>● Flooring</td>
</tr>
<tr>
<td>● Gas supply (non-medical/domestic)</td>
</tr>
<tr>
<td>● Heating / failure</td>
</tr>
<tr>
<td>● Heights (working at)</td>
</tr>
<tr>
<td>● Incinerators</td>
</tr>
<tr>
<td>● IT installation / failure</td>
</tr>
<tr>
<td>● Kitchens / Catering (ward / central production)</td>
</tr>
<tr>
<td>● Laboratories</td>
</tr>
<tr>
<td>● Legionella</td>
</tr>
<tr>
<td>● Lifts, passenger / goods</td>
</tr>
<tr>
<td>● Medical Engineering (EBME)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Estates related services/installation guide (not comprehensive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Non-potable water</td>
</tr>
<tr>
<td>● Nurse call</td>
</tr>
<tr>
<td>● Paging / bleeps</td>
</tr>
<tr>
<td>● Pest Control / Infestation</td>
</tr>
<tr>
<td>● Piped Medical Gas</td>
</tr>
<tr>
<td>● Postal / Courier Services</td>
</tr>
<tr>
<td>● Potable water</td>
</tr>
<tr>
<td>● Radioactive source</td>
</tr>
<tr>
<td>● Road accident on an NHS site</td>
</tr>
<tr>
<td>● Refrigeration</td>
</tr>
<tr>
<td>● Sewage / drainage</td>
</tr>
<tr>
<td>● Site / building closure part / full</td>
</tr>
<tr>
<td>● Sterilisation (surgical instruments)</td>
</tr>
<tr>
<td>● Telecoms</td>
</tr>
<tr>
<td>● Theft / vandalism (service disruption following)</td>
</tr>
<tr>
<td>● Waste management / disposal</td>
</tr>
</tbody>
</table>

### NHS Never Events (2012/13)

- **#13.** Suicide using non-collapsible (bed / curtain / shower) rails etc.
- **#15.** Falls from windows
- **#16.** Entrapment in bedrails
- **#20.** Wrong medical gas administered
- **#24.** Severe scalding of patients
Available resources

The resources below are all available to provide support in the reporting and learning from serious incidents.


National Patient Safety Agency. Seven Steps to Patient Safety. 2004. Available at: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59787&q=0%2acseven+steps+to+patient+safety%2ac


Care Quality Commission. Essential standards of quality and safety. CQC. 2010. Available at: www.cqc.org.uk


The NHS Commissioning Board’s framework for collaborative commissioning, model agreement and FAQs. Available at http://www.commissioningboard.nhs.uk/resources/resources-for-ccgs/

UK National Screening Committee Screening Incidents Toolkit. Available at www.screening.nhs.uk/si-toolkit

UK National Screening Committee Screening Incidents eLearning module. Available at cpd.screening.nhs.uk/si-elearning

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 (as defined by *No Secrets*, available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008486.)

In *Working together to safeguard children (2010)* abuse is defined as follows: ‘abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by ‘inflicting harm’ or by failing to act to prevent harm’.

Abuse reported to the NRLS should include incidents of abuse which relate directly to NHS funded care i.e. not incidents which may be revealed during an inpatient stay for example. All incidents of abuse must be reported as a Safeguarding issue.

**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.

For the purpose of the guidance the following terms have been used to describe the roles of different commissioning function:

- **Lead Commissioning Area Team** - refers to the Area Team who is responsible to commissioning specific service e.g. Prescribed Specialised Services, Health in the Justice System services (prisons, sexual assault referral centres and immigration referral centres), Health care for armed forces and their families.

- **Area Team (local)** - refers to the area team responsible for the geographical area within which the provider is located. All local area teams have divisions who are responsible
for commissioning primary care services, screening and immunisation programmes and public health. The local Area Team may be the Lead Commissioning Area Team for the provider in some cases.

- **Main Commissioner for Provider** – refers to the commissioner who commissions the majority of services for a provider. For an NHS Trust this is likely to be a Clinical Commissioning Group. For a primary care provider this will be the local Area Team. NB: ‘main commissioner’ can relate to volume of services commissioned rather than overall cost i.e. specialised services represent a large proportion of cost but might only represent a small proportion of available services.

- **Commissioner leading oversight of the incident** – this could be any of the above commissioners but refers to the commissioner leading oversight of the incident in question with provider. The Safety and Quality Team within the commissioner overseeing the incident are responsible for closing serious incidents.

**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.

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

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

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

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

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

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

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

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

**Investigation** The act or process of investigating – a detailed enquiry or systematic examination.
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 Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare provider.

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

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

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

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

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

Primary Care refers to services provided by GP practices, dental practices, community pharmacies and high street optometrists and commissioned by the NHS Commissioning Board from April 2013

Prolonged pain and/or prolonged psychological harm – pain or harm that a service user has experienced, or is likely to experience, for a continuous period of 28 days.

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.

Quality Surveillance Groups Virtual teams established across a health economy either at the level of the relevant NHS CB area team or regional team, bringing together organisations and their respective information and intelligence gathered through performance monitoring, commissioning, and regulatory activities. By collectively considering and triangulating information and intelligence, QSGs will work to safeguard the quality of care that people receive.
**Risk** The chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequences.

**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.

**Serious Incident** A serious incident requiring investigation is defined as an incident that occurred in relation to NHS-funded services and care resulting in one of the following:
- unexpected or avoidable death of one or more patients, staff, visitors or members of the public;
- serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm);
- a scenario that prevents or threatens to prevent a provider organisation’s ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, IT failure or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- allegations of abuse;
- adverse media coverage or public concern about the organisation or the wider NHS;
- one of the core set of never events.

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

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

**Specialised services** Specialised services are commissioned by the NHS Commissioning Board 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. More information on specialised services is available at [http://www.commissioningboard.nhs.uk/resources/spec-comm-resources/](http://www.commissioningboard.nhs.uk/resources/spec-comm-resources/)
**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 holidays
References


